IMPROVING PRECONCEPTION CARE FOR WOMEN WITH DIABETES: DEVELOPMENT AND FEASIBILITY STUDY OF A MOBILE APPLICATION

by

Chidiebere Hope Nwolise

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School of Health Sciences
Faculty of Health and Medical Sciences
University of Surrey

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Statement of Originality

This thesis and the work to which it refers are the results of my own efforts. Any ideas, data, images or text resulting from the work of others (whether published or unpublished) are fully identified as such within the work and attributed to their originator in the reference/bibliography or in footnotes. This thesis has not been submitted in whole or in part for any other academic degree or professional qualification.

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Abstract

Introduction

Women with diabetes are at increased risk of adverse maternal and fetal outcomes. Preconception care can minimise risk of complications and improve outcomes, but current provision is inadequate. Mobile technology, particularly smartphone apps, could improve preconception care provision but research is lacking in this area.

Aim

The study aimed to critically appraise the literature with respect to PCC educational interventions and highlight limitations of current interventions, and to develop a Preconception and Diabetes Information (PADI) app for women with type 1 or 2 diabetes and explore the system’s feasibility and acceptability.

Methods

A systematic review of the literature and a 2-phase mixed methods study design, (1) development and (2) feasibility and acceptability, were used. The app was developed via a co-design approach with women with diabetes, healthcare professionals and an app development company. A 3-month pre- and post-intervention study assessed preliminary outcome estimates (preconception care knowledge, attitudes and behaviours), user acceptability was also explored. Data collection methods included focus groups, semi-structured interviews and questionnaires.

Results

The systematic review showed that PCC educational interventions had a positive effect on patient and behavioural outcomes, however, PCC uptake was low and the use of eHealth for PCC of women with DM was still in its infancy. The 2-phase mixed methods study design indicated a high level of enthusiasm and interest towards a preconception care app that could overcome shortfalls in current preconception care service provision. Improvements were recorded in knowledge of pregnancy planning and pregnancy-related risks, perceived benefits and self-efficacy to seek preconception care, and patient activation measure, following the 3-month app usage. Participants found the PADI app acceptable (satisfaction rating was 72%), useful and informative. Usage was episodic and influenced by functionality (manual data input) and personal factors (pregnancy intention, time/memory and conflicting priorities) that participants felt could be overcome via personalisation, automation, improved interactivity and daily reminders.

Conclusion

This is the first study to explore the acceptability and feasibility of a preconception care app for women with diabetes. It has positive implications in terms of overcoming barriers to preconception care provision and uptake, and changing preconception behaviours. In order that the contribution of the PADI app can be fully realised, further evaluation is required.
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Chapter 1: Introduction

1.1 Diabetes Mellitus

1.1.1 Epidemiology

Diabetes mellitus (DM) is a global public health challenge and one of the most prevalent chronic diseases occurring in Western and developing countries (Shaw et al., 2010; International Diabetes Federation [IDF], 2017). DM results in high healthcare expenditure, costing the National Health Service (NHS) £10 billion pounds every year, due to the increased use of health services, higher hospitalisation rates, medication, emergency and continuing care (Zhang et al., 2010; Hex et al., 2012). Recent global estimates show that 425 million people have DM, and this figure is projected to rise to 629 million people by 2045 (IDF, 2017). The prevalence of DM in women has also risen dramatically. Recent figures (IDF, 2017) indicate that 204 million women have DM compared to 199.5 million in 2015. As a result of the increased prevalence of DM amongst women of childbearing age, the number of high-risk pregnancies (that is, pregnancies that place both mother and baby at increased risk of developing complications) will also increase. DM is thus increasingly becoming a major issue in the field of women’s health (Wahabi et al., 2010).

1.1.2 Aetiology and diagnosis

DM is caused by a deficiency in insulin secretion or resistance to the actions of insulin (IDF, 2017). Abnormalities in carbohydrate, fat and protein metabolism subsequently occur as a result of the deficient action of insulin (American Diabetes Association [ADA], 2010). DM is diagnosed when a patient has a fasting blood glucose level greater than 7.0mmol/l and a two-hour post-prandial glucose level greater than 11.1mmol/l (World Health Organization [WHO], 2006). DM is also measured using the glycated haemoglobin (HbA1c), a laboratory test which reflects the degree of control of blood glucose over the preceding 2-3 months (National Institute for Health and Care Excellence [NICE], 2015). A diagnosis of DM is made if the HbA1c level is ≥ 6.5% or 48 mmol/mol (WHO, 2011a). DM is a progressive disease associated with macrovascular (e.g. coronary heart disease and stroke) and microvascular (e.g. nephropathy, retinopathy and neuropathy) complications, which can lead to premature death if not managed properly (Diabetes UK [DUK], 2012; IDF, 2017). DM is best managed through diet, exercise, oral medication and insulin injection or pump therapy (ADA, 2010; IDF, 2017).

1.1.3 Classification

DM is mainly classified into two types, Type 1 and Type 2 (WHO, 1999; ADA, 2010). Type 1 (T1DM) is caused by the auto-immune destruction of the pancreatic β-cells of the islets of
Langerhans and results in an absolute deficiency of insulin (ADA, 2010). Although T1DM may occur at any age, it is more common in childhood or adolescence, and accounts for about 5-10\% of the total number of people with DM (ADA, 2010). In contrast, type 2 (T2DM) occurs when the amount of insulin produced by the pancreatic β-cells is insufficient or if the body develops resistance to the insulin produced (ADA, 2010; IDF, 2017). This is the more common form, affecting about 90-95\% of the people with DM (ADA, 2010). Although formerly more prevalent in adults, it is now occurring in children and young adults due to the rise in obesity, physical inactivity and poor diet (ADA, 2010; Gourdy, 2013; Egan, Murphy and Dune, 2015). The risk of developing T2DM increases with age; the risk of developing this disease is six times greater among people from black and Asian minority ethnic groups (Gourdy, 2013; IDF, 2017). A third type, gestational DM, which occurs or is first diagnosed during pregnancy, is caused by glucose intolerance and affects about 7\% of pregnancies (ADA, 2010). It resolves after delivery but women and their babies are at risk of developing T2DM in the future (IDF, 2017).

1.1.4 Diabetes and pregnancy
DM during pregnancy is of major concern because pre-existent microvascular and macrovascular complications can exacerbate as a result of pregnancy, increasing the risk of adverse outcomes for both mother and baby (NICE, 2015). Women with DM are at increased risk of miscarriage, pre-eclampsia, preterm delivery and maternal death, with the risk of perinatal mortality and congenital malformation being five and two times greater than that of the general population, respectively (Confidential Enquiry into Maternal and Child Health [CEMACH], 2005; Macintosh et al., 2006; McCance, 2011; Knight et al., 2014). The risk of congenital malformation and perinatal mortality in women with T2DM is comparable and sometimes higher than in women with T1DM (CEMACH, 2007; Temple and Murphy, 2010; Singh et al., 2013). However, women with T2DM are less likely to plan their pregnancies, receive preconception care (PCC), take the recommended 5mg of folic acid or attend pre-pregnancy clinics and more likely to be taking teratogens (potentially harmful medication to the fetus) at conception (CEMACH, 2007; Murphy, Temple and Ball, 2010; NHS Digital, 2016). PCC, which significantly reduces diabetes-related complications during pregnancy, is therefore vital for women with DM given the severity of the complications and adverse outcomes.

1.2 Preconception care
Preconception care (PCC) is defined by Bhutta et al. (2011) as any intervention that is provided to women (and couples) of reproductive age before pregnancy, regardless of
pregnancy status or desire, to improve the health outcomes of women and their newborn. Temple (2010) highlights two distinct components of preconception care:

1. Preconception counselling, which entails discussion and education.
2. Preconception care, which entails planning a pregnancy in partnership with healthcare professionals.

1.2.1 Preconception counselling and preconception care

1. Preconception counselling

This is defined by Temple (2010) as the education of, and discussion with, women of reproductive age about pregnancy and contraception. Preconception counselling should be an essential element of every consultation in primary and secondary care (outpatients visit), and should be provided to women from adolescence (ADA, 2010; NICE, 2015). Temple (2010) highlights that it is the responsibility of all healthcare professionals to provide preconception counselling, and this ‘discussion’ should include future plans for pregnancy, benefits of PCC and how it can improve pregnancy outcomes, as well as contact details of the PCC team and how women can access PCC. Women should be advised of the need to take folic acid supplements before pregnancy, avoid potentially teratogenic medications such as statins and angiotensin-converting enzyme (ACE) inhibitors and use reliable contraception until blood glucose levels have been optimised. They should also be informed that poor glycaemic control increases the risk of adverse pregnancy outcomes.

2. Preconception care (PCC)

Temple (2010) asserts that PCC is the additional care needed to prepare women with DM for pregnancy, and involves a close partnership between the woman and her diabetes team. According to Temple (2010), PCC should ideally begin 6-12 months before conception in a woman with DM, however, the time required depends on a number of factors including glycaemic control and the presence of complications. PCC includes optimising glucose control, prescribing high dose folic acid supplements, reviewing medications to ensure that women avoid potentially teratogenic medications and discussing maternal and fetal risks.

1.2.2 PCC and diabetes mellitus

The benefits of PCC have been well established, hence, national and international guidelines are consistent in recommending PCC as the strategy for improving pregnancy outcomes in women with DM (Mahmud and Mazza, 2010; Temple, 2011). The endorsed PCC components for women with DM include: improving awareness of the risks associated with DM and pregnancy, optimising glucose monitoring and blood glucose levels, taking 5mg of folic acid one month before and up to twelve weeks into pregnancy, using contraception in
order to avoid unplanned pregnancy, stopping teratogenic medications e.g. angiotensin converting enzyme (ACE) inhibitors and statins, screening for complications of DM, receiving rubella vaccination, maintaining healthy weight and modifying lifestyle (diet, exercise, smoking and alcohol cessation) (Scottish Intercollegiate Guidelines Network [SIGN], 2010; Canadian Diabetes Association [CDA], 2013; NICE, 2015; ADA, 2017). Table 1.1 details NICE guidance in relation to components of PCC for women with DM.

Table 1.1: Components of PCC for women with diabetes mellitus

<table>
<thead>
<tr>
<th>Components of PCC</th>
<th>Information discussed</th>
</tr>
</thead>
</table>
| Contraception and planning for pregnancy | • Highlight importance of avoiding unplanned pregnancy from adolescence for women with DM.  
• Advise that risks associated with pregnancy in women with DM increase with duration of DM.  
• Blood glucose targets, glucose monitoring, medicines for treating DM and medicines for complications of DM will need to be reviewed before and during pregnancy.  
• Explain extra time and effort is needed to manage DM during pregnancy and that she will have frequent contact with HCPs. |
| Information and advice | • Establishing good glucose control before conception and continuing throughout pregnancy reduces risk of miscarriage, congenital malformation, stillbirth and neonatal death.  
• Information about how DM affects pregnancy and how pregnancy affects DM.  
• Individualised dietary advice.  
• Offer those who have a BMI above 27 kg/m² advice on how to lose weight.  
• Take folic acid (5mg/day) until 12 weeks gestation. |
| Monitoring blood glucose, HbA1c and ketones | • Monthly measurement of HbA1c level.  
• Offer blood ketone testing strips and a meter for self-monitoring of blood glucose.  
• Agree individualised targets for self-monitoring of blood glucose.  
• A fasting plasma glucose level of 5-7 mmol/l on waking and  
• A plasma glucose level of 4-7 mmol/l before meals at other times of the day.  
• Advise to keep their HbA1c level below 48 mmol/mol (6.5%), if this is achievable without causing problematic hypoglycaemia.  
• Advise those whose HbA1c level is above 86 mmol/mol (10%) not to get pregnant. |
| Reviewing safety of current medication | • Advise to use metformin as an adjunct or alternative to insulin when the likely benefits outweigh the potential for harm.  
• Use isophane insulin as the first choice for long-acting insulin.  
• Angiotensin-converting enzyme inhibitors and angiotensin-II receptor antagonists should be discontinued.  
• Statins should be discontinued. |
| Retinal and renal assessment | • Offer retinal assessment at first appointment (unless retinal assessment in the last 6 months).  
• Advice to defer rapid optimisation of blood glucose control until after retinal assessment and treatment completed.  
• Offer renal assessment before discontinuing contraception, if serum creatinine, albumin creatinine ratio or estimated glomerular filtration rate (eGFR) is abnormal, referral to a nephrologist should be considered. |

Adapted from preconception care for women with DM (NICE, 2015)
1.2.3 Benefits of PCC and pregnancy planning

PCC offers the earliest opportunity to reduce risks of complications and adverse outcomes, ensuring women enter pregnancy in the best possible health and have the greatest chance of giving birth to a healthy baby. There is substantial evidence that PCC is associated with improved glycaemic control in early pregnancy and reduction in major congenital malformations (Temple, 2011). In a meta-analysis (Wahabi et al., 2010) of 11 cohort studies, PCC was associated with a lower risk of congenital malformations [(relative risk; RR: 0.25; 95% confidence interval; CI: 0.15-0.42)], pre-term delivery (RR, 0.70; 95% CI: 0.55-0.90) and perinatal mortality (RR: 0.35; CI: 0.15-0.82). In addition, PCC was found to reduce first trimester HbA1c by an average of 2.43% (95% CI: 2.27-2.58). Inadequate PCC and pregnancy planning among women with DM can have severe consequences. For example, according to the mothers and babies: reducing risks through audits and confidential enquiries across the UK (MBRRACE-UK) report (Knight et al., 2014), the four women with pre-gestational DM who died had poorly controlled blood glucose levels before and during pregnancy; highlighting the importance of PCC advice and optimising glycaemic control.

The babies of women with T1DM and T2DM have an increased risk of developing adverse outcomes because high blood glucose levels (hyperglycaemia) in the peri-conception period, i.e. the time preceding, including and immediately after conception, exerts a teratogenic effect on the fetus (Macintosh et al., 2006; Corrigan et al., 2009; Wahabi et al., 2010). The relationship between high blood glucose level and poor pregnancy outcomes have been confirmed by several studies. For example, a meta-analysis (Inkster et al., 2006) of 13 studies involving women with T1DM and T2DM reported a 3-fold increase in malformations, spontaneous abortions and perinatal death in pregnancies of women with poor glycaemic control. In addition, Bell et al. (2012) found a linear increase in risk of congenital anomaly with increase in HbA1c above 6.3% (45 mmol/mol) and for each 1% (11 mmol/mol) increase in HbA1c, the risk of a pregnancy being affected by a congenital anomaly increased by nearly 30%. Figure 1.1 below shows the association between peri-conceptional HbA1c and the risk of congenital malformations.

Glycaemic control is one of the main components of PCC for women with DM; NICE (2015) specifically advises women to plan their pregnancy, aim for a target HbA1c of 6.5% (48mmol/mol) and avoid pregnancy if HbA1c is greater than 10% (Table 1.1). Optimum blood glucose control before conception and during pregnancy can reduce the occurrence of miscarriage, fetal malformations and mortality (Wahabi et al., 2010; Temple, 2011; Knight et al., 2014). The meta-analysis by Inkster et al. (2006) recorded a reduced risk of congenital malformations for every one percent reduction in HbA1c. A second meta-analysis (Guerin et
al., 2007), showed a step-wise reduction in the risk of malformations with improved HbA1c, i.e., a 12% risk of malformation was recorded for a HbA1c of 12%, 6% risk for a HbA1c of 9% and three percent risk for a HbA1c of 6%. However, despite the benefits of improved glycaemic control, Ludvigsson et al. (2018) found that the rate of malformation in women with optimum HbA1c was still twice that of the general population; highlighting that other aspects of PCC are equally important for improving maternal and fetal outcomes.

Fig 1.1 Association between peri-conception HbA1c in women with pre-existing DM and the risk of a pregnancy affected by major congenital anomaly.

CEMACH (2007) found an association between adverse pregnancy outcome and unplanned pregnancy (odds ratio [OR] = 1.8) and no contraceptive use in the 12 months prior to pregnancy (OR = 2.3). Women with DM are thus advised to plan their pregnancy and use effective contraception until their HbA1c is stable at recommended levels (CEMACH, 2007; NICE, 2015). CEMACH (2005) defines planned pregnancies as pregnancy which was desired before conception, for which contraception was stopped, and the woman attempted to achieve optimal blood glucose before conception. All other pregnancies are regarded as unplanned. In a qualitative study of 29 women with DM, Murphy et al. (2010a) found that 70% of women were not using reliable contraception prior to conception, and none of the women in the study, including those who experienced an adverse outcome, specifically
considered the implications of an unplanned pregnancy. Evidence shows that many unplanned pregnancies occur from failure to use contraception or use it properly, and unplanned pregnancy combined with uncontrolled DM at conception contributes to the high burden of maternal and fetal mortality and morbidity (Negrato et al., 2012; McCance, 2011; NICE, 2015).

Safe and effective contraception is important to minimise complications and adverse outcomes for all women with DM. There are 15 different methods of contraception for women with DM to choose from: *combined hormonal contraception* (combined oral contraceptive pill, patch and vaginal ring), *progestogen-only methods* (pills, injection and implants), *intrauterine devices* (copper IUD and levonorgestrel-releasing intrauterine system IUD), *sterilisation* (female and male), *barrier methods* (male and female condom, diaphragm and vaginal ring), *natural family planning* (cervical mucus assessment method and devices for measuring hormones) and *emergency contraception* (oral-progestogen only pills and copper IUD) (UK MEC, 2009; FPA, 2010). The IUD may be particularly suited to women not planning a pregnancy in the next one year, while for women without vascular disease, the combined hormonal contraception is considered safe. Women who have longstanding DM, hypertension, microvascular or cardiovascular complications, who smoke, have a BMI of ≥ 35Kg/m² should avoid estrogen-containing contraception as the progestogen only methods may be more suitable (Gourdy, 2013).

NICE (2015) recommends that women receive PCC education incorporating contraception use to prevent unplanned pregnancies, from adolescence. The choice of contraception needs to be based on women’s own preferences and any risk factors such as nephropathy, neuropathy or retinopathy (Gourdy, 2013; WHO Medical Eligibility Criteria, MEC, 2015). Choosing a safe and reliable contraception for a woman with DM requires careful consideration and the chosen method must not induce risks such as thromboembolic and cardiovascular complications (UK MEC, 2009). Thus, HCPs need to refer to the WHO MEC for Contraceptive Use (WHO MEC, 2015). It is recommended that women planning a pregnancy start taking folic acid 3 months before stopping contraception (Blumer et al., 2013).

Folate deficiency has been identified as a risk factor for abruption placentae, pre-eclampsia, spontaneous abortion and stillbirth (Scientific Advisory Committee on Nutrition, SACN, 2009; Gaskins et al., 2014). Three cohort studies (Hasan et al., 2009; Byrne, 2011; Gaskins et al., 2014) found that folic acid intake during pregnancy may be associated with a reduction of 20-60% in the risk of miscarriage or spontaneous abortion in the general population.
Additionally, the intake of folic acid one month before pregnancy was found to reduce the risk of neural tube defects (NTDs) by 72% in the general population (De-Regil et al., 2010).

Compared to women in the general population, women with DM have a higher risk of having babies with NTDs such as spina bifida and anencephaly (King, 2011), hence, it is recommended that all women with DM should be prescribed a higher dose of folic acid (NICE, 2015). NICE (2017) distinguishes between the folic acid dosage for non-diabetic women and those with DM planning a pregnancy, and recommends that the former consume 0.4 mg of folic acid daily, while women with DM consume a higher dose of 5mg daily until the twelfth week of pregnancy to prevent NTDs. Roland et al. (2005), in a study of 535 women with T1DM and T2DM, confirmed that folic acid was associated with a significant reduction in the risk of malformations (odds ratio, (OR): 0.3; 95% CI: 0.09-1.0; \( P = 0.04 \)).

Other PCC requirements that contribute to improving pregnancy outcomes include: a review of women’s medication, rubella vaccination, screening for complications, smoking and alcohol cessation and weight management. Medication review is important because there are increasing numbers of women of reproductive age with DM using statins and ACE inhibitors (which can cause fetal abnormalities and impair the renal function of the fetus) to reduce risk of cardiovascular and renal complications e.g. hypertension, kidney disease and nephropathy (Temple, 2011). These medications should be stopped and replaced with safer alternatives before conception. Women should also be advised to avoid illicit drugs and over-the-counter medication as these can adversely affect the fetus (Seshadri et al., 2012).

Rubella vaccination should be arranged if the woman is not immune, to prevent congenital rubella syndrome (CRS) (Mason et al., 2014). Smoking cessation reduces the occurrence of low birth weight (LBW), congenital malformations, miscarriage, preterm delivery and stillbirth while alcohol cessation reduces the incidence of fetal alcohol syndrome (FAS) (Seshadri et al., 2012). Women should be screened for diabetic complications, including retinopathy and nephropathy, which can deteriorate during pregnancy; evidence suggest an association between nephropathy and fetal malformations, pre-eclampsia and pre-term delivery (Bell et al., 2012; Ringholm et al., 2012). Women with severe diabetic retinopathy are advised to postpone conception until treated and stable for at least 6 months. Satisfactory blood pressure is important (<130/80 mmHg), and thyroid function status should be assessed and managed prior to conception as hypothyroidism may reduce fertility, increase the risk of miscarriage and affect fetal brain development (Blumer et al., 2013).
Obesity is associated with an increased risk of adverse outcomes and attaining a healthy weight (body mass index, BMI 18.5 to 24.9 kg/m²) reduces the risk of birth defects, miscarriage, perinatal and maternal morbidity and mortality (Gardiner et al., 2008; Papachatzı et al., 2013). NICE (2015) also advises that women with a BMI over 27 kg/m² should be supported to reduce their weight. PCC targets all the factors of poor pregnancy outcomes, hence, in order to reduce complications and adverse outcomes, it is vital that women with DM receive PCC education (preconception counselling) and understand the need for pregnancy planning.

1.2.4 Limitations of current PCC service provision

A recent National Pregnancy in Diabetes (NIPD) audit (NHS Digital, 2016) reported significant variations between services in meeting the NICE guideline recommendations for pregnancy planning. Only 8% of women achieved HbA1c ≤ 6.5% (48mmol/mol), took folic acid and stopped teratogenic medications. One-third of women with T2DM took folic acid in 75% of services and those from lower socio-economic groups were the least prepared for pregnancy. The audit concluded that the low awareness of pregnancy planning and risks was due to the failure of the primary care referral pathways and specialist diabetes services in providing PCC education. Furthermore, although current guidelines (CEMACH, 2007; NICE, 2015) recommend the use of contraception until a stable HbA1c level is achieved, as many as two-thirds of women with DM do not recall discussing contraception with their healthcare professionals (HCPs), are unsure of suitable contraception options or are not using reliable contraception before pregnancy (Cartwright et al., 2009; Murphy et al., 2010a). Consequently, despite contraception being freely available in some parts of the world, such as the UK, women with DM are less likely to be using contraception than women without DM (Shawe, 2008; Vahratian, 2009; Gourdy, 2013).

It is evident that despite information on clinical guidance being readily available to HCPs, the scarcity of information on how to best implement PCC services hinders progress (Hughes et al., 2016). Thus, PCC service provision has remained inadequate and fragmented with less than 50% of women with DM receiving PCC advice (CEMACH, 2007; Murphy et al., 2010b; Egan et al., 2016). Two-thirds of all pregnancies are still unplanned despite the knowledge that babies of women with unplanned pregnancies are more likely to be small for gestational age, admitted to the neonatal intensive care unit and to have a longer stay in hospital (Holmes et al., 2017). Moreover, various barriers including inadequate resources to provide PCC, busy clinics, unsupportive HCPs, lack of trust in HCPs, lack of transport, distance to travel, childcare requirements and time constraints further inhibit the extent to which women engage in PCC (Infanti et al., 2014; Singh et al., 2010; Spence et al., 2010). Women with
DM thus have a poor understanding of pregnancy-related risks and the consequences of having an unplanned pregnancy to themselves or their baby (McCorry et al., 2012; Dean et al., 2013; Xaverius et al., 2013; O’Higgins et al., 2014). These inadequacies in PCC service provision are not specific to a particular country but adversely affect the health of women with DM globally, of especially those in developing countries which face the greatest barriers to PCC (World Health Organisation [WHO], 2012a; WHO, 2013).

The slow progress in this field is also due to the location of the PCC services (Murphy et al., 2010). Ideally, PCC services should be provided in both primary and secondary care. However, the predominance of PCC services in specialist hospitals means that many women, particularly those with T2DM cared for in primary care, lack adequate access to PCC (Murphy et al., 2010b; Steel et al., 2015). Although Klinke and Toth (2003) argue that PCC should be provided by general practitioners (GPs) in primary care; this approach has been deemed opportunistic and dependent on the number of women attending the practice (Shannon et al., 2014; Hughes et al., 2016). PCC service provision in primary care has been further criticised by Earle et al. (2017), who note that GPs do not fully understand the need for PCC in women with DM.

The lack of clarity regarding PCC responsibility by HCPs in secondary care further contributes to the aforementioned slow progress within the field (CEMACH, 2007; Hughes et al., 2016). King (2011) maintains that PCC should be provided by a specialist multidisciplinary team with the appropriate competency as described in Skills for Health (2010). Yet, there are ongoing arguments amongst specialists regarding the HCP best placed to provide PCC. In the UK, secondary care clinicians, such as the diabetes specialist nurse (DSN) (Scott, 2005) and midwives (Hughes et al., 2016; Chief Nursing Officers, 2010) are deemed to have PCC responsibility, while in the USA, it is the gynaecologic and obstetric clinicians who assume this responsibility (Schwarz et al., 2011). However, van Heesch et al. (2006) note that midwives do not view themselves as having a role in PCC due to inadequate knowledge and time constraints. Indeed, a general decline in HCPs’ input in PCC has been highlighted with several studies concluding that many HCPs are not adequately trained to provide PCC (Charron-Prochownik and Michel, 2006; CEMACH, 2007; Shannon et al., 2014; Earle et al., 2017). Undeniably, the deficiencies in PCC service provision for women with DM has become a significant public health issue (Hughes et al., 2016; Shannon et al., 2014). There is therefore an urgent need for more effective PCC service provision.
1.3 Rationale for the study

Given the undeniable need for a PCC educational (preconception counselling) resource for women with DM, various initiatives have been developed to improve awareness and encourage women to seek PCC. The READY-Girls (reproductive-health education and awareness of diabetes in youth for girls) is one example of an educational program, which used CDs (Charron-prochownik et al., 2008; Fischl et al., 2010) and DVDs (Charron-prochownik et al., 2013), to improve reproductive health awareness in young women with DM in America. Another educational program, available both in DVD and website format, titled “Women with diabetes – things you need to know (but maybe don’t), has been developed for women with DM in the UK (Holmes et al., 2012, 2013). The DVD is currently being used as a preconception counselling resource by diabetic teams in Northern Ireland.

Other PCC initiatives for women with DM include a preconception leaflet in East Anglia, UK titled EASIPOD (East Anglia study for improving pregnancy outcomes in women with DM) which was mailed annually to all women aged 16-45 years identified from specialist and primary care diabetes registers (Murphy et al., 2010b). PROCEED (preconception care in diabetes for Derby and Derbyshire) is a multi-faceted initiative that uses various means, including mass media (television, radio and newspaper), websites and social media (twitter) to improve PCC awareness in women with DM and HCPs (King, 2013). Diabetes UK also has a web page that hosts information and short video clips on PCC (e.g. Rebel Rebel) to encourage women to plan their pregnancy. However, despite these initiatives, a systematic review of 18 qualitative studies carried out by Earle et al. (2017) highlighted that women with DM were unaware of available educational resources; sub-optimal levels of PCC awareness and experiences were also recorded across studies.

1.3.1 Women’s views and experiences of PCC

Women with DM, of reproductive age, face various challenges particularly when contemplating pregnancy and several factors influence their decision to seek (or not seek) PCC prior to pregnancy. For example, the nature and quality of existing relationship with HCPs play an important role. Women who had a good relationship described the positive emotional and practical consequences of this positive patient-provider relationship which encouraged them to seek PCC and plan their pregnancy, while those who did not were less likely to seek PCC (The diabetes and pregnancy group, 2005; Murphy et al., 2010a; Charron-prochownik et al., 2006b). For women who desired PCC advice, several constraints including busy clinics, lack of staff continuity, unfamiliar HCPs, poor patient-provider relationships, stereotypes held by HCPs and embarrassment (for younger women) made it difficult to be pro-active in seeking advice (Spence et al., 2010; O’Higgins et al., 2014).
The diabetes and pregnancy group (2005) in France, carried out a survey of 138 women, and noted that inadequate knowledge of PCC and pregnancy-related risks contributed to low rate of PCC uptake in French women with T1DM. Spence et al. (2010) also found that lack of awareness about the rationale for planning pregnancy played a major role in the poor uptake of pre-pregnancy care services in the UK. Two other UK studies (Lavender et al., 2009; O’Higgins et al., 2014) found that the general apathy towards PCC was influenced both by a lack of information and emphasis from HCPs on the importance of PCC. Inadequate information and preparation for pregnancy contributed to women’s emotional burden, making them more anxious and afraid of a pregnancy complicated by DM (Lavender et al., 2009; McCorry et al., 2012).

It has been established that advice of PCC and risks alone is not effective in preventing unplanned pregnancy, the way such information is provided is also important (Murphy et al., 2010a). Spence et al. (2010) found that some women were told to plan without information on why and how. In addition, women who reported receiving PCC felt that glycaemic control was prioritised by HCPs, hence, women focused on controlling their blood glucose levels which is important to reduce adverse outcomes. However, the discussion had an adverse effect on women’s psychological well-being and they reported feeling anxious and fearful afterwards (Griffiths et al., 2008). Lavender et al. (2009) also reported that women advised to avoid pregnancy, due to the potential risks, chose to ignore this advice and went ahead to conceive. Findings also suggested that women who knew about PCC did not attend because they were either discouraged by HCPs paternalistic and authoritarian behaviour or had a past negative PCC experience. Earle et al. (2017) highlighted that women want to feel empowered with information and supported from preconception to pregnancy, and the authoritarian approach used by some HCPs only led to fear, resistance, resentment and non-compliance with directives.

The need for HCPs to focus on positive aspects of pregnancy rather than only on the problematic aspects for women with DM has been highlighted (O’Higgins et al., 2014; Earle et al., 2017). Several studies have reported that PCC information framed in a motivating, positive and supportive way was more likely to be heard by women and translated into action (Egan et al., 2016, Earle et al., 2016, Spence et al., 2010). It has also been noted that women with DM need support and reassurance about PCC and pregnancy, whilst coping with the various challenges of DM. To encourage uptake of PCC by women with DM, O’Higgins et al. (2014) suggest establishing PCC as something every woman with DM will do irrespective of pregnancy plans. Given the various challenges of traditional PCC, it is
evident that there is still a long way to go before PCC becomes the norm for women with DM. Hence the use of more ubiquitous technology, such as a mobile phone, to supplement traditional PCC could help improve awareness, coverage and uptake.

1.3.2 Potential of mobile phone use for PCC

Concerns have been raised that the current ad-hoc nature of PCC service provision, absence of written hospital policies, poor patient-provider relationships, negative PCC experiences and lack of agreement both regarding PCC remit and the most effective strategies to encourage the uptake of PCC services could be detrimental to the health of women (WHO, 2012a, 2013; Shannon et al., 2014; Murphy et al. 2010a). Emphasis is therefore being placed on developing and testing alternative approaches to PCC provision, and moving away from a PCC model that is traditionally provided by HCPs within a clinic setting. Innovative strategies for improving PCC provision through eHealth technology (DVDs and CD-ROMs) have been found to be effective ways of changing behaviours and improving knowledge of PCC (Charron-Prochownik et al., 2008; 2013; Fischl et al., 2010; Holmes et al., 2012). However, they are now outdated and offer limited scope to the many women without access to computers and DVD players, who increasingly rely on smartphone apps to access health information (Tripp et al., 2014; Chen and Mangone, 2016; Krishnamurti et al., 2016). Thus, the use of more contemporary technologies for PCC, such as smartphone applications (apps), need to be explored in line with the WHO eHealth strategy (2012), NHS Five Year Forward View (2014) and the Personalised Health and Care 2020 framework (National Information Board [NIB] 2014), which seek to promote patients’ use of smartphones and apps for self-management and access to the information needed in order to avoid complications.

Mobile health, the medical and public health practice that is supported by mobile devices (WHO, 2011b), is one way to improve the provision of PCC. Mobile health (mHealth) is a component of eHealth, the cost-effective and secure use of information and communication technology, ICT, in support of health and health-related fields (WHO, 2005). According to the International Telecommunications Union (ITU, 2010), 90% of the world’s population now own a mobile phone, and almost half of the 7.4 billion mobile devices currently in use are smartphones with the capacity of computers and the internet (Eng and Lee, 2013; Derbyshire and Dancy, 2013; Silva et al., 2015; Klasnja and Pratt, 2012). The capacity of smartphones to help improve PCC awareness has been recognised by the World Health Organisation (2013) and other researchers (O’Higgins et al., 2014; Hughes et al., 2016). Smartphones have now overtaken laptops and desktop computers as the device used to
access the internet (Ofcom, 2016; Deloitte, 2016). Although smartphones are currently more common in developed countries, global smartphone subscriptions are projected to increase from 3.2 billion in 2015 to 6.6 billion in 2021, covering 70% of the world’s population (Ericsson Mobility Report, 2016). The smartphone is thus the most popular mobile device and is technologically advanced, easily accessible, mobile and has the potential to influence a large population (Tripp et al., 2014; Pew Research Center, 2016). Smartphone functionalities are facilitated by apps.

Apps are software programs designed to run on smartphones, increasingly being used in order to facilitate the cost-effective delivery of health interventions (Hebden et al., 2012; Derbyshire and Dancy, 2013). In a qualitative study by O’Higgins et al. (2014), women with DM of reproductive age suggested the development of a mobile app to help provide PCC education, increase knowledge of diabetes and pregnancy, and improve PCC uptake. Thus, the smartphone app, an adjunct to traditional PCC, has the potential to serve as an intervention medium to deliver PCC education and improve awareness. Advancement in technology has made it possible for health information to be incorporated into easily accessible digital formats, such as a smartphone app, and this is rapidly changing the health education and information paradigm (Willcox et al., 2015). Evidence suggests that apps can help improve women’s knowledge of family planning and contraception, reduce body mass index (BMI), connect young teenage women with contraceptive information and reproductive health services and increase antenatal care attendance (Carter et al., 2013; Gilliam et al., 2014; Chen and Mangone, 2016; Krishnamurti et al., 2017).

There is increasing evidence that mHealth interventions, particularly apps, can successfully change behaviours and improve outcomes (Zhao et al., 2016; Irvine et al., 2015; Carter et al., 2013; Kirwan et al., 2013; Gustafson et al., 2014). The scarcity of studies using pervasive technology, e.g. mobile apps to support PCC behaviour change for women with DM reflects a gap in the evidence base. Insufficient PCC understanding, perceived lack of support, negative PCC experiences and poor patient-provider relationships are some of the most frequently cited barriers to PCC uptake and contributors to unplanned pregnancy (Murphy et al., 2010a; Earle et al., 2017). Hence, for meaningful change to occur, it is important that the PCC information is provided in a supportive way and with positive intervention language. Few PCC educational interventions in the literature (Egan et al., 2016; Holmes et al., 2012; 2013) make reference to the use of supportive approach for women with DM, yet, this has been extensively discussed in the qualitative literature (Spence et al., 2010; O’Higgins et al., 2014; Earle et al., 2017). For example, Holmes et al. (2013) suggest emphasising the benefits of performing relevant behaviours, such as using
contraception and quitting smoking, in a non-authoritarian manner. Hence, the use of a (hybrid) mobile app to educate women about pregnancy and contraception, and support them to optimise blood glucose levels before and during pregnancy, while making use of a supportive approach and positive intervention language, is warranted.

Apps have contributed to healthy behavioural changes in a number of areas including medication management, diet control, physical activity, lifestyle improvement, smoking cessation and diabetes management (Zhao et al., 2016). Apps have also been successfully used in order to improve diabetes self-management and monitoring (Kollmann et al., 2007; Cafazzo et al., 2012; Kirwan et al., 2013). With traditional methods of PCC provision, such as face-to-face methods, failing to sufficiently engage women with DM in PCC, a smartphone-based intervention could provide an alternative means of improving activation, changing behaviours and reducing barriers to seeking PCC. However, the use of mHealth technology for PCC is still in its infancy and to date, no study has examined the use of a smartphone app for PCC among women with DM. In order for this type of technology in PCC to develop, research into its acceptability and feasibility is therefore needed.

1.4 Aim of the study

The aim of the study was to develop a Preconception and Diabetes Information (PADI) app for women with T1DM and T2DM and explore the system's feasibility and acceptability.

1.5 Research questions

The research questions addressed in this study are outlined below; research question 1 is addressed in Chapter 2 while research questions 2 to 7 are informed by the issues and gaps highlighted in the literature (as discussed in Chapter 2), and the qualitative findings (as discussed in Chapters 6 and 7).

1. What are the current methods and limitations of providing PCC educational interventions, and what is the relationship between PCC educational interventions and patient and behavioural outcomes?
2. What are the views and experiences of women with T1 or T2DM and healthcare professionals (doctors and nurses) in relation to PCC?
3. What are the views and experiences of women with T1 or T2DM and healthcare professionals (doctors and nurses) regarding the use of the PADI app in practice?
4. What are the factors that inhibit/facilitate the use of the PADI app?
5. What is the acceptability of the overall app, as measured by satisfaction, usefulness, ease of use and attitudes towards the receipt of the intervention?

6. What are the preliminary estimates of the effect of the PADI app on PCC knowledge, attitudes and behaviours?

7. What are the suggestions for future app development?

1.6 Rationale for research approach and methodology

A systematic review of the literature and feasibility study using mixed methods were deemed the most appropriate approach to answer the research questions and develop an understanding regarding the acceptability of the PADI app intervention. Systematic reviews are used to identify, evaluate and summarise the findings of relevant individual studies, demonstrate gaps in the literature and provide justification for the research (University of York, 2009). Feasibility studies are used in order to assess whether the study can be done or whether the intervention is acceptable to the target population and shows potential of being successful (Orsmond and Cohn, 2015). A co-design approach with healthcare professionals, women with DM and a digital agency was used to develop and test the app in order to ensure that it meets the needs of women with DM and that its content is appropriate and acceptable (Steen et al., 2011; Whittaker et al., 2012; Mummah et al., 2016). Thus, feasibility studies incorporating several stages of user feedback can help identify and solve problems of intervention acceptability, compliance, delivery, recruitment and retention (Craig et al., 2008; Mummah et al., 2016).

1.7 Personal interest

I first became interested in DM while studying Endocrinology as part of my undergraduate degree in Physiology. During this time, I completed an independent research project titled ‘The Effect of Oestrogen on Fasting Blood Glucose, Blood Electrolyte Composition and Bleeding Time in Albino Rats’. This enabled me to gain an in-depth understanding of the role of oestrogen in blood glucose homeostasis and insulin sensitivity, which stimulated my interest in diabetes research. Furthermore, while studying for a Master’s degree in International Health and Management, I developed a keen interest in maternal and women’s health research, particularly in issues surrounding maternal mortality and PCC.

Since graduating in 2011, I have been interested in diabetes research and how it affects women’s health. This is of particular importance to me because coming from a developing country, Nigeria, I have witnessed the negative consequences (e.g. maternal mortality) resulting from inadequate PCC awareness, as well as the geographic and financial barriers
to maternal health services, particularly for women with DM. Even though maternal mortality has declined, many women still experience adverse outcomes arising from the failure to plan their pregnancies (WHO, 2012a; WHO, 2013). The problem is further exacerbated in women with DM of reproductive age and they experience increased adverse outcomes of pregnancy, compared to the background population (NICE, 2017). This problem is not specific to a particular region but is of global public health concern.

Although DM is a matter of growing concern that affects maternal and child health, PCC has been shown to be an effective strategy to combat this challenge (Wahabi et al., 2010). PCC is also cost-effective and reduces the cost of care per patient by facilitating early visitations to antenatal care clinics, less hospitalisation for complications and a reduced occurrence of congenital abnormalities (Egan et al., 2016). However, an optimal approach to reaching more women with DM with PCC information has not been found. Technology may offer a potential solution to this problem. My interest in the use of ICT for PCC stems from the realisation that this is a technological age and that technology is affecting all spheres of life, including healthcare (WHO, 2012b). ICT is being used on a global scale in order to improve access to care and mitigate the current challenges faced by healthcare systems, particularly the shortage of healthcare workers, variable quality of care and the barriers of traditional face-to-face care. Mobile phone technology in particular provides an innovative approach to healthcare and is helping to eliminate geographic and financial barriers to health in developed and developing countries.

Mobile phones are available worldwide, and an increase has been experienced in the growth of mobile apps. Hence, I intend to explore the incorporation of health education intervention into a smartphone (app). Mobile phone use for health (mHealth) is bridging the gap between the rich and the poor, thereby rendering care more accessible to hard-to-reach populations and low-income/disadvantaged communities. Therefore, I am hopeful that the use of mobile technology can increase access to PCC for women; a PCC mobile app intervention can be easily scaled up and adapted into a sustainable PCC programme that can be used by women in both developed and developing countries. My desire to contribute towards providing equitable access to PCC for women in developed and developing countries, combined with a strong interest in health education especially women’s health and DM, are the main motivating factors that led me to conduct this research.
1.8 Structure of thesis

This thesis is organised into eight chapters. The first chapter introduces the study and provides a justification as to why it should be conducted. Background information is provided about the burden of DM and its associated complications, benefits of PCC for women with DM and current challenges, and the potential of a smartphone app to increase PCC knowledge and awareness amongst women with DM. The study aim and research questions, along with a rationale for the research approach and methodology are then provided.

Chapter 2 systematically reviews the literature with respect to the methods currently being used to provide PCC education, and examines the relationship between PCC educational interventions (including the use of technology as an intervention tool) on patient and behavioural outcomes. Any existing gaps in the literature from which the research questions are formulated are highlighted. Additionally, recommendations for future research are made.

Chapter 3 discusses behaviour change and the normalisation process theory, the two theoretical frameworks used in the study. It also discusses the research design, epistemological approach of the study and the philosophical basis of mixed methods research. The use of a mixed methods study design and the ethical considerations of the study are addressed. Practicalities and access issues are considered.

Chapter 4 discusses the PADI app development and rationale for the app content. The sample selection, research setting and app development process are addressed. The rationale for the methods of data collection (focus groups and interviews) and the instruments used in order to collect the data are presented. Subsequently, the methods of data analysis are reported.

A discussion of the methods used in the feasibility study is presented in Chapter 5. It also discusses the rationale for the methods of data collection (questionnaires, interviews and software log of activity) and the instruments used in order to collect the data. The methods of data analysis are presented. The results are presented sequentially in Chapters 6 and 7. Chapter 6 focuses on phase one, namely the development of the PADI app. The results from the analysis of the data sets collected from the focus group and interviews with HCPs and women with DM are reported.
Chapter 7 focuses on the second phase of the study, namely the feasibility and acceptability of the PADI app intervention. The results from two (pre and post-PADI app intervention) questionnaires and user experience interviews are presented.

Chapter 8 discusses the reported findings in relation to the literature, provides a critical review of the methodology and identifies study strengths and limitations. The contribution of the study to the body of knowledge is presented. Recommendations and suggestions for additional research are made, followed by a conclusion of the main points.
2. Chapter 2: Review of the literature

2.1 Overview
Rapid technological advancement has created new opportunities to improve PCC awareness and health outcomes, therefore it was important to understand how technology was being used in order to support PCC services for women with DM. Hence, this review aimed to evaluate and quantify the impact of different methods of PCC provision for women with DM. The literature review was conducted using a systematic approach and two guidelines: the National Health Service (NHS) Centre for Reviews and Dissemination (CRD) guidelines for conducting reviews in healthcare (University of York, 2009) and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Moher et al., 2009).

The literature review answered the following questions:

- What are the current modes of delivery for providing PCC education to women with DM?
- What is the relationship between PCC educational interventions (including eHealth technology) and patient and behavioural outcomes?
- What are the limitations in current PCC practice and gaps in the literature?

2.2 Search strategy
A systematic approach was used to search the literature for relevant articles. The review was limited to studies conducted between January 2003 and December 2017 to reflect current and emerging trends in the design and conduct of PCC interventions for women with DM. This restriction was also applied because smartphones were first introduced in 2003 and formed the focal point of this research. The reviewed literature drew on a wide range of evidence. The following electronic databases were searched: MEDLINE, Embase, Cumulative Index to Nursing and Allied Health (CINAHL), PsycINFO, Maternity and Infant Care, British Nursing Index (BNI), Web of Science, Scopus and ScienceDirect.

Both medical subject headings (MESH) and key words were used in various combinations when searching the databases. The following keywords were used: ‘preconception care’, ‘education’, ‘counselling’, ‘diabetes’, ‘pregnancy outcomes’, ‘knowledge’, ‘behaviour change’, ‘birth defects’, and ‘women’. The strategy used for the search was developed to meet the specific requirements of each electronic database, and in accordance with their subject headings or search structure. The search structure for MEDLINE is presented below:
The truncation symbol was used in the middle of a word in order to capture both American and British spellings of the word and at the end to capture various forms of the word. The Boolean operators OR and AND were applied to combine terms and give the search a precise focus. In addition to electronic databases, the reference lists of retrieved articles, reviews and related articles were hand-searched for potentially relevant papers. Other relevant databases, for example, Google Scholar, NHS Evidence and Cochrane Library were also searched in order to identify any existing papers and reviews related to the topic. No language or geographical restrictions were applied in order to refine the search.

2.2.1 Study selection
The titles, abstracts and full papers were initially screened by the researcher and verified by the study supervisors (NC and JS). The search protocol included the identification of potentially relevant articles, the screening of the identified papers based on their titles and abstracts, the examination of the full text of potentially relevant studies for eligibility, and the application of the inclusion criteria in order to select the studies included in the review.

The search yielded 2,702 hits, most of which were duplicates and studies not relevant to the review. These articles were exported into RefWorks (reference management software) in order to allow for duplicates to be identified and excluded. The titles and abstracts of 1,437 articles were then screened against the inclusion criteria and the potentially eligible studies identified, while those that failed to meet the inclusion criteria were excluded. After excluding 1,411 articles that did not meet the eligibility criteria, 26 full text articles were selected for critical review, of which 14 met the eligibility criteria (Figure 2.1).
The criteria for including studies in the literature review were informed by the PICOS (population of interest, intervention, comparator, outcomes assessed and included studies) method (University of York, 2009). For the study to be included in the literature review, the following inclusion criteria were applied.

**Inclusion criteria**
- Women of reproductive age with pre-existing T1DM or T2DM and not pregnant at the time of the PCC intervention.
- PCC interventions including but not limited to education, counselling, or advice on the use of folic acid, insulin therapy, glycaemic control, screening for diabetes complications, contraception use, and blood glucose monitoring.
- Studies utilising a standard care comparator group or where the intervention group serves as the control (pre-post studies).
- Studies reporting on maternal and neonatal outcomes, and knowledge and attitudes towards PCC.
- Quantitative studies, or more specifically, randomised controlled trials, before and after studies, and observational studies (cohort, cross-sectional and case control).

**Exclusion criteria**
Articles were excluded if there was an agreement that the article met one or more of the following exclusion criteria:
- Did not contain any human data.
- Contained no original data (in the case of a commentary, meeting abstract or editorial).
- The population of interest was not women with DM.
- Did not assess the impact of a PCC educational intervention.

**2.2.2 Data abstraction and quality assessment**

**Data abstraction**
The data were subsequently extracted by the researcher and checked by the supervisors (NC and JS) for accuracy and completeness. The researcher was not masked to the articles’ authors, journals, or institutions. The data extracted include the following: general information (e.g. author, title of study, country in which the study was conducted and year of publication), eligibility (type of study, participants, type of intervention, outcome measure and comparator), population (from which the sample was recruited) and setting (in which the
intervention was delivered), description of the intervention (e.g. duration, dose, type of intervention, mode of delivery and theoretical basis), outcomes / results (e.g. statistical techniques used, length of follow-up, results of study analysis and details of outcome measurements), study limitations and any mitigation strategies (see Appendix 1 for a copy of the data extraction form).

Quality assessment

The quality of the reviewed studies was assessed using a modified version of the Effective Public Health Practice Project (EPHPP) quality assessment tool for quantitative studies, which was developed by EPHPP, Canada (Thomas et al., 2004; Sanderson et al., 2007). It contains summary judgments and an accompanying dictionary that increases standardisation and minimises subjectivity in the study quality assessment. This tool includes items on selection bias, study design, minimising confounders, blinding, data collection, and withdrawals and dropouts (see Appendix 2 for a copy of the EPHPP quality assessment tool). Each of these six aspects of quality received a score out of 3 to make up a total score of 18. The studies were given a rating out of 18, and the quality of the evidence was graded as strong (rating≥ 14), moderate (rating 7-13), or weak (rating 1-6). Although less weight was given to studies of poorer quality, no papers were excluded based on their quality.

2.2.3 Narrative synthesis

In this review, the main focus was on extracting data on intervention descriptions (study design, samples and intervention overviews), outcome measures and the examinations of the effectiveness of interventions. The results are presented as a narrative summary.

2.3 Search results

The 14 included studies evaluated two categories of PCC health education delivery in use for women with DM, namely health education provided by health care professionals (HCPs; n=9) and health education using eHealth technologies (CD-ROMs and DVDs; n=5). Of the included studies, nine focusing on PCC health education delivery by healthcare professionals were found to investigate the effect of PCC education on maternal and child health outcomes (Murphy et al., 2010b; Tripathi et al., 2010; Temple et al., 2006a, 2006b; Neff et al., 2014; Boulot et al., 2003; Galindo et al., 2006; Kekäläinen et al., 2016; Egan et al., 2016). Four studies focusing on the use of eHealth technology for the PCC of women with DM (Charron-Prochownik et al., 2008, 2013; Fischl et al., 2010; Holmes et al., 2012) investigated the effect of the eHealth technology on knowledge and attitude towards PCC, and one study (Holmes et al., 2017) investigated the effect of eHealth technology on
maternal and child health outcomes. Of the 14 included articles, one study discussed its findings in two articles (Temple et al., 2006a, 2006b). Hence, 14 articles reporting 13 studies were included.

2.3.1 Study characteristics

The summary characteristics of the reviewed articles are presented in Table 2.1 and include the focus, content, outcome measures and study design of the interventions. All studies involved evaluating the effect of a PCC educational intervention provided to women with DM either face-to-face or via eHealth PCC. The evidence identified was all quantitative in nature and included two retrospective and eight prospective cohort studies, three randomised controlled trials (RCTs) and one before and after study. Eight studies included women with both T1DM and T2DM, and six studies focused on women with T1DM. In all studies, except two (Holmes et al., 2012; 2017) where health education was delivered in women’s homes, health education was delivered in clinical settings; highlighting the current emphasis on the PCC received within a healthcare (clinic) setting.

Women were recruited from specialist and primary care diabetes clinics. Timing, frequency and the intervention duration for some studies were not specified (Holmes et al., 2012; Tripathi et al., 2010; Neff et al., 2014; Boulot et al., 2003; Galindo et al., 2006; Kekäläinen et al., 2016; Egan et al., 2016). Follow-up periods ranged from 3 months to 12 years. Most studies were observational (Murphy et al., 2010b; Tripathi et al., 2010; Temple et al., 2006a, 2006b; Neff et al., 2014; Boulot et al., 2003; Galindo et al., 2006; Kekäläinen et al., 2016; Egan et al., 2016; Holmes et al., 2017), with data collected from medical, pregnancy and birth records, or databases. Of the included studies, four (Charron-Prochownik et al., 2008; Fischl et al., 2010; Holmes et al., 2012; Charron-Prochownik et al., 2013) used previously validated and reliable questionnaires. Although the methods of data collection were different for the face-to-face and eHealth PCC studies, there was consistency in the findings and methods of data collection used within each category. Sample sizes ranged from n=58 to n=680. All studies, except one (Holmes et al., 2012), had a separate intervention and control group.

All studies were conducted in developed country settings (United States, n=3; United Kingdom, n=6; France, n=1; Spain, n=1; Finland, n=1; and Republic of Ireland, n=2), highlighting the increased prioritisation of PCC for women with DM in these countries. Studies, which adopted eHealth for the PCC of women with DM, were based in either the United States (n=3) (Charron-Prochownik et al., 2008, 2013; Fischl et al., 2010) or in the United Kingdom (n=2) (Holmes et al., 2012, 2017), perhaps reflecting the increasing use of
information and communication technology (ICT) to support PCC service provision in these countries. All (n=14) studies provided robust evidence of the impact of PCC education on maternal and child health outcomes, as well as on the knowledge and attitudes to PCC. Their findings were based on a rigorous quantitative analysis.

2.3.2 Study quality
Studies varied but were either of moderate or high quality, as shown in Table 2.1 below. Of the included studies, four had a rating of ≥ 14 (Fischl et al., 2010; Charron-Prochownik et al., 2013; Murphy et al., 2010b; Holmes et al., 2017) and ten were rated between 7-13 (Charron-Prochownik et al., 2008; Holmes et al., 2012; Tripathi et al., 2010; Temple et al., 2006a, 2006b; Neff et al., 2014; Boulot et al., 2003; Galindo et al., 2006; Kekäläinen et al., 2016; Egan et al., 2013). All studies used appropriate study designs, namely, randomised controlled trials, before and after, and cohort studies, but lacked details on blinding and allocation concealment. Although small sample sizes (Charron-Prochownik et al., 2008; Fischl et al., 2010; Holmes et al., 2012), selection bias (Charron-Prochownik et al., 2008; Holmes et al., 2012; Kekäläinen et al., 2016), and confounding (Holmes et al., 2012; Boulot et al., 2003; Galindo et al., 2006) were the underlying weaknesses in most studies, these were acknowledged and addressed by the authors.
Figure 2.1. PRISMA flowchart of included studies
<table>
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<tr>
<th>Author or country</th>
<th>Study population</th>
<th>Methods or focus</th>
<th>Intervention</th>
<th>Findings</th>
<th>Quality assessment</th>
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<tr>
<td><strong>1. Evaluation of PCC Educational Interventions Provided by Healthcare professionals</strong></td>
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<td>Boulot et al. (2003) - France</td>
<td>435 pregnant women with DM.&lt;sup&gt;a&lt;/sup&gt; T1DM&lt;sup&gt;b&lt;/sup&gt;, n=289 (intervention =140/289, 48.5% received the intervention, control=149). T2DM&lt;sup&gt;c&lt;/sup&gt;, n=146 (intervention= 35/146, 24% received the intervention, control=111).</td>
<td>Prospective cohort study. To determine if PCC interventions improved pregnancy outcomes in women with DM.</td>
<td>Oral PCC educational intervention delivered by health care professionals (HCPs&lt;sup&gt;d&lt;/sup&gt;; diabetologists). Advice regarding blood glucose optimisation, DM complications, dietary modification, self-monitoring of blood glucose levels, and insulin therapy. Information was collected on HbA1c &gt;8% in the first trimester. The duration of the intervention was not specified. The face-to-face time with the women was not indicated.</td>
<td>Significantly lower no. of women with HbA1c &gt;8% in the intervention group compared with the control group (4.3% vs. 55%; P&lt;.001 and 2.9% vs. 27.9%; P&lt;.001) for T1DM and T2DM, respectively.</td>
<td>(9/18)</td>
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<td>Galindo et al. (2006) - Spain</td>
<td>127 Women with T1DM and T2DM. Intervention, n=15/127, 12% received the intervention, control, n=112.</td>
<td>Prospective cohort study. To investigate the effect of DM on the pregnancy outcome.</td>
<td>Oral PCC educational intervention delivered by health care professionals (HCPs). Advice regarding the self-monitoring of blood glucose levels and the intensification of insulin therapy. The duration of the intervention was not specified. The face-to-face time with the women was not indicated.</td>
<td>3/15 (20%) of pregnancies in the intervention group and 14/112 (12.5%) in the control group resulted in congenital malformations. 1 spontaneous abortion was recorded in the intervention group compared with 9 in the control group.</td>
<td>(9/18)</td>
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<td>Temple et al. (2006a, 2006b) - the United Kingdom</td>
<td>290 pregnancies to women with T1DM. Intervention, n=110/290, 37.9% received the intervention, control, n=180.</td>
<td>Prospective cohort study. To investigate the relationship between PCC and obstetric outcomes in women with T1DM.</td>
<td>Oral PCC educational intervention provided by HCPs (doctors, dieticians and DSNs&lt;sup&gt;f&lt;/sup&gt;). Advice regarding blood glucose monitoring, glycaemic control, initiation of folic acid supplements after stopping contraception, smoking cessation, and avoidance of teratogens, such as ACE&lt;sup&gt;g&lt;/sup&gt; inhibitors and statins. Targets were set for pre- and postprandial blood glucose levels. The intervention group attended a PCC centre at intervals of 1-3 months.</td>
<td>There were lower spontaneous abortion rates (5.7% vs. 14.0%; P=.06), adverse pregnancy outcomes (2.9 vs. 10.2; P=.03), and premature delivery (5.0% vs. 14.2%; P=.02) rates in the intervention group compared with the control group.</td>
<td>(13/18)</td>
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<td>Author or country</td>
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<td>Murphy et al. (2010b) - the United Kingdom</td>
<td>680 women with T1DM and T2DM. Intervention, n=181/680, 26.6% received the intervention, control, n=499.</td>
<td>Prospective cohort study. To investigate the association between PCC and obstetric outcomes.</td>
<td>Oral PCC educational intervention delivered by HCPs (doctors, nurses and midwives). Structured education regarding PCC. The content of the intervention was not described in the paper. The frequency of the face-to-face time with the women ranged from 1 to 7.</td>
<td>The intervention group presented significantly earlier for PNC ( h 6.7 \text{ vs. 7.7 weeks; } P &lt; .001 ), and was unlikely to be taking ACE inhibitors (1.1 vs. 4.6%; ( P = .05 )) and statins (0 vs. 7.6%; ( P &lt; .001 )) at conception compared with the control group. HbA1c improved in the intervention group and was sustained through the first trimester (6.9% vs. 7.6%; ( P &lt; .001 )).</td>
<td>(14/18)</td>
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<td>Tripathi et al. (2010) - the United Kingdom</td>
<td>588 women with T1DM and T2DM. Intervention, n=240/588, 40.8% received the intervention, control, n=297.</td>
<td>Prospective cohort study. To investigate the association between PCC and obstetric outcomes, as well as pregnancy planning indicators.</td>
<td>Oral PCC educational intervention provided by HCPs. Counselling regarding PCC. The content of the intervention was not described. The duration of the intervention was not specified. The face-to-face time with the women was not indicated.</td>
<td>The PCC intervention led to significant improvements in HbA1c before (OR ( 1.91, 95% \text{ CI 1.10 to 3.04; } P = .002 )) and during pregnancy (OR ( 2.05, 95% \text{ CI 1.39 to 3.03; } P &lt; .001 )), and in the folic acid intake (OR ( 4.88, 95% \text{ CI 3.26 to 7.30; } P &lt; .001 )) in the intervention group compared with the control group.</td>
<td>(11/18)</td>
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<td>Neff et al. (2014) - the Republic of Ireland</td>
<td>505 women with T1DM. Intervention, n=70/505, 14% received the intervention, control, n=394.</td>
<td>Retrospective cohort study. To analyse the effect of PCC on obstetric outcomes.</td>
<td>Oral educational intervention provided by HCPs (DSNs, endocrinologists, dieticians). Advice regarding insulin therapy, discontinuation and the replacement of teratogens, such as ACE inhibitors and statins, intake of 5mg of folic acid and retinal assessment. The face-to-face time with the women was not indicated.</td>
<td>PCC education led to better HbA1c (6.9 vs. 7.8%); ( P &lt; .001 ) and earlier presentation for PNC (6 ± 2 vs. 8 ± 6 weeks; ( P &lt; .001 )) in the intervention group compared with the control group.</td>
<td>(13/18)</td>
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<td>Author or country</td>
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<td>Kekäläinen et al. (2016) - Finland</td>
<td>145 pregnancies to women with T1DM. Intervention, n=96/145, 66% received the intervention, control, n=49.</td>
<td>Retrospective cohort study. To evaluate the effect of pregnancy planning on glycaemic control and pregnancy outcomes.</td>
<td>Oral educational intervention provided by HCPs (doctors). Advice regarding glycaemic control, screening for diabetes complications and hypertension, medication review, and folic acid supplementation. The face-to-face time with the women was not indicated.</td>
<td>The intervention group had significantly lower HbA1c before conception (7.06% vs. 9.11%; P &lt;.001) which was sustained throughout pregnancy (6.37% vs. 7.28%; P &lt;.001). The congenital malformation rate was lower (2.5% vs. 11.1%; P &lt;.001) in the intervention group compared with the control group.</td>
<td>(12/18)</td>
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<td>Egan et al. (2016) - Ireland</td>
<td>414 women with T1DM and T2DM. Intervention, n=149/414, 36% received the intervention, control, n=265. T1DM, n=111/269 (41%) received the intervention, T2DM, n=38/146 (26%)</td>
<td>Prospective cohort study. To investigate the effect of a pre-pregnancy educational programme on the risks of adverse pregnancy outcomes.</td>
<td>Oral PCC educational intervention delivered by HCPs (endocrinologist, DSN and dietician). Structured pre-pregnancy care programme involving patient education, medication review, assessment and treatment of diabetes complications and thyroid function status, intake of 5mg of folic acid, intensive glucose monitoring with preconception target HbA1c of &lt;6.1%. Particular focus on the positive aspects of pregnancy. The face-to-face time with women was not indicated.</td>
<td>The intervention group were less likely to smoke (8.7 vs. 16.6%, P=.03) or take teratogens at conception (0.7 vs. 6.0, P=.008) compared to the control group. First (6.8% vs. 7.6%, P &lt;.001), second (6.2% vs. 6.6%, P &lt;.001) and third trimester HbA1c (6.1% vs. 6.5%, P=.001) remained significantly improved, compared with the control group.</td>
<td>(13/18)</td>
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<td>Charron-Prochownik et al. (2008) - the United States</td>
<td>53 adolescent girls with T1DM (16-19.9 years). Intervention, n=37 (CD-ROM- 17, book-20), control, n=16.</td>
<td>Randomised controlled trial. To develop and assess the clinical feasibility of a PCC programme for young women with DM.</td>
<td>PCC educational intervention provided via the eHealth application. The READY-Girls programme was developed by the authors. The CD-ROM contained information on DM and its effects on reproductive health, sexuality, puberty and pregnancy; advantages of PCC; sessions on decision-making and communication skills development.</td>
<td>The knowledge (F2,40.1=3.77; P=.03) and perceived benefits (F2,40.1=3.48; P=.04) of PCC significantly improved by the end of the study. A significant increase in the intention to seek PCC and</td>
<td>(12/18)</td>
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The intervention participants watched a CD-ROM and received a comprehensive session on the content of the CD-ROM at their routine clinic visit. This lasted for about an hour. To utilise effective family planning ($F_{1,37}=5.75; P=.02$) was recorded.

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<td>Fischl et al. (2010) - the United States</td>
<td>88 adolescent girls with T1DM (13-19.9 years). Intervention, n=43, control, n=45.</td>
<td>Randomised controlled trial. To assess the effectiveness of PCC on behavioural and cognitive outcomes.</td>
<td>PCC educational intervention provided via eHealth application. The READY-Girls preconception care programme was used to promote the benefit of PCC. The intervention participants watched an educational CD-ROM, read a book, and received a nurse consultation over 3 consecutive clinic visits at intervals of 3 months.</td>
<td>Knowledge ($F=32.34; P&lt;.001$) and perceived benefit of PCC ($F= 9.70; P=.003$) increased by the end of the study. A significant improvement over time in the actual initiation of the PCC discussion with the diabetes health care team ($F= 14.6; P&lt;.001$).</td>
<td>(16/18)</td>
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<td>Holmes et al. (2012) - the United Kingdom</td>
<td>97 women with DM (16-40 years). T1DM, n=89, T2DM, n=8.</td>
<td>Before and after study. To determine if an educational DVD increases knowledge and changes the attitudes of women toward PCC.</td>
<td>PCC educational intervention provided via the eHealth application. The authors developed and explored the use of a DVD to raise awareness of pregnancy planning and prevention of unplanned pregnancies. Women watched an educational DVD with information on pregnancy planning, contraception use, pregnancy complications, and PCC advice. The number of times they watched the DVD or the duration of the intervention was not reported.</td>
<td>Significant improvement in self-confidence to use contraception to prevent unplanned pregnancies and access PCC (OR 3.3, CI 1.9, to 4.7; $P&lt;.001$). Significant reduction in perceived barriers to PCC (OR -0.7, CI -1.2 to -0.2); $P=.01$).</td>
<td>(12/18)</td>
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<td>Charron-Prochownik et al. (2013) – the United States</td>
<td>109 adolescent girls with T1DM and T2DM (13-19 years). Intervention, n=51, control, n=58.</td>
<td>Randomised controlled trial. To examine the long-term effect of the READY-Girls programme on PCC knowledge and behaviour.</td>
<td>PCC educational intervention provided via the eHealth application. The authors developed and explored the use of a DVD to raise awareness of pregnancy planning and prevention of unplanned pregnancies. Women watched an educational DVD with information on pregnancy planning, contraception use, pregnancy complications and PCC advice.</td>
<td>Increased intention ($F(6.824)= 2.56; P = .03$) to initiate the diabetes discussion with HCPs. Significant increase in the intention to seek PCC and plan a pregnancy ($F(6.534)=2.58; P=.02$).</td>
<td>16/18</td>
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<td>Author or country</td>
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<td>Holmes et al. (2017) - the United Kingdom</td>
<td>248 women with T1DM and T2DM. Intervention, n=135; watched DVD subgroup, n=58 (43%), Control, n=114.</td>
<td>Prospective cohort study. To evaluate the effect of a regional implementation of a preconception counselling DVD into routine diabetes care on pregnancy planning indicators.</td>
<td>The authors explored the use of a DVD resource to prepare women with DM for pregnancy. Women of childbearing age across Northern Ireland were given the educational DVD by their HCPs either face-to-face in clinics or by post. The DVD intervention contained three sections as follows: (1) things you need to know — information on contraception, risks, reasons for planning and a pre-pregnancy checklist; (2) things you might not know — support team, blood glucose target, ketoacidosis, hypoglycaemia and diet; (3) things you may want to know — information on 1st, 2nd and 3rd trimester, delivery and post-delivery.</td>
<td>Women who watched the DVD were less likely to smoke at conception (1.9% vs. 20.6%, P=.02) compared with the control group. The intervention participants were also more likely to be taking 5mg of folic acid (92.7% vs. 75%, P=.05) and have improved preconception HbA1c (7.3% vs. 8.2%, P=.02) compared with the control group.</td>
<td>(14/18)</td>
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- DM: diabetes mellitus, T1DM: type 1 diabetes mellitus, T2DM: type 2 diabetes mellitus, PCC: preconception care
- HCPs: Health care professionals, DSN: Diabetes specialist nurse, ACE: angiotensin-converting enzyme, PNC: prenatal care
2.4 Findings

The 14 articles reporting on 13 studies were grouped into two main categories based on their mode of PCC health education delivery:

A. Evaluation of the PCC education provided by HCPs (n=9)
B. Evaluation of the PCC education provided via eHealth technology (n=5).

2.4.1 Evaluation of the PCC education provided by HCPs

PCC education traditionally provided in clinical settings by health care professionals is associated with positive maternal and child health outcomes (Murphy et al., 2010b; Tripathi et al., 2010; Temple et al., 2006a, 2006b; Neff et al., 2014; Boulot et al., 2003; Galindo et al., 2006; Kekäläinen et al., 2016; Egan et al., 2016). An overview of the interventions, outcome measures, and their effects are described in the following two points.

1. Maternal health outcomes
2. Child health outcomes

2.4.1.1 Maternal health outcomes

Of the included studies, two prospective cohort studies (Boulot et al., 2003; Galindo et al., 2006) explored the effect of a PCC educational intervention on the levels of glycosylated haemoglobin (HbA1c). Boulot et al. (2003) assigned women with T1DM and T2DM to either an intervention group (n=175), where they received the PCC education before conception (PCC uptake was 48.5% in women with T1DM and 24% in women with T2DM), or to a control group (n=360) receiving standard care. The 435 women were recruited from tertiary perinatal centres. The results showed that the educational intervention was effective in enabling more women in the intervention group to attain HbA1c <8%. The intervention participants had improved HbA1c in the first trimester with a significantly lower number of women with T1DM (4.3% vs. 55%) and T2DM (2.9% vs. 27.9%) having HbA1c >8% compared with those in the control group (P<.001).

In this study (Boulot et al., 2003), it can be seen that the PCC education played an important role in the improvement of glycaemic control and contributed to more women in the PCC group having HbA1c below 8% and closer to the recommended threshold. The results further indicated that glucose optimisation preconception and in the first trimester was achievable through PCC for both women with T1DM and T2DM. A similar study by Galindo et al. (2006) in Spain included women with both T1DM and T2DM. The intervention group
(n=15) received preconception counselling (uptake = 12%), whereas the control group (n=112) only presented to medical care when pregnant. Although Galindo et al. (2006) did not set out to measure the effect of a PCC intervention on maternal HbA1c, the intervention group had significantly improved HbA1c (<7%) compared with those in the control group (P=.02).

Another prospective cohort study conducted in the United Kingdom (Temple et al., 2006a, 2006b) considered the effect of PCC education on maternal HbA1c, spontaneous abortion, preterm deliveries, and gestational age at presentation for prenatal care. The educational intervention was provided to women of reproductive age attending the pre-pregnancy care centre (uptake = 37.9%). Statistically significant differences were found among the intervention participants who had improved and sustained HbA1c (6.5% vs. 7.6%; P<.001) throughout pregnancy, presented earlier for prenatal care (6.6 vs. 8.3 weeks; P<.001), fewer spontaneous abortions (5.7% vs. 14.0%, P=.06), and preterm deliveries (5.0% vs. 14.2%, P=.02). The results suggested that PCC was associated with a significant reduction in obstetric risks and improvement in glycaemic control.

Temple et al. (2006a, 2006b) also found that in later pregnancy, the difference in HbA1c between the intervention and control groups became less pronounced, for example (5.5 vs. 5.8%) in the 28th week and (5.6 vs. 5.8%) in the 32nd week of pregnancy, respectively. The reason for these comparable results was unclear from the study. However, the optimised HbA1c observed in the control group (in later pregnancy) may have been due to improved knowledge, skills and confidence to manage diabetes or improved diabetes care during pregnancy (Holmes et al., 2017).

Two other prospective cohort studies (Murphy et al., 2010b; Tripathi et al., 2010) reported the effects of PCC education on HbA1c, gestational age at presentation for prenatal care, and folic acid intake in women with T1DM and T2DM. Murphy et al. (2010b) provided PCC education to women with T1DM and T2DM in a diabetes specialist clinic (uptake = 26.6%). During the 3-year study period by Murphy et al. (2010b), all women who received a structured education programme were assigned to the intervention group (n=181), while those who did not, were assigned to a control group (n=499). Significantly more women in the intervention group took 5mg of folic acid before conception (88.2% vs. 26.7%, P<.001), had significantly improved and sustained HbA1c values (6.9% vs. 7.6%; P<.001), and an earlier date of presentation for prenatal care compared with those in the control group (6.7 vs. 7.7 weeks; P<.001).
The role of PCC education in promoting healthy preconception behaviours and pregnancy planning was also explored by Tripathi et al. (2010), who assigned women receiving PCC counselling to the intervention group (n=240; 40.8%) and those who did not, to the control group (n=297). The results showed that participants receiving the intervention had significantly improved and sustained levels of HbA1c (≤7% vs. >7%) 3 months before conception (P=.002) and during the first trimester of pregnancy (P<.001), higher rates of folic acid intake 3 months before pregnancy (P<.001), and presented earlier for prenatal care (≤8 weeks vs. >8 weeks; P=.001) compared with the control group.

Additionally, three recent studies (Neff et al., 2014; Egan et al., 2016; Kekäläinen et al., 2016) reinforced the benefits of PCC education on HbA1c and pregnancy outcomes. Neff et al. (2014), in a retrospective cohort study, recruited women with T1DM from specialist diabetes centres and assigned to the intervention group those who received health education (n=70; 14%), while those in the control group had received standard care (n=394). The intervention participants had significant improvements to HbA1c <7% (6.9% vs. 7.8%; P<.001) and earlier prenatal care presentation (6±2 weeks vs. 8±6 weeks; P<.001) compared with those who received standard care. However, the effect on the rate of spontaneous abortion (10% vs. 16%, P=.12) or preterm delivery (15% vs. 15%, P=.46) was not found to be statistically significant. According to Neff et al. (2014), the significantly higher maternal age and weight in the intervention group may have reduced the effect of the intervention, and thus led to comparable results.

Furthermore, the intervention group had HbA1c of 6.3% at delivery, indicating that educational PCC interventions can enable women to optimise their blood glucose levels and sustain this throughout pregnancy. This result is supported by Kekäläinen et al. (2016), who in another retrospective cohort study also allocated women with T1DM who received the PCC education (n=96; 66%) to the intervention group and those who did not, to the control group (n=49). Statistically significant differences were observed in the intervention group, who had improved and sustained HbA1c (7.1% vs. 9.1%; P<.001) and reduced adverse pregnancy outcomes (17.7% vs. 34.7%, P=.06).

Similarly, Egan et al. (2016) in a prospective cohort study provided a pre-pregnancy care programme to women with T1DM and T2DM in specialist diabetes clinics across the Irish Atlantic seaboard. During the 8-year study period, women who received a standardised educational programme were assigned to the intervention group (n=149; 36%) and those who did not, to the control group (n=265). The results showed that the participants receiving the intervention had an increased folic acid intake (97.3% vs. 57.7%, P<.001), and also had
significantly improved preconception (7.4% vs. 8.1%, \(P=.002\)) and first trimester (6.8% vs. 7.6%, \(P<.001\)) HbA1c, which was sustained throughout pregnancy. Although improvements in HbA1c for the intervention group remained statistically significant when compared to the control group, second (6.2% vs. 6.6%, \(P<.001\)) and third (6.1 vs. 6.5%, \(P=.001\)) trimester HbA1c for all participants had improved. Egan et al. (2016) also found similar miscarriage and pre-term delivery rates (\(P=.09\)) amongst the intervention and control groups. This supports the findings by Neff et al. (2014) indicating that a significantly higher maternal age may have lessened the effect of the PCC intervention, and the HbA1c levels of <7% maintained by both groups in the second and third trimesters may have contributed to the lower and comparable rates of adverse outcomes.

2.4.1.2 Fetal health outcomes
Boulot et al. (2003) demonstrated that women with T1DM who received PCC education had significantly lower rates of perinatal mortality and congenital malformation (\(P<.005\)) compared to those in the control group. Furthermore, women with DM whose HbA1c was > 8% in the first trimester had double the risk of developing adverse fetal outcomes, such as perinatal mortality (\(P<.005\)), congenital malformation (\(P<.01\)), and preterm delivery (\(P<.005\)). Additionally, six further studies (Murphy et al., 2010b, Temple et al., 2006a, 2006b, Galindo et al., 2006, Kekäläinen et al., 2016, Egan et al., 2016) reported similar findings. Temple et al. (2006a, 2006b) and Egan et al. (2016) found that women who received a PCC educational intervention experienced a significantly reduced risk of adverse outcomes (including shoulder dystocia, stillbirths, and neonatal death) compared with those receiving standard care (\(P=.03; P=.007\), respectively.

Similarly, Murphy et al. (2010b) and Kekäläinen et al. (2016) found that the intervention participants experienced a significant reduction in congenital malformations compared with those in the control group (\(P=.009; P=.001\), respectively. Furthermore, Egan et al. (2016) observed that the babies of the intervention participants had significantly reduced admissions to the neonatal intensive care unit (44.3% vs. 62.0%, \(P=.002\)) compared with the control group. Galindo et al. (2006) further identified a positive relationship between the increase in maternal HbA1c levels (>7%) and the occurrence of fetal malformations. Additionally, Tripathi et al. (2010) and Neff et al. (2014) found a significant association between the lack of preconception care education and the increased risk of adverse fetal outcomes (\(P=.03\)).

Across all reviewed studies, PCC education was associated with improved HbA1c and reduced maternal and fetal adverse outcomes. However, most studies (n=8) reported low
levels of PCC uptake, ranging from 12% (Galindo et al., 2006) to 36% (Egan et al., 2016), amongst women with DM.

2.4.2 Evaluation of the PCC education provided via eHealth technology

Low levels of PCC uptake among women with DM have elicited interest in the use of multimedia technologies, such as CD-ROMs and DVDs as an intervention tool for PCC education.

Four studies (Charron-Prochownik et al., 2008, 2013; Fischl et al., 2010; Holmes et al., 2012) investigated the effect of eHealth technology on knowledge and PCC behaviours while one recent study (Holmes et al., 2017) investigated the effect of the eHealth intervention on maternal and child health outcomes. Charron-Prochownik et al. (2008), in an RCT, developed and used an interactive computer programme (CD-ROM) to promote PCC knowledge. Adolescent girls with T1DM, recruited from one diabetes clinic, were randomised to receive the 3-month CD-ROM intervention (n=37) or standard care (n=16). The outcomes were assessed using self-completed questionnaires at baseline, immediately following the CD-ROM viewing and at 3 months after the intervention. Significant improvement in knowledge ($P<.05$), perceived benefits ($P=.04$), and reduced barriers to seeking PCC ($P=.01$) were reported in the intervention participants.

An RCT by Fischl et al. (2010), which lasted 9 months, similarly used an interactive CD-ROM to deliver PCC health education. Adolescent girls with T1DM, recruited from two university-based diabetes clinics, were randomised to either the intervention group (n=43), where they watched 2 CD-ROMs, read a book, and met with a nurse for counselling, or standard care (n=45). This was conducted over three consecutive clinic visits at intervals of 3 months. During the first visit, they viewed a CD-ROM containing information on diabetes and its effect on reproductive health, sexuality, puberty and pregnancy. The second visit involved viewing a CD-ROM containing tasks to improve communication skills related to seeking preconception counselling and the third visit involved reading a print version of the CD-ROM. After the final session, they met with a nurse to discuss issues relating to PCC. Compared with those receiving standard care, the intervention participants had significantly improved knowledge and perceived benefits of PCC ($P<.001$), reduced barriers to seeking PCC ($P<.001$), and an increased intention to initiate the PCC discussion with health care professionals ($P<.001$). The effect on the intention to use contraception was not significant ($P=.10$).
A UK, before and after, study by Holmes et al. (2012) sought to explore whether an educational DVD would improve PCC knowledge and behaviour. The participants were recruited from two National Health Service (NHS) hospitals. The intervention involved women watching the contents of a DVD and the outcomes were assessed pre- and post-DVD intervention. Postal questionnaires were used in order to assess the beliefs and attitudes associated with preventing unplanned pregnancies and seeking preconception care before and after watching the DVD. Women with T1DM and T2DM (n=97) who watched the contents of the DVD individually in their homes showed a significant increase in perceived benefits and attitudes to contraceptive use ($P= .001$), receiving PCC ($P=.003$), knowledge of pregnancy planning ($P<.001$), and pregnancy-related risks ($P<.001$). There was a significant improvement in self-efficacy, that is participants’ self-confidence to use contraception to prevent an unplanned pregnancy and access PCC ($p < 0.001$), and knowledge of pregnancy planning and pregnancy-related risks ($p<0.001$).

Charron-Prochownik et al. (2013), using an RCT, assessed the long-term effect (12 months) of an educational DVD on knowledge and attitudes to PCC in adolescent girls with T1DM and T2DM. The participants, recruited from two hospitals, received the intervention over three consecutive (clinic) visits. They viewed DVD-1 containing the PCC information at baseline, DVD-2 with exercises on the application of the information in DVD-1 at three months and read a book version of DVD-1 at six months. Participants, who were randomised to receive the intervention (n=51), demonstrated a significant increase in PCC knowledge ($P=.001$), and in their intention to discuss PCC and contraception with health care professionals ($P=.03$, $P=.003$), compared with those in the control group who received standard care (n=58).

Finally, a more recent cohort study by Holmes et al. (2017) conducted across all five diabetes-antenatal clinics in Northern Ireland evaluated the effect of a preconception counselling DVD on the pregnancy planning indicators for women with T1DM and T2DM. Women who received and watched the educational DVD (n=58) were allocated to the intervention group and those who did not (n=114), to the control group. Women who received and watched the DVD at home were more likely to plan their pregnancies (87.5% vs. 64.7%, $P= .001$), take folic acid (80.7% vs. 42.3%, $P<.001$) and have improved HbA1c (6.7% vs. 7.4%, $P<.001$), which was sustained throughout pregnancy. Lower rates of miscarriage (1.7% vs. 14.0%, $P=.01$) and admission to the neonatal unit (26.8% vs. 32.6%, $P=.05$) were also recorded for the intervention group compared with the control group.
2.5 Methodological issues

Research tools

Nine studies exploring PCC education provided by healthcare professionals (Murphy et al., 2010b; Tripathi et al., 2010; Temple et al., 2006a, 2006b; Neff et al., 2014; Boulot et al., 2003; Galindo et al., 2006; Kekäläinen et al., 2016; Egan et al., 2016) and one study on eHealth technology (Holmes et al., 2017) used similar methods of data collection, e.g. medical records, pregnancy or birth records (both vital statistics and hospital records). There was also consistency in study findings, which increases the reliability of the data collection methods.

The four research studies evaluating PCC education delivered via eHealth technology (Charron-Prochownik et al., 2008, 2013; Fischl et al., 2010; Holmes et al., 2012) utilised questionnaire surveys. The research tool (a theory-based reproductive health and diabetes instrument) was replicated across all four studies and the findings were similar, despite having been conducted in different settings (clinic and home) and on different dates. This not only increases the reliability of the data collection tool and quality of evidence, but also indicates that the instrument should be appropriate for this study.

Reliability and validity

All studies evaluating PCC education provided by healthcare professionals (Boulot et al., 2003; Temple et al., 2006a, 2006b; Galindo et al., 2006; Murphy et al., 2010b; Tripathi et al., 2010; Neff et al., 2014; Kekäläinen et al., 2016; Egan et al., 2016) and the study evaluating eHealth technology (Holmes et al., 2017) adopted a predominantly observational approach. They did not address the issue of reliability and validity within their studies. However, some confidence can be placed in the evidence generated for the following reasons: there was agreement in the results obtained across studies and the majority used appropriate statistical techniques in the form of logistic regression to confirm the association between PCC education and outcomes, thereby ruling out the effect of confounding factors. This increases confidence that the impact of the PCC educational intervention was more likely to be causally related to the outcomes, rather than to confounding factors.

The other four studies on eHealth technology (Fischl et al., 2010; Charron-Prochownik et al., 2008, 2013; Holmes et al., 2012) addressed reliability and validity through the use of a valid and reliable questionnaire. There was consistency in the use of the same instrument, that is, the Reproductive Health Attitude and Behaviour (RHAB) questionnaire. The role of confounders were minimised in three studies (Fischl et al., 2010; Charron-Prochownik et al., 2008, 2013) where randomisation was used in order to reduce selection bias and
confounding. It is not evident whether Holmes et al. (2012) controlled for confounders (such as maternal age, weight, diabetes type, duration and diabetes complications), which may undermine the internal validity of the study. However, the overall findings across the four studies were similar and consistent, which increased the reliability of the findings.

**Sampling**
The studies on PCC educational interventions delivered by healthcare professionals utilised relatively large sample sizes (range: 127-680) (Murphy et al., 2010b; Tripathi et al., 2010; Temple et al., 2006a, 2006b; Neff et al., 2014; Boulot et al., 2003; Galindo et al., 2006; Kekäläinen et al., 2016; Egan et al., 2016). While the studies on educational interventions delivered via eHealth technology utilised smaller sample sizes (range: 58-248) (Charron-Prochownik et al., 2008, 2013; Fischl et al., 2010; Holmes et al., 2012, 2017). Thus, the demonstration of statistical significance in studies utilising sample sizes under 100 (Charron-Prochownik et al., 2008; Fischl et al., 2010) should be interpreted with caution. However, the successful use of smaller samples in the eHealth PCC studies, for demonstrating knowledge and behaviour change, suggested that similar studies can be conducted using smaller samples.

Sample size calculation was mentioned in only two studies (Holmes et al., 2012, 2017). By not reporting sample size considerations, it is difficult to determine whether the authors considered the risk of type 1 or type 2 errors within their results. Furthermore, the small sample size and lack of power calculations in these educational PCC intervention studies limit the extent to which the study results can be generalised to a wider population of women with DM. Furthermore, the use of observational cohort design in several studies (Murphy et al., 2010b; Tripathi et al., 2010; Temple et al., 2006a, 2006b; Neff et al., 2014; Boulot et al., 2003; Galindo et al., 2006; Kekäläinen et al., 2016; Egan et al., 2016; Holmes et al. 2017) may increase potential for selection bias. Additionally, due to the difficulty in recruiting women with T2DM, a lower representation of T2DM women was evident across all studies (Boulot et al., 2003; Holmes et al., 2012, 2017; Egan et al., 2016, Murphy et al., 2010b), which could in turn reduce the generalisability of the findings.

**Location of the data collection**
The interventions were all carried out in developed countries (as mentioned in section 2.3.1); the extent to which the findings can be applicable to other settings such as developing countries is limited. Also in recent times, the US and the UK appear to be channelling more effort into this area of research (see section 2.3.1). It is worth highlighting that the nature of PCC service provision in the UK has been described as fragmented and ranked poorly in
comparison to other European countries, such as the Netherlands (Murphy et al., 2010b). In terms of the use of eHealth technology for PCC, studies have only been conducted in the USA (n=3) and UK (n=2). The small number of studies using eHealth technology for PCC reflects the slow rate of eHealth adoption in this area of practice.

**Description of interventions**

The studies evaluating the PCC educational interventions provided by healthcare professionals were predominantly cohort studies (Boulot et al., 2003; Galindo et al., 2006; Temple et al., 2006a,b; Murphy et al., 2010b; Tripathi et al., 2010; Neff et al., 2014; Kekäläinen et al., 2016; Egan et al., 2016). These studies generally lacked information on the use of underlying theoretical models and on the duration of the PCC interventions provided in healthcare settings, while most studies assessing eHealth technological interventions (Fischl et al., 2010; Charron-Prochownik et al., 2008, 2013; Holmes et al., 2012, 2017) adopted the expanded health belief model (EHBM) of behaviour change and provided information on the duration of the eHealth interventions. The majority of authors provided explicit descriptions of their interventions, thereby improving clarity with reference to the content of the interventions and the reliability, as studies can be replicated more easily.

**Description of outcomes**

Ten cohort studies, i.e. nine studies on PCC education provided by HCPs and one study on PCC education provided via eHealth technology, measured patient (maternal and child) outcomes: women’s HbA1c level (prior to pregnancy, and in the first, second and third trimesters), obstetric complications (including miscarriage or spontaneous abortions and preterm deliveries), gestational age at the first presentation for prenatal care, adverse outcomes (including congenital malformations, stillbirth, and neonatal death), pregnancy planning indicators (including folic acid intake and avoidance of teratogenic medications), and rate of admission to neonatal intensive care units (NICU). Four studies using eHealth to provide PCC education (Fischl et al., 2010; Charron-Prochownik et al., 2008, 2013; Holmes et al., 2012) measured behavioural outcomes: knowledge of PCC (pregnancy planning and pregnancy-related risks) and attitudes (including benefits, barriers and self-confidence to seek PCC). The authors were consistent in the outcomes measured, which in turn increased the reliability of the review result.

2.6 Summary

The review summarised and critically appraised the literature on current methods for providing PCC education to women with T1DM and T2DM. The effect of PCC educational
interventions (including the use of eHealth technology) on patient and behavioural outcomes were identified and examined in each case. Although the evidence was consistent across studies, only a limited number of robust controlled studies on PCC educational interventions for women with DM were found. The studies were generally of moderate quality, with only four assessed as high-quality (Murphy et al., 2010b; Fischl et al., 2010; Charron-Prochownik et al., 2013; Holmes et al., 2017). The methodological issues identified in these studies, including selection bias and confounding, call for caution in interpreting their findings.

The reviewed evidence suggested that educationally-based PCC is instrumental to the achievement and maintenance of optimised HbA1c by women with T1DM and T2DM. The influence on preconception and first trimester HbA1c is of significance because fetal development (organogenesis) occurs before many women realise that they are pregnant. Optimised HbA1c during the early developmental stages contributes to a reduction in adverse pregnancy outcomes, which may help explain the significant reduction in perinatal mortality, preterm delivery and spontaneous abortions in the reviewed studies. Furthermore, the ability to achieve and maintain optimised HbA1c from preconception to delivery is of particular importance to women with T1DM for whom diabetes management and glycaemic control, are often difficult (Murphy et al., 2010b).

PCC educational interventions also played an important role in motivating women with T1DM and T2DM to plan their pregnancy, take 5mg of folic acid, stop smoking and avoid teratogenic medications. Kekäläinen et al. (2016) observed that improved pregnancy planning amongst the intervention group reduced their rate of congenital malformation to that of the general population. Despite these positive benefits, the inadequacy in traditional PCC education in meeting the needs of women with DM was widely recognised (Murphy et al., 2010; Tripathi et al., 2010; Boulot et al., 2003; Galindo et al., 2006; Kekäläinen et al., 2016). The PCC uptake was below 50% in all studies except one (Kekäläinen et al., 2016), and challenges across studies in terms of how to improve awareness and encourage women to seek PCC prevailed.

eHealth technologies have shown considerable promise in terms of helping to deliver preconception health education that increases knowledge and supports behaviour change (Fischl et al., 2010; Charron-Prochownik et al., 2008, 2013; Holmes et al., 2012). This review highlighted their potential to empower women with DM to make informed reproductive health decisions that will reduce unplanned pregnancies and adverse outcomes. The study by Holmes et al. (2017) further demonstrated the role of eHealth PCC in improving HbA1c and pregnancy planning, and in reducing the rates of miscarriage and admissions to the NICU.
2.7 Gaps in the literature

There are gaps within the literature with respect to knowledge and understanding, methodology and theory, each of which is explored below:

a. Gaps in knowledge and understanding

Preconception care education and its incorporation into eHealth technology (such as multimedia and mobile technology) appear promising as effective strategies for promoting the knowledge of PCC, and maternal and child health outcomes. Several researchers (Charron-Prochownik et al., 2008, 2013; Fischl et al., 2010; Holmes et al., 2012, 2017) utilised multimedia technology (CD-ROMs and DVDs) for the PCC education of women with DM. However, none of them utilised mobile technology, particularly smartphones (mobile phones with the capacity of internet and computers) or apps (applications designed to run on smartphones, which are increasingly being used to provide health education) in order to address the issue of inadequate PCC. Therefore, the scarcity of research that uses smartphone apps for PCC combined with the limitations of traditional PCC, underscore the need for research in this area. Furthermore, because it is unknown whether app use for PCC education is feasible and acceptable, a feasibility study is required.

The review revealed that more women with T1DM (managed in specialist hospitals) than T2DM (managed in primary care within communities) received PCC advice. A lack of awareness of the PCC services provided predominantly in hospitals has been highlighted as a key reason for their low attendance rates at PCC clinics and uptake of PCC services (Murphy et al., 2010b). This highlights the need to use a more universal type of technology, such as smartphone apps, in order to reach women with both types of DM. Furthermore, only four out of fourteen educational interventions supported healthy behavioural changes through knowledge optimisation, and just two (Holmes et al., 2012; Egan et al., 2016) used positive intervention language. This highlights the need for the development of a PCC app, utilising a supportive approach, in order to optimise PCC knowledge and support healthy behavioural changes.

Studies evaluating the effect of the PCC educational interventions provided by HCPs did not measure educational outcomes, thus it is unknown whether the PCC education had any effect on women’s PCC knowledge. Very few studies (n=4) also explored knowledge or attitudinal change as part of their investigations and only two included women with T1DM
and T2DM. This calls for a future study exploring knowledge and attitudes to PCC before and after the intervention, and that includes women with T1DM and T2DM.

**b. Gaps in methodology**

Although studies using eHealth for PCC were predominantly quantitative in nature, two (Charron-prochownik *et al.*, 2008; Holmes *et al.*, 2012) sought participant input prior to developing the technology (i.e. mixed methods research approach was used to some extent). However, in-depth user experience was not addressed. It is important for future eHealth studies to seek participant input prior to development and assess patient satisfaction. Clearly, there is a need for a feasibility study using mixed methods and a co-design approach.

**c. Gaps in theory**

The review also revealed that most studies in this field (excluding those that used eHealth technology to provide PCC education) utilised an observational approach and were highly clinically oriented. As a result, they were not underpinned by theory or located within a conceptual framework.

The issues and gaps highlighted within the review formed the basis of the research questions developed within the mixed methods study as described in Chapter 1.5. The next chapter presents the theoretical framework underpinning the app intervention and study.
3. Chapter 3: Theoretical framework and study design

3.1 Theoretical framework overview

The role of preconception care (PCC) in reducing risks of pregnancy-related complications and adverse outcomes was demonstrated in the previous chapters, which also showed the inadequacy in current PCC uptake and slow eHealth adoption rate in this field. Despite the global increase in smartphone-based health app usage (Eng and Lee, 2013; Silva et al., 2015), there is a dearth of evidence exploring how this technology can be used to support improved PCC behaviours. Predicted increases in the number of women with DM of childbearing age means that there is an urgent need to adopt a more innovative approach.

This section will discuss the theoretical frameworks used (Figure 3.1). The rationale for the PADI app intervention developed and used in the study, and anticipated benefits will be explained.

3.2 Normalisation process theory (NPT)

New technological interventions that address behaviour change are more likely to result in significant effect on health and care when they are implemented and ‘normalised’ into practice (Murray et al., 2010). However, technological health innovations are often faced with implementation challenges after development, resulting in a gap between new technology and its recommendation to patients (Grol and Grimshaw, 2003; Woolf, 2008). Hence, the use of theoretical frameworks, such as knowledge to action (KTA), implementation of change model, PARIHS (promoting action on research implementation in health services) model and normalisation process theory (NPT), have been recommended (Rycroft-Malone, 2004; Graham et al., 2006; Grol and Wensing, 2013; May et al., 2009; Murray et al., 2010). These implementation theories map onto the broader field of implementation science (IS) — the study of techniques to promote the integration of research findings and innovations into health policy and practice (Eccles and Mittman, 2006; May et al., 2011; Murray et al., 2010).

Normalisation process theory (NPT) developed by May et al. (2009) and noted to be particularly useful for behaviour change interventions, was deemed the most useful framework to guide the feasibility study and support the early development stages of the PADI app. The framework helps to optimise development, evaluation and implementation of eHealth interventions, and bridge the translational gap between research and practice (May et al., 2007, 2011; May and Finch, 2009; Murray et al., 2010; Morrison and Mair, 2012).
Fig 3.1 The two frameworks (NPT and EHBM) underpinning the PADI app development and study
NPT is a well-established theory, adopted and used by over 200 studies to guide intervention implementation. It also helps researchers to recognise factors that promote or inhibit the integration of new technology into routine practice; it explains how interventions will work, become sustainable and ingrained into everyday practice such that it ‘disappears’ from view (i.e. becomes normalised). NPT seeks to identify component parts for understanding and evaluating the process (implementation) that would enable an intervention, such as the PADI app, not only to be incorporated and normalised into everyday work of individuals and groups (embedded), but also sustained in practice (integration) (Murray et al., 2010).

NPT has four constructs that enable early consideration of factors that may affect adoption and implementation of an intervention at the individual, clinician and organisational level. The constructs highlight crucial areas of consideration prior to developing a new technology and help to ensure that (1) the technological intervention would be easy to understand, meaningful and beneficial to participants and healthcare organisations (coherence/sense making), (2) the target user groups would see the intervention as a good idea and be committed to investing time, energy and work into its implementation (cognitive participation/engagement), (3) it will fit with existing working practices and skill set, and target user groups would be prepared to do the work needed for the intervention to happen, e.g. using it in routine practice (collective action), (4) participants can appraise the interventions and contribute feedback which can be used to improve the intervention (reflexive monitoring). In order to give the app the best chance of being accepted and adopted by women with DM, healthcare professionals and healthcare organisations, it was important that this study addressed the issues raised within the NPT constructs. It was envisaged that this would be achieved by using NPT to guide the intervention development and study design (as described in chapter 4, phase 1 development). Table 3.1 below describes the four NPT constructs in more detail.

Using NPT to guide the intervention development
Adoption of new innovations in practice affects both patients and HCPs because it constitutes a new way of receiving care and / working. Hence, Presseau et al. (2009) highlight clinician time-constraint and patient preference as potential barriers to adoption and acceptance of a new technology. In order to identify potential factors (barriers and facilitators) that could affect adoption or acceptance of the PCC app, a co-design approach with HCPs and women with DM would be used (see Chapter 4). This approach would help to ensure that target user groups are involved in the development of the app and that their
views (including any concerns) regarding the app use in practice are explored. It is recognised that interventions which are difficult to understand or fit into normal daily practice would not appeal to HCPs or policy makers (Mair et al., 2008; Murray et al., 2010), hence this co-design approach would help to optimise the intervention content, features and design. An exploratory study would be an appropriate approach to elicit participants’ views and inform the app development.

Table 3.1 Normalisation Process Theory (NPT) constructs

<table>
<thead>
<tr>
<th>NPT construct and components</th>
<th>Topic areas to consider and explore within the framework and study</th>
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<tbody>
<tr>
<td>Coherence: Sense-making work that people do when they are faced with operationalising a new technology.</td>
<td>The value attributed to introducing a new eHealth intervention, i.e. the PCC app and the meaning it makes to participants.</td>
</tr>
<tr>
<td>Differentiation: Understanding how a set of practice differs from each other, e.g. face-to-face consultation and use of eHealth.</td>
<td>Is the intervention easy to understand and describe?</td>
</tr>
<tr>
<td>Communal specification: People working together to build a shared understanding of the aims, objectives and benefits of a set of practice or a way of working.</td>
<td>Is it different from other interventions?</td>
</tr>
<tr>
<td>Individual specification: Understanding specific tasks and responsibilities around a set of practice or way of working.</td>
<td>Does it have a clear purpose and do participants have a shared sense of its purpose?</td>
</tr>
<tr>
<td>Internationalisation: Understanding the value, benefit and importance of a set of practice or way of working.</td>
<td>Are the benefits likely to be valued by women with DM and HCPs?</td>
</tr>
<tr>
<td>Cognitive participation: relational work that people do to build and sustain a community of practice around a new technology.</td>
<td>The commitment made by participants.</td>
</tr>
<tr>
<td>Initiation: A core problem, and whether or not key participants are driving a new set of practice forward.</td>
<td>Are HCPs and women with DM likely to think that it is a good idea?</td>
</tr>
<tr>
<td>Enrolment: Participants may need to organise or reorganise themselves in order to contribute to the work involved – rethinking relationships.</td>
<td>Can they see the point of the intervention easily?</td>
</tr>
<tr>
<td>Legitimation: Ensuring participants believe that they can make a contribution.</td>
<td>What kind of skills and experience do participants have with regards to using apps and technology for healthcare?</td>
</tr>
<tr>
<td>Activation: Identifying the actions and procedures required to sustain a new practice.</td>
<td>Will HCPs and women with DM be prepared to invest time, energy and work into it? This includes undergoing any training or investing time needed to deliver the intervention?</td>
</tr>
<tr>
<td>Collective action: operational work that people enact to make a new technology function; previously referred to as normalisation process model (NPM).</td>
<td>Effort invested in the intervention by participants.</td>
</tr>
<tr>
<td>Interactional Workability (IW): How an e-health intervention might affect interactions between people and practices.</td>
<td>How will providing the PCC app intervention affect the work of HCPs? Do they think it would promote or impede their work?</td>
</tr>
<tr>
<td></td>
<td>What effect will it have on the support they offer to</td>
</tr>
</tbody>
</table>
Relational Integration (RI): How the intervention might affect the existing knowledge and relationships.

Skill Set Workability (SSW): How the intervention might affect the current division of labour. This reveals the degree to which the e-health initiative will fit with existing working practices, skill set and perceived job role.

Contextual integration (CI): How the intervention might affect the organisation in which it is set.

Relational Integration (RI):
Do they think it would change (i.e. enable or impede) interactions between HCPs and women with DM? Is the work compatible with their current working practices?

Skill Set Workability (SSW):
How would the intervention impact on their workload, and what impact will there be on resources such as time?

Contextual integration (CI):
How does it fit with the overall goals of their organisations, their capacity to undertake the implementation and wider policy agenda?

Reflexive monitoring: appraisal work that people do to assess and understand how a new technology affects them and others.

Systematisation: participants may seek to determine how effective and useful it is for them and others.

Communal appraisal: participants work together to evaluate the worth of a set of practices - is it working?

Individual approval: participants work experientially to appraise its effect on them and the context (an intervention that is complicated to use or adds to HCPs' workload may well have low uptake even if beneficial to patients).

Reconfiguration: Modifying, redefining or changing a technology to make it workable in practice.

Perceptions of benefit to patients and HCPs.

How do users perceive use of the intervention, is it likely to be perceived as advantageous for patients?

What may be required to make the intervention workable in practice? Can users contribute feedback about the intervention and is there room for the intervention to be adapted or improved following user experience?

Using NPT to guide the study design
Mair et al. (2012) note that many eHealth implementation efforts are unsuccessful due to inadequate consideration of the wider issues, outlined in the NPT constructs, which affect implementation of technological innovations in healthcare setting. Hence, the first phase of the study would be designed to ensure that important contextual issues that can affect future implementation of the PADI app, are incorporated in early discussion of the app development. To achieve this, a qualitative approach incorporating focus groups and interviews would be adopted (see Chapter 5); the discussion would explore whether participants (HCPs and women with DM) perceive the PCC app intervention as potentially useful to women with DM and healthcare organisations (general practices and NHS hospitals) that provide PCC, and if they would be willing to recommend and adopt it within their respective healthcare organisations. It would also be important to understand how the app would fit into routine practice, affect current PCC service provision and if it would be consistent with existing work practices (see Chapter 6, for phase 1 results).

It was also envisaged that exploring user experience, following development and preliminary testing of the app, would provide useful feedback that could inform future development of the app intervention. Hence a mixed methods research methodology, with 2
3.3 **Behaviour change intervention for women with DM**

Based on the theory of behaviour change (Expanded Health Belief Model), this study aimed to develop an intervention that would address a number of factors associated with PCC and shortfalls in service provision that women with DM experience (Earle et al., 2017; O’Higgins et al., 2014; Infanti et al., 2014). It has been recognised that insufficient access, a lack of information, poor clinician knowledge and PCC uptake, contribute to inadequate pregnancy planning and blood glucose control, which can contribute to increased prevalence of preventable obstetric complications (O’Higgins et al., 2014; Earle et al., 2017). In addition, teratogenic medications (e.g. ACE inhibitors and statins) which should be avoided before pregnancy are increasingly used for hypertension, reno-protection and cardiovascular risk reduction in patients with DM.

Many women with DM are also not sufficiently aware of the benefits of health promotion (e.g. folic acid intake, physical activity and healthy diet) and health checking behaviours (attending screening for microvascular complications), or the need to avoid health risk behaviours (e.g. inadequate blood glucose control, smoking and alcohol consumption) before and during pregnancy (McCorry et al., 2012; Dean et al., 2013; Xaverius et al., 2013; O’Higgins et al., 2014). Hence, as most women tend to seek medical care after conception (Galindo et al., 2006; Frayne et al., 2016), a more innovative means of providing PCC information and changing behaviours, is paramount.

Improved PCC awareness and behaviours in women with DM is vital to reducing pregnancy related risks (Earle et al., 2017; Holmes et al., 2012), and smartphone apps provide a platform through which health behaviours of individuals and groups can be changed (Prestwich et al., 2018). According to Handel (2011), a recognised benefit of mobile health apps is that they support patient-centred models of healthcare, which emphasise patient involvement and self-management. Consequently, app-based interventions that support people to make healthy behavioural changes such as quitting smoking, achieving healthy weights, reducing alcohol consumption and eating healthier diets have increased rapidly (Free et al., 2011; Gustafson et al., 2014; Zhao et al., 2016). The need for women with DM to become more actively involved in PCC and have the confidence to involve the diabetes team in pregnancy planning to help achieve a healthy pregnancy and baby, have been highlighted (ADA, 2003; Wouters, 2005). Hence, a PCC app, underpinned by the expanded health belief model (EHBDM), would be instrumental in providing health education needed to change behaviours and support women to become more proactive in planning a pregnancy.
3.3.1 The expanded health belief model (EHBM)

The PCC app intervention was designed to alter cognitive factors embedded within the constructs of the Expanded Health Belief Model (EHBM), a social cognitive model used to predict health behaviours. The EHBM is underpinned by six main constructs that are believed to influence behaviour change (Figure 3.2): Perceived Susceptibility, Perceived Severity, Perceived Benefits, Perceived Barriers, Cues to Action, and Self-Efficacy (Burns, 1992; Charron-Prochownik et al., 2001).

Figure 3.2 Expanded Health Belief Model (EHBM) constructs
Perceived susceptibility is the perception of vulnerability to reproductive health problems e.g. pregnancy-related complication while perceived severity is the belief of the seriousness of the problem. Perceived benefits is one’s opinion that a behaviour change e.g. seeking PCC will promote positive reproductive health, and perceived barriers is the assessment of obstacles that may deter a behaviour change (Janz and Becker, 1984). Cues to action are people, actions, or things that trigger a change in behaviour (Stretcher and Rosenstock, 1997). Self-efficacy is the belief or confidence in one’s own ability to perform effective reproductive health behaviours e.g. using contraception to prevent an unplanned pregnancy (Bandura, 1977; Charron-Prochownik et al., 2001).

The EHBM proposes that knowledge improves attitudes (perceived benefits and self-efficacy minus barriers) which then increases likelihood of a behaviour change. Motivational cues (ability to make informed decisions and discuss PCC with a HCP) also contribute to behaviour change. It was anticipated that the PCC app intervention would help improve knowledge and attitudes, and result in behaviour change particularly regarding optimising blood glucose levels, seeking PCC and preventing unplanned pregnancy. According to Charron-prochownik et al. (2001), several major constructs of the EHBM correlate with reproductive health behaviours in women with DM. In a study by Janz et al. (1995), the construct of perceived benefits was found to be most influential. Women who received PCC were more knowledgeable and perceived greater benefits of PCC for themselves and their babies. For eHealth PCC studies, similar findings were noted. Compared to the standard care group, the intervention group had greater perceived benefits of reproductive health and PCC along with fewer barriers to seeking PCC (Charron-Prochownik et al., 2008, 2013; Fischl et al., 2010; Holmes et al., 2012). The use of EHBM in several eHealth studies exploring PCC, helped inform the decision to use it in this study.

3.3.2 The preconception and diabetes information (PADI) app intervention

The aim of PCC is to optimise each woman’s health before pregnancy in order to decrease risks during pregnancy and improve birth outcomes (Frayne et al., 2016). Evidence suggests that women’s PCC knowledge and attitudes are key factors that contribute to inadequate PCC uptake and pregnancy planning (Spence et al., 2010; Earle et al., 2017). For example, despite the established effects of folic acid (De-regil et al., 2010), less than one-third of all women take or aware of the importance of preconception folic acid. Additionally, the literature suggests that patients with DM who are more knowledgeable about PCC, are more likely to plan their pregnancies, seek PCC and to have improved health outcomes (Holmes et al., 2012; 2017).
National and international guidelines (NICE, 2015; Frayne et al., 2016) have identified healthy behaviours which when adopted before and during pregnancy reduce risks of complications and adverse outcomes. These include use of contraception to avoid unplanned pregnancy, folic acid supplementation, registering for prenatal care in the first trimester, smoking and alcohol cessation, attaining a healthy weight, absence of infection (e.g. human immunodeficiency virus and sexually-transmitted infections), optimal blood glucose control, avoidance of teratogenic and over-the-counter medications, as well as discussing pregnancy intentions with the healthcare team.

For most people, behaviour change occurs gradually over time with the individual progressing from one stage to the other and for many health behaviours, initiation does not lead to significant benefits unless these changes are maintained over an extended period of time (Prestwich et al., 2018). Poor rates of adherence to behaviours highlight the need for improved self-management strategies (Handel, 2011); one way to improve self-management is through remote access to health information, via smartphone apps (Calvillo et al., 2013; Zhao et al., 2016). Apps are also useful for educating, supporting and encouraging patients to adopt healthier behaviours in order to improve health outcomes (Mertz, 2012; Prestwich et al., 2018).

The PADI app would therefore be developed to improve the PCC that women with DM receive. It was anticipated that providing comprehensive PCC information and advice via a smartphone application would help improve the process by which women with DM receive PCC information and advice.

The PADI app would provide information and advice on the topics, outlined in figure 3.3 below (subject to changes according to results from the research process). This would be done in order to increase awareness regarding pregnancy planning and pregnancy-related risks; encourage women to prepare for pregnancy (e.g. stop smoking, have BMI in normal range, take 5mg folic acid), optimise blood glucose levels before and during pregnancy, collaborate with diabetes team during pregnancy planning and make informed reproductive health decisions that would reduce risk of complications and adverse outcomes (e.g. using contraception until recommended HbA1c is attained).

The intervention would use a supportive approach, and also provide social support, instruction on how to perform the behaviours, and self-monitoring of blood glucose (SMBG) function. The PCC app intervention would therefore aim to empower women with the knowledge and confidence to take control of their health, plan their pregnancies, adopt and
maintain behaviours that would increase the likelihood of a healthy pregnancy and baby. Furthermore, it was envisaged that a feasibility study would help provide preliminary information on intervention acceptability, satisfaction, and effect on knowledge, attitudes and behaviour.

Fig 3.3 PADI app information topics

Summary
The preceding section has discussed the behaviour change theory which underpinned the PADI app intervention and the normalisation process theory used to guide the intervention development and study. The rationale for the PADI app content and the predicted mechanism of behaviour change (based on the EHBM) have been discussed. A mixed methods research approach, encompassing an initial qualitative study followed by a quantitative and qualitative strand, are identified as the most appropriate research methodology to support the two theoretical frameworks used in this study.
3.4 Study design overview

A mixed methods feasibility study with two phases, phase 1 (PADI app development) and phase 2 (feasibility and acceptability of intervention), was used in this study. Phase 1 explored participants’ PCC views and experiences, as well as their opinions regarding the development and use of the Preconception and Diabetes Information (PADI) app, while phase 2 provided information regarding preliminary intervention estimates, experiences and satisfaction with the app content and functionality. The mixed methods study design is discussed in detail in Chapter 4 and 5. This section explores the epistemological approach of the study and the philosophical basis of the mixed methods research, specifically focusing on a feasibility study. The specific mixed methods research approach used, as well as the stages of intervention development and evaluation are then considered. Finally, the ethical considerations of the study and practicalities issues are discussed.

3.5 Epistemology

There are three main approaches to research — quantitative, qualitative and mixed methods. Debates about these three research approaches date back to ancient Western philosophy and are still ongoing (Johnson et al., 2007). On the one hand, there are those (e.g. Socrates and Plato) who believe in singular/universal truths, others who believe in multiple/relative truths (e.g. sophists such as Georgia and Protagoras), and those who believe in mixtures of the two extremes (e.g. Aristotle’s golden mean and Hume’s moderate scepticism) (Johnson et al., 2007). These debates continue to affect how we gain knowledge — our expectations and view of knowledge, and the methods we use to gain knowledge.

Generally, mixed methods research is an approach to knowledge that considers multiple perspectives and viewpoints (including quantitative and qualitative research) (Johnson et al., 2007; Creswell and Plano-Clarke, 2011). The distinction between quantitative and qualitative research lies in the philosophical assumptions of each, i.e. post-positivism and constructivism respectively, and the methods they use to investigate a particular area of interest. Quantitative research is based on the assumption that behaviour can be explained using objective facts that are independent of the researcher; it uses hypotheses to examine the relationship between variables in order to establish cause and effect (Scotland, 2012; Creswell, 2014). Post-positivists employ methods that enable the replication and comparison of groups e.g. experiments and surveys (Creswell, 2014). In contrast, qualitative research follows the notion that multiple realities exist, it is subjective and based on interactions with people (Guba and Lincoln, 1994; Creswell, 2014). Qualitative researchers make sense of data and interpret the meanings people make of the world, thus the constructivist generates
theory and patterns of meaning by using focus groups, observations and unstructured or semi-structured interviews (Creswell, 2014).

Despite the acceptance of mixed methods research (MMR) as a distinct methodology, many unresolved questions exist about the philosophical assumptions underpinning this approach (Creswell, 2014; Johnson et al., 2007). These philosophical assumptions are ‘a set of beliefs that guide inquiries’ (Creswell and Plano-Clarke, 2011) and perspectives used to look at the world (Bowling, 2009). Philosophical assumptions are also referred to as worldviews or paradigms. Advocates of mixed methods have therefore proposed the following paradigms for MMR: Transformative-emancipatory, Pragmatism, Critical Realism and Dialectics. However, pragmatism has remained one of the most commonly used paradigms because it offers the best opportunities for answering research questions and enhancing knowledge on a specific research topic (Johnson and Onwuegbuzie, 2004; Bryman, 2007; Creswell and Plano-Clarke, 2011; Johnson et al., 2007; Morgan, 2007; Tashakkori and Teddlie, 2010).

Proponents (Morgan, 2007; Creswell, 2014; Creswell and Plano-Clarke, 2011) argue that in pragmatism, the world is not seen as ‘an absolute unity’, thus in mixed methods research, various approaches to data collection and analysis are considered, rather than an absolute subscription to one method alone (such as quantitative or qualitative). Hence, this study upholds the pragmatic paradigm and does not embrace any one system of philosophy and reality in particular, as there is freedom of choice in utilising both qualitative and quantitative methods and assumptions in developing and testing the PADI app intervention (Creswell, 2014). Furthermore, Johnson et al. (2007) argue that pragmatism provides an ‘epistemological justification’ and logic for mixing approaches and methods in research because the combination of methods and ideas helps to adequately frame, address and answer different research questions. This paradigm supports the use of both qualitative and quantitative research questions in this study (see Chapter 1).

As a philosophical underpinning for mixed methods, the ultimate value of pragmatism lies in the incorporation of different methods, paradigms, as well as approaches to data collection and analysis, while investigating a research topic. Thus, due to the multi-faceted, complex and dynamic nature of health service research, it is evident that neither constructivism nor post-positivism alone should constitute the sole approach to scientific enquiry. However, in accepting pragmatism, there is a danger of over-prioritising research questions such that they become more important than either the method or philosophical assumption that underlie the methods. Yet, it is evident that agreeing with only one view will not provide the most informative, complete, balanced and useful research results nor will it provide an in-
depth understanding of the research problem or topic (Johnson et al., 2007; Tashakkori and Teddlie, 2010; Creswell and Plano-Clarke, 2011).

A key criticism of the pragmatic approach is that mixing quantitative and qualitative methods can be deemed inappropriate (Greene, 2008; Mertens, 2012), especially with reference to philosophical assumptions. Pragmatism has nevertheless gained popularity as a philosophical perspective because it is the foundation for the rejection of the incompatibility thesis and addresses the dualism that drives the ‘paradigm wars’ (Bryman, 2006, 2007; Biddle and Schafft, 2015). It provides support for building a practical, multi-perspective and flexible research philosophy. Greene and Caracelli (1997) acknowledge that while philosophical differences exist between various methods of inquiry, these philosophical perspectives are independent and can be mixed (using appropriate methods) to achieve the best combination for a given scientific enquiry. With this in mind, mixed methods was deemed the best research approach for this study.

3.6 Mixed methods research approach

Mixed methods, often referred to as a new methodology, the origin of which dates back to the late 1980s and early 1990s, has been in use in medicine and epidemiology since the mid-19th century (Maxwell, 2016). It came into existence from the efforts of several writers from different disciplines, who searched for means to systematically and coherently combine qualitative and quantitative methods into a distinct type of research. Creswell and Plano-Clarke (2011) however link the origin of mixed methods to Campbell and Fiske (1959), who discussed the need to include multiple forms of quantitative data in studies investigating behavioural characteristics, and Denzin (1978), who advocated the use of multiple data sources, both qualitative and quantitative in nature, in the conduct of scholarly studies. The evolution of mixed methods research (MMR) over the years has largely been due to the growing complexity of research problems and the need for more evidence-based research in applied settings (Creswell, 2014; Creswell and Plano-Clarke, 2011).

The Medical Research Council (MRC) guidance on the development and evaluation of complex health interventions highlights the importance of incorporating both qualitative and quantitative methods within a single study to enhance its findings (Craig et al., 2008). However, the evidence derived from the reviewed literature in Chapter 2 indicated that there was a scarcity of mixed methods research exploring the use of technology for the PCC of women with DM. This was an important element of consideration during the formulation of the research questions and study design. The MMR approach is of particular benefit in
mHealth development and feasibility studies where the research questions are best answered by a combination of two or more approaches (Mummah et al., 2016).

### 3.6.1 Embedded sequential mixed method approach

An embedded design is a mixed methods approach where a second method is embedded or nested within a primary research method (Creswell, Plano Clarke, 2011). In this design, the researcher may add a quantitative (supplemental) strand / phase, such as an intervention, to a larger qualitative design such as an exploratory study. The purpose of including the quantitative data are tied to but different from the purpose of the qualitative data.

In an embedded sequential design (Figure 3.4), the qualitative and quantitative strands are implemented in two distinct phases, with data collection and analysis of one type of data occurring after the collection and analysis of the other data type. In line with the principles of embedded MMR design, the researcher will begin by collecting and analysing qualitative data (i.e. focus groups and interviews) to understand the participants, establish a need for and inform the intervention. Using these results, the researcher will develop a relevant intervention (i.e. the PADI app) and test it with a quantitative (before and after study) design. Following the quantitative phase, a qualitative phase will also be conducted to enhance understanding of the quantitative phase and obtain participants’ feedback in order to improve the intervention (Creswell, Plano Clarke, 2011). The two methodologies used in this embedded design are distinct and will be implemented independent of each other; the data collection and analysis will also be kept separate.

The point of integration, i.e. the explicit interrelating of the study’s quantitative and qualitative strand, is a point within the process of MMR where the quantitative and qualitative strands are mixed (Morse, Niehaus, 2009; Creswell, Plano Clarke, 2011). According to Creswell and Plano Clarke (2011), mixing occurs at four points during an MMR study: design, data collection, data analysis or interpretation. The researcher will only mix / bring the two strands together during the discussion (interpretation) of the results. This is the only point in the research process where mixing will occur. Mixing during interpretation occurs when the quantitative and qualitative strands are mixed during the final step of the research process, after the researcher has collected and analysed both sets of data. It involves drawing inferences / conclusions that reflect what was learned from the combination of results (see Chapter 8).

Mixed methods research helps to improve an intervention, facilitate the interpretation of study findings and identify interventions that are more likely to be effective in larger future
studies (O’Cathain et al., 2013). Hence, MMR would help provide a detailed justification as to why the PADI app intervention does or does not work (Mummah et al., 2016; Whittaker et al., 2012). In order to ensure success, health interventions should undergo various stages of development and evaluation, as discussed below.
Fig 3.4 Embedded mixed methods research (Adapted from Creswell and Plano Clarke, 2011)
To ensure that an intervention is as effective as possible, the MRC guidelines recommend that the development of the intervention should be based on available evidence and theory, followed by feasibility and pilot testing, along with a large-scale evaluation using RCT and implementation (Craig et al., 2008). More recently, development and evaluation frameworks (Whittaker et al., 2012; Mummah et al., 2016) have been specifically developed for mobile app interventions and these supports, build on and extend the MRC framework (Craig et al., 2008).

Furthermore, Craig et al. (2008) argue that the various stages are not necessarily linear or cyclical, as this is dictated by the design of the study in question. Nevertheless, the authors recommend following a systematic approach and the PADI app intervention started with the development phase. A combination of all three evidence-based frameworks was therefore used to inform the PADI app development (Table 3.2).

Table 3.2  PADI app development and evaluation process

<table>
<thead>
<tr>
<th>Stages</th>
<th>Components</th>
</tr>
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<tbody>
<tr>
<td>Development</td>
<td>• Identification of evidence base and theory.</td>
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<tr>
<td></td>
<td>• In-depth understanding of the target population (via interviews and focus group discussions).</td>
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<tr>
<td></td>
<td>• Develop prototype and gather feedback.</td>
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<tr>
<td></td>
<td>• Build an initial intervention incorporating app analytics.</td>
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<tr>
<td>Feasibility and acceptability</td>
<td>• Conduct a small-scale evaluation (with or without randomisation) to test potential efficacy.</td>
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<tr>
<td></td>
<td>• Analyse app usage behaviour.</td>
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<tr>
<td></td>
<td>• Assess usability and satisfaction.</td>
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<tr>
<td></td>
<td>• Conduct interviews to understand user experience.</td>
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<tr>
<td></td>
<td>• Test recruitment, data collection and intervention delivery.</td>
</tr>
<tr>
<td>Evaluation*</td>
<td>• Conduct RCT to assess efficacy of intervention.</td>
</tr>
<tr>
<td></td>
<td>• Further gather and interpret data from app analytics, questionnaires and interviews.</td>
</tr>
<tr>
<td>Implementation*</td>
<td>• Publish findings to advance knowledge.</td>
</tr>
<tr>
<td></td>
<td>• Implement intervention.</td>
</tr>
<tr>
<td></td>
<td>• Analyse usage data.</td>
</tr>
<tr>
<td></td>
<td>• Continue to refine product to increase usability.</td>
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</tbody>
</table>

* Beyond the scope of this study (future work)

3.8 Ethical considerations

This research used the three main ethical principles on which the standards of ethical conduct in healthcare are based: principle of beneficence, respect for autonomy and justice (Holloway and Wheeler, 2010; Babbie, 2013). These principles helped to ensure that the rights of the research participants were protected. Each principle is discussed below:
a) The Principle of Beneficence
This principle requires researchers to act for the benefit of the study participants. It helps to ensure that participants do not experience any harm during the study and instead benefit from it. The World Medical Association (WMA, 2013) maintains that the risks must be kept to a minimum and should be carefully weighed against the benefits for the individual. The NHS Research Ethics Committee considered the study to entail low risk, burden or intrusion for participants.

Furthermore, should any sensitive issues arise, or should the participant become distressed, actions to reduce or eliminate the risk, such as stopping the interview, seeking verbal consent to continue or referring the participant to appropriate counselling services, would be taken (Ryan et al., 2009). However, no physical, psychological or emotional risk pertaining to the involvement in the study was identified during phase 1 (PADI app development) or phase 2 (feasibility and acceptability of intervention). Additionally, all participants were given the opportunity to ask questions before, during and after the study; the researcher’s contact details (email and telephone number) were also provided to the participants in order to enable them to discuss any concerns.

Ethics approval was obtained from the National Research Ethics Service (NRES) Committee East Midlands-Derby (see Appendix 3), the University of Surrey Ethics Committee (the study sponsor) (see Appendix 4) and the Research Governance Committee at the three NHS hospitals (see Appendices 5 to 7). Each hospital also supported the researcher’s application to obtain an honorary research contract.

b) Respect for Autonomy
This involves respecting the decision-making capacities of individuals. It is achieved by allowing the participants in a research study to make an independent, free and informed choice without pressure or coercion. This principle of respect for autonomy ensures that researchers consider the effect their actions and choices will have on the study participants involved in the research (Holloway and Wheeler, 2010).

The decision of an individual to participate in research must be completely voluntary and should be based on a full understanding of what the research entails (Gray, 2012; Ryan et al., 2009). The Department of Health (DH, 2005) highlights these as pertinent features of research that is conducted for the benefit of individuals, patients, healthcare professionals and the general public. The DH also emphasises the protection of participants’ dignity, rights, safety and wellbeing as the primary consideration of any research. Holloway and Wheeler (2010) further affirm that informed consent is at the centre of all research and
appropriate arrangements should be made for obtaining informed consent. Details of how informed consent was obtained in this study are provided below.

Obtaining Informed Consent

Informed consent involves ensuring that potential participants have sufficient information about the study before deciding whether or not to participate (Holloway and Wheeler, 2010; Babbie, 2013). This was achieved by preparing and presenting participants with a written participant information sheet (PIS) (see Appendix 8). For participants to be able to make an informed decision regarding participation, the PIS contained information regarding the research study and sponsoring body/institution, purpose of the research, benefits of taking part and any risks involved. It also outlined the participants’ level of involvement, assurance of confidentiality, liberty to withdraw at any time and the names of the people to contact for further questions or problems (Holloway and Wheeler, 2010; Ryan et al., 2009).

The PIS for healthcare professionals and women with DM (for phases 1 and 2 of this study) were designed with this in mind, and were friendly, simply worded and easy to understand (see Appendix 8). Participants were given a copy of the PIS at least one week before providing written consent to participate and were given the opportunity to ask any questions about the study. Participants were advised that they do not have to participate in the study and that they can withdraw from the study at any time without prejudicing their care. Once the participant consented to take part in the study, a consent form was signed by both the participant and the researcher (see Appendix 9). A copy of this was kept in the research portfolio. The design of the consent form allowed participants to take part in some or all research activities and included tick-boxes, where they could indicate what they will/would not do.

c) The Principle of Justice

This principle requires the researcher to be fair to the study participants and preserve their right to privacy. It is the researcher’s duty to protect the privacy of the participants. In this study, precautions were taken to ensure anonymity and confidentiality of data, in line with the Data Protection Act (1998) and the Declaration of Helsinki (WMA, 2013).

Confidentiality is recognised as the basis of the patient-practitioner-researcher relationship, as without it, trust in any encounter would be undermined. Information can thus only be given to a third party with the consent of the research participant. The DH (2005) upholds the need for everyone involved in the research to be aware of their ethical and legal duties and to ensure that systems are put in place to protect confidentiality. Participants were assured that the information obtained in interviews and questionnaires would be confidential,
anonymised and that any identifying features would be removed (Crinson and Leontowitsch, 2006).

The questionnaires and audio recording were coded and anonymised and did not include the participants’ name or address. Numbers were assigned to each participant and used instead in order to collect correct and comprehensive information about each participant. The audio recordings were only heard by the researcher. The content of the audio recording was transferred to a secure hard drive and stored in a locked cabinet within a locked office, and all electronic data were password-protected on a university computer. The data from the questionnaires and interviews will be held for a period of 10 years and destroyed afterwards, in accordance with the University's policy.

Ethical principles were followed during the conduct of the study in order to ensure that the rights of the participants were protected and that they were informed about the research prior to commencement. Care was taken to ensure that they consented to participate freely and that they were made aware of their right to say no or withdraw from the study without prejudice to their future care or employment.

3.9 Practicalities and access

Prior to the commencement of data collection at the study sites, it is important that researchers seek and gain permission for entry to the setting and access to participants (Holloway and Wheeler, 2010; Harding, 2013). Gaining access ensures that the setting can be observed, individuals at the site can be spoken to, necessary documents can be disseminated, and potential participants can be approached or interviewed.

In order to obtain access to the three hospital sites and general practice (GP) used in the study, several meetings were organised between the researcher, supervisors and key personnel at each site (Holloway and Wheeler, 2010; Babbie, 2013). In addition to the Research and Development (R & D) manager, relevant members of staff also included consultants, nurses and GPs, whose patients were later recruited into the study. These meetings were used to discuss the nature of the research, study design and data collection methods. Furthermore, it created an opportunity for the researcher to familiarise herself with the study setting (Holloway and Wheeler, 2010). Additionally, ongoing communication was maintained between the researcher, diabetes nurse and other HCPs through the use of e-mail and telephone contact.
However, despite being granted access to study sites and permission to recruit participants (Appendices 5-7), the researcher experienced challenges in recruiting women with DM, who met the inclusion criteria (as discussed in Chapter 4 and 5), from clinic settings. Very few women informed the consultant/diabetes nurses that they were planning a pregnancy. It was therefore important for the researcher to consider alternate sources of recruitment, such as social media, which has become a new and powerful method for recruiting participants, especially women, for health research studies (Fenner et al., 2012; Topolovec-Vranic and Natarajan, 2016). Furthermore, Liu et al. (2016) argue that people with DM are increasingly using Twitter for health conversations and peer support, making it an ideal platform to recruit women with DM. Following an amendment to the study protocol, all participants for phase 1 and the majority of study participants for phase 2 (as described in section 4.4 and 5.4) were subsequently recruited via Twitter.

Summary

The preceding section has presented the overall study design, epistemological approach of the study, the researcher’s pragmatic stance, the justification of the mixed methods feasibility study and the stages of the PADI intervention development and evaluation. The ethical principles guiding the study, and practicalities and access issues were also presented.

The next chapter explores phase 1 methodology and the PADI app development process.
4. Chapter 4: Phase 1 Methodology and App Development

4.1 Overview
This chapter explores phase 1 methodology and the PADI app development process. The co-design and iterative approach used to develop the app will be explained. Following this, the study setting and sample selection are considered. The methods of data collection (focus groups and interviews), tool development and analysis are then described.

4.2 Development of the PADI app
A co-design approach with healthcare professionals (HCPs), women with DM and Netsells Ltd. (an award-winning digital agency with expertise in building cutting edge mobile applications based in York, UK) was specifically used to inform and develop the PADI app’s content and features (Sanders and Stappers, 2008; Steen et al., 2011). Co-design has been described as a collaborative activity between researchers and study participants, with the participants taking on the role of experts in forming ideas and concepts based on their personal or professional experiences (Sanders and Stappers, 2008). Focus groups and interviews were used to identify the views, needs, preferences and expectations of the target population regarding the PADI app in line with the guidelines (Craig et al., 2008; Whittaker et al., 2012; Mummah et al., 2016); Figure 4.1 below shows the phase 1 flowchart. Evidence has shown that involving participants in intervention development facilitates a better fit between a product and the end users’ needs or preferences, resulting in more successful innovations and end user satisfaction (Steen et al., 2011; Liem and Sanders, 2013). The development process of the PADI app is outlined below.

PADI app design and prototype development
Following participants’ input regarding the PADI app features and content, the app design was then discussed with the app developer (Netsells) in July 2016, which then created wireframes (a visual guide representing the skeletal framework of the app) (Experience UX, 2017). The wireframes were used to detail the app layout, prioritise components and determine how the app screens would link together. They took into account the functionality of the screen, content, layout, app behaviour and sequencing of the app’s function. The output of the wireframe work was then used to create an initial prototype, a design model of the final user interface (UI), which gave the first detailed impression of how the UI or app screens would look and work.
The PADI app prototype was designed to provide a series of informational pages (see Chapter 3) and a place to submit and view blood glucose readings by day, week and month. However, this initial design output highlighted (to the researcher and supervisor) potential usability issues regarding layout, colours and navigation. The prototype was then revised several times to ensure that the final UI was simple, user-friendly and attractive. PADI was developed in both Swift (programming language for iOS) and Java (Android development...
An application programming interface (API) was also developed to allow the storage and retrieval of user data records. The API routine connected the PADI app to Netsells’ remote server and along with the creation of user accounts, allowed authentication with the data in the database. The API was developed using the Hypertext Preprocessor (PHP) framework Laravel, one of the most popular programming languages for web application back-end development (Bean, 2015). The resulting app design and content (prototype) was tested by Netsells to ensure optimal functionality before being released for further testing. The prototype was subsequently presented to a selection of participants [patients (n=4), HCPs (n=3), supervisors (n=2), researchers (n=4) and members of the public (n=2)], to test the full app functionality over the course of 14 days and provide feedback.

This pre-testing involved two cycles of feedback (see Figure 4.2) and led to minor textual changes in the informational content, the addition of a weight management section, a modification of the blood glucose (BG) diary to include the PCC target range (4-9mmol/l) and a pop-up feature that alerts and redirects participants to the BG management page, and the correction of an error in the graphical display of the BG readings. The pre-testing was considered complete when the changes made were tested by the participants and their needs satisfied. The final PADI app (Figure 4.3) therefore contained pregnancy planning information, a BG diary with graphical display and reminders, and built-in app analytics to collect app usage data in line with the guidelines (Mummah et al., 2016). Figure 4.3 below shows the PADI app development process. Following this stage, the app was further tested for 3 months in order to determine the system’s feasibility and acceptability (see Chapter 5).
Fig 4.2 PADI app development process

**Phase 1**

Co-design of the PADI app with healthcare professionals, women with DM and app developers

- PADI app prototype developed

**Cycle 1**

Piloting with healthcare professionals, women with DM, researchers, supervisors and the lay public

- Feedback

- Changes incorporated into the PADI app prototype

**Cycle 2**

Piloting with healthcare professionals, women with DM, researchers, supervisors and the lay public

- Feedback

- Consensus

**Final development and trial of app with women**
Figure 4.3 Screenshots of the Final PADI app

Welcome screen

Home screen

Menu screen
Blood glucose diary showing reading outside PCC target range
Figure 4.3 Screenshots of the final PADI app

Blood glucose diary showing daily blood glucose reading

Blood glucose diary reminder

Graphical display of average blood glucose levels
Reflection on app development process

The app development took 5 months (July-November 2016) and during this time, close liaison was maintained with the app development team at Netsells Ltd; it was important that meetings were held regularly to discuss progress, problems or feedback. To ensure that discussions held with the app development team were productive, the researcher ensured that she was familiar with the app development process and related technical terminology but used lay language to communicate her research to the development team. It was agreed from the outset, that regular progress reports would be sent to the researcher to keep her updated and ensure timely completion of the app.

Before the app development commenced, the researcher and development team had several in-depth discussions about the app and its content. However, the prototype development took longer than anticipated because the app development team and researcher struggled to reconcile their varying perspectives of the app. Hence, the first set of prototypes, even after being revised a few times, had usability issues (see section 4.2). Hence, after going back and forth a number of times, it became evident to the researcher that in order to move forward with development, she had to create a schematic diagram of how she expected the app and its content (including the welcome screen, menu screen, home page, information pages and diary) to look and function. This was then communicated to the development team who immediately understood the direction in which the researcher wanted the app design to take.

The developers took this design onboard and changed the prototype. Both the researcher and the development team agreed that the final design was indeed more contemporary and usable. Having the researcher’s design to work with gave the developers direction and facilitated the app development. This experience enabled the researcher to understand the importance of maintaining frequent communication, receiving regular update reports and developing a visual representation of the app (i.e. abstract ideas have to be made concrete) in order to expedite the development process and prevent time lost by going back and forth during the early development stage.

4.3 Research setting

The research settings for phase 1 of the study included one general practice and the diabetes clinic of two NHS hospitals, based in the South of England. These sites were selected as they provide specialist diabetes services to women in Surrey, Sussex and Hampshire. Participants were also recruited via social media (i.e. Twitter).
Phase 1 participants were recruited between February and September 2016. The data collection and analysis were completed in September 2016.

4.4 Sample selection
A purposive sampling strategy was used in order to ensure the adequate representation of clinicians and women with DM for this phase of the study (Patton, 2002; Creswell and Plano-Clarke, 2011). The study sample comprised a total of 36 participants: phase 1 (19 participants; 10 women with DM and 9 HCPs) and phase 2 (17 women with DM).

The number of participants was guided by previous studies using a co-design approach to develop mHealth apps and their sample varied from nine to fourteen participants (Cafazzo et al., 2012; Krishmanurti et al., 2017; Reade et al., 2017). For this study, a total of 19 participants, comprising HCPs (n=9) and patients (n=10), were recruited in order to ensure that the sample was sufficiently large if anyone decided to withdraw from the study, and to increase confidence that the data generated was comprehensive. Furthermore, although Guest et al. (2006) and Cafazzo et al. (2012) found that data saturation occurred after the analysis of twelve interviews, Francis et al. (2010) concluded that saturation is reached after thirteen to fifteen interviews. The larger sample size used in this study was to ensure data saturation and that no new findings emerged. For participants to be included in phase 1 of this study, they either had to be healthcare professionals involved in diabetes care or women of reproductive age (18-45 years) with T1 or T2DM.

Clinicians were recruited from two NHS hospitals and one GP practice in the South of England. A lead research nurse facilitated the recruitment of clinicians (n=7) from one NHS hospital. HCPs, who indicated interest in participating in the study, provided the nurse with their contact details, which were then passed to the researcher. The researcher, with the help from supervisors, further identified and recruited two other HCPs from one NHS hospital and GP practice. The researcher then sent them the healthcare professional information sheet, discussed the study with them and answered any questions. A signed consent form was then obtained.

A consultant at one of the NHS hospitals facilitated the recruitment of women with DM for this phase by handing out study information packs (comprising the invitation letter, information sheet and consent form) to patients attending the diabetes clinic, however no participants were recruited from this site after several months. Following this delay in recruitment, an amendment form was sent to the NHS Research Ethics Committee and
approval was obtained; all patients for phase 1 (n=10) were then recruited via social media (i.e. Twitter). A tweet was sent out via the University of Surrey and School of Health Sciences Twitter account, inviting eligible participants to contact the study researcher if they were interested in taking part in the study. Women who expressed interest in taking part provided the researcher with their contact details. The researcher then contacted the participants, sent them a participant information sheet and provided them with an opportunity to ask questions. A signed consent form was then obtained.

4.5 Data collection
The method used in the first phase of the research was qualitative in nature, using interviews and focus groups. Specifically, an exploratory approach was used in order to explore participants’ perceptions about PCC and experience of app use, as well as their views, needs, expectations and attitudes towards the use of a PCC mobile app. This approach was vital in order to develop a PCC mobile app intervention that was acceptable, feasible and relevant to women with DM and HCPs (Yardley et al., 2015; Mummah et al., 2016).

Qualitative research is used to provide insight into people’s different experiences and viewpoints (Marks and Yardley, 2004; Krueger, 2015). It was therefore necessary to use data collection methods that allowed participants to talk freely, as this often provides a more accurate insight into individuals’ inner thoughts and feelings (Harding, 2013). This phase of the study used both focus groups and interviews, the two most widely used methods for gaining insight into participants’ perspectives and experiences (Marks and Yardley, 2004; Harding, 2013). These methods of data collection have also been recommended for use in mHealth studies during the development of smartphone apps (Jurascio et al., 2015; Mummah et al., 2016; Whittaker et al., 2012).

4.5.1 Focus groups
Wilkinson (2011) described focus groups as ‘a way of collecting qualitative data which usually involves engaging a small number of people in an informal discussion about a particular topic or set of issues’. Focus groups were first used in the 1940s by Robert Merton and colleagues (Krueger, 2015; Silverman, 2014) and have gained recognition over the past 20 years as a qualitative data collection method in the field of healthcare research (Marks and Yardley, 2004; Holloway and Wheeler, 2010). The advantages of the focus group include flexibility, production of quick responses and low cost (Babbie, 2013).

This method of data collection was deemed relevant to the current research because as Krueger (2015) argues, focus group discussions are particularly useful for exploring people’s
knowledge and experiences and can be used to examine what people feel or think about an idea or product, that is, they are used in order to gather opinions. The participants in a focus group discussion (FGD) have certain characteristics or experiences in common and are thus similar in a way that is important to the researcher. The ideal group size is between five to eight people (Krueger, 2015), although smaller sizes of three to four people have been reported (Barbour, 2007).

Focus groups however have some challenges, such as the difficulty associated with assembling these types of groups (Babbie, 2013). For example, in this study, women with DM were geographically dispersed and available at different times, therefore an FGD was not feasible and individual semi-structured interviews were used. Furthermore, due to difficulties in arranging a mutually convenient time for all HCPs to attend the FGD, one FGD comprising three participants and six individual semi-structured interviews were conducted with this professional group.

4.5.2 Semi-structured interviews
 Interviews have become the most common method of data collection in qualitative research (Holloway and Wheeler, 2010) and are referred to as the gold standard (Barbour, 2008). Interviews are flexible and adaptable (Robson, 2011). Interviews provide an opportunity for the researcher to listen to the views and experiences of one participant for an extended period of time and to ask questions using probes in order to further explore ideas. Furthermore, a researcher can formulate questions based on participants’ responses, rather than asking only pre-formulated questions. The significance of this is that emergent issues can be examined in subsequent interviews. Each interview is therefore different in terms of wording and sequencing, however, distinct patterns common to all interviews in a study emerge during the analysis (Holloway and Wheeler, 2010).

Interviews can be structured, unstructured or semi-structured. The semi-structured approach, also known as a focused interview, is the most popular method in health and social care research (Hancock et al., 2009). This approach was used to interview the remaining phase 1 participants (six HCPs and ten women with DM). Semi-structured interviews provide more in-depth access to participants’ views, understandings, experiences and opinions, and as such can achieve a level of depth that may not be available to other methods (Babbie, 2013; Silverman, 2014). Thus, the semi-structured interview was used to explore participants’ perceptions and experiences in relation to PCC service provision, mobile app use and the PADI app development. The flexibility involved in semi-structured interviews allowed the researcher to adjust the interview in order to meet the study
objectives. She was also able to prompt the participants for more information, and they in turn explored their thoughts and exerted more control over the interview as their ideas took precedence. Furthermore, the meanings of words and phrases were followed up and clarified.

Semi-structured interviews can be conducted face-to-face whereby the researcher and participant meet. Although this interaction can be affected by bias, such as the researcher’s appearance, gender or ethnicity, face-to-face interviews facilitate attention to non-verbal behaviours and to the rapport between the researcher and the participant (Bowling, 2009; Holloway and Wheeler, 2010). Alternatively, telephone interviews are used as an alternative to face-to-face interviews when interviewing busy professionals and patients with limited availability. Telephone interviews are an effective means of interviewing and are particularly useful when the participants are geographically dispersed, such as the women with DM in this study. A limitation of telephone interviews however is that the researcher may not get to know or deeply interact with the participants. However, this method also has several advantages including immediate response, anonymity of participants and effective use of time (Holloway and Wheeler, 2010). Bowling (2009) adds that data collected via telephone interviews are as accurate as the face-to-face method. Hence, both face-to-face and telephone interviews were used.

4.5.3 Tool development and piloting

Tool development

Two separate topic guides informed by the literature (Holmes et al., 2012, 2013; Charron-Prochownik et al., 2006a) were developed for phase 1: one for the healthcare professionals (HCPs) and a second one for women with DM (see Appendix 10). These ensured that specific areas were covered but it was also possible to probe into and clarify emerging information within the FGD and interviews. The guides incorporated questions on PCC knowledge and attitudes, as well as app development.

The women with DM/patient interview guide was developed from previously published semi-structured interview questions by Charron-Prochownik et al. (2006a). The questions addressed items pertaining to awareness and the understanding of diabetes and PCC, complications associated with pregnancy, the prevention of complications with PCC and the use of contraception. The section on app development contained questions relating to the acceptability and use of apps in general and PCC in particular; these were formulated by the researcher. Similar questions were used in a recent formative research on app development (Cai et al., 2017). Similarly, the healthcare professional topic guide was developed based on
the research conducted by Holmes et al. (2012, 2013). The guide contained questions related to the aspects of diabetes, PCC and pregnancy planning that women with DM need to be aware of, as well as questions on the use of a PCC app in practice.

Marks and Yardley (2004) note that care should be taken in preparing the schedule in order to ensure that it is engaging, uses appropriate vocabulary, provides opportunities for various views to be expressed, and allows the participants to raise points not already covered in the schedule. In developing the schedules, questions were designed to be open-ended and follow a logical sequence, while probes that elicited more detailed information were also included.

Piloting
Piloting is vital for identifying potential problems and reducing the likelihood of collecting flawed data (Harding, 2013). Four researchers were interviewed and used to pilot the HCP and patient schedules, while one woman with DM and one HCP also piloted the patient and HCP topic guides, respectively. Following this, and a discussion with the academic supervisors, adjustments were made to the flow and wording of the HCP and patient interview guide.

4.5.4 Data collection process
Conducting the focus group
An FGD was conducted with three HCPs, i.e. one DSN and two diabetes research nurses. They were contacted well in advance and sent reminders a few days before the discussion. The HCP topic guide was used to guide the FGD, with the researcher acting as the moderator/facilitator of the group, asking questions, keeping the discussion flowing and encouraging group members to fully participate and interact with each other. As Krueger (2015) notes, ‘the researcher’s function is that of a moderator, a listener, and an observer, and in the end, an analyser of the discussion’. An assistant moderator (a fellow PhD student) took notes during the discussion, kept track of the order of speakers and recorded key issues. The researcher also made notes that helped guide the discussion.

According to Kitzinger (1995), it is important for the participants in an FGD to feel at ease, therefore the setting has to be comfortable and the atmosphere should be relaxed. The FGD was conducted in the diabetes centre of an NHS hospital in the South of England (i.e. the HCPs’ workplace). The small group sat in a semi-circle and the digital audio recorder was placed in the centre and used to record the discussions, which lasted 50 minutes. The FGD participants responded to the researcher and to each other. The FGD in this study used a
semi-structured approach in order to give participants the opportunity to express themselves freely, while also covering all areas of interest to the researcher. The FGD was also analysed as an interview, as recommended by Krueger (2015), in keeping with the study objectives seeking to understand various perspectives.

Conducting the semi-structured interviews

Healthcare professionals

The semi-structured interviews with the professional group, comprising six HCPs (three doctors and nurses), took place mainly via face-to-face method and one telephone interview. These interviews took place at a time that was convenient for the participants. The face-to-face interviews were conducted in the diabetes centre at one NHS hospital in the South of England or the workplace of the HCPs. Similarly to the FGD, all participants were contacted well in advance and sent reminders a few days before the discussion. The HCP topic guide was used to guide the discussion with the researcher acting as the interviewer. The interviews were audio-recorded and lasted between 30 and 50 minutes. During the interviews, notes were taken recording key topic headings, responses and any factors of interest, such as interruptions, notes on the setting and impressions of the process. Silverman (2014) suggests recording what the researcher sees and hears, the researcher’s behaviour and how the researcher is being treated.

Women with DM

The individual interviews with the patient group, comprising ten women with DM, were mostly conducted by phone, and took place at a time that was convenient for all participants. One interview, with one of the youngest women who was a student, was conducted face-to-face in a quiet meeting room at the University in the South of England. Participants were contacted one to two weeks in advance and were sent reminders a few days before the interview. The patient interview schedule was used to guide the interviews, which were audio-recorded and lasted between 20 and 30 minutes.

Prior to commencing the interview, it is important for the interviewer to establish and maintain rapport with the participants (Fox, 2006; Hennink et al., 2011) in order to generate rich data that are relevant to the research questions. It is more difficult to establish rapport during telephone interviews (Braun and Clarke, 2013; Harding, 2013); hence, the researcher took time at the beginning of each interview to engage in everyday conversation and explain the reason for the interview, including the project aim and how the interview data will be handled. Hennink et al. (2011) recommend that the interview should feel like a conversation
to the participant, but stress that it is not a two-way conversation and that the interviewer’s role is to obtain information and views.

The interviewing style used was aimed at building and maintaining rapport by relating to participants on a personal level and asking questions using the conversational style as recommended by Fox (2006) and Hennink et al. (2011). Furthermore, if participants encountered difficulties in answering certain questions, prompts were used sensitively to encourage further elaboration and dialogue regarding the topic. To further establish rapport, the researcher offered to answer questions at the end of the study as recommended by Harding (2013), and participants were encouraged to contact the researcher (via email or telephone) with any other questions or ideas that they may have.

Recording the data
The discussions (one focus group discussion and sixteen interviews) were digitally recorded and all participants consented to the audio recording. It was important to obtain an accurate recording of the discussion that could be played several times in order to facilitate the accurate conversion of the recordings from audio to a text-based format (transcription). Participants who may initially be self-conscious and concerned about the recording instrument quickly forget about it within a few minutes.

4.5.5 Data management and analysis
Qualitative data analysis (QDA) has been described as an iterative, complex and non-linear process that also employs a systematic, orderly and structured approach (Holloway and Wheeler, 2010). The analysis of data commenced immediately after conducting the first focus group discussion and interview with HCPs and patients; data collection therefore occurred alongside the analysis. An early commencement of the analysis enabled the researcher to identify areas that required more information, questions that were not fully answered and which needed adapting or pursuing in future interviews. Krueger (2015) adds that analysing data while the collection is ongoing provides an opportunity for the researcher to learn and improve. Initial findings were also explored in subsequent interviews. The audio recordings generated from the FGD and interviews were listened to repeatedly in order to gain familiarity with the dataset’s content before drafting the transcripts.

All data generated were transcribed verbatim by the researcher as soon as possible after the discussion with the two groups of participants. This is particularly important in a focus group discussion in order to remember who made each comment (Krueger, 2015). Bazely and Jackson (2013) recommend that researchers complete the transcription process themselves
in order to build familiarity with the data. The researcher transcribed the data by first listening
to the entire discussion and interviews in order to grasp the overall content and then listening
and transcribing the entire audio recordings using Microsoft Word. Krueger (2015) notes that
the researcher represents the voice of the study participants and as such needs to clearly
communicate their feelings about a topic while accurately representing the different voices
and views. The recordings were therefore listened to again while reading the transcript in
order to ensure transcription accuracy.

Furthermore, Harding (2013) argues that transcription involves interpretation because
spoken language requires punctuation to be added, period, dashes, etc., which reflects the
transcriber’s interpretation of what was said. By the end of the transcription process, the
researcher had become very familiar with the data and had started to note down initial
analytic ideas; hence, Braun and Clarke (2013) perceive transcription as part of the analytic
process. The transcribed data were then prepared for coding and analysis by using the QSR
NVivo 10 computer software package.

QSR NVivo was used as a data handling management system for the data collected from
the FGD and semi-structured interviews. NVivo was used because it allows large volumes of
data to be handled with speed, facilitates the exploration of relationships between codes,
and aids interpretation (Bazely and Jackson, 2013). The use of NVivo for conducting the
qualitative data analysis is supported by Babbie (2013) and Braun and Clarke (2013). The
transcripts of the sixteen interviews and one FGD were imported into NVivo as ‘sources’
followed by the process of thematic analysis as discussed by Braun and Clarke (2006,
2013).

Thematic analysis
Thematic analysis (TA) is defined as a method for identifying, analysing and reporting
patterns (themes) within the data (Braun and Clarke, 2006, 2013). However, TA often goes
further than this and interprets various aspects of the research topic and describes the
dataset in rich detail. Gibson and Brown (2009) report that TA has three main aims, namely
to examine commonalities by collating all the materials across a dataset that have something
in common, identifying differences across datasets and examining relationships by exploring
how different parts of the analysis fit together and contribute to the overall understanding of
different issues.

As a method, TA has received criticism in relation to the fact that looking at similarities and
differences removes most of the background detail and generates accounts that can be
distant from the experience of individuals. However, this has been rejected by Gibson and Brown (2009), who argue that thematic analysis is a means of linking different experiences and ideas together and comparing and interrelating different features or examples of the data. TA was previously seen as a poor method because it was not a 'named' method of analysis in the same way as other methods, e.g. grounded theory (Meehan et al., 2000). Additionally, there was lack of agreement about what it entailed and how to conduct it (Boyatzis, 1998; Tuckett, 2005). Moreover, it was not characterised as a method but as a tool to be used across different methods. Thus, TA was a poorly demarcated, rarely acknowledged, yet widely used qualitative analytic method until 2006, when Braun and Clark introduced it as a distinct method for analysing data.

TA has since become a widely accepted method that has been used in researching various topics including experiences of online gaming, living with multiple sclerosis and mobile app development (Robinson et al., 2013; Jurascio et al., 2015). One of its strengths is that it is a flexible approach that can be used within any paradigm and theoretical framework. In using TA, it is important for the researcher to be interpretive in order to identify themes that go beyond the surface meaning of the data and link to broader concerns (Braun and Clarke, 2013). Thematic analysis comprises six stages: reading and familiarisation with the data, generating initial codes, searching for themes among codes, reviewing themes, defining and naming themes, and writing (finalising the analysis).

Producing the findings.

Coding is the initial process of grouping and labelling data so that they reflect broader perspectives, from which emerging themes and patterns are identified. A code draws attention to a commonality or difference within a dataset (Gibson and Brown, 2009). The data were analysed by reading the narrative and then assigning labels based on the meaning elicited from the narrative. Rapley (2011) emphasises the importance of engaging with every line of text and of highlighting categories or taking note of what is of interest to the researcher. Tagging and naming selected texts (extracts) within the data led to the identification of initial topics organised using a system of nodes (codes) in NVivo.

After the initial coding process, the transcripts and recordings were read and listened to again for emphasis and meaning that were subsequently incorporated into the transcripts. Codes were further identified by summarising, selecting and interpreting the narrative data (Harding, 2013). The list of codes were then revisited and refined, and decisions were made about which category each code belonged to. This led to codes being moved or merged,
sub-categories being developed and/or new categories being created. The categories then became the themes for analysis, with the codes sorted into the different themes and the coded data extracts collated within the relevant themes. The aim of this process was to find all possible themes and sub-themes. Krueger (2015) refers to a theme as ‘an idea that can be seen running through different responses’.

According to Patton (2002), the researcher has an obligation to ‘fairly represent the data and communicate what the data reveal given the purpose of the study’. The analyses of data in this phase resulted in the identification of commonalities and differences in the views and experiences of both groups of participants in relation to PCC, use of technology for healthcare and the development and feasibility of an app for PCC. Braun and Clarke (2013) note that a theme is significant when it comes up numerous times, however, a higher frequency does not mean that the theme is more important to understanding the data. A researcher’s judgement is the key tool in determining which themes are more crucial to answering the research questions. Essentially, each theme should tell a story about the content and meaning of the data using extracts from the coded and collated data (Braun and Clarke, 2013).

TA can be inductive or deductive and this study incorporated both approaches (Braun and Clarke, 2013). The themes in this phase were determined by both multiple readings and interpretations of the raw data (inductive approach) and the research questions outlined by the researcher (deductive approach). Although a mixed inductive and deductive approach was used to elicit themes, the approach was largely inductive because the researcher was committed to examining the data without the constraint imposed by existing literature or preconceptions (Moses and Knutsen, 2007; Braun and Clarke, 2013). This approach was used in analysing the transcripts generated from both groups of participants (HCPs and women with DM).

The transcripts of the discussions with HCPs and women with DM were initially coded separately, however, while writing up the analysis (i.e. at the final TA stage), it emerged that the themes from both datasets were thematically consistent. Braun and Clarke (2013) acknowledge that writing is a deep analytic and interpretative work that is undertaken in order to make sense of and interpret the patterns identified within the data. Writing is therefore the process through which the analysis of data reaches its final form. Hence, a decision was made to present the findings from HCPs and women with DM together (see Chapter 6). Examples of coded interview transcripts, HCPs and women with DM, are shown in Appendix 11.
4.5.6 Validity and reliability: trustworthiness

Qualitative research, frequently criticised for lacking scientific or methodological rigour and analytical transparency, needs to be systematic and organised in order to improve validity and reliability (Noble and Smith, 2015). Validity in qualitative research refers to the integrity and relevance of the research methods undertaken and the accuracy with which the findings reflect the data (Long and Johnson, 2000). In this study, several strategies were employed in order to promote validity (credibility). For example, the research instruments were piloted to ensure that the study questions made sense to the participants; Guest et al. (2012) note that piloting facilitates the collection of valid data. Themes and interpretations were supported with verbatim quotes directly connecting the researcher’s interpretation with participants’ actual words (Creswell, 2014; Guest et al., 2012).

A common critique of qualitative research is that the reported data are selected to support the author’s conclusions or further an agenda. Hence, Guest et al. (2012) recommend presenting data that contradict common themes in order to prevent ‘analytic cherry-picking’. Creswell and Plano-Clarke (2011) argue that in real life, evidence for themes is expected to diverge and include more than only positive information. Similarities and differences across themes were included in order to ensure the representation of different perspectives. A clear description of the research process, i.e. recruitment, methods of data collection, analyses and findings, was also provided to increase research transparency (Guest et al., 2012; Noble and Smith, 2015).

Reliability in qualitative research indicates that the researcher’s approach is consistent across different researchers, projects or analytical procedures (Noble and Smith, 2015). Several strategies were used to ensure the reliability (dependability) of the findings including checking the transcripts for errors and constantly comparing the data with the codes. In order to further promote rigour in the research process, portions of the interview data were independently coded by two other PhD students, and data workshops were held to discuss the coding and codebook; any discrepancies were discussed and resolved. The data were also discussed and reviewed with the PhD supervisors. Guest et al. (2012) note that reviewing both coding and summaries in this way facilitates coding reliability and provides checks on individual biases.

Summary

Chapter 4 has provided an account of the methodology and app development process for phase 1 of this study. First, a description of the co-design and iterative approach used to
develop the PADI app was provided. This chapter also discussed the research setting, sample selection and development of data collection tools, as well as the methods of data collection (focus groups and interviews) and analysis. For each method, the rational for its use, as well as the strengths and weaknesses were provided. The data collection methods were followed by the data analysis method, i.e. thematic analysis. The research was designed and conducted so that reliability and validity issues were addressed. Measures were taken to reduce the effect of researcher bias that may be inherent in qualitative research and to ensure that the findings were an accurate and true account of the topic under investigation. These measures involved a comprehensive description of the research procedure, a rich description of data with verbatim quotes, checking the accuracy of transcripts against codes and inter-coder agreement. The next chapter explores Phase 2 of the study.
5. Chapter 5: Phase 2 Methodology

5.1 Overview
A mixed methods approach was used to explore the PADI app’s feasibility and acceptability in phase 2 of this study. This chapter begins with a description of the feasibility and acceptability of the PADI app. Following this, the study setting and sample selection are considered. The methods of data collection (questionnaires, semi-structured interviews and software log of activity), tool development and data analysis are then described.

5.2 Feasibility and acceptability of the PADI app intervention
Feasibility studies, research conducted on a small scale in order to ascertain whether the study can be done (National Institute for Health Research [NIHR], 2014), have been explicitly recommended by the Medical Research Council (Craig et al., 2008) as a prerequisite for the development and evaluation of complex interventions (i.e. interventions with several interacting components). They provide evidence as to whether an intervention should be further tested for efficacy (Bowen et al., 2010). Thabane et al. (2010) argue that feasibility testing prior to the main trial increases the likelihood of trial success. Conducting a feasibility study before a large trial has several advantages which include: providing preliminary data for the primary outcome measure, determining the integrity of the study protocol, testing data collection instruments, e.g. questionnaires, determining recruitment, retention and consent rates, and exploring intervention acceptability (Craig et al., 2008; Lancaster et al., 2002; Thabane et al., 2010). Additionally, several researchers have recommended using feasibility studies in order to determine the demand for an intervention; the practicality of conducting the intervention; the usability, implementation and potential efficacy of the intervention (Bowen et al., 2009; Arain et al., 2010; Mummah et al., 2016).

Feasibility studies have been conducted in numerous clinical and public health areas, such as critical (Arnold et al., 2009) and cancer care (Kearney et al., 2006), pain (Martorella et al., 2014) and diabetes management (Cafazzo et al., 2012), lifestyle modification e.g. diet, weight and smoking cessation (Whittaker et al., 2008; Knight-Agarwal et al., 2015; Hebden et al., 2012), promotion of PCC awareness (Charron-Prochownik et al., 2008) and pregnancy-related risks (Krishnamurti et al., 2017). The feasibility aspect of this study was therefore designed to explore study processes (intervention design, recruitment and retention), acceptability, experiences of app use, satisfaction, app usage behaviour and usability (problems and opportunities for improvement) and provide preliminary outcome estimates.
Examining the feasibility and acceptability of the intervention

Current guidelines (Craig et al., 2008; Whittaker et al., 2012; Mummah et al., 2016) recommend conducting a small-scale evaluation (with or without randomisation) in order to test the app intervention following development; hence, a pre- and post-intervention design with two data collection points, at the beginning and after 3 months of app usage, explored the feasibility of the PADI app. According to Orsmond and Cohn (2015), this helps ascertain whether the interventions show promise of being successful with the intended population. The 3-month intervention time frame was informed by previous studies that have developed eHealth interventions for PCC, pregnancy and diabetes (Charron-Prochownik et al., 2008; Cafazzo et al., 2012; Krishmanurti et al., 2017). Following this, semi-structured interviews were conducted with participants who used the app for 3 months in order to explore their views and experiences and ascertain the intervention’s acceptability (see Figure 5.1 for phase 2 flowchart).

5.3 Research setting

The research settings for phase 2 of the study included the diabetes clinics of two NHS hospitals, based in the South of England. These sites were selected as they provide specialist diabetes services to women in Surrey, Sussex and Hampshire. Participants were also recruited via social media (i.e. Twitter).

Phase 2 participants were recruited from December to March 2017. The data collection and analysis were completed in July 2017.

5.4 Sample selection

A purposive sampling strategy was used in order to ensure the adequate representation of women with DM in this phase of the study (Patton, 2002; Creswell and Plano-Clarke, 2011). The study sample comprised a total of 36 participants: phase 1 (19 participants; 10 women with DM and 9 HCPs) and phase 2 (17 women with DM).

Women with T1 and T2DM were recruited from two NHS hospitals in the South of England and via social media (i.e. Twitter). For a feasibility study, a sample size of 12 participants is recommended (Julious et al., 2005), and has been used by various mHealth studies (Whittaker et al., 2012; Tatara et al., 2013; Robinson et al., 2013; Knight-Agarwal et al., 2015). The target sample for this phase was (n=12); a total of (n=17) participants with T1 and T2DM were recruited to allow for loss due to follow up (estimated at 20%) (National Institute of Health [NIH], 2014).
Potential participants, who attend the diabetes outpatient clinics at the two district general hospitals, were approached by a member of the healthcare team when they came for their clinic appointments and asked whether they were planning a future pregnancy and were willing to speak to the researcher about participating in the study. They were then approached by the researcher who explained the study to them, provided them with an information sheet and asked them to contact her if they were willing to participate. Those who agreed to participate in the study were recruited.

Additionally, patients were recruited via social media. A tweet was sent out via the University of Surrey and School of Health Sciences Twitter account as well as by other researchers and organisations involved in diabetes research, e.g. Diabetes UK, Women with Diabetes and the College Diabetes Network (CDN), inviting eligible participants to contact the study researcher if they were interested in participating in the study. If women indicated interest, they provided the researcher with their contact details. The researcher then contacted them, sent them an information sheet, explained the study to them and provided them with an opportunity to ask questions. All participants who indicated interest were screened for eligibility using the following inclusion criteria:

**Inclusion criteria**

- Woman of reproductive age (18-45 years) with T1 or T2DM.
- Diagnoses of diabetes by a healthcare professional for more than 6 months.
- Currently not pregnant but planning a pregnancy (in the next 5 years or want children at some point in the future).
- Owns an iOS or Android smartphone.

The (n=17) women with T1 and T2DM who met the inclusion criteria and provided written informed consent were enrolled in the study, given the link to the free app download (from Apple and Google Play stores) and asked to download the app on their smartphones. Participants who were recruited from clinics (n=2) received a face-to-face demonstration of the key components and functionality of the PADI app by the study researcher, while the same information was communicated to those recruited via Twitter (n=15) remotely (via email and telephone). They were asked to use the app for 3 months for PCC and the self-monitoring of blood glucose levels, and to contact the researcher if they had any questions or experienced any problems during app usage.
Phase 2: Feasibility & acceptability of the PADI app intervention

Women with DM (18-45 years, planning a pregnancy and own smartphone)

Eligible to participate

Details added to study record

Patient information given at least one week prior to data collection

Participants agree to participate & consent obtained

Refusal recorded

Training on app use & information on app download given

Yes

No

1st questionnaire administered at baseline
2nd questionnaire administered after 3 months of app use

User experience interviews conducted after 3 months of app use

Fig 5.1 Phase 2 flowchart
5.5 Data collection for phase 2 (feasibility and acceptability of intervention)

As mentioned in section 5.1, phase 2 of this study adopted a mixed methods approach. The quantitative method is discussed first, followed by the qualitative method and software log of activity.

5.5.1 Patient questionnaire

Two questionnaires (a pre-intervention questionnaire and a post-intervention questionnaire completed after the 3-month intervention) were used to collect data in order to answer the following research question:

What are the preliminary estimates of the effect of the PADI app on PCC knowledge and attitudes and the Patient Activation Measure?

Questionnaires are one of the most useful, popular and accepted quantitative methods in health research. They are mainly used in survey research, but are also widely adopted in experimental research (Babbie, 2013). They ensure respondents are asked the same question without interviewer bias in order to identify the respondents’ true opinion or position (Neuman, 2006; Bowling, 2009). It determines the extent to which the respondents in a study hold a particular attitude or perspective (Babbie, 2013). In this study, questionnaires were used because they were deemed to be the most practical means of assessing an individual’s feelings, self-management levels, attitudes and behaviours (Marks and Yardley, 2004).

The ordering of questions (within a questionnaire) has been identified as an important factor that can affect responses. According to Babbie (2013), demographic questions are best placed at the end of the questionnaire and the use of open- and closed-ended questions increases the flexibility of the questionnaire design, making it more interesting. Therefore, a mix of closed-ended and open-ended questions was included in the two questionnaires used, with demographic questions placed at the end of the pre-intervention questionnaire. The questionnaires also had clear instructions for completion so as to guide the respondents. A copy of each questionnaire is provided in Appendix 12.

Question types

A mix of questions was used:

Closed-ended questions

Closed questions give respondents a set of answers and ask them to select the most applicable option from a pre-determined list (Parahoo, 2006). Closed questions are popular because they can provide uniformity and are analysed more easily. Yes/No and
True/False/Not Sure questions/statements were used. Likert scales (a composite measure made up of standardised response categories to determine the intensity of different items) with five categories were also included.

**Open-ended questions**

Open questions, with space for free comments, offer respondents the opportunity to write their opinion and provide their own answers to questions and statements (Oppenheim, 2000). This was considered especially useful to gather feedback regarding the participant’s experience in terms of app use and suggestions for improvement.

A number of disadvantages to using questionnaires have been identified. For example, the researcher has no control over the conditions or order in which the questionnaire is completed (Neuman, 2006; Bowling, 2009). Furthermore, although questions were adapted from existing questionnaires in the literature, the choice of questions remains subjective and may not be appropriate for the respondent (Kent, 2001), hence, the researcher piloted the questionnaire with one woman with DM and one DSN prior to the study. Other disadvantages of questionnaires include their rigid structure, simplification of complex issues and an inability of respondents to express their views about a topic or express themselves freely.

However, these limitations were overcome by incorporating open-ended sections into the questionnaire and collecting qualitative data using semi-structured interviews (as discussed in section 5.5.5). The two questionnaires used in this study were also worded in simple, everyday language in order to make them easy to understand and questions were asked without ambiguity, double-barrelled statements or double negatives. This was important as participants may not ask for clarifications while completing the questionnaires (Neuman, 2006; Babbie, 2013).

### 5.5.2 Methods of questionnaire administration

There are three main methods of administering the questionnaire and eliciting responses. They are self-administered questionnaires, questionnaires completed by the interviewer and telephone questionnaires. Two types of self-administered questionnaires, mail and online, were used in this study as participants were geographically dispersed.

**Mail questionnaire**

The most common form of self-administered questionnaires is the mail questionnaire, whereby a questionnaire is sent to a respondent, accompanied by a letter of invitation and a
self-addressed, stamped (reply-paid) envelope for returning the questionnaire. This method can however be affected by low response rates (Babbie, 2013), which can be partially overcome by sending reminder questionnaires. Incentives, such as gift certificates, money or prize draws, although not adopted in this study, have been shown to have a positive effect on the response rate (Petrolia and Bhattacharee, 2009). This method was found to be less successful compared to the online questionnaire, which is rapidly becoming a popular method of collecting questionnaire data.

**Online questionnaire**

Technological advancement has caused an explosion of interest in the internet as a tool for collecting questionnaire data (Couper and Miller, 2008). Some questionnaires are administered via email while others are conducted via websites (Babbie, 2013). Respondents may either receive an email with the questionnaire attached or one directing them to a website where they can complete the questionnaire. Online questionnaires are easy and convenient as participants can choose when to complete the questionnaire. This approach also increases reach and accessibility, and it is thus ideal for geographically dispersed participants. Online questionnaires are also cheaper to conduct. However, given that there may be some concerns over anonymity, researchers using this approach must ensure that all identifying features are kept separate from the returned questionnaires. This method has lower non-response rates when compared to the more conventional mail survey (Denscombe, 2009).

**5.5.3 Questionnaire development**

Two booklets, 7-9 pages in length were developed for this aspect of the study. The first page of the questionnaire contained information about the study, how long it will take to complete (10 - 15 minutes) and simple instructions on how to complete the questionnaire.

It contained five ‘Yes/No’ questions with further open-ended questions and fifteen 5-point Likert scale statements, designed to assess participants’ knowledge of reproductive health. There were twenty ‘True/False/Not Sure’ questions designed to assess their knowledge of PCC and thirteen 5-point Likert scale statements to assess their levels of activation. Questionnaire 1 contained an additional ten demographic information questions. Questionnaire 2 comprised all the questions (minus the ten demographic information questions) plus two additional sections aimed at evaluating respondents’ satisfaction with the app. A simple visual scale asked respondents to rate the app from 0 to 100, while a free text section asked them to provide additional information regarding their experience of app usage and suggestions for improvement.
The two questionnaires, used to assess patients’ reproductive health, attitudes and behaviour (RHAB), knowledge of PCC and level of patient activation, were developed from the following instruments (Charron-Prochownik et al., 2006b; Hibbard et al., 2005; Holmes et al., 2012). Section one (comprising 20 questions exploring reproductive health, attitudes and behaviour) was divided into six scales: cues to action (five questions), perceived susceptibility (four questions), perceived benefit (two questions), perceived barriers (two questions), self-efficacy (three questions) and outcome expectations (four questions). Section two comprised 20 questions on knowledge of pregnancy planning (11 questions) and pregnancy-related risks (9 questions) and section three had 13 patient activation measure (PAM) questions. The rationale and description of the choice of instruments are provided below.

Reproductive Health Attitudes and Behaviour (RHAB) multi-dimensional reproductive health and diabetes instrument

The RHAB is a validated theory-based instrument that measures the decision-making factors related to reproductive health and preconception care behaviours in women of reproductive age with DM. This instrument was adapted by Charron-Prochownik et al. (2006b) from the ‘Pregnancy and Diabetes Interview Schedule’ previously created and validated by Janz et al. (1995). The psychometric properties of the 48-item RHAB questionnaire were tested in a population of 87 adolescent women with DM and found to have acceptable levels of validity and reliability (Cronbach’s alpha = 0.65 - 0.83). It has since been used in several eHealth PCC studies designed to improve PCC behaviours (Charron-Prochownik et al., 2008, 2013; Fischl et al., 2010; Holmes et al., 2012). Hence, it was used in this study to measure changes in PCC beliefs and attitudes at baseline and following the PADI app intervention.

Charron-Prochownik et al. (2006b) identified unplanned pregnancies in women with DM as a complex problem and observed that various interconnected factors such as demography, psychology, behaviour and social characteristics contribute to poor pregnancy planning behaviours in this group of women. They concluded that preconception behaviours can be explained by the health belief model (HBM), theory of reasoned action (TRA) and social cognitive theory (SCT), thus, the RHAB examines constructs of these three social cognition models. The RHAB was developed for use in young women with DM in America, hence, it was modified in terms of language in order to make it more applicable to a UK study population. For example, contraception was used in place of birth control, in line with another UK study (Holmes et al., 2012). Furthermore, as the target behaviour is PCC, the instrument centred on achieving normal blood glucose levels, obtaining PCC and using effective contraception to prevent unplanned pregnancies.
Questionnaire length is a key factor that contributes to participants’ response burden (the effort required to answer a questionnaire) (Rolstad et al., 2011); increased response burden may result in lower questionnaire completion, response rates and data quality (Rolstad et al., 2011). To avoid participant response burden, an abridged (20-item) version of the 48-item RHAB questionnaire was used. The items in the abridged RHAB questionnaire used in this study were taken directly from the RHAB scale and contained the following six constructs: cues to action (motivation to seek PCC), perceived susceptibility (women’s belief of their personal susceptibility to problems, such as unplanned pregnancies and pregnancy-related complications), perceived benefits (benefit of receiving PCC and using contraception to prevent an unplanned pregnancy), perceived barriers (barriers to seeking PCC), self-efficacy (self-confidence to get PCC and use contraception to prevent an unplanned pregnancy), and outcome expectations (participants’ belief that the outcomes are influenced by their own decisions to use contraception and seek PCC).

It was important to maintain the content validity (the degree to which the instrument measures the intended idea) by using it in a population that was similar to the original authors and other researchers that have used the RHAB (Charron-Prochownik et al., 2006b; Charron-Prochownik et al., 2008, 2013; Fischl et al., 2010; Holmes et al., 2012; Komiti et al., 2013). Questionnaire content was also reviewed by the study supervisors to ensure that it was valid for use in this population before being piloted. These steps were taken to ensure that the abridged questionnaire was comparable to other studies using the RHAB.

Preconception care knowledge instrument
This part of the instrument consisted of items from Holmes et al. (2012). The research team at Queens University, Belfast adapted the knowledge (K) questionnaire for use in women with DM in the UK from a validated instrument (Charron-Prochownik et al., 2006c) with acceptable levels of validity and reliability (Cronbach’s alpha = 0.65-0.83). The instrument was used to evaluate PCC knowledge and rate the levels of understanding specific to an educational DVD content in 97 women with DM, of reproductive age, before and after receiving an educational DVD intervention. The Knowledge (K) questionnaire aligned with the PADI app content. It was therefore used in this study to assess respondents’ knowledge and understanding of PCC based on the information provided in the PADI app before and after the educational PADI app intervention.

Specifically, participants' knowledge of pregnancy planning and pregnancy-related risks was assessed. In this section, women were asked to report their knowledge of PCC using True/False/Not Sure. Of the 20 statements, 11 were True (T) and 9 were False (F).
Individual pre- and post-PADI app knowledge responses were expressed as percentage of participants correct. The overall knowledge of pregnancy planning and risks, and perceived understanding of how diabetes affects pregnancy were evaluated.

Patient activation measure (PAM)

Patient activation has been identified as an important determinant of health behaviour, and a good predictor of self-care and improved outcomes (Greene et al., 2005; Hibbard and Gilburt, 2014). It is a behavioural concept, concerned with patients' involvement, participation and active engagement in their own health (Hibbard et al., 2005; Hibbard and Gilburt, 2014). According to NHS England (2016), patient activation is of particular importance to people living with long-term conditions (LTCs). Individuals with LTCs who report higher levels of patient activation are more likely to engage in positive health behaviours and to manage their health conditions more effectively (Hibbard and Gilburt, 2014). Hence, healthy behavioural changes and adherence to difficult medical and/or lifestyle programmes are also more likely to be consistent and longer lasting in those patients with a high level of activation (Mukoro, 2012). Patient activation can be improved by (eHealth) educational interventions (Solomon et al., 2012), and the best way to assess the extent of behaviour change is to measure the level of patient activation before and after an intervention using the patient activation measure (PAM) (Solomon et al., 2012).

During tool development, the PAM was appraised with respect to content, appropriateness and psychometric properties. The overall suitability to support the research design and answer the research questions was also considered. The PAM was deemed to be a suitable scale for measuring patients' self-beliefs, confidence to manage health-related tasks and knowledge of the condition (Dixon, Hibbard and Tusler, 2009). It is a 13-item instrument, incorporating elements of self-efficacy and readiness to change, and the most widely used measure of activation (Hibbard et al., 2005; Hibbard and Gilburt, 2014).

The PAM is a validated measure that provides consistent and accurate means of assessing changes in patients' level of activation over time. It was originally developed by Hibbard et al. (2004) as a 22-item scale, and subsequently as a 13-item short form (Hibbard et al., 2005). A convenience sample of 1,515 patients with and without LTCs were used to establish the validity and reliability of the 22-item PAM. Good internal reliability (Cronbach’s alpha = 0.84 - 0.89) has been consistently demonstrated in studies that have explored the psychometric properties of the 13-item PAM in different populations, languages and settings across the
The results have consistently demonstrated that individuals with improved PAM are significantly more likely to engage in a wide range of health behaviours, such as eating healthy diets, exercising regularly, quitting smoking, attending screenings, regular check-ups and immunisation (Hibbard et al., 2004, 2005; Greene and Hibbard, 2012; Mosen et al., 2007). They are also more likely to seek health information from a variety of sources including reliable websites (Fowles et al., 2009). Higher activation in patients with DM is particularly associated with improved diabetes self-management and blood glucose levels (HbA1c), adherence to medication, regular foot and eye checks, improved quality of life (QOL), lower use of emergency rooms and hospitalisation (Mosen et al., 2007; Rask, 2009; Greene and Hibbard, 2012; Remmers et al., 2009).

The PAM segments respondents into 4 levels of activation (reflecting a developmental progression from the passive receipt of care toward greater activation) (Greene and Hibbard, 2012). Level 1: Patients who do not feel in control of their own health and care, level 2: patients who have low confidence in their ability to manage their health, level 3: patients who have some experience and success in making behavioural changes and level 4: patients who have made most of the behavioural changes and can maintain these over time. Level 1 is the lowest, while level 4 is the highest. The degree of certainty attached to the PAM that an increase in PAM levels will lead to improved behaviours, healthcare engagement and outcomes (Hibbard et al., 2004, 2005) constituted an important factor of consideration during the instrument development.

5.5.4 Data management and analysis
Microsoft Excel© was used for the organisation, collation and recording of the data from each participant. The processing of the questionnaire was consistent, and a clear record of the returned questionnaires was kept. Each participant was assigned a study number and the same number was used throughout the study to allow the data on demographic information, knowledge and attitudes to PCC and PAM to be collated. A coding manual/schedule was developed in Excel and used during the data entry process. The responses were assigned numerical codes and recorded in the codebook. The data were then entered into the Statistical Package for the Social Sciences (SPSS) version 23 prior to conducting the quantitative analysis. Data were summarised using frequencies and descriptive statistics.
The narrative data from the open-ended questions were analysed and grouped into categories, labelled and assigned numerical codes. The data gathered from the closed questions were analysed using SPSS. All demographic data were expressed as n (%) for categorical variables and mean ± standard deviation (SD) for continuous variables. The mean, SD, median, interquartile range (UQ - LQ) and range (maximum-minimum) descriptive statistics were produced for each preliminary outcome estimate. Comparisons between the pre- and post-intervention questionnaires allowed for any differences to be established. The data analysis methods for the RHAB, knowledge of PCC and PAM items are provided in detail below.

Reproductive Health Attitudes and Behaviour (RHAB) instrument
This section contained six sections, as already described. All questionnaire measures (theoretical constructs) were based on 5-point Likert scales, where Not at all = 1, A little = 2, Somewhat = 3, A moderate amount = 4 and A lot = 5; 1 = the lowest score and 5 = the highest score. The frequency of responses was examined by combining the number of people selecting the same scores (Pallant, 2010). This was summarised using tables and figures. All responses were expressed as numbers and percentages (n, %).

The total RHAB scores represented the sum of the items within each construct. Perceived susceptibility was determined by summing up the four Likert-type items; the perceived benefit of PCC, the sum of two Likert-type items; the perceived barriers to PCC, the sum of two Likert-type items; self-efficacy, the sum of three Likert-type items and of the outcome expectations, the sum of four Likert-type items. For example, in order to obtain the total score for perceived susceptibility, which is a 4-item scale, using a response scale from 1 to 5 (not at all to a lot), the minimum value would be 4 and the maximum value would be 20. If a participant answered 1 to every item, the overall score would be 1 x 4 = 4. If a participant answered 5 to each item, that score would be 5 x 4 = 20. The cumulative responses to each construct were collated in order to determine any changes in participants’ overall attitudes and behaviours pre- and post-PADI app intervention. Higher summative scores show a stronger level of belief in the construct.

Preconception care knowledge
Questions specific to the PADI app content regarding pregnancy planning and pregnancy-related risks were scored as correct or incorrect. Individual pre- and post-PADI app knowledge responses were expressed as percentage of participants correct. The results were presented using a table.
**Patient activation measure (PAM)**

The PAM was based on 5-point Likert scales, where Strongly disagree = 1, Disagree = 2, Agree = 3, Strongly agree = 4 and Not Applicable (N/A) = 5. The frequency of responses was examined by combining the number of people selecting the same scores. This was summarised using figures and expressed as (n, %).

The total PAM score was further calculated by adding up the responses to the 13 questions. If all questions were answered and no N/A is used, the raw score range is between 13 and 52. If there is at least one item including an N/A response, the total score will then be divided by the total number of items completed by the participant and multiplied by 13. The raw score is then transformed to a scale from 0-100 with the aid of a nomogram provided by Hibbard *et al.* (2005) to give the PAM score. Higher PAM scores indicate higher patient activation. On the basis of the PAM score, participants were segmented into one of four activation levels (as already described in section 5.5.3).

**Statistical analysis**

Comparisons between pre- and post-intervention (for the RHAB, PCC knowledge and PAM) scores were carried out using Wilcoxon-signed rank test, the non-parametric alternative to the t-test, because the data was from a non-random sample with scores that were not normally distributed and sample size < 30. The effect size (strength of the difference arising from the impact of the intervention) of the measures was reported using Cohen’s criteria (Cohen, 1988): 0.1=small effect; 0.3=medium effect and 0.5=large effect. It has been recommended that cut-off points for smaller samples (n≤20) be set to *P* = 0.10 or 0.15 rather than the conventional 0.05 to compensate for the small sample size (Stevens, 1996; Pallant, 2013). However, for this feasibility study, results could be considered significant when *P* ≤ 0.05.

Internal consistency (the degree to which all the items making up the scale measure the same underlying constructs) for the pre- and post-intervention questionnaires were also analysed to demonstrate their reliability. Internal consistency was measured using Cronbach’s coefficient alpha; values range from 0-1, with higher values indicating higher reliability (Pallant, 2013). Scales with few items (e.g. less than 10) are more likely to have low values.

**5.5.5 Semi-structured interviews**

The sample for this phase was obtained from the participants recruited for the intervention phase (Creswell, 2014), and consisted of (n=6) participants who consented to being
interviewed. This sample size is considered adequate to gain an in-depth understanding of user experiences and usability issues (Nielsen, 1993, 2012).

The semi-structured style of interview, via the telephone, was selected as the best means of generating data regarding participants’ experiences of app use because participants were geographically dispersed across the UK and North America. Furthermore, this method has been recommended for collecting feedback regarding participants’ views and experiences of app use (Whittaker et al., 2012; Mummah et al., 2016). It has also been used by several mHealth intervention studies (Robinson et al., 2013; Fjeldsoe et al., 2012; Cai et al., 2017; Milward et al., 2017) to explore the intervention’s usability, acceptability, benefits, challenges, usefulness and recommendations for improvement. Moreover, semi-structured interviews provide insight into participants’ engagement with technology that may not be captured by quantitative methods (Yardley et al., 2016).

As initially discussed in section 4.5.2, the strength of this medium of interviewing is the flexibility to adjust or tailor the interview to the goals of the study. Thus, based on the answers given to the previous questions, subsequent questions can be formulated and explored. In this phase, the questions were standardised using a topic guide in order to ensure that specific areas were covered but with room to probe into issues and clarify emerging information.

Tool development and piloting
The interview schedule was developed from review of relevant literature and the work of Hebden et al. (2012). Themes and topics with pre-established questions were employed to guide the direction of the discussion with the women. During the development of the schedule, it was important for questions to be open-ended, logical, and sequential, and probes to elicit more detailed information were included. One woman with DM and one HCP piloted the interview schedule. A copy of the interview schedule is provided in Appendix 10.

Data collection process
The interviews, which took place from April to July 2017, were conducted with six participants over the phone. For semi-structured interviews to be successful, it is important to gain participants’ trust (Denzin and Lincoln, 2005). Frequent interaction with the participants during recruitment helped to build rapport and participants were encouraged to contact the researcher with any questions regarding the study. Furthermore, the interviewing style was intended to maintain rapport and questions were asked in a manner that ensured participants felt like they were involved in a discussion (Hancock et al., 2009). When
participants encountered difficulty in answering certain questions, probes were used sensitively to encourage elaboration on the topic.

**Recording interview data.**
The interviews, lasting between 20 and 30 minutes, were digitally recorded for transcription and all participants consented to the audio recording of the interviews. This was important in order to obtain an accurate record of the interview, which can be repeatedly played at a later stage to aid transcription.

**Data management and analysis.**
The audio recordings generated from the six interviews were listened to repeatedly in order to gain familiarity with the dataset’s content prior to drafting the transcripts. The analysis started while the data collection was ongoing.

Interview data were transcribed verbatim using Microsoft Word as soon as possible after the interview with the participants. The digitally recorded interviews were listened to several times in order to ensure that the transcripts contained reliable information. Data were prepared for coding and analysis by using NVivo 10, as already described in section 4.5.5. The analysis used a largely inductive approach to generate the following three themes: feasibility and acceptability of the intervention, engagement with the intervention and future development of the intervention. See Appendix 11 for a coded transcript sample. Trustworthiness was ensured, as already described (see section 4.5.6).

**5.5.6 Software log of activity**
A software log of activity enables the collection of patient engagement data. According to Yardley *et al.* (2016), it is important to understand engagement with mobile health interventions in order to develop interventions that are effective and meet users’ needs. Analytics data provide an opportunity to measure various aspects of engagement, such as how frequently participants access the app, the time spent on the app, the number and type of pages visited, the features used, and the response to notifications or reminders (Yardley *et al.*, 2016; Taki *et al.*, 2017). The app analytics built into the PADI app specifically measured the software log of activity.

All (n=17) phase 2 participants were included in the software log of activity. The logging of app data was conducted at the end of the 3-month intervention period and was used in order to demonstrate the uptake and utilisation of the PADI app. This set of data was stored on a
secure server that was only accessible to Netsells (the app development company), who ensured the secure transfer of data to the researcher for analysis purposes. The recorded data were examined to identify how often participants engaged with the app, i.e. frequency of app use, and location of users who interacted with the app.

User engagement with app interventions can be measured in several ways including user experience interviews (Yardley et al., 2016). Although this form of data collection is subjective, it enables researchers to reliably explain usage patterns generated via the software log of activity. A strength of the software log of activity is that it can be collected without any user burden. However, a drawback of this method of data collection is that it can be difficult to interpret the data generated. Yardley et al. (2016) also note that this method does not measure user engagement with behaviour change, and qualitative research is needed to explain the observed differences in usage patterns. Therefore, in line with the recommendations by Yardley et al. (2016), the software log of activity was used to supplement the user experience interviews.

Summary
Chapter 5 has discussed the methodology used in phase 2 of this study. First, a description of the feasibility and acceptability of the PADI app was provided. This chapter also discussed the research setting, sample selection and development of data collection tools, as well as the methods of data collection and analysis used in phase 2 of this study. Questionnaires and semi-structured interviews were the methods of data collection used in phase 2. For each method, the rationale for its use, as well as the strengths and weaknesses were provided. The data collection methods were followed by the data analysis methods, i.e. descriptive statistics and statistical analysis for quantitative data and thematic analysis for qualitative data.

The research was designed and conducted so that reliability and validity issues were addressed. Measures were taken to reduce the effect of researcher bias that may be inherent in qualitative research (as already described in Chapter 4, section 4.5.6).

The next two chapters (6 and 7) present the findings from phases 1 and 2 of the study.
6. Chapter 6: Phase 1 results and preliminary discussion

6.1 Overview of chapter: PADI app development

This chapter presents the findings from analysis of data collected during phase 1 to direct development of the PADI app (that is, focus group and interviews). An initial overview of the participants will be followed by a thematic analysis of the views and experiences of women with diabetes and healthcare professionals regarding PCC, development and use of the PADI app in practice. In addition, findings are concurrently discussed in the context of ‘in line’ with other studies. Further discussion in context of App development is found in Chapter 8.

6.1.1 Demographic profile

A total of 19 participants comprising healthcare professionals (HCPs, n=9) and women with diabetes mellitus (DM; n=10) took part (Table 6.1).

Table 6.1 Participants descriptive table

<table>
<thead>
<tr>
<th>No</th>
<th>Identifier</th>
<th>Role</th>
<th>Setting</th>
<th>No of years in profession</th>
<th>Provided PCC as part of role</th>
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<tbody>
<tr>
<td>1</td>
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<td>32</td>
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<tr>
<td>2</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>No</th>
<th>Identifier</th>
<th>Diabetes mellitus type &amp; duration (years)</th>
<th>Geographical location</th>
<th>Age (years)</th>
<th>Received PCC advice</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>P1</td>
<td>Type 2 (5)</td>
<td>Scotland</td>
<td>43</td>
<td>No</td>
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<tr>
<td>11</td>
<td>P2</td>
<td>Type 1 (17)</td>
<td>Wales</td>
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</tr>
<tr>
<td>12</td>
<td>P3</td>
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<td>England</td>
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<td>No</td>
</tr>
<tr>
<td>13</td>
<td>P4</td>
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<tr>
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<tr>
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<tr>
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<td>Ireland</td>
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HCPs included nurses (n=6, diabetes specialist and research nurses) and doctors (n=3, general practitioner, obstetrician and endocrinologist). Participants had extensive experience in the care of patients with DM with the majority (n=8) having over 10 years [range 5-44 years]. Most of the HCPs (n=7) worked in the hospital (secondary care) setting providing specialist diabetes services while (n=2) worked in general practice (primary care), in the South of England. Most participants (n=6) provided PCC as part of their role (Table 6.1). Women with DM were geographically dispersed across England, Scotland, Wales and (Northern) Ireland (Table 6.1). The average age of participants was 34 years and majority (n=9) had T1DM with an average diabetes duration of 22 years. Five women reported that they had received PCC. Of the five women who had not received any PCC, three reported an unplanned pregnancy and one had experienced two miscarriages.

6.2 Findings

Three main themes emerged from the analysis: current state of PCC, adoption of technology and technology-assisted PCC. Each theme comprised of two or more sub-themes and was organised using sub-sections as shown in Table 6.2 below.

<table>
<thead>
<tr>
<th>Table 6.2</th>
<th>Themes and subthemes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Main themes</strong></td>
<td><strong>Sub-themes</strong></td>
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</tbody>
</table>
| 1. Current state of PCC | Understanding of PCC | • Understanding of blood glucose control  
• Understanding of folic acid intake  

Preconception care service provision | | • Provision of advice  
• Inconsistency in advice  
• Factors hindering PCC provision  

Women's experiences of receiving PCC advice | | • Missed opportunities and inadequate information  
• Dissatisfaction with HCPs’ attitudes |
| 2. Adoption of technology | Use of technology for healthcare information | |
| | Mobile apps trump all | • Perceived benefits regarding use of a PADI app  

Acceptability and feasibility of a PADI app | | • Potential for integration |
| 3. Technology-assisted PCC | PADI app development | • Intervention content  
• Self-monitoring functions  
• Reminders  
• Intervention language  

Factors affecting implementation | | • Cost and organisational support  
• Facilitating content and design factors  
• Hindering content and design factors |
6.3 Current state of PCC

This theme illustrates the current PCC situation, explores participants’ understanding of PCC, clinicians’ provision of PCC advice and women’s experiences of receiving PCC.

6.3.1 Understanding of PCC

Understanding of PCC varied between participants (n=19) with healthcare professionals (HCPs) being understandably more aware of PCC and pregnancy-related complications than women, whose understanding of the same issues was limited and sometimes non-existent. For example, HCPs were of the opinion that PCC helped to improve diabetes control and reduce risk of complications during pregnancy while women believed diabetes control was the main focus of PCC, as shown below.

*Preconception care is, care provided to women planning to become pregnant all in an attempt to optimise their health status before they become pregnant … just to make sure that their diabetes is under control … and they don’t have complications for which pregnancy would be a contraindication.* (HCP5, interview 2)

*It’s just really getting ready for your pregnancy more than anything else and the care which the hospital can offer you. Also, there really isn’t much, it’s all … working on HbA1c I think for most people.* [P5, 39 years]

The emphasis on blood glucose control in women’s discussion of PCC was in line with the qualitative study by Earle et al. (2017) in which glycaemic control was the focus of concern for those who attended PCC. The authors explained that many women with DM struggled with attaining good control and often sought extra support when hoping to get pregnant or in early pregnancy.

As well as diabetes control, HCPs recognised the importance of identifying and managing complications, and medication reviews as vital PCC strategies for a healthy pregnancy and baby; however, their concerns regarding potential complications and need to minimise them were not expressed by women. For example, while one HCP stressed the need for women to see their HCPs to get screened for complications and discuss current medications as part of PCC, all women lacked sufficient understanding of potential complications or how to minimise them.

*It’s organising patients so that they’re in the best possible shape when they are planning a pregnancy and making sure that any complications have been identified so they can be dealt with before entering pregnancy, and that all medication is appropriate for use in pregnancy.* [HCP6, interview 3]

*No, I don’t really know much at all … not really much about the PCC, diabetes itself I do have a bit of understanding of but not in a sort of preconception way* [P1, 43 years]

Similar to this study, Earle et al. (2017) also found that women (with and without prior pregnancies) had insufficient understanding of risk of complications. In contrast, Chuang et
al. (2010) found that knowledge gaps were particularly significant for women without prior pregnancies compared to women with prior pregnancies.

Other women in the study also reported a lack of understanding of PCC for women with DM. For example, one woman felt PCC meant family planning and a second woman believed it involved monitoring fertility, having ovulation calendars and taking multi-vitamins, as shown in the data extract below.

*I’m thinking like vitamins. Kind of just all of the general things that women do when they would like to conceive like planning out, not planning out, but having like a calendar for ovulation, stuff like that, vitamins, just being healthy in general. I can’t think of anything specific for diabetes though just because I don’t know anything.* [P4, 23 years]

Different levels of PCC understanding were reported by participants (both HCPs and women); with women specifically having limited understanding of PCC, how to optimise their health before pregnancy and reduce risk of pregnancy-related complications. Several studies in the literature (Spence et al., 2010; Lavender et al., 2010; O’Higgins et al., 2014; Murphy et al., 2010a; Shawe et al., 2008) also found that women with DM lacked sufficient understanding of PCC and how to prepare for pregnancy. Earle et al. (2017) further reported that the dominant message that seemed to be provided and taken on board by most women was that high blood glucose levels could cause complications in pregnancy.

### 6.3.1.1 Understanding of blood glucose control

Participants, both HCPs and women, were generally aware of the need to improve blood glucose control before pregnancy. Several authors (Berg and Sparud-Lundin, 2009; Chuang et al., 2010; Collier et al., 2011; Griffiths et al., 2008; King and Wellard, 2009; Shawe et al., 2008) also found that many women were aware of the need to address blood glucose levels prior to pregnancy. However, some women lacked understanding of the rationale for optimising preconception blood glucose (BG) levels or the need to maintain this good control especially in early pregnancy. The rationale was however fully understood by HCPs who were keen to highlight the various complications that can affect pregnancy in women with diabetes if their BG levels were uncontrolled. For example, one doctor explained how pregnancy generally exacerbated existent diabetes complications and disrupted glycaemic control. Although women agreed that diabetes control was needed before pregnancy, in-depth understanding of the subject was lacking, as noted below.

*So, diabetes and all the hormones involved make the pregnancy affect diabetes by making diabetes control more difficult, then there are the complications that you can get microvascular, macro vascular complications from diabetes, that can be exacerbated by a pregnancy.* [HCP6, interview 3]

*I know about like the importance of controlling your blood sugars and having HbA1c of a certain range before conceiving and things but nothing, I don’t really know too much on the subject.* [P2, 22 years]
Other HCPs (n=3) reported that the woman’s level of diabetes control prior to pregnancy influenced the development of microvascular complications, for example nephropathy (renal disease) and retinopathy (eye disease), which would ideally require assessment and management prior to conception. However, none of the women in the study (n=10) mentioned that microvascular complications could worsen due to uncontrolled diabetes or that attending retinal and renal screening could help in identifying and managing pre-existing complications before pregnancy.

HCPs (n=5) also highlighted that poor glucose management before and during pregnancy could cause several problems for women with DM and their fetus, including macrosomia and shoulder dystocia which could impact the mode of delivery and increase the need for a caesarean section. They emphasised that these complications and adverse outcomes all had detrimental effects on the health of both the woman and baby. A doctor in secondary care described some of the obstetric problems caused by poor diabetes control, in the extract below.

The main issues relate to baby becoming very big [macrosomia]… still birth or intrauterine deaths also from poorly controlled diabetes, and when the babies are very big, they pose problems at delivery … a good proportion are delivered by caesarean section and for those that have a natural birth, there is risk of difficulty in delivering their shoulders [shoulder dystocia] and that of course poses problem, injuries to the baby in the form of lack of oxygen, fractures or/and nerve injuries. [HCP5, interview 2]

Two women agreed that uncontrolled diabetes during pregnancy could result in adverse outcomes; however, their understanding was limited to either the ‘baby growing too big’ or ‘possibility of a miscarriage.’ This agrees with the study by Spence et al. (2010) which found that some women’s knowledge of pregnancy-related risks was that women with DM ‘have really big babies.’ It was apparent that most women did not realise the extent of pregnancy-related risks or the effect that high blood glucose levels could have on their pregnancy and the likelihood of experiencing pregnancy-related complications, as noted below.

I don’t really know much. I mean I’m sure it’s more difficult to control your blood glucose levels but yeah I’m not really sure. [P4, 23 years]

Not really, no … because I think it’s not something that I know of personally, it’s not something I know much about [P1, 43 years]

HCPs highlighted that priority should be given to blood glucose management as this helped to prevent complications. Yet, despite a general awareness of the need for optimised diabetes control among participants, many women were still unaware of basic PCC information such as the risks of uncontrolled diabetes to the woman or her baby and importance of planned pregnancy. This is in line with O’Higgins et al. (2014) who found that although women with DM knew that glucose control was crucial for a safe and healthy baby,
they still had inadequate understanding of the risks of poorly controlled DM on pregnancy outcomes.

### 6.3.1.2 Understanding of folic acid intake

The role of folic acid in preventing birth defects was recognised by some clinicians and women. For example, a clinician in secondary care and a woman with DM highlighted the need for a higher dose of folic acid in order to help with the baby’s development, reduce the risks of disabilities, such as spina bifida, and improve the likelihood of a healthy baby.

HCPs explained how the recommended folic acid dosage for women with DM was higher, noting that whereas women with DM needed 5mg folic acid (the higher dose), other women were advised to take the lower dose of 400 µg. Although HCPs seemed to understand the importance of folic acid, there was uncertainty regarding timing and duration. This uncertainty was also evident among the women.

*Ladies with diabetes need to be on 5mg of folic acid rather than the 400 microgrammes that is readily available over the counter, so they need to go ask for it be specifically prescribed.* [HCP6, interview 3]

*Well I don’t know a huge amount about that [folic acid] other than I know you are supposed to take it for a while before you conceive ideally and then continue to take it during pregnancy, I think that’s to do with the baby’s spine development but I haven’t been told any more details about that . . . Is it 5 mg or something like that rather than 4 or something, I think I’m not a 100% sure.* [P6, 29 years]

This is similar to the findings of Earle et al. (2017) whereby some women who recognised the need to take folic acid were unsure as to how long to take it before becoming pregnant, and some reported taking it only during pregnancy.

Knowledge gaps were significant for women in the study and they reported not being given adequate folic acid information. For example, another woman who learnt about the importance of folic acid supplementation as part of a course in dietetics, acknowledged receiving insufficient information on the recommended dosage for women with DM, as shown below.

*Well, I don’t really know too much about it. I know obviously about the importance of like folic acid supplementation because that’s just a topic I’ve just covered now myself in University . . . I don’t really know too much on the subject.* [P2, 22 years]

Spence et al. (2010) and Shawe (2008) acknowledged that very few women with DM knew that the recommended folic acid dose was higher than the general maternity population or that over-the-counter folic acid may not provide them with levels required by women with DM (which was only available on prescription in the UK).

This insufficient knowledge of folic acid could lead to misconceptions. For example, a woman who reported being prescribed folic acid by a HCP during two prior pregnancies that
sadly ended in miscarriage, wrongly associated folic acid with this negative pregnancy outcome.

It’s something that I was sort of told to take when I was expecting my daughter, but I didn’t actually take it ... I think partly because in my own mind, I had miscarried twice before I had my daughters and both times I had taken folic acid. So it was something in my head telling me “don’t take it, try and do something different.” but it was a coincidence that I wasn’t taking it and I had my daughters. [P1, 43 years].

Inadequate awareness of PCC and folic acid in particular may be the reason why it was linked to miscarriage by this participant who further reported not knowing why the folic acid was prescribed. This finding is supported by other studies (Spence et al., 2010; Earle et al., 2017) which found that very few women were aware of the rationale for folic acid use. It has also been noted that although previous pregnancy loss may encourage some women to seek PCC, this was not the case for most women (Earle et al., 2017).

Overall, all HCPs noted that PCC could help to reduce risk of complications and negative pregnancy outcomes while women agreed that health optimisation before pregnancy was important. Two participants, a secondary care nurse and woman, recognised that pregnancy in women with DM was high-risk, highlighting the need for all women with DM to receive PCC to help improve their health, before pregnancy.

I mean it’s still appalling—maternal death, preeclampsia, intrauterine death, still births, early miscarriage, but getting the preconception in there reduces all these various risks so much. [HCP7, interview 4]

You want to go into [pregnancy] being as healthy as possible because so much can happen during pregnancy especially when you are type 1 so you want to start it being as healthy as possible. [P5, 39 years]

However, one woman concluded that seeking PCC was not prioritised by many women with DM due to insufficient understanding of PCC or its benefits and deemed it “something that’s not really thought about that much.” [P1, 43 years]. This is in line with the argument, by Lavender et al. (2010), that inadequate understanding could lead to apathy towards PCC because women did not understand how important it could be to them.

6.3.2 Preconception care service provision

6.3.2.1 Provision of advice

HCPs’ accounts of providing PCC advice were different from women’s views of being given advice. HCPs (n=6) whose roles involved PCC reported giving advice to all women with DM of childbearing age during clinic consultations. They reported using these routine appointments to encourage women to discuss their pregnancy intentions and attend medication reviews before conception. Although most women (n=9) acknowledged that they had frequent contacts with their diabetes health care team e.g. endocrinologists, general
practitioners (GPs), diabetes specialist nurses (DSNs), dieticians, and psychologists either via telephone, email or face-to-face, only half (n=5) reported receiving PCC advice from their healthcare team.

"Any woman of childbearing age, I’ll always ask them if they are planning to have children, and then, people know that they can come to me and talk to me about when they are planning, so that we can make the necessary arrangements, do the necessary investigations, change the medications around. [HCP6, interview 3]"

"I see a pre-pregnancy consultant at my hospital and I also see the diabetes specialist nurses and I have email contacts and phone contacts with them pretty much all the time if I need it and I also see a psychologist. [P5, 39 years]"

HCPs highlighted close monitoring of women with DM as being instrumental to identifying potential complications. They also noted that the possibility of women being on teratogenic medications such as statins and ACE inhibitors that could adversely affect the fetus during pregnancy was an issue of key concern and underscored the importance of pre-pregnancy care. A nurse in secondary care reported using these consultation time to help women optimise their blood glucose levels, encourage intake of folic acid, identify and prevent use of harmful medications in pregnancy.

"It’s so important and generally it can be just taking time to get their control good, getting them onto folic acid. Yeah and especially ladies with type 2, younger age and women having babies later, you’ve got the risks that they might be on tablets that they shouldn’t be on for the pregnancy and that’s kind of a key thing. [HCP7, interview 4]"

This secondary care nurse identified high risk categories of women for whom PCC is essential, as younger women, those with T2DM and older women (over 35 years). But, participants (n=5) whose ages spanned between 22-43 years could not recall receiving any PCC advice from their care team. Despite being classified as ‘high risk’, some younger aged women who were students (n=2) did not receive any PCC advice and could not understand why they were overlooked despite being of childbearing age, as shown below.

"Given perhaps that I’m a student maybe my diabetes team don’t look at me as being of childbearing age … but I have never had any like any particular input [PCC advice] from my care team … I don’t know whether it’s just the healthcare team I’m with necessarily, but I would have thought that being like a 22 year old female, they would have like warned– like talked more to me about [PCC], and like the importance of it. [P2, 22 years]"

In terms of providing PCC advice to younger women with DM, Spence et al. (2010) reported that young nulliparous women felt that pregnancy advice was often withheld until they reached the appropriate age, which frustrated women as they believed there was no appropriate age when it came to discussing pregnancy plans. Women further felt that pregnancy advice was often provided in a manner that confirmed certain preconceived ideas and social stereotypes held by their HCPs; for example, they were more likely to be asked about pregnancy plans once they were engaged or married.
Hence, for half of the women (n=5), contacts and consultations with their diabetic team did not involve provision of PCC advice. Furthermore, it was important for all women of reproductive age to receive PCC (including contraception) advice as absence of PCC information could impact on whether or not women planned their pregnancies. Three women (n=3) who did not receive any PCC advice prior to conception reported having unplanned pregnancies, as noted below.

My first pregnancy was a massive shock … I just happened to do a test one day and it was positive and that was that, so I didn’t actually have anything pre-gestation at all. [P7, 40 years]

6.3.2.2 Inconsistency in advice

Provision of PCC advice and services in primary and secondary care was inconsistent and lacked standardisation amongst HCPs. For example, Spence et al. (2010) reported wide variability in knowledge of recommended blood glucose target range among women with DM (including those who received PCC). In this study, women (n=5) who received PCC provided different accounts of the PCC advice received from their respective HCPs, as shown below.

It’s [PCC] to try and maintain your HbA1cs at a reasonable rate below 7, also to make sure preconception to be off other prescriptions, medications and to have a healthy diet. [P9, 29 years]

My consultant she has spoken to me about pregnancy and … that you need to keep your blood sugars in a good range, your HbA1c … below 6.5 for a while before conceiving or thinking about conceiving and to speak to your diabetes team if that is something that you are planning to do so they can offer extra support. [P6, 29 years]

It was not clear whether any of the women were given advice on contraception, medication reviews or attending screening for complications. Three clinicians in secondary care acknowledged that although women with poor glucose control were asked to delay pregnancy, they were often advised to speak to their GP about contraception, as this was not seen as the responsibility of clinicians in secondary care.

It [contraception] isn’t our remit but we would say if you are planning- you know someone’s HbA1c isn’t good and we want them to delay … we would usually say, "see your GP for adequate contraception to have a- or suggest having a coil fitted" but we don’t actually do contraception. [HCP2, FG1]

This HCP’s response suggested that secondary care clinicians tended to focus on other aspects of PCC such as glucose control, lifestyle modification, medication review and screening for complications. This view was supported by this doctor’s account of what her PCC advice contained.

Try and get as fit as you possibly can, try and eat as healthily as you possibly can, and don’t drink too much alcohol, and really try to avoid alcohol, stop smoking, let’s look at your medication, see what pills and portions you are on, let’s have a look at the diabetes complications that you already have, let’s make sure you get screened for it and so make sure your medication is as good as possible. [HCP6, interview 3]
On the other hand, contraception appeared to be of particular importance to HCPs in primary care (n=2). For example, one primary care nurse highlighted discussing contraception, in addition to other PCC needs with women of childbearing potential during clinic consultations.

> Just as I see people for reviews … I would talk through their contraception, their [pregnancy] plans, folic acid. [HCP8, interview 5]

This was supported by another primary care doctor who reported also providing contraception and folic acid advice to women with DM. It was noted that primary care clinicians, e.g. GPs, had a duty to encourage women to avoid unplanned pregnancies by using contraception and to consume 5mg folic acid in preparation for a pregnancy.

> We always had a sort of thing that either the patient should be taking the contraceptive pill or 5mg folic acid, one or the other just to make sure that at the point of conception they would have on board 5mg folic acid. [HCP4, interview 1]

Murphy et al. (2010) highlighted the significance of contraceptive services in relation to PCC, arguing that contraception advice was particularly relevant for younger women for whom pregnancy may seem a long way off. However, none of the (n=5) women in the study who received PCC reported that they received contraception advice as part of PCC. These shortcomings in PCC service provision may be due to various factors which are presented below.

### 6.3.2.3 Factors hindering PCC provision

Effective PCC provision was reported to be hindered by a number of factors including level of involvement in PCC provision, service configuration and lack of pregnancy planning.

#### Level of involvement in PCC provision

Clinicians’ job roles influenced their level of PCC knowledge and awareness. Some nurses (n=3) who were not directly involved in providing PCC advice explained that they had limited knowledge of PCC and the is issues and challenges facing women with DM, as shown in the focus group discussion below.

> I don’t know. I presume that they will have to be advised that they will have more frequent monitoring than they would do normally … I don’t know, you probably know, [to Assistant Moderator] do they have amniocentesis that is different to anyone else because they have diabetes? But that’s not preconception, that’s when they’ve conceived but pre-pregnancy, I don’t know if there is anything else they do. [To HCP3] You don’t know either? [HCP2, FG1]

> I don’t have that kind of experience myself, sorry … Well, if they are type 1 probably they know about their disease quite well because they have been living with it for a long time, so usually they are quite well informed [about diabetes and pregnancy]. [HCP3, FG1]

> I mean we are mostly talking about the type 1 patients aren’t we? … You won’t get many type 2 who get pregnant because usually the type 2 are the older age group so you’re mostly talking about type 1 patients. [HCP2, FG1]
This finding agrees with the study by Mortagy et al. (2010) in which there was a contrast in perspective between GPs with and without specialist interest in DM, while the former were more informed and involved in providing PCC education, the latter were uncertain as to their role and involvement in PCC of women with DM. However, it was of concern that most GPs saw T2DM as a disease of the elderly rather than something that might affect women of childbearing age. Hence, as Earle et al. (2017) highlighted, this view may have a bearing on the service GPs provide and the emphasis they place on providing PCC or referring women to specialist PCC centres.

The criteria for allocating PCC responsibility was not clear from discussions however it emerged that PCC responsibility was given to some clinicians but not others, who were equally in contact with women with DM of reproductive age. This meant that clinicians without PCC responsibility who came in contact with women planning a pregnancy referred them to other clinicians, as noted below.

If I came across someone who was planning a pregnancy if they had diabetes then they would be referred into the hospital to the specialist. [HCP2, FG1]

Service configuration

The different configuration in services for women with T1 and T2DM also affected PCC provision and uptake. PCC services were reported to be mostly provided in secondary care which catered for T1DM. While most T1DM women received their PCC advice at the hospitals, T2DM women who were mainly seen in primary care missed out of receiving important PCC advice. A secondary care nurse noted that lack of PCC for women with T2DM, particularly poor diabetes control and lack of folic acid in the first few weeks of pregnancy, increased the risk of complications and adverse outcomes.

So those first 12 weeks of organ forming can be– you can miss them before the lady realises she is pregnant and then they’ve had awful control, they haven’t had their folic acid.’ [HCP7, interview 4]

Mersereau et al. (2011) acknowledged that lack of knowledge and awareness was a barrier to PCC for women with T2DM, and they were the least knowledgeable about the risks of DM and pregnancy. HCPs who provided PCC were therefore concerned about the inequality in PCC service provision amongst women with DM. A primary care doctor reported that despite the increase in pregnancies to women with T2DM, many of them were unlikely to receive PCC compared to those with T1DM.

We are seeing more patients that are going into pregnancy with type 2 DM, and I think those are the patients that sometimes get missed … and our patients with type 1 DM … will get their preconception/conception advice at the hospital [HCP4, interview 1]
This indicated that some GP practices did not provide PCC advice to women with T2DM. The inadequate provision of advice to T2DM women was supported by a nurse in secondary care who stressed that many T2DM women, referred to her for PCC by their GPs, did not attend their PCC appointments and often conceived without adequate pregnancy preparation.

There is all these ladies who aren't getting [PCC] and if a GP rang me and said "oh my lady is type 2, she wants to get pregnant", I would be like "oh that's great, when is she coming to have a chat with me?" we make ourselves so accessible, but it doesn't happen and the type 2 ladies do tend to have quite poor control when they conceive. [HCP7, interview 4]

Across several studies (Chuang et al., 2010; Griffiths et al., 2008; King, Wellard, 2009; McCorry et al., 2012; Mersereau et al., 2011; O’Higgins et al., 2014; Shawe 2008; Spence et al., 2010; Woolley et al., 2015), there was uncertainty between clinicians in primary and secondary care as to who was responsible for the delivery of PCC and the practitioner best placed to provide it. According to Mortagy et al. (2010), secondary care clinicians highlighted seeing many pregnant women with T2DM who had uncontrolled blood glucose levels and noted that as key members of the multidisciplinary team, the GP’s role was crucial yet missing particularly with regards to providing PCC advice to young women with T2DM.

In addition, Murphy et al. (2010) acknowledged that better integration between DM care and PCC services was needed across primary and secondary care, stressing that failure to provide a more coordinated care will have devastating consequences for women.

Lack of pregnancy planning

HCPs reported that many women with DM did not plan their pregnancies or disclose their pregnancy intentions to their healthcare teams. They felt that this limited their ability to provide effective PCC especially as antenatal care only provided a short window for HCPs to help women reduce risks of complications and adverse outcomes.

We all know that, well I wouldn't like to say how many pregnancies are planned and the patients take your advice before hand? … You still get women, who become pregnant and then think about it afterwards and so you are sort of scrambling about to do what you can, and some women genuinely don't know that they are pregnant, some women don't make plans beforehand obviously. [HCP4, interview 1]

HCPs further noted that many women did not discuss their pregnancy plans with their healthcare teams because they were uncertain and anxious about pregnancy. Women therefore preferred to wait until they had established that the baby was healthy, usually after the first trimester, before discussing their pregnancy with their diabetic team. They explained that women did not respond well to being asked about their pregnancy intentions during consultations, making it an uncomfortable subject for both HCPs and women.
Mersereau et al. (2011) described the contrasting perspectives of HCPs and women with DM with regards to pregnancy planning. According to the authors, HCPs believed women with DM were often in denial and not compliant or proactive in managing their DM. Women on the other hand reported that they wanted their lives to be as normal as possible despite having DM, and wanted to feel the joy of preparing for pregnancy or being pregnant which they noted would not happen if they involved HCPs; women desired normalcy in the context of such a high-risk and medicalised experience.

6.3.3 Women’s experiences of receiving PCC advice

Only two women expressed satisfaction with the level of PCC advice and support received from their diabetes team. The majority of women felt their experience of receiving PCC was sub-optimal due to several factors including missed opportunities, inadequate PCC information and HCPs' attitudes.

6.3.3.1 Missed opportunities and inadequate information

Women reported that various opportunities such as clinic appointments or consultations which they believed could be used by HCPs to provide comprehensive PCC advice were often not properly utilised. Half of the women (n=5) recalled numerous encounters with their HCPs in which they were told about their sub-optimal blood glucose control but without accompanying PCC targets to aim for should they decide to conceive, as shown in the data below.

So, preconception I didn’t get any advice at all which really isn’t good enough … I could remember several appointments with the consultant at the hospital [and] them always saying “oh your levels are too high” but never ever giving me, “if you keep below this number things will be better.” [P3, 40 years]

Majority of women in one qualitative study (McCorry et al., 2010) attributed their limited knowledge of PCC and pregnancy-related risks to a lack of information from HCPs. Similarly in Lavender et al. (2010), women reported having vague chats with HCPs which left them with no clue about where or how to access PCC.

Women in the study reported being given fragmented advice by HCPs which did not provide them with adequate knowledge to make changes; thus this advice was not well received. For example, one woman reported constantly being told by her diabetes team to avoid a pregnancy but without adequate explanation, as noted below.
It was every time I showed up at the clinic “do not get pregnant, do not get pregnant accidentally” that kind of sermon … “let us know when you want to get pregnant”… they didn’t tell me why just that “when you do get pregnant its very dangerous” but not going into details which I think would have helped. [P10, 43 years]

In two other studies (Lavender et al., 2010; Spence et al., 2010), women reported being advised not to get pregnant or have any more children (due to risks) but were not told why, and interpreted it as HCPs wanting control or dictating if and when they can have children. Consequently, the women did not seek PCC, engage with HCPs to plan their pregnancy or adhere to the HCPs’ advice.

PCC advice was limited and much emphasis seemed to be on reducing the likelihood of complications by attaining good blood glucose control. However, some women were still not sufficiently aware of the implications of having HbA1c levels outside the target range and began pregnancy with sub-optimal blood glucose control, as shown below.

It was about 9 or 10 then … but I don’t remember any diabetic consultant suggesting that before I became pregnant or asking you know if I was thinking of becoming pregnant or anything like that. [P3, 40 years]

Participants reported generally not getting enough information from HCPs. They believed opportunities to provide PCC advice were often missed and vital preconception information such as the need to take 5mg folic acid at least 3 months before conception or the HbA1c target to aim for, were sometimes not provided.

Some diabetes care teams don’t tell girls that they need to be on the 5 [mg folic acid] instead of the 4 [µg folic acid] and they don’t tell them to try and get their HbA1c in good order or their basal rates checked which I think is a bit silly really … in clinics they are just given so little information. [P5, 39 years]

6.3.3.2 Dissatisfaction with HCPs’ attitudes

Women with DM were able to achieve healthy pregnancy outcomes especially with effective PCC provision, however this message was reported to be downplayed and HCPs seemed to focus more on complications. This approach to PCC provision was met with disapproval, as noted below.

I think it’s scare-mongering in a way, if you don’t do this, baby is going to be that. [P3, 40 years]

Several studies in the literature (Collier et al., 2011; Griffiths et al., 2008; King and Wellard, 2009; Mersereau et al., 2011; Murphy et al., 2010; Shawe, 2008) have highlighted that HCPs often focused on the risks and negative outcomes of DM and pregnancy rather than on the opportunities for change. These literature suggest that the focus of information and advice given to women with DM was quite negative and this negativity hindered the patient/provider relationship and the likelihood of women seeking PCC. Some studies (Griffiths et al., 2008 ;
McCorry et al., 2012) have reported that instead of being informed and supported, some women felt fearful and anxious after receiving advice from their HCPs which deterred them from further seeking PCC. This view was echoed by another woman who believed that HCPs had an unsupportive attitude towards pregnancy in women with DM and stated that women were often only told about adverse outcomes of pregnancy, for example.

A lot of diabetes management come from like scare tactics and from what I gather with pregnancy that can be the same, so it’s all like “oh you are gonna do this otherwise you are gonna give birth to some deformed child” which is quite negative. [P5, 39 years].

Participants were unhappy with HCPs judgemental attitudes and highlighted that this discouraged women with DM from disclosing their pregnancy intentions or seeking PCC advice from their HCPs. Several studies (King, Wellard, 2009; Lavender et al., 2010; O’Higgins et al., 2014; Shawe, 2008; Woolley et al., 2015) have highlighted that HCPs adopt communication styles that are perceived by women to be authoritarian and paternalistic. Shawe (2008) stressed that this style of communicating was a form of social control, which made women feel judged, nagged, undermined, intimidated and less receptive to advice or care. Earle et al. (2017) highlighted that this style of communicating was intended (erroneously) to be informative and to encourage behaviour change but Spence et al. (2010) noted that it made women see HCPs as unsupportive to their needs.

Participants reported that dissatisfaction with HCPs’ attitudes often caused women with DM to seek health information from other sources, as noted in this quote below.

Particularly in diabetes I think sometimes it’s very difficult because people often feel reluctant to be honest with healthcare professionals because they feel that they are judged a lot of the time and sometimes I think people don’t always want to go to somebody who is medical to find things out. [P7, 40 years]

Women were reported to also be critical of HCPs in three other studies (O’Higgins et al. 2014; Richmond, 2009; Woolley et al., 2015), noting that HCPs often did not appreciate the work it took to manage DM during pregnancy or while preparing for pregnancy. Women desired to have more control over their pregnancy or plans for pregnancy and wanted HCPs to focus more on their pregnancy and not just on the DM. Lavender et al. (2010) thus proposed that HCPs should seek to normalise the experience of pregnancy for women with DM to ensure that they have a positive experience by balancing their need for safety with that of enjoyment.

It appeared that women were reticent to approach HCPs for PCC advice due to their attitudes and approach to PCC service provision. Women’s report of seeking health information via other sources, warranted further exploration, the findings of which are presented below.
6.4 Adoption of technology

This section will discuss participants’ views and experiences regarding the use of interactive technology available via the Internet and smartphones, experience of using apps, benefits and perceived acceptability of the PADI app.

6.4.1 Use of technology for healthcare information

All women with DM (n=10) reported using technology as a supplement to information received from HCPs and to fill knowledge gaps. The benefits of using technology for health information were also recognised by HCPs especially as they believed that it would make information readily accessible. This was felt to be particularly important due to current clinic time constraints, mainly office hours, and the challenges that this created for women who were working and had to make child care arrangements in order to attend.

Women also reported limited availability of some HCPs due to their heavy work load, busy clinics and time constraints. Thus, many women were disinclined (unless absolutely necessary) to travel to and from clinics because they felt that ‘sometimes you can’t always access healthcare professionals when you need them.’ [P7, 40 years] This agrees with the study by Spence et al. (2010) which cited busy clinics as a barrier to seeking PCC.

HCPs recognised that current PCC practice, which used traditional leaflets and face-to-face engagement, required women to travel to clinics to receive advice. A nurse noted that with advancement in technology, women could access PCC information from the comfort of their own homes which could help to reach women planning a pregnancy but who do not present to medical care until already pregnant, as noted below.

What I’m trying to do is gather leaflets from all around that companies have made… and see which ones we are happy giving out … that’s another piece of paper and also the lady’s got to come in and engage with us to get it. But actually, if you are thinking of getting pregnant you might google things at home first and rather than us meeting a lady when she is already pregnant but now to get in there with preconception care. [HCP7, interview 4]

HCPs felt that increased access to health information would reduce patients’ travel to hospital and encourage women to discover information themselves, become independent and less reliant on healthcare professionals. This mapped onto interactional workability which is concerned with the effect of technology on people and practices. Furthermore, HCPs and women believed many patients were inclined to turn to technology (including the Internet, smartphones and apps) for support due to its wide reach, convenience and impact, as shown in the data extracts below.

We are in the realm of technology and so it’s become part and parcel of a lot of activities and service provision, so it’s something which more or less brings a lot of information to the doorstep of the patients. [HCP5, interview 5]
If I had a specific question ... I might I suppose read articles on the Internet that has to do with healthcare. [P6, 29 years]

Other women agreed and reported using the Internet for seeking healthcare information which they accessed via the smartphone. The internet was reportedly used to supplement or substitute face to face care. Spence et al. (2010) found that women who wanted more information or had negative experiences with HCPs or healthcare turned to ICT. Search engine Google, also known as Dr Google, was a popular source of health information that was frequently visited by patients in the study. The portability of smartphones meant that information could easily be accessed anywhere and anytime, and women in the study reported using their phones to seek information from ‘Dr Google’ as shown in the extract below.

I google quite a lot of things, I know. Dr Google in all things. I have practically got my phone glued to my hands ... if I need to know, if like something comes to mind that I want to think of, it’s usually my phone that I tend to use. [P2, 22 years]

Another woman supported this view and added that she consulted Dr Google for information when she was not feeling well, and Google in turn provided her with both a diagnosis and remedy to the problem. In addition to diagnosis of various conditions, the Internet was also consulted by participants for reproductive health advice. For example, one woman reported that she would rather consult the internet for information on contraception than discuss it with a member of her healthcare team.

I will just look online probably on the NHS website or something. I don’t think I will bother asking anyone in relation to that [contraception]. [P5, 39 years]

Women reported using social media sites including Facebook and Twitter to access health information or consult diabetes charities with an online presence such as Diabetes UK and juvenile diabetes research fund (JDRF), and the smartphone made accessing these sites very convenient. They also noted using support groups on social media for information and support regarding PCC and pregnancy. These support groups were very useful for providing practical advice rather than text-book knowledge as done by HCPs and was an opportunity for women to learn from the lived experiences of others.

Well there are online groups like on Facebook which are geared towards pregnancy and pre-pregnancy ... they give you advice on a more practical level, people who have been there and done it rather than just the hospital reading from a book or from what they know. [P5, 39 years]

Furthermore, women in the study who consulted search engines for information noted that PCC information, especially for women with DM, was lacking. One woman expressed concern about the lack of available information given that PCC was very important to women with diabetes.
When you google it ... there doesn't seem to be much out there about like preconception especially with diabetes because obviously, it needs to be tightly controlled, your blood sugar and things, but there doesn't seem to be much. [P2, 22 years]

In line with this study, Earle et al. (2017) reported that women who used the Internet as a source of information when planning pregnancy were surprised by the lack of information and stressed the need for PCC information for women with DM to be made more readily available and easily accessible.

6.4.2 Mobile apps trump all

Participants, HCPs (n=4) and women (n=10), mentioned using apps on their smartphones daily to manage different aspects of their lives. Participants noted the benefits of using apps, citing that it made information easily accessible and helped to improve knowledge. Their use ranged from personal to professional and they reported using various gaming, banking, communications, music, shopping, social media, information, pregnancy and health apps.

Participants generally expressed a liking for technology and apps in particular due to their usefulness and convenience. Apps were therefore reported to be used by health-based charities for handling daily activities and participants for seeking information on specific subjects that they might want to find out more about, as noted in the extracts below.

So I use a smartphone to use twitter and Facebook and Instagram for the Charity and also personally ... I use a lot of them ... social media apps, communications apps for talking to patients and things, banking, mobile phone apps, oh, there are so many, things like planning meetings, countdowns, making picture collages ... things like that. [P5, 39 years]

I've got an app on geography, I'm trying to improve my knowledge on maps and stuffs but actually having it on my phone ... I can just do it. I have got a book of maps somewhere in my house but to go and find it or the time you know, you could play on the app [HCP7, interview 4]

All participants, HCPs and women, agreed that apps were pervasive and commonly used by women of reproductive age for various activities. They reported that women with DM of childbearing age were tech-savvy and found, downloaded and used apps to manage different aspects of their reproductive and diabetes health. Participants noted that apps were popular tools for health and diabetes management, and were used for monitoring diet, exercise and blood glucose levels, as shown below.

You can use an app almost for everything now. So you enter your details and then you can keep track of your period and everything. So you can also add all the other things that you need to check, so [if] its blood glucose or if you have to do some other tests. [HCP3, FG1]

I use 2 apps mainly- I use my Fitness Pal to like calculate foods and keep track of what I'm eating, I use the Carb and Cal app too for obviously when I need to estimate carbohydrate intake. [P2, 22 years]

App use appeared to be ingrained into women’s daily lives and even women who described themselves as being non tech-savvy (n=3), still used different apps on a daily basis.
Furthermore, women in the study generally used numerous apps for different purposes and had wide ranging experience of using apps. They all mentioned that they were more likely to use an app that was simple and beneficial, as noted below.

So I use an iPhone where I use the kind of regular Facebook, Instagram, twitter, I have my bank apps, I have the train line apps, I have a libraries app that I use, I have a weather app but again I’m not a huge app person … I am not a big techy person but if something is easy to use and helpful, then it would be something I would use regularly. [P9, 29 years]

6.4.2.1 Perceived benefits regarding use of a PCC mobile app

Many women with DM were savvy users of technology especially mobile phones, and the use of a PCC app sat comfortably within their skill set workability (the degree to which the e-health initiative fits within existing skill set). There was a consensus among participants (clinicians and women) that apps were generally easy to use and appealed to women of different age groups. It was felt by participants that an app with PCC information would be of benefit to women with DM who were planning a pregnancy as they were motivated to stay healthy in order to achieve good pregnancy outcomes, as shown in the extracts below.

I think it’s a great idea to be honest. I mean everything now is apps and technology, and there is nobody who doesn’t know, even my mum knows how to use an iPhone and she is nearly 60 so it would be a great idea. [P8, 35 years]

I think great because that’s what people use … most women can intuitively work through [apps] regardless of age and stage … I’m working with a girl … she wants to start a pregnancy in the best possible shape both physically and biochemically … if there was any kind of sophisticated [PCC] app for her, that’s the sort of person who would benefit from it. [HCP8, interview 5]

Two studies (Collier et al. 2011; King and Wellard, 2009) in the literature explained that women with DM were often concerned about the health of their unborn baby or baby-to-be; the desire for a healthy baby motivated them to be as healthy as possible and ensure the best outcomes for their baby.

Another nurse in secondary care noted the usefulness of the Internet and apps in providing healthcare information. A PCC app could be used to enhance the experience of women and their partners as it would enable them to jointly access the information in the app and keep themselves informed on issues related to diabetes and pregnancy.

So you would kind of hope the lady or her partner or someone will be like “well hang on if you are gonna be doing this [pregnancy], do a bit of research” and google, and the internet and apps is the way forward, definitely. The partners are very involved, want to know about their ladies’ diabetes and want to know how it’s going to affect them and their babies. So actually it’s something their partners as well can look at with them which will improve their experience generally. [HCP7, interview 4]

Most clinicians (n=7) recognised the challenge involved in persuading women to discuss their pregnancy intentions and/or establish rapport with their healthcare team prior to pregnancy. One nurse stated that a PCC app had the potential to increase engagement with
HCPs via knowledge optimisation, so that women were fully informed about PCC and could approach their healthcare providers with confidence. Women agreed that the convenience of a PCC app would not only appeal to a large number of women with DM but also had the potential to increase PCC uptake.

Phoning someone up and asking things you might think you ought to know can be a bit embarrassing and put you off whereas if you just look it up, at least it will give you the confidence when you then go and speak to someone like a healthcare professional. [HCP7, interview 4]

You might actually get more women actively seeking it [PCC], if that sort of thing was available… if I was gonna have another baby, I think I would be more likely to look it up like that now than see the diabetic specialist or whatever, I think I would probably do that first. [P3, 40 years]

Hence, relational integration (how the intervention might affect the existing knowledge and relationships) and interactional workability (the degree to which the proposed technology enables or impedes interaction between HCPs and patients) were generally positive. Furthermore, a doctor felt that a PCC app would help inform women of the importance of working with their healthcare providers in order to attain good pregnancy outcomes, as shown the data extract below.

It would bring about the engagement with the service providers so that they know they should work together for their own benefit. So, I think it’s a really good thing and if they’ve got the app by them, to be looking at, at their leisure which is even more important, rather than going to see—, it’s even more appealing, in that sort of sense. [HCP5, interview 2]

HCPs and women reported that a PCC app also has the potential to address the constraint of current PCC service provision because it precludes the need to constantly travel to a hospital to receive information, thereby reducing patient travel to hospital. A nurse in secondary care further noted that many women were occupied (with work and child care) and constantly going to the hospital during preconception and pregnancy left them with a negative experience.

I think it’s useful, I think that it’s something that is accessible at all times, you don’t need to have an appointment or anything similar it’s just something that is there, available all the time. [P7, 40 years]

The women appreciate not being dragged to a hospital every 5 minutes … they’ve got other things going on. Yeah and pregnancy and preconception is meant to be a lovely healthy time isn’t it, you don’t want to associate it with always being at a hospital, almost gives you the impression that you are ill. [HCP7, interview 4]

Additionally, it was reported by women and HCPs that women with DM had a close relationship with their phones, and a PCC app with information on diet, blood glucose control, folic acid, etc. would be an ideal way for women to receive pertinent PCC advice. Most importantly the need to make PCC information more accessible to women with DM was highlighted, as shown below.

I can literally see the point, I’ve got quite a few … girls with type 1 … they are all in their 20’s and they all use phones all the time. So that would be a good way to communicate with them … diet,
Glis, reminders and general information, folic acid, all sorts of stuff could be useful on apps. [HCP8, interview 5]

I think it’s brilliant, I mean you look at anybody now if you are outside or anywhere, getting a coffee, everybody’s got a phone in their hands … I think people would [use it] because they need the help. [P8, 35 years]

6.4.3 Acceptability and feasibility of a PCC mobile app

Overall, views on use of a PADI app were positive. Most HCPs (n=7) and all women (n=10) acknowledged that women with DM needed PCC advice. Although the use of an app for PCC was a novel approach, they agreed that the incorporation of PCC information within an easily accessible and highly accessed platform had the potential to improve provision of PCC information.

So women do need [PCC] advice and if you are going to put it in an app and it’s something that’s easily accessible then yeah I guess it’s a good idea. [HCP4, interview 1]

It [PCC]’s not something that I know of personally, it’s not something I know much about so to be able to have an app to go into and get information from, I think is really important. [P1, 43 years]

Another woman reported the urgent need for a PCC app and noted that for women who were not provided with PCC information by their healthcare team, a PCC app was an ideal way to deliver relevant PCC information.

I think it’s probably the best way to get information across to people like myself who obviously haven’t been informed of like the importance of preconceptation especially in diabetes … I think it’s a good idea. To get the message out there is better than– to have some understanding is more important than having no understanding. [P2, 22 years]

Participants, women and HCPs, expressed confidence in women’s ability to engage and interact with the app, and to use it effectively for PCC. It was noted, by HCPs and women, that a PCC app could easily be integrated into women’s lives and would provide a handy, yet discrete way for women to access PCC information. Participants further admitted that this medium of providing PCC was preferred to the use of leaflets, as noted in the data extracts below.

I think it’s a brilliant idea. Easy to access, you’ve got the information there so it’s something you can discreetly look at on your phone. It’s not like you are sitting there with a textbook on diabetes and pregnancy. It’s just something people could look up when they are commuting on the train, standing in the post office for an hour, they can look at their app which would make it a lot easier for ladies to look up things. [HCP7, interview 4]

I think more women would use something like that these days. I don’t think a lot of women now would go and sort of pick up leaflets … If there was an app they could download, I think they probably would. [P3, 40 years]

It was also thought by participants, HCPs and women, that a PCC mobile app would be easier to update compared to traditional leaflets and hence increase confidence that the information provided was up-to-date and relevant, for example;
If you were gonna pick up a leaflet, it could have been printed years ago, couldn’t it? But I guess it’s easy to update an app. [P3, 40 years]

I mean NICE guidelines have just updated so that’s kind of put… so many things are now wrong– leaflet information out there. Yeah, I think an app is a lovely idea. [HCP7, interview 4]

Women noted the difficulties in accessing PCC information via the traditional means such as healthcare professionals or leaflets, noting that whilst access to both could not always be guaranteed, a PCC app would provide a readily available repository of information which could help address shortcomings of current PCC practice.

I think having something there that I know that I can always reach for and look at if I am suddenly having any question or a concern or I’m looking for more information because you can’t always call a doctor and you can’t always go look on a pamphlet or search online. [P4, 23 years]

It would be good to have somewhere to go to get information specifically for diabetes and preconception. [P9, 29 years]

6.4.3.1 Potential for integration

The majority of clinicians (n=7) recognised the potential benefit of a PCC app and indicated that they would recommend the app when developed to women with DM. For example, a nurse in primary care and a doctor in secondary care were quite enthusiastic about integrating the app into their consultations and recommending it to women in their care. This indicated that the PADI app will easily fit into HCPs’ existing working practices and skillset, therefore skillset workability was positive.

Yeah. Definitely, yes. Just as I see people for reviews, and I always talk to anybody in the range where I think they might possibly be thinking about having a baby, I would talk through their contraception, their plans, folic acid, control and what are you using to monitor, would you like anything else that’s out there? So yeah, most definitely. [HCP8, interview 5]

Yeah … we are in the realm of technology and if obviously it will help with her preconception care, and then the subsequent pregnancy, yes, why, yes. [HCP5, interview 2]

Furthermore, another nurse who previously worked in primary care stated that she was likely to suggest a PCC app (if one existed) to women with DM who approached her with pregnancy intentions because of her insufficient expertise and knowledge of PCC.

If I knew about this kind of app when I was working at the GP and I have some patients that “oh you know that I’m type 1 and I’m thinking about having a baby”, probably I would suggest because … maybe my knowledge is not enough. [HCP3, FG1]

HCPs (n=4) reported the need for women with DM to be made aware of the existence of the app and noted recommendations by HCPs (particularly GPs) as effective ways of raising awareness of the app. Two nurses in secondary care felt that recommendations by a HCP would encourage women to use the app, as indicated in the focus group discussion below.

So you have to make aware … so kind of advertising or saying that there is this kind of opportunity because otherwise how can the patient know if no one will tell them. You have to really think, “ok, I want an app because I am diabetic and I am planning to have a baby,” so you have to specifically search for that one, it’s not a usual search … But if it’s someone else that is your
healthcare professional will suggest it, probably you will use it, because it's someone that you consider. [HCP3, FG1]

Yeah, yeah, absolutely, more your GP. [HCP1, FG1]

Advertisements was another way of raising awareness of the PADI app and ensuring that it got to the right audience. Another nurse in secondary care suggested placing advertisements in general practices within the community in order to reach women with DM (especially those with T2DM) who received their care in GP surgeries;

It's something that could be advertised in like a poster up in the GP surgery, do you have diabetes? Are you planning to get pregnant? Look at it. It's out there. [HCP7, interview 7]

Apart from primary care, the app also had a place in secondary care. Some clinicians (n=3) stated that the app was likely to be adopted within their organisations as they were often keen to trial new innovations that would contribute to patients’ health improvement, thus increasing the likelihood of contextual integration (CI). CI is concerned with the degree to which the app fits (integrates) with the overall goals and structure of the organisation, and the capacity of the organisation to undertake the implementation. Adoption however depended both on appraisal of the app’s usefulness and user acceptance, as shown below.

I don’t see why not ... I guess sometimes with a lot of things we seem to trial things in the hospital, get feedback and then kind of launch them. [HCP7, interview 5]

Two HCPs, a doctor and nurse, however expressed concern about the use of an app for PCC information. The doctor acknowledged that an app may have a possible role in PCC but stressed that PCC provision involved medical interventions that could only be provided by a healthcare professional within a clinic setting, thus giving rise to some reluctance in accepting an app for PCC, as shown below.

I really don't know because I’m personally not convinced that it is necessarily going to be the answer that it’s going to solve a lot of women’s problems. I think if someone knows they need PCC, they need to come really to the [clinic] it’s not something that can be delivered via an app, its medications review, complications review screening that can’t be done by an app and has to be done by a person… because actually the stuffs that you need, you need nurses and doctors for. [HCP6, interview 3]

The nurse on the other hand, noted that an app might introduce bias and possibly result in a digital divide whereby women with smartphones have better access to PCC while those without smartphones will be unable to access the PCC information, as shown below.

It would be population-biased because I can’t suggest it to all my ladies because I know that not all of the ladies can afford to have a mobile phone let alone a smartphone. So we are going back to postcodes, lotteries- the people that can afford things get better quality care, allegedly. [HCP9, interview 6]

These concerns may affect confidence in the applicability of a PCC app to women with DM. However, all women (n=10) recognised the need, benefits and usefulness of a PCC app, and the majority of clinicians (n=7) reported that the proposed app appeared feasible to be
integrated into their practices and recommended to their patients. They were willing to use the app in their practices and expressed interest in seeing the proposed app when completed.

6.5  Technology-assisted PCC

This section will address the development of the proposed PADI app and the app’s potential for adoption and implementation following development.

6.5.1  PADI app development

6.5.1.1  Intervention content

HCPs and women provided suggestions for the app content. The majority of HCPs (n=8) suggested including information on importance of pregnancy planning, pregnancy-related risks for the woman and baby, and general health advice for the preconception period. Although some women expressed limited knowledge when asked about PCC content, this formed the basis of their suggestions which were mainly for more accessible PCC information and awareness of pregnancy planning and risks. The need for PCC education in general, and information on blood glucose control, diet, diabetes and pregnancy, and supplementation were particularly emphasised (see Appendix 13 for full list of suggested app content). For example;

They have to know the impact the disease would have on their pregnancy, and the impact, of the pregnancy on their disease. They have to know of lifestyles that would improve their health status, so avoid smoking, excessive alcohol intake, be advised that they take folic acid, healthy diet in general, exercise, so it’s more of health promotion together with their specific medical needs … compliance with treatment, adherence to healthy lifestyle and avoiding pregnancy if they are not in the right sort of health status. [HCP5, interview 2]

Well considering I don’t really have much, I have never been told much information on it. Anything really, anything that’s relevant to me, to my age, my condition, … just getting the message across to people … When you realise this can happen to you, then I think that’s the best way, for me personally anyways, it’s the best way to get the message across and relay the importance of it and how things can and things do go wrong with, like obviously an unplanned pregnancy in diabetics [P2, 22 years]

For majority of clinicians (n=8), having comprehensive PCC information in the PADI app would not only improve women’s knowledge and confidence (relational integration) but also the patient-clinician interaction (interactional workability). Furthermore, because many women already used apps for managing many aspects of their health (including SMBG; self-monitoring of blood glucose), a PCC app which incorporated SMBG functions would fit within their competence boundaries and satisfy the skill-set workability condition for implementation.
6.5.1.2 Self-monitoring of blood glucose (SMBG) functions

Monitoring of blood glucose levels was an important component of PCC and diabetes self-management, and most participants (n=17) felt that the addition of a built-in blood glucose diary to the app would be of added benefit to women planning a pregnancy. Two participants, a primary care doctor and woman, highlighted that an information app may not encourage engagement but a built-in diary would make the app more useful and reduce the burden involved in using two separate apps, to self-monitor and receive PCC advice.

To me I’m not really sure if using an app would be any different than like giving someone a brochure … I would prefer having a brochure rather than having an app if it’s … just for providing information. But if it was to be something like tracking your blood glucose levels, providing information … I think that would be more useful than just providing information in like my experience of using apps. [P4, 23 years].

A lot of them do that separately. But having something all in one place, I mean it’s that thing about keeping it as simple as possible and you know easily accessible [HCP4, interview 1]

Another woman agreed with this view while noting the advantage of using one app for both PCC and blood glucose monitoring.

That would be something that you want to keep track of anyways so if it was on the app it would be better than having two or three different things on your phone. [P9, 29 years]

Women reported using several apps for their blood glucose management including iBGStar, Monster and mySugr, and felt that a diary built into the PCC app would help women stay focused, improve self-monitoring and keep their glucose levels on track as they plan for pregnancy. Other women in the study (n=3) commented on the mobility and convenience of entering and monitoring glucose levels that the app would provide and noted that this would be especially beneficial. It was also suggested that the diary utilise a graphical display of information rather than plain display of numbers, as this would be easier to visualise and help identify trends in blood glucose readings, for example.

I think it would be a great idea because if you have your phone in your hand it’s so easy to pull up your app and enter your levels … with the app you are just entering everything quickly and it’s easy to see … if you have graphs you can see your levels going up and down. [P8, 35 years]

Furthermore, the relevance of good control to fertility was noted by another woman who highlighted that aiming for optimised control should be a target for women planning a pregnancy in order to improve their chances of conception, and a PCC app with a diary would contribute to helping women achieve optimised levels.

From what I have heard if your blood glucose is high, then it’s more difficult to get pregnant so I feel like that would probably be more of a priority to try and lower your blood glucose … I think that’s more of like a goal setting thing in my mind … if you know it’s out of range, there are things you can do to bring it down. [P4, 23 years]

The built-in diary also had the capacity to provide both healthcare professionals and patients with information regarding patients’ BG levels. The PADI app could easily be incorporated
into existing patterns of activities which further demonstrates its potential to fulfil the condition for contextual integration. For example, a nurse in secondary care commented that it would be especially useful to women who received their care in general practice as it may come to replace their existing blood glucose diaries.

*I can see that some of them can be quite excited about the idea … in primary care, it could well have a place because then maybe they are not using the latest monitor, they are only using the one that the GP sent them because it is the cheapest on the market, so an app that may take over that role may be very, very beneficial.* [HCP1, FG1]

Clinicians (n=5) also suggested in the long-run, having the diary connected to the patients metres to reduce user burden.

6.5.1.3 Reminders

Some HCPs (n=3) and the majority of women (n=8) agreed that a reminder should be added to the app to remind users of pre-pregnancy activities and BG readings. Opinion was split over the type of reminder to be included. For example, some participants (HCPs, n=2 and women, n=4) recommended using notifications to remind women about pre-pregnancy activities such as assessments to go for and supplements to take, as shown in the data extracts below.

*I think it’s then reminders that this is a cardiovascular disease- diabetes, so how’s the blood pressure … have you had your cholesterol checked this year? It’s all the broader stuff as well because people just think sugar for diabetes and actually it’s good to get those reminders that these other things need to be done.* [HCP8, interview 5]

*I think that’s a good thing to have because I think sometimes … people go in with good intentions but obviously if like it takes a while to get pregnant or whatever, they can lose interest which is obviously a bit alarming because especially with diabetics, you need to maintain looking after yourself and obviously like supplementations and all things like that so having reminders and like notifications and things would be a good thing to include.* [P2, 22 years]

Caution was however advised by some women regarding the use of reminders for things such as pre-pregnancy activities, appointments and BG reading to avoid putting women under pressure, as reported to be done by healthcare professionals. They suggested avoiding anything that would make women feel under pressure, as shown below.

*I would be a bit wary about it because it could be a bit annoying because again you do feel a bit nagged by healthcare professionals and stuff so you wouldn’t want the app to come across too naggy.* [P6, 29 years]

Other participants (HCP, n=1 and women, n=4) expressed preference for a built-in reminder to monitor BG levels. A doctor reported that it was preferable to have a reminder that allowed women with both T1 and T2DM to have control over the SMBG function and a woman noted that having such a reminder within the app would help increase engagement with the blood glucose diary.
Well I know it’s very individual because if you’ve got somebody with type 2 they are not going to need to monitor as often, but certainly, people, women with type 1 are going to be monitoring more often … but you could put something into your app that would just alarm the person to test however many times you decide they need to test. [HCP4, interview 1]

Reminders for anything, that’s always good in that it keeps people using things … a reminder sort of alarms, to remind you to do things. The diary is great if it could run sort of hand in hand with the reminder. I know when I had to do mine on a regular basis sort of 3x a day, it would have been handy just to have something to sort of remind me to do it. [P1, 43 years]

Women also indicated that it would be more useful for women trying to improve their glucose control to have a built-in reminder for BG levels, stressing that it would alert them to take their readings and encourage better self-monitoring. It was also important that the diary could be adjusted, that is turned off or on, depending on user preference.

6.5.1.4 Intervention language

Some participants, clinicians (n=4) and women (n=4), suggested using positive and encouraging language to provide the PCC information to women in order to improve their knowledge of PCC, including pregnancy planning and risks, and the benefits of adopting healthy preconception behaviours, as shown in the data extracts below.

It’s important the ladies know [of pregnancy-related risks and complications], definitely, but at the same time it’s kind of saying these risks can be reduced. It is possible, that’s why we want preconception care … so like giving all the information but I guess in a positive way … Giving the ladies a bit of knowledge is power and a bit of positivity like actually this is fine “I need to get my sugar sorted, I need my folic acid. Actually I want this baby and I can do the best I can by getting my preconception sorted.” [HCP7, nurse]

I think like a positive spin on things would be important so like positive reinforcement as opposed to” if you don’t do this, this would happen”, more like “if you do this, this would help your baby develop safely”, or “this would help you feel better or this would increase your chances of conceiving” … making sure that the app, although provided education it wasn’t too negative and it was more from a positive point of view I think that’s probably the most important thing. [P6, 29 years]

Several studies (King, Wellard, 2010; Shawe, 2008; Spence et al., 2010) have reported that many women perceived having DM as ‘hard work’ particularly in terms of the physical and emotional effort required to achieve and maintain good blood glucose levels. The pressures faced by women with DM especially those with T1DM regarding their control was highlighted by another woman who further stressed the importance of using a supportive approach within the PADI app.

Obviously things don’t always go right particularly when you’ve got type 1 day to day wise, and we often hear about ourselves being poorly-controlled, “oh you must be doing something wrong” … and sometimes that’s very difficult to hear … and anything that would be a [PCC] mobile app would be beneficial to not come across as anything that was making people feel that they were under pressure to do anything, that this was the best option, it needs to be something positive. [P7, 40 years]

In line with this study, Earle et al. (2017) stressed that focusing on positive changes that women might make when planning a pregnancy was more likely to encourage women to
engage more with the support being offered. Similarly, Collier et al. (2011) reported that women were more receptive to care, and advice provided using a positive approach, and this approach encouraged them to find out more about various aspects of preparing for pregnancy. It was agreed by women and HCPs that a positive and supportive approach to PCC would promote women’s confidence and increase the app’s potential to be recommended and incorporated into clinical consultations and used by women.

6.5.2 Factors affecting implementation

All participants (n=19) recognised a number of factors, including cost and organisational support, as well as facilitating/hindering content and design factors, that could facilitate, or hinder acceptance, recommendation and adoption of the app once developed.

6.5.2.1 Cost and organisational support

Cost was perceived to be both a facilitator and a barrier to adoption and implementation, and a woman stated in a matter of fact way that ‘a lot of people won’t pay for apps’ [P5, 39 years]. Furthermore, a nurse in secondary care highlighted that cost would play a role in the overall uptake of the app and noted that ‘the way to meet most people would be for the app to be free … or at least very [affordable].’ [HCP7, interview 7] This was supported by other women with DM (n=5) which highlighted the need for the PADI app to be affordable in order to encourage uptake.

Furthermore, HCPs noted that in light of the financial constraints facing the NHS, cost would affect the ability of NHS organisations to adopt and integrate the app into routine care, as noted in the data below.

Every hospital is struggling financially, we are leasing resources and various things so I must admit generally if there is a cost … but apart from that, the reason we do this job or we work in a hospital is to make a difference and improve things with people so from that side of things … people still want to drive things forward and improve care. [HCP7, interview 7]

However, HCPs felt that cost was not the only factor to consider with regards to adopting new technology such as a PCC app, the app also had to have the backing of the hospital stakeholders including other healthcare professionals. This organisational support for the app was crucial to allow HCPs, especially nurses in secondary care, freely recommend the app, promote and publicise it both within and outside their respective NHS organisations, as noted below.

So if it provided the information and kind of everything else and the hospital are happy then I’d be happy to have posters up. We have a meeting where we meet with the GPs and the diabetes leads in the area, it would be presented there, and everything … but generally as long as my hospital and my team, antenatal team were happy, I would be happy to, because it’s helping benefit women. [HCP7, interview 5]
6.5.2.2 Facilitating content and design factors

Informative and up-to-date information
Clinicians reported that they were very cautious about recommending technology to patients and highlighted the need for the app to contain accurate, relevant and evidence-based information that was accepted by the target user group.

* I think if it’s well produced and if you’ve got something that has been researched, that’s sound, that the patients like, that is recognised, and that it’s got accepted advice, then I think we would. I mean, in general, I recommend websites to patients but you have to be careful, you have to be very careful about what you do recommend. [HCP4, interview 1].

Other clinicians (n=2) reported that they would carry out quality assurance checks on the app before recommendation, as noted below.

* If there was an app, I would download it and have a look at it and make sure I was happy, but if it was relevant and up to date, yeah, I don’t see a problem … being updated, not just being put out there but if you are providing information that is, it’s not medical as such but it’s so important, it’s also important to make sure that its updated. [HCP7, interview 4]

Efficiency
Women further noted that an app that was efficient and helped to expedite access to PCC information had a clear advantage over Internet search engines such as Google. Thus, this utility could promote the PAD1 app’s uptake and engagement, as noted below.

* I think for me, the biggest thing that I would want to use an app for is if it’s providing me with something that I can’t get otherwise. So you can google for hours preconception care for type 1 diabetes or type 2 diabetes but if all that information was neatly packaged in an app, I think that would be nice. [P4, 23 years]

Simplicity and ease of use
Participants, clinicians and women, noted that simplicity in design and delivery of information was a very important factor for promoting adoption. They felt that it was vital that the app used easy to understand language while at the same time providing essential PCC information, and by so doing, maximise benefit for women, as noted below.

* I think if it was like user friendly, not too overpowering but delivers the key information points needed like the absolute importance of supplementation, the importance of blood glucose control, the effect of not having blood glucose control. So, that delivered the key messages in a simple way. [P2, 22 years]

* It’s so much easier to read kind of either bullet points or short paragraphs rather than just an essay … so just making it memorable what they are reading. [HCP7, interview 4]

This opinion was supported by another woman.

* So easy to use, I mean, that’s a trademark of a good app anyway and gives you the information you need to help you with your preconception care in a way that you can understand it. [P10, 43 years]
Relevant content and features

In addition to provision of advice via a static app, it was important for the PADI app to contain other features that were considered relevant to women with DM and thus more engaging. For example, a PCC app that was compatible with patients’ existing app usage activities and that tied in with women’s self-management practices such as blood glucose monitoring was more likely to be recommended by clinicians and used by women with DM, as noted below.

I think if the right things are on it. That it has all their [blood glucose] readings, it has one place that they could go to get all the readings and [PCC] advice that they may need. [HCP1, FG1]

I guess just depending what was on it really, if I thought it was going to be useful for me, that would motivate me, if I thought it was gonna educate me then I’d be interested … so if I thought, “oh this is quite handy because I can keep track of my blood sugar or I can keep all the information in one place” … that would motivate me to get the app [P6, 29 years]

Attractiveness

Participants connected the look of an app to its potential usability i.e. the more appealing it looked, the more likely it was to attract users who would consider downloading and using it. Women recommended avoiding the ‘clinical’ look of medical or health apps and making use of nice bright colours and ensuring that although the app was for promotion of women’s health, it still looked interesting, as shown below.

I think women tend to go for things that can be quite cute … Although you want it simple, you don’t want it boring or plain … I think possibly if it was sort of like a clinical thing, I think if it looks, although I know it’s educational and sort of towards healthcare and things, I think if it doesn’t look too interesting then you kind of tend to bypass. [P1, 43 years]

6.5.2.3 Hindering content and design factors:

Missing health promotion information

For HCPs, it was important that the app contained vital information on PCC including assessments (retinal, renal, thyroid) and the absence of this vital information would be a barrier to recommendation, as noted below.

What will not make me recommend it is if it does not address the general aspects of care such as the health promotion aspect of care because they are key to the control … If it does not appreciate that there should be baseline investigations … I’m talking of the eye examination, I’m talking of kidney assessment, and I’m talking of at least thyroid function because the thyroid T test I’m pretty sure can easily be missed. [HCP5, interview 2]

Complexity

It was reported by HCPs and women that user engagement would reduce if the app was difficult to use. They agreed that a complex app would hinder recommendation and uptake, as shown in the data below.

If it’s too complicated. The things that put patients off, whatever it may be, for whatever reason, if it’s too complicated, too fiddly and it’s not easy to use, with easy instructions. [HCP1, FG1]
I want something not too complicated. I think if it gets too sort of complicated or technical, it can put people off depending on your own level of using things like that. [P1, 43 years]

6.6 Phase 1 findings and the expanded health belief model (EHBM)

Although women with DM had limited understanding of PCC and pregnancy-related risks, both healthcare professionals (HCPs) and women with DM recognised that women who had DM were more vulnerable and susceptible to reproductive health problems, such as pregnancy-related complications. They also believed that when these problems occur, they could be severe, e.g. having uncontrolled blood glucose levels during pregnancy could lead to major complications such as miscarriage and macrosomia, and lack of folic acid could affect the baby’s development and result in an NTD such as spina bifida.

There was a perception amongst participants, HCPs and women with DM, that receiving PCC advice and optimising one’s health before pregnancy was beneficial. More specifically, the use of a mobile app for PCC was recognised as an opportunity to reduce barriers to PCC service provision and uptake and, improve access to PCC information. It was also highlighted that providing pertinent PCC information to women, via the PADI app intervention, could help improve their knowledge, independence and self-efficacy. Knowledge optimisation in turn could enable them to seek PCC and take actions that increase the likelihood of a healthy pregnancy and baby, e.g. discussing pregnancy plans with HCPs. Hence, the PADI app could motivate women to adopt healthy preconception behaviours.

The additional app components, such as blood glucose diary and reminder, could also encourage women to monitor blood glucose levels before and during pregnancy. An easy-to-use PCC app that provides information using simple and positive intervention language, and that contains relevant content and features could be instrumental in ensuring that women understand the need to plan their pregnancy and seek PCC in order to reduce risk of complications. The app could also serve to remind women of the benefits of seeking PCC, reassure them that they can have healthy babies with PCC, and signpost them to available PCC resources and HCPs that they can contact for PCC. Table 6.3 below shows how phase 1 findings fit with the EHBM.
Table 6.3 Phase 1 findings and the EHBM constructs

<table>
<thead>
<tr>
<th>Constructs</th>
<th>Themes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perceived susceptibility</td>
<td>Understanding of PCC</td>
</tr>
<tr>
<td>Perceived severity</td>
<td>Understanding of PCC</td>
</tr>
<tr>
<td>Perceived benefits minus barriers</td>
<td>Understanding of PCC; Use of technology for healthcare information; PADI app development</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>PADI app development; factors affecting implementation</td>
</tr>
<tr>
<td>Cues to action</td>
<td>PADI app development; factors affecting implementation</td>
</tr>
</tbody>
</table>

6.7 Summary of key findings

This chapter presented analysis of data from discussions, conducted between March to October 2016, with nine HCPs and ten women with DM, and the key findings that emerged. It provided detailed insight into what information HCPs would like women to know before pregnancy, as well as the information women themselves would like to see in a PCC app developed specifically for women with DM. Suggestions from both HCPs and women with DM were used to inform the design and development of the PADI app [see Chapter 4 and Appendix 14 for app screenshots].

Phase one findings highlighted the views and experiences of participants regarding PCC and use of the PADI app in practice. It showed that PCC information delivery for women with DM was inconsistent and limited with various factors, including service configuration, lack of pregnancy planning and HCPs’ judgemental attitudes, hindering effective provision and uptake. Challenges in current PCC service provision placed women at a disadvantage with regards to receiving information, and majority reported sub-optimal PCC experiences and general dissatisfaction with current PCC approach. Findings also indicated that a PADI app, incorporating PCC information and SMBG functions, would be highly feasible and acceptable to participants. Women and HCPs recognised the gaps in current PCC service provision and highlighted that an app could increase PCC knowledge, accessibility and uptake. HCPs highlighted the PADI app’s potential to improve engagement with HCPs, confidence to seek PCC and pregnancy outcomes, and were willing to recommend and integrate it into clinical consultations.

Findings suggested that the app has potential to be implemented into routine healthcare practice given its capacity to confer an interactional advantage between patients and HCPs, improve knowledge and confidence, and fit within users’ skill set and clinicians’ work practices. Concerns regarding the applicability of the app to women with DM could pose as potential barriers to recommendation and integration by some HCPs. Yet, many women were reticent to approach HCPs with pregnancy intentions despite insufficient awareness of
PCC. Hence, highlighting the need for a change in current approach to PCC information delivery and the PADI app is one way to achieve this.

Participants’ views regarding factors that could affect implementation of the PADI app were also explored. Overall, participants identified only very few factors that would prevent women in the study from using the app once developed however uptake and user engagement can be hindered if the app is complex, expensive or negative. For clinicians, complexity and cost were key points to consider during development that could affect uptake, in addition to up-to-date and relevant information. Furthermore, for a PADI app to be adopted by women with DM, recommended by clinicians and embedded into routine care, organisational, content and design factors have to be taken into consideration during development of the PADI app. By so doing, promote the potential for adoption and implementation.

The results of the feasibility testing of the PADI app with women with T1 or T2DM forms the focus of the next chapter.
7. Chapter 7: Phase 2 results

7.0 Overview of chapter: Intervention

This chapter presents the results from analysis of data collected in Phase 2, feasibility and acceptability of the PADI app intervention, from questionnaires and interviews. Presentation of questionnaire data in section 1 is followed by a thematic analysis of the views and experiences of women with DM regarding the PADI app use in section 2.

7.1 Section 1: Quantitative results

This section presents an analysis of the data collected from two questionnaires, administered at pre-intervention (Questionnaire 1) and post-intervention (Questionnaire 2). Data relating to recruitment, retention and a descriptive overview of participants are presented, followed by a preliminary evaluation of the effects of the app intervention on participants’ knowledge and attitudes to preconception care (PCC), and patient activation measure (PAM). The pre- and post- PADI app intervention results are presented separately followed by a brief comparison of results. This study was not powered to detect statistical changes therefore results should be interpreted with caution.

7.2 Eligibility, recruitment, retention and attrition levels

Between December 2016 and March 2017, 38 women with T1 and T2DM expressed interest in joining the study (three responded to an invitation received during a visit to an NHS hospital and 35 to a twitter advert). Two (5%) were later excluded as they had completed their families and therefore were not eligible for inclusion and 19 (50%) declined participation after receiving further study information. Reasons for non-participation included work/time constraint (5/19, 26%), personal reasons (2/19, 11%) and a lack of financial reward (1/19, 5%). Most (11/19, 58%) however did not give a reason.

Seventeen (45%) women were therefore recruited (using the inclusion criteria described in chapter 4) exceeding the recruitment target of 12 participants. All participants returned the pre-intervention questionnaire, and were provided information on how to download and use the app. Hence, all (n=17) recruited participants received the PADI app intervention. Of the 17 participants who enrolled into the study, one left the study after one month and 16 were sent the post-intervention questionnaire. Eleven (65%) completed and returned Questionnaire 2, however, five did not respond to the post-intervention questionnaire invitations. The attrition rate (the percentage of participants who did not complete the study) was estimated at (6/17) 35%. The reasons given for leaving the study included work/time constraint (n=1) and no longer planning a pregnancy (n=1). Four other participants did not give a reason and could not be contacted despite several attempts. Figure 7.1 shows the
flow of participants through the study, loss to follow up, and number of participants who completed the study.

Figure 7.1  Study flow diagram

7.3  Sample
The sociodemographic characteristics of the 17 women who completed the pre-intervention questionnaire are outlined in Table 7.1 and demographics data are expressed as n (%) for categorical variables and mean ± SD for continuous variables.
7.3.1 Characteristics of participants

Participants were geographically dispersed across North America (n=4, 24%) and UK (n=13, 76%). All participants were white, with the majority married or living with partner (n=11, 65%). Age ranged from 20 to 43 years (range =23). The majority of participants (n=16, 94%) had type 1 DM, were employed (n=14, 82%) and had a first or higher academic degree (n=11, 65%). Most women (n=12, 70%) reported plans for a pregnancy in the near future (i.e. next year or in 1-5 years). Table 7.1 below shows the demographic characteristics of the (n=17) study participants.

Table 7.1a Demographic data

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total sample</strong></td>
<td>17</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Demographic characteristics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>31.3 ± 6.7</td>
<td></td>
</tr>
<tr>
<td>Marital status</td>
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<td></td>
</tr>
<tr>
<td>Married/living with partner</td>
<td>11</td>
<td>65%</td>
</tr>
<tr>
<td>Single (never married)</td>
<td>6</td>
<td>35%</td>
</tr>
<tr>
<td>Diabetes type</td>
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<td></td>
</tr>
<tr>
<td>Type 1</td>
<td>16</td>
<td>94%</td>
</tr>
<tr>
<td>Type 2</td>
<td>1</td>
<td>6%</td>
</tr>
<tr>
<td>Diabetes duration</td>
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<td></td>
</tr>
<tr>
<td>Less than 1 year</td>
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<td>6%</td>
</tr>
<tr>
<td>Over 5 years</td>
<td>16</td>
<td>94%</td>
</tr>
<tr>
<td>Race or ethnic group</td>
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</tr>
<tr>
<td>White British</td>
<td>9</td>
<td>53%</td>
</tr>
<tr>
<td>Irish</td>
<td>2</td>
<td>12%</td>
</tr>
<tr>
<td>Any other white background</td>
<td>6</td>
<td>35%</td>
</tr>
<tr>
<td>Geographical location</td>
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<td></td>
</tr>
<tr>
<td>United Kingdom</td>
<td>13</td>
<td>76%</td>
</tr>
<tr>
<td>America</td>
<td>2</td>
<td>12%</td>
</tr>
<tr>
<td>Canada</td>
<td>2</td>
<td>12%</td>
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<tr>
<td>Highest educational qualification</td>
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<tr>
<td>Higher degree (M.Sc or PhD)</td>
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<td>First degree (B.Sc)</td>
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<tr>
<td>Other diplomas</td>
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<tr>
<td>A / AS / S levels</td>
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<td>12%</td>
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<td>Other academic qualifications</td>
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<tr>
<td>None of these qualifications</td>
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<td>6%</td>
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<td>Employment status</td>
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<td>Employed full-time/part time</td>
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<td>82%</td>
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<td>6%</td>
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<tr>
<td>Student</td>
<td>2</td>
<td>12%</td>
</tr>
<tr>
<td>Currently considering or planning to have children</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In less than 1 year</td>
<td>6</td>
<td>35%</td>
</tr>
<tr>
<td>In 1-5 years</td>
<td>6</td>
<td>35%</td>
</tr>
<tr>
<td>Over 5 years</td>
<td>3</td>
<td>18%</td>
</tr>
<tr>
<td>Do not know/unsure</td>
<td>2</td>
<td>12%</td>
</tr>
<tr>
<td>Previously had a pregnancy that ended in:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Miscarriage</td>
<td>1</td>
<td>6%</td>
</tr>
<tr>
<td>Ectopic pregnancy</td>
<td>1</td>
<td>6%</td>
</tr>
<tr>
<td>Other (e.g. termination or preterm birth)</td>
<td>2</td>
<td>12%</td>
</tr>
</tbody>
</table>
Table 7.1b Demographic characteristics for responders and non-responders at 3 months

<table>
<thead>
<tr>
<th>Demographic characteristics</th>
<th>Responders (n=11)</th>
<th>Non-responders (n=6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>31 ± 6.6</td>
<td>31.83 ± 7.5</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Higher degree (M.Sc or PhD)</td>
<td>6 (35.3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>First degree (B.Sc)</td>
<td>2 (11.8)</td>
<td>3 (17.6)</td>
</tr>
<tr>
<td>Other diplomas</td>
<td>1 (5.9)</td>
<td>1 (5.9)</td>
</tr>
<tr>
<td>A / AS / S levels</td>
<td>2 (11.8)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Other academic qualifications</td>
<td>0 (0)</td>
<td>1 (5.9)</td>
</tr>
<tr>
<td>None of these qualifications</td>
<td>0 (0)</td>
<td>1 (5.9)</td>
</tr>
<tr>
<td><strong>Race or ethnic group</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White British</td>
<td>4 (23.5)</td>
<td>5 (29.4)</td>
</tr>
<tr>
<td>Irish</td>
<td>2 (11.8)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Any other white background</td>
<td>5 (29.4)</td>
<td>1 (5.9)</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married/living with partner</td>
<td>8 (47.1)</td>
<td>3 (17.6)</td>
</tr>
<tr>
<td>Single/never married</td>
<td>3 (17.6)</td>
<td>3 (17.6)</td>
</tr>
<tr>
<td><strong>Employment status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed full-time/part time</td>
<td>9 (52.9)</td>
<td>5 (29.4)</td>
</tr>
<tr>
<td>Full-time homemaker</td>
<td>1 (5.9)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Student</td>
<td>1 (5.9)</td>
<td>1 (5.9)</td>
</tr>
<tr>
<td><strong>Currently considering or planning to have children</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In less than 1 year</td>
<td>6 (35.3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>In 1-5 years</td>
<td>2 (11.8)</td>
<td>4 (23.5)</td>
</tr>
<tr>
<td>Over 5 years</td>
<td>2 (11.8)</td>
<td>1 (5.9)</td>
</tr>
<tr>
<td>Do not know/unsure</td>
<td>1 (5.9)</td>
<td>1 (5.9)</td>
</tr>
</tbody>
</table>

Age was similar for responders and non-responders. However more responders than non-responders had a first or higher degree (n=8, 47.1% vs n=3, 17.6%), were non-British (n=7, 41.2% vs n=1, 5.9%), married or living with partner (n=8, 47.1% vs n=3, 17.6%), employed (n=9, 52.9% vs n=5, 29.4%) and planning to have a baby in <1 year (n=6, 35.3% vs 0, 0%).

7.4 Findings from pre-PADI app intervention questionnaire

The study findings from the pre-intervention questionnaire are presented below in relation to the following research question:

**What is the effect of the PADI app on attitudes and knowledge of PCC and patient activation measure (PAM)?**

Attitudes and knowledge of PCC and patient activation were assessed using a pre- and post-intervention questionnaire. The pre-intervention questionnaire comprised of three sections and had a total of 53 items including Yes/No, True/False/Not Sure and Likert type questions.
7.4.1 Section one: Reproductive health attitude and behaviour (RHAB)

The RHAB comprised 20 questions exploring reproductive health, attitudes and behaviour which were divided into the following six areas: cues to action, perceived susceptibility, perceived benefit, perceived barriers, self-efficacy and outcome expectations.

7.4.1.1 Cues to action (motivation to seek PCC)

This section contained both closed ended and open ended questions. Cues to action include motivation to seek PCC. Figure 7.2 shows the number of women who reported that they had received cues to action prior to the intervention.

![Cues to action](image)

Figure 7.2 Women’s cues to action pre-intervention

A high number of women in the study reported that they had previously received PCC advice (n=15, 88%) and discussed how diabetes affects pregnancy (n=13, 76%) with a healthcare professional (HCP) (figure 7.2). However, the number who received contraception advice from a HCP was <50% (n=8, 47%). The proportion who discussed PCC and contraception use with others (partner, friends, family, colleagues, etc) was also low (n=6, 35%).

Content analysis of free-text data from the open-ended questions showed specific HCPs e.g. doctors (endocrinologist or diabetes consultant) and diabetes specialist or practice nurses, and others (family, colleagues, friends and partners) who provided advice and this information acted as cues to action.

Women reported receiving advice on how DM affects pregnancy from doctors (consultant, n=4; GP, n=1), nurses (n=4), both nurses and doctors (n=3). PCC advice was also received from doctors (consultant, n=3; obstetrician/gynaecologist, n=2 and GP, n=1), nurses (n=3),
both nurses and consultants (n=4). Furthermore, women reported discussing contraception with doctors (obstetrician, n=2; GP, n=1) and nurses (n=2).

Apart from cues received from HCPs, five (29%) women noted discussing PCC with family, partners, colleagues and friends while four (24%) received contraception advice from family, friends, and school. This indicated that women used a network of friends and families to access information, and perhaps consulted HCPs occasionally especially regarding contraception.

The other five areas of the RHAB contain Likert-type questions with the response ranging from (1) not at all to (5) a lot (Table 7.2). The results are presented in detail below.

7.4.1.2 Perceived susceptibility

Perceived susceptibility was assessed to determine women’s belief of their personal susceptibility to problems such as unplanned pregnancy and pregnancy-related complications. Of the 17 participants, 10 (59%) indicated that they were either a little or not worried at all about having an unplanned pregnancy and 12 (71%) were a little or not worried about developing a sexually transmitted infection. Furthermore, 8 (48%) reported that they felt moderately or very susceptible to a pregnancy-related complication while 10 (59%) were moderately or very worried that their baby could develop health problems.

7.4.1.3 Perceived benefits and barriers to seeking PCC

With regards to perceived benefits, there was a very high level of agreement amongst participants (n=16, 94%) that having blood glucose levels in the normal range (Mdn=5, IQR=0) and seeking PCC improved the chances of having a healthy baby (Mdn=5, IQR=0.5).

With regards to barriers, 11 (64%) participants reported that they would find seeking PCC not at all or a little difficult while 9 (53%) would find following the PCC advice given by a HCP not at all or a little difficult.
Table 7.2 Responses to the pre-intervention RHAB questionnaire

<table>
<thead>
<tr>
<th>Reproductive health, attitudes and behaviour (RHAB) question</th>
<th>Pre-intervention (n, %)</th>
<th>Total n=17</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not at all/ A little 1 &amp; 2</td>
<td>Somewhat 3</td>
</tr>
<tr>
<td>Perceived susceptibility</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How much do/did you worry that you could become pregnant?</td>
<td>10 (59)</td>
<td>5 (29)</td>
</tr>
<tr>
<td>How much do/did you worry that you could catch a sexually transmitted infection (e.g. HIV/AIDS)?</td>
<td>12 (71)</td>
<td>3 (18)</td>
</tr>
<tr>
<td>How much do/did you worry that you could develop health problems if you become pregnant?</td>
<td>3 (18)</td>
<td>6 (35)</td>
</tr>
<tr>
<td>How much do/did you worry that if you become pregnant your baby could develop health problems?</td>
<td>4 (24)</td>
<td>3 (18)</td>
</tr>
<tr>
<td>Perceived benefits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Would having blood sugar levels in the normal range (4.0-7.5 mmol/l) before becoming pregnant improve your chances of having a healthy baby?</td>
<td>0 (0)</td>
<td>1 (6)</td>
</tr>
<tr>
<td>Would seeking preconception care improve your chances of having a healthy baby?</td>
<td>0 (0)</td>
<td>1 (6)</td>
</tr>
<tr>
<td>Perceived barriers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How difficult do you think it would be to seek preconception care</td>
<td>11 (64)</td>
<td>2 (12)</td>
</tr>
<tr>
<td>How difficult do you think it would be, to follow the preconception care advice given by a health professional (e.g. attending retinal screening)?</td>
<td>9 (53)</td>
<td>4 (24)</td>
</tr>
<tr>
<td>Perceived self-efficacy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How confident are you that you could get PCC before getting pregnant.</td>
<td>1 (6)</td>
<td>3 (18)</td>
</tr>
<tr>
<td>How confident are you that you could change your insulin, medication and diet to keep your blood sugar levels in normal range, even if you are not yet pregnant, but planning a pregnancy.</td>
<td>1 (6)</td>
<td>4 (24)</td>
</tr>
<tr>
<td>How confident are you that you could delay becoming pregnant until your blood sugar levels are within the normal range.</td>
<td>0 (0)</td>
<td>3 (18)</td>
</tr>
<tr>
<td>Outcome expectations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Would you say that getting PCC would help you get normal blood sugar levels?</td>
<td>1 (6)</td>
<td>4 (24)</td>
</tr>
<tr>
<td>Would you say that getting PCC would help you understand how diabetes affects pregnancy?</td>
<td>1 (6)</td>
<td>2 (12)</td>
</tr>
<tr>
<td>Would you say that getting PCC would help you decide what contraception method to use?</td>
<td>6 (36)</td>
<td>2 (12)</td>
</tr>
<tr>
<td>Would you say that getting PCC would help you prevent an unplanned pregnancy?</td>
<td>4 (24)</td>
<td>3 (18)</td>
</tr>
</tbody>
</table>

7.4.1.4 Perceived self-efficacy

Self-efficacy was assessed to determine participants’ confidence to get PCC and use contraception to prevent an unplanned pregnancy. 14 (82%) were moderately or very confident that they could delay becoming pregnant until their blood glucose levels were in the normal range. 13 (76%) respondents reported that they were moderately or very
confident that they could get PCC before becoming pregnant. 12 (71%) felt moderately or very confident that they could change their insulin, medication and diet in order to keep their blood sugar levels in normal range when planning a pregnancy.

### 7.4.1.5 Outcome expectations of PCC

This assessed the level of participants' belief that outcomes were the result of their own decisions regarding using contraception and seeking PCC. 14 (82%) participants indicated that getting PCC would be moderately or very helpful in understanding how diabetes affects pregnancy and 12 (71%) reported that getting PCC would be moderately or very helpful in getting normal blood sugar levels. Furthermore, 9 (53%) reported that getting PCC would be moderately or very helpful in deciding what contraception method to use while 10 (58%) agreed that getting PCC would be moderately or very helpful in preventing an unplanned pregnancy.

### 7.4.1.6 Total Reproductive health and attitudes (RHAB) summative scores

The cumulative responses to each construct were collated to determine participants’ overall attitudes and behaviours pre-intervention (Table 7.3). Higher summative scores show a stronger level of belief in the construct.

Perceived benefits and self-efficacy were highest pre-intervention, indicating that participants already had a strong belief in the benefits of PCC and their own confidence to seek PCC before pregnancy. Furthermore, barriers to seeking PCC was lowest showing that participants’ perception of the level of difficulty in accessing and adhering to PCC advice was low, pre-intervention.

#### Table 7.3 Summary of beliefs and attitudes associated with preventing an unplanned pregnancy and seeking PCC pre-intervention

<table>
<thead>
<tr>
<th>Questionnaire Measures</th>
<th>Possible scale range</th>
<th>Pre-intervention attitudes Total (n=17)</th>
<th>Mean &amp; Standard deviation</th>
<th>Median (LQ-UQ)</th>
<th>Range (Min-Max)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Susceptibility</td>
<td>4-20</td>
<td>11.53 ± 3.17</td>
<td>12 (9-14)</td>
<td>13</td>
<td>(5-18)</td>
</tr>
<tr>
<td>Benefit</td>
<td>2-10</td>
<td>9.47 ± .94</td>
<td>10 (9-10)</td>
<td>3</td>
<td>(7-10)</td>
</tr>
<tr>
<td>Barriers</td>
<td>2-10</td>
<td>4.94 ± 2.14</td>
<td>4 (3.5-6)</td>
<td>8</td>
<td>(2-10)</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>3-15</td>
<td>12 ± 1.62</td>
<td>12 (11.5-13)</td>
<td>7</td>
<td>(8-15)</td>
</tr>
<tr>
<td>Outcome expectations</td>
<td>4-20</td>
<td>15.1 ± 3.72</td>
<td>16 (11.5-18)</td>
<td>13</td>
<td>(7-20)</td>
</tr>
</tbody>
</table>
7.4.2 Section two: Preconception care (PCC) knowledge

PCC knowledge was assessed using 20 True (T; 11)/False (F; 9) statements. Individual pre-intervention knowledge responses were expressed as percentage of participants correct (Table 7.4). Overall knowledge of pregnancy planning and pregnancy-related risks were evaluated.

7.4.2.1 Pregnancy planning

Pre-intervention pregnancy planning knowledge scores were highest for two items: speaking to a healthcare professional about medication (100%, n=17) and quitting smoking (100%, n=17), and lowest for items regarding recommended folic acid dosage for women with DM (n=6, 35%) and suitability of all insulin during pregnancy (n=1, 6%).

7.4.2.2 Pregnancy-related risks

Similarly, with regards to knowledge of risks, scores of 100% were recorded for four items: (1) high blood glucose levels during pregnancy and maternal problems, (2) high blood glucose levels during pregnancy and fetal problems, (3) women having control over the baby’s health and (4) being able to have a healthy baby (n=17, 100%). However, the lowest score was recorded for the risk of miscarriage in women with DM (n=8, 47%).
### Table 7.4 Knowledge of PCC: correct answers pre-intervention

<table>
<thead>
<tr>
<th>Knowledge statement</th>
<th>Correct response</th>
<th>Pre-intervention no of participants correct (n=17)</th>
<th>Pre-intervention % of participants correct</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Knowledge of Pregnancy Planning</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Women who are planning a pregnancy should discuss medication use with a healthcare provider</td>
<td>T</td>
<td>17</td>
<td>100</td>
</tr>
<tr>
<td>2. Women who are planning a pregnancy should stop smoking</td>
<td>T</td>
<td>17</td>
<td>100</td>
</tr>
<tr>
<td>3. Before becoming pregnant, ideally your HbA1c should be below 6.5% (48.0 mmol/mol)</td>
<td>T</td>
<td>16</td>
<td>94</td>
</tr>
<tr>
<td>4. Women with diabetes cannot use hormonal contraception</td>
<td>F</td>
<td>16</td>
<td>94</td>
</tr>
<tr>
<td>5. Women with diabetes have very limited choices of contraception</td>
<td>F</td>
<td>15</td>
<td>88</td>
</tr>
<tr>
<td>6. Women with diabetes should take folic acid daily when planning a pregnancy</td>
<td>T</td>
<td>14</td>
<td>82</td>
</tr>
<tr>
<td>7. Women who are planning a pregnancy should stop drinking alcohol</td>
<td>T</td>
<td>13</td>
<td>77</td>
</tr>
<tr>
<td>8. All over the counter drugs are safe and can be taken by women with diabetes who are planning a pregnancy</td>
<td>F</td>
<td>12</td>
<td>71</td>
</tr>
<tr>
<td>9. If you have Type 2 diabetes and are planning to become pregnant you may need to change from tablets to injections of insulin</td>
<td>T</td>
<td>7</td>
<td>41</td>
</tr>
<tr>
<td>10. Women with diabetes should take the same amount of folic acid as all other women planning a pregnancy</td>
<td>F</td>
<td>6</td>
<td>35</td>
</tr>
<tr>
<td>11. All insulin are suitable for use during pregnancy</td>
<td>F</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td><strong>Knowledge of Pregnancy-related Risks</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. High blood glucose levels during pregnancy do not increase the risk of problems for the mother</td>
<td>F</td>
<td>17</td>
<td>100</td>
</tr>
<tr>
<td>13. High blood glucose levels during pregnancy do not increase the risk of problems for the baby</td>
<td>F</td>
<td>17</td>
<td>100</td>
</tr>
<tr>
<td>14. Women with diabetes have little control over the health of their baby</td>
<td>F</td>
<td>17</td>
<td>100</td>
</tr>
<tr>
<td>15. Chances of a woman having a healthy baby increase as she improves her health prior to conception</td>
<td>T</td>
<td>17</td>
<td>100</td>
</tr>
<tr>
<td>16. Women with diabetes can have a healthy baby</td>
<td>T</td>
<td>16</td>
<td>94</td>
</tr>
<tr>
<td>17. Blood glucose levels before pregnancy can affect the health of the baby</td>
<td>T</td>
<td>16</td>
<td>94</td>
</tr>
<tr>
<td>18. Women with diabetes have an increased risk of having a large baby making delivery more difficult</td>
<td>T</td>
<td>16</td>
<td>94</td>
</tr>
<tr>
<td>19. Women with diabetes do not have an increased risk of having a baby with birth defects</td>
<td>F</td>
<td>12</td>
<td>71</td>
</tr>
<tr>
<td>20. Women with diabetes have an increased risk of miscarriage</td>
<td>T</td>
<td>8</td>
<td>47</td>
</tr>
</tbody>
</table>

- Pre intervention responses (scored as correct and incorrect). Three possible responses: true, false, not sure.
- Question adapted from Holmes et al. (2012)

#### 7.4.3 Section three: Patient activation measure (PAM)

Patient activation measure (PAM-13) was used to assess participants’ level of activation (Hibbard et al. 2004, 2005). The 13 item scale has five possible response options ranging from 1) disagree strongly 2) disagree 3) agree 4) agree strongly and 5) not applicable (N/A). Participants need to answer 10 out of the 13 questions for a valid score. All participants answered the 13 questions.

Pre-PADI app intervention data showed that the majority of responses clustered around agree or agree strongly. Figure 7.3 below shows the number of participants who agreed or strongly agreed with each PAM statements.
All (n=17, 100%) participants agreed or strongly agreed with the following four PAM statements—
1: When all is said and done, I am the person who is responsible for taking care of my health, 2: Taking an active role in my health care is the most important thing that affects my health,
3: I am confident I can help or reduce problems associated with my health and
7: I am confident that I can follow through on medical treatments I may need to do at home.

Most participants (≥11, 65%) also agreed or strongly agreed with other PAM statements except for item 9: I know what treatments are available for my health problems where 10 (59%) disagreed or strongly disagreed and 7 (41%) agreed or strongly agreed with the statement.
7.4.3.1 Total pre-intervention PAM score

The total PAM score was calculated and used to segment participants into one of four levels of activation (as described in Chapter 5). Level 1: = <47.0; Level 2 = 47.1–55.1, Level 3 = 55.2–67.0, and Level 4 = >67.1. At baseline, 11 participants (64.7%) were at level 4, four participants (23.5%) at level 3, two participants (11.8%) at level 2 and none were at the lowest level of activation (level 1). The pre-intervention mean and standard deviation were 44.7 ± 4.3, and the scores ranged from 37 to 51 (range =14).

7.5 Findings from post-PADI app intervention questionnaire

After the intervention, participants were sent a follow-up questionnaire. In addition to the three sections contained in the pre-intervention questionnaire, the post intervention questionnaire contained an additional satisfaction rating scale and open-ended section where participants could comment on their experience of using the PADI app or provide suggestions for improvement. 11 participants completed the post intervention questionnaire.

7.5.1 Section one: Reproductive health attitude and behaviour (RHAB)

7.5.1.1 Cues to action (motivation to seek PCC)

All (n=11, 100%) women who completed the post-intervention questionnaire reported that they had discussed diabetes and pregnancy, and PCC with a HCP during the intervention. More than half (n=6, 54.5%) discussed contraception with a HCP, while 7 (63.6%) discussed PCC and 4 (36.5%) discussed contraception use with others (family, partners, colleagues and friends).

Content analysis of free text comments from questionnaire 2 showed that in addition to doctors (consultants and GPs, n=5) and nurses (n=1), participants also discussed PCC with other PCC team members including dieticians (n=3). Likewise, DM and pregnancy was discussed with doctors (consultants and GPs, n=4), nurses (n=2) and other PCC team members (n=2). Contraception was also discussed with doctors (consultants and GPs, n=3; obstetrician, n=1) and nurses (n=1).

The other five RHAB areas contain Likert-type questions with responses ranging from (1) not at all to (5) a lot (Table 7.5). The results are presented below.

7.5.1.2 Perceived susceptibility

After the intervention, most respondents reported that they were a little or not worried about having an unplanned pregnancy (n=8, 73%) and developing a sexually transmitted infection
Furthermore, only a small number of participants (n=3, 27%) considered themselves or their baby (n=4, 36%) moderately or very susceptible to developing complications and health problems.

### 7.5.1.3 Perceived benefit and barriers to seeking PCC

With regards to perceived benefits, there was agreement amongst nearly all participants (n=10, 91%) that having blood glucose levels in the normal range improved the chances of having a healthy baby (Mdn=5, IQR=0). Likewise, all participants (n=11, 100%) indicated that seeking PCC would improve the chances of having a healthy baby (Mdn=5, IQR=1).

With regards to barriers, a small number of respondents (n=3, 27%) reported that they would find it moderately or very difficult to seek PCC and only one (9%) felt that following the PCC advice given by a HCP would be moderately or very difficult.

### 7.5.1.4 Perceived self-efficacy

Nearly all participants reported that they were moderately or very confident that they could get access to PCC before becoming pregnant (n=9, 82%) and change their insulin, medication and diet to keep their blood sugar levels in normal range when planning a pregnancy (n=10, 91%). Furthermore, 8 (73%) participants were moderately or very confident that they could delay becoming pregnant until their blood glucose levels were in the normal range.

### 7.5.1.5 Outcome expectations of PCC

Most participants (n=9, 82%) reported that getting PCC would be moderately or very helpful in their understanding of how diabetes affects pregnancy. Opinions were however divided over the capacity of PCC to help influence choice of contraception, achieve normal blood glucose levels and prevent unplanned pregnancy.

For example, 3 (27%) respondents felt that getting PCC would be of no or little help, 3 (27%) indicated that PCC would be of some help while 5 (45%) reported that PCC would be moderately or very helpful in deciding what contraception method to use. Likewise, 5 (45%) participants reported that PCC would be of no or little help, 3 (27%) thought that PCC would be of some help while 3 (27%) felt that PCC would be moderately or very helpful in preventing an unplanned pregnancy.
Table 7.5 Responses to post-intervention RHAB questionnaire

<table>
<thead>
<tr>
<th>Reproductive health, attitudes and behaviour (RHAB) question</th>
<th>Post- intervention (n, %)</th>
<th>Total n=11</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not at all/ A little 1 &amp; 2</td>
<td>Somewhat 3</td>
</tr>
<tr>
<td>Perceived susceptibility</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How much do/did you worry that you could become pregnant?</td>
<td>8 (73)</td>
<td>2 (18)</td>
</tr>
<tr>
<td>How much do/did you worry that you could catch a sexually transmitted infection (eg HIV/AIDS)?</td>
<td>10 (91)</td>
<td>1 (9)</td>
</tr>
<tr>
<td>How much do/did you worry that you could develop health problems if you become pregnant?</td>
<td>4 (36)</td>
<td>4 (36)</td>
</tr>
<tr>
<td>How much do/did you worry that if you become pregnant your baby could develop health problems?</td>
<td>2 (18)</td>
<td>5 (46)</td>
</tr>
<tr>
<td>Perceived benefits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Would having blood sugar levels in the normal range (4.0-7.5 mmol/l) before becoming pregnant improve your chances of having a healthy baby?</td>
<td>0 (0)</td>
<td>1 (9)</td>
</tr>
<tr>
<td>Would seeking preconception care improve your chances of having a healthy baby?</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Perceived barriers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How difficult do you think it would be to seek preconception care</td>
<td>7 (64)</td>
<td>1 (9)</td>
</tr>
<tr>
<td>How difficult do you think it would be, to follow the preconception care advice given by a health professional (e.g attending retinal screening)?</td>
<td>7 (64)</td>
<td>3 (27)</td>
</tr>
<tr>
<td>Perceived self-efficacy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How confident are you that you could get PCC before getting pregnant?</td>
<td>0 (0)</td>
<td>2 (18)</td>
</tr>
<tr>
<td>How confident are you that you could change your insulin, medication and diet to keep your blood sugar levels in normal range, even if you are not yet pregnant, but planning a pregnancy?</td>
<td>0 (0)</td>
<td>1 (9)</td>
</tr>
<tr>
<td>How confident are you that you could delay becoming pregnant until your blood sugar levels are within the normal range?</td>
<td>0 (0)</td>
<td>3 (27)</td>
</tr>
<tr>
<td>Outcome expectations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Would you say that getting PCC would help you get normal blood sugar levels?</td>
<td>2 (18)</td>
<td>3 (27)</td>
</tr>
<tr>
<td>Would you say that getting PCC would help you understand how diabetes affects pregnancy?</td>
<td>1 (9)</td>
<td>1 (9)</td>
</tr>
<tr>
<td>Would you say that getting PCC would help you decide what contraception method to use?</td>
<td>3 (27)</td>
<td>3 (27)</td>
</tr>
<tr>
<td>Would you say that getting PCC would help you prevent an unplanned pregnancy?</td>
<td>5 (45)</td>
<td>3 (27)</td>
</tr>
</tbody>
</table>

7.5.1.6 Total reproductive health and attitudes (RHAB) summative scores

The cumulative responses to each construct were collated to determine participants' overall attitudes and behaviours post- PADI app intervention (Table 7.6). High summative scores indicate a strong level of belief in the construct.
Table 7.6 Summary of beliefs and attitudes associated with preventing an unplanned pregnancy and seeking PCC post-intervention

<table>
<thead>
<tr>
<th>Questionnaire Measures</th>
<th>Possible scale range</th>
<th>Mean &amp; Standard deviation</th>
<th>Median (LQ-UQ)</th>
<th>Range (Min-Max)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Susceptibility</td>
<td>4-20</td>
<td>9.18 ± 2.60</td>
<td>9 (8-10)</td>
<td>10 (6-16)</td>
</tr>
<tr>
<td>Benefit</td>
<td>2-10</td>
<td>9.55 ± .93</td>
<td>10 (9-10)</td>
<td>3 (7-10)</td>
</tr>
<tr>
<td>Barriers</td>
<td>2-10</td>
<td>4.27 ± 2.24</td>
<td>3 (3-7)</td>
<td>6 (2-8)</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>3-15</td>
<td>12.55 ± 1.81</td>
<td>12 (12-14)</td>
<td>6 (9-15)</td>
</tr>
<tr>
<td>Outcome expectations</td>
<td>4-20</td>
<td>15.1 ± 3.72</td>
<td>16 (11.5-18)</td>
<td>13 (7-20)</td>
</tr>
</tbody>
</table>

Perceived self-efficacy and benefits were highest post-intervention, indicating increased belief in benefits of PCC and confidence to seek PCC while perceived barriers remained low.

7.5.2 Section two: Preconception care (PCC) knowledge

Women’s knowledge of pregnancy planning and risks was measured after the intervention using questionnaire 2 (Table 7.7). The results are presented below.

7.5.2.1 Pregnancy planning

Knowledge scores were 100% for six items: (1) speaking to a HCP about medication, (2) quitting smoking, (3) pre-conception HbA1c value, (4) use of hormonal contraception, (5) choices of contraception and (6) safety of over the counter medication (n=11, 100%). The lowest post-intervention score was recorded for the suitability of all insulin during pregnancy (n=4, 36.4%).

7.5.2.2 Pregnancy-related risks

For knowledge of risks, scores of a 100% were achieved for five items: (1) high blood glucose levels during pregnancy and maternal problems, (2) high blood glucose levels during pregnancy and fetal problems, (3) women having control over the baby’s health, (4) being able to have a healthy baby and (5) risk of having a large baby (n=11, 100%). Knowledge of miscarriage in women with DM (n=9, 81.8%) was also high, post-intervention.
<table>
<thead>
<tr>
<th>Knowledge statement</th>
<th>Correct response</th>
<th>Post-intervention no of participants correct (n=11)</th>
<th>Post-intervention % of participants correct</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Knowledge of Pregnancy Planning</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Women who are planning a pregnancy should discuss medication use with a healthcare provider</td>
<td>T</td>
<td>11</td>
<td>100</td>
</tr>
<tr>
<td>2. Women who are planning a pregnancy should stop smoking</td>
<td>T</td>
<td>11</td>
<td>100</td>
</tr>
<tr>
<td>3. Before becoming pregnant, ideally your HbA1c should be below 6.5% (48.0 mmol/mol)</td>
<td>T</td>
<td>11</td>
<td>100</td>
</tr>
<tr>
<td>4. Women with diabetes cannot use hormonal contraception</td>
<td>F</td>
<td>11</td>
<td>100</td>
</tr>
<tr>
<td>5. Women with diabetes have very limited choices of contraception</td>
<td>F</td>
<td>11</td>
<td>100</td>
</tr>
<tr>
<td>6. Women with diabetes should take folic acid daily when planning a pregnancy</td>
<td>T</td>
<td>10</td>
<td>90.9</td>
</tr>
<tr>
<td>7. Women who are planning a pregnancy should stop drinking alcohol</td>
<td>T</td>
<td>10</td>
<td>90.9</td>
</tr>
<tr>
<td>8. All over the counter drugs are safe and can be taken by women with diabetes who are planning a pregnancy</td>
<td>F</td>
<td>11</td>
<td>100</td>
</tr>
<tr>
<td>9. If you have Type 2 diabetes and are planning to become pregnant you may need to change from tablets to injections of insulin</td>
<td>T</td>
<td>6</td>
<td>54.5</td>
</tr>
<tr>
<td>10. Women with diabetes should take the same amount of folic acid as all other women planning a pregnancy</td>
<td>F</td>
<td>8</td>
<td>72.7</td>
</tr>
<tr>
<td>11. All insulin are suitable for use during pregnancy</td>
<td>F</td>
<td>4</td>
<td>36.4</td>
</tr>
<tr>
<td><strong>Knowledge of Pregnancy-related Risks</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. High blood glucose levels during pregnancy do not increase the risk of problems for the mother</td>
<td>F</td>
<td>11</td>
<td>100</td>
</tr>
<tr>
<td>13. High blood glucose levels during pregnancy do not increase the risk of problems for the baby</td>
<td>F</td>
<td>11</td>
<td>100</td>
</tr>
<tr>
<td>14. Women with diabetes have little control over the health of their baby</td>
<td>F</td>
<td>11</td>
<td>100</td>
</tr>
<tr>
<td>15. Chances of a woman having a healthy baby increase as she improves her health prior to conception</td>
<td>T</td>
<td>10</td>
<td>90.9</td>
</tr>
<tr>
<td>16. Women with diabetes can have a healthy baby</td>
<td>T</td>
<td>11</td>
<td>100</td>
</tr>
<tr>
<td>17. Blood glucose levels before pregnancy can affect the health of the baby</td>
<td>T</td>
<td>10</td>
<td>90.9</td>
</tr>
<tr>
<td>18. Women with diabetes have an increased risk of having a large baby making delivery more difficult</td>
<td>T</td>
<td>11</td>
<td>100</td>
</tr>
<tr>
<td>19. Women with diabetes do not have an increased risk of having a baby with birth defects</td>
<td>F</td>
<td>7</td>
<td>63.6</td>
</tr>
<tr>
<td>20. Women with diabetes have an increased risk of miscarriage</td>
<td>T</td>
<td>9</td>
<td>81.8</td>
</tr>
</tbody>
</table>

- Post app responses (scored as correct and incorrect). Three possible responses: true, false, not sure.

### 7.5.3 Section three: Patient activation measure (PAM)

Post PADI app intervention results showed that all the participants’ responses clustered around agree or strongly agree. Thus all (n=11) participants who completed questionnaire 2 agreed or strongly agreed with 12 out of the 13 PAM items (Figure 7.4).
7.5.3.1 Total post-intervention PAM score

PAM had improved following the intervention whereby the majority (n=10, 91%) were now at level 4, with only one (9%) participant at level 3. Mean and standard deviation for the post-intervention PAM score was 48.5 ± 3.2 and the participants’ scores ranged from 43 to 52 (range= 9).

7.5.4 Comparison of PADI app intervention results pre and post-intervention

Results of the pre- and post-intervention questionnaires were compared to explore feasibility and preliminary estimates of the intervention.

**RHAB:** The PADI app intervention had a positive effect on four out of the five RHAB constructs. That is, perceived benefits of PCC (9.47±.94 vs 9.55±.93, mean difference= +0.29) and self-efficacy to seek PCC (12±1.62 vs 12.55±1.81, mean difference= +0.6) increased pre to post-intervention. See Table 7.8 below for a summary of beliefs and attitudes associated with preventing an unplanned pregnancy and seeking PCC.
Table 7.8  Summary of beliefs and attitudes associated with preventing an unplanned pregnancy and seeking PCC

<table>
<thead>
<tr>
<th>Questionnaire Measures</th>
<th>Possible scale range</th>
<th>Pre-intervention attitudes</th>
<th>Post-intervention attitudes</th>
<th>Mean difference</th>
<th>Median</th>
<th>$P^*$</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mean &amp; standard deviation</td>
<td>Mean &amp; standard deviation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Median</td>
<td>Median</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Susceptibility</td>
<td>4-20</td>
<td>11.53 ± 3.17</td>
<td>9.18 ± 2.60</td>
<td>-2.4</td>
<td>9</td>
<td>0.07</td>
<td>0.34</td>
</tr>
<tr>
<td>Benefit</td>
<td>2-10</td>
<td>9.47 ± .94</td>
<td>9.55 ± .93</td>
<td>0.1</td>
<td>10</td>
<td>0.29</td>
<td>0.20</td>
</tr>
<tr>
<td>Barriers</td>
<td>2-10</td>
<td>4.94 ± 2.14</td>
<td>4.27 ± 2.24</td>
<td>-0.7</td>
<td>3</td>
<td>0.32</td>
<td>0.19</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>3-15</td>
<td>12 ± 1.62</td>
<td>12.55 ± 1.81</td>
<td>0.6</td>
<td>12</td>
<td>0.18</td>
<td>0.25</td>
</tr>
<tr>
<td>Outcome expectations</td>
<td>4-20</td>
<td>15.1 ± 3.72</td>
<td>15.1 ± 3.72</td>
<td>Nil</td>
<td>13</td>
<td>0.75</td>
<td>0.06</td>
</tr>
</tbody>
</table>

*Pre-intervention scores versus post-intervention score by Wilcoxon signed rank test
Perceived susceptibility to unplanned pregnancies and complications (11.53±3.17 vs 9.18±2.60, mean difference = -2.4) and perceived barriers to seeking PCC (4.94±2.14 vs 4.27 ± 2.24, mean difference = -0.7) decreased pre to post-intervention.

There was however no change with regards to outcome expectations which remained the same pre and post intervention (15.1 ± 3.72).

A Wilcoxon signed-rank test revealed that there may be a trend towards significance in perceived susceptibility following the PADI app intervention (pre-intervention median, Md = 12; post-intervention Md= 9), z=-1.79, P= 0.07, with a medium effect size (r=0.34). Apart from outcome expectations, there were modest but no significant changes in other measures which also had small effect sizes (see Table 7.8).

In addition, the Cronbach alpha coefficient for the RHAB constructs (Table 7.9) ranged from 0.4 to 0.7 (pre-intervention) and 0.6 to 0.9 (post-intervention), indicating acceptable internal consistency that compares closely to those found in previous studies which used the RHAB (Charron-Prochownik et al. 2006; Holmes et al. 2012). Thus, indicating that the questionnaire used was a reliable method to measure the included theoretical constructs.

Table 7.9 Cronbach alpha for each theoretical construct within the RHAB

<table>
<thead>
<tr>
<th>RHAB Theoretical Construct</th>
<th>Pre-intervention</th>
<th>Post-intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cues to action</td>
<td>0.6</td>
<td>0.8</td>
</tr>
<tr>
<td>Perceived susceptibility</td>
<td>0.6</td>
<td>0.6</td>
</tr>
<tr>
<td>Perceived benefits</td>
<td>0.5</td>
<td>0.7</td>
</tr>
<tr>
<td>Perceived barriers</td>
<td>0.5</td>
<td>0.9</td>
</tr>
<tr>
<td>Self-efficacy</td>
<td>0.4</td>
<td>0.8</td>
</tr>
<tr>
<td>Outcome expectations</td>
<td>0.7</td>
<td>0.6</td>
</tr>
</tbody>
</table>

**PCC Knowledge**

The PADI app intervention also had a positive effect on knowledge of PCC which resulted in considerable variation in knowledge scores pre to post intervention especially with regards to pregnancy planning (Table 7.10). Compared to pre-intervention where scores of 100% were obtained for two items (speaking to HCP about medication and quitting smoking), post-
intervention results showed scores of 100% for six items (speaking to a HCP about medication, quitting smoking, pre-conception HbA1c value, use of hormonal contraception, choices of contraception and safety of over-the-counter medication).

Furthermore, increase in knowledge scores were recorded for all other items pre to post intervention including higher dose of folic acid, daily intake of folic acid, and avoidance of alcohol and safety of insulin during pregnancy.

Table 7.10  Knowledge of PCC: correct answers pre and post-intervention

<table>
<thead>
<tr>
<th>Knowledge statement</th>
<th>Correct response</th>
<th>Pre-intervention no and % of participants correct (n=17)</th>
<th>Post-intervention no (% of participants correct (n=11)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge of Pregnancy Planning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Women who are planning a pregnancy should discuss medication use with a healthcare provider</td>
<td>T</td>
<td>17 (100)</td>
<td>11 (100)</td>
</tr>
<tr>
<td>2. Women who are planning a pregnancy should stop smoking</td>
<td>T</td>
<td>17 (100)</td>
<td>11 (100)</td>
</tr>
<tr>
<td>3. Before becoming pregnant, ideally your HbA1c should be below 6.5% (48.0 mmol/mol)</td>
<td>T</td>
<td>16 (94)</td>
<td>11 (100)</td>
</tr>
<tr>
<td>4. Women with diabetes cannot use hormonal contraception</td>
<td>F</td>
<td>16 (94)</td>
<td>11 (100)</td>
</tr>
<tr>
<td>5. Women with diabetes have very limited choices of contraception</td>
<td>F</td>
<td>15 (88)</td>
<td>11 (100)</td>
</tr>
<tr>
<td>6. Women with diabetes should take folic acid daily when planning a pregnancy</td>
<td>T</td>
<td>14 (82)</td>
<td>10 (91)</td>
</tr>
<tr>
<td>7. Women who are planning a pregnancy should stop drinking alcohol</td>
<td>T</td>
<td>13 (77)</td>
<td>10 (91)</td>
</tr>
<tr>
<td>8. All over the counter drugs are safe and can be taken by women with diabetes who are planning a pregnancy</td>
<td>F</td>
<td>12 (71)</td>
<td>11 (100)</td>
</tr>
<tr>
<td>9. If you have Type 2 diabetes and are planning to become pregnant you may need to change from tablets to injections of insulin</td>
<td>T</td>
<td>7 (41)</td>
<td>6 (55)</td>
</tr>
<tr>
<td>10. Women with diabetes should take the same amount of folic acid as all other women planning a pregnancy</td>
<td>F</td>
<td>6 (35)</td>
<td>8 (73)</td>
</tr>
<tr>
<td>11. All insulin are suitable for use during pregnancy</td>
<td>F</td>
<td>1 (6)</td>
<td>4 (36)</td>
</tr>
<tr>
<td>Knowledge of Pregnancy-related Risks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. High blood glucose levels during pregnancy do not increase the risk of problems for the mother</td>
<td>F</td>
<td>17 (100)</td>
<td>11 (100)</td>
</tr>
<tr>
<td>13. High blood glucose levels during pregnancy do not increase the risk of problems for the baby</td>
<td>F</td>
<td>17 (100)</td>
<td>11 (100)</td>
</tr>
<tr>
<td>14. Women with diabetes have little control over the health of their baby</td>
<td>F</td>
<td>17 (100)</td>
<td>11 (100)</td>
</tr>
<tr>
<td>15. Chances of a woman having a healthy baby increase as she improves her health prior to conception</td>
<td>T</td>
<td>17 (100)</td>
<td>10 (91)</td>
</tr>
<tr>
<td>16. Women with diabetes can have a healthy baby</td>
<td>T</td>
<td>16 (94)</td>
<td>11 (100)</td>
</tr>
<tr>
<td>17. Blood glucose levels before pregnancy can affect the health of the baby</td>
<td>T</td>
<td>16 (94)</td>
<td>10 (91)</td>
</tr>
<tr>
<td>18. Women with diabetes have an increased risk of having a large baby making delivery more difficult</td>
<td>T</td>
<td>16 (94)</td>
<td>11 (100)</td>
</tr>
<tr>
<td>19. Women with diabetes do not have an increased risk of having a baby with birth defects</td>
<td>F</td>
<td>12 (71)</td>
<td>7 (64)</td>
</tr>
<tr>
<td>20. Women with diabetes have an increased risk of miscarriage</td>
<td>T</td>
<td>8 (47)</td>
<td>9 (82)</td>
</tr>
</tbody>
</table>

The Wilcoxon signed rank test indicated a statistically significant increase in knowledge of participants following the PADI app intervention, $z= -2.67$, $P = .008$, with a large effect size...
The median score on the knowledge of PCC questionnaire increased from pre-intervention (Md= 82, IQR=41-94) to post intervention (Md = 100; IQR= 72-100).

Knowledge of risks also increased, compared to pre-intervention whereby four scores of 100% were achieved, post-intervention results had five scores of 100%. Moreover, an increase was recorded in knowledge of miscarriage post-intervention (82%) which when compared to pre-intervention (47%), was one of the highest post-intervention scores (100% being the highest score). Although the median score increased from pre- to post-intervention, overall, increase in knowledge of risks was not found to be significant pre-intervention (Md=94; IQR=82.5-100) to post-intervention (Md= 100; IQR=86.35-100); P= 0.92, z= 0.11, with a very small effect size (r= .03).

**Patient activation measure (PAM)**

Furthermore, positive effects were also recorded in PAM levels pre-to post intervention (Table 7.11). Of the (n=11) participants who completed questionnaire 2, two (18.2%) had increased their PAM levels from 2 to 4, three (27.3%) from 3 to 4 and five (45.5%) who were already at level 4 had increased PAM scores post intervention. Only one participant remained at the same level of activation (level 3) pre and post intervention.

There was also an increase in total PAM scores (44.7±4.3 vs 48.5±3.2, mean difference= +3.8), pre to post intervention (Table 7.11).

<table>
<thead>
<tr>
<th>Possible scale range</th>
<th>Pre-intervention</th>
<th>Post-intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cronbach alpha</td>
<td>Mean &amp; standard deviation</td>
</tr>
<tr>
<td>13-52</td>
<td>0.86</td>
<td>44±4.3</td>
</tr>
</tbody>
</table>

A Wilcoxon Signed Rank Test indicated a statistically significant increase in patient activation measure (PAM) following the app intervention, z= -2.73, P = 0.006, with a large effect size (r=.52). The Median score on the PAM scale increased from pre-intervention (Md= 45; IQR=41-48) to post intervention (Md =48; IQR=46-52). The Cronbach alpha scores for the 13-item PAM (Table 11) remained consistently high pre- (0.86) to post-intervention (0.87).
Section four: Satisfaction with intervention

This section presents participants’ rating and feedback regarding the PADI app intervention. All (n=11) participants who completed questionnaire 2 rated the PADI app in terms of their overall satisfaction with the app and its functionalities. Participants rated the app from 0-100, where 0=not satisfied at all and 100=completely satisfied.

The average app rating based on the scores of all (n=11) participants = 71.8 (range 25-90). A small number of participants (n=2, 18.2%) rated the app ≤50 while the majority (n=9, 81.8%) gave it a rating above 60 (Figure 7.5). Satisfaction with the intervention is further explored in the user experience interviews, the findings of which are presented later in this chapter.

Figure 7.5  Overall app satisfaction rating

Content analysis showed that the six participants who included comments found the informational content useful and informative. Five were however interested in improved functionality of the blood glucose diary while one wanted an improvement to the general app features. In summary, they suggested (a) integration of the app with other diabetes management technology; (b) increased interactivity via logging and tracking other parameters such as insulin, downloading and/emailing blood glucose readings and using free text to make...
notes of blood glucose readings; (c) synchronisation of blood glucose data between devices (e.g. iPad and iPhone) and (d) using notifications twice a day to enter blood glucose reading.

7.5.6 Questionnaire completion

Missing data was identified for the preconception knowledge (K) section of the pre-intervention questionnaire (Questionnaire 1). Three women with T1DM did not answer question 4: If you have Type 2 diabetes and are planning to become pregnant you may need to change from tablets to injections of insulin. Perhaps the women with T1DM did not find the question relevant to them. Although this shows that missing data did occur, this was low as all other questions were completed. The post-intervention questionnaire (Questionnaire 2) had no missing data.

7.6 Summary

17 participants enrolled at baseline and 11 completed the study and post-intervention questionnaire. Participants were recruited between December and March 2017. The majority of participants had T1DM, were educated and planning a pregnancy in the near future (next one year or 1-5 years). The recruitment target of 12 was achieved and exceeded in order to allow for loss due to follow up. However, there was some attrition during the study, with only 65% (n=11) of participants remaining at the end of the 3-month study.

The aim of the study was to test the feasibility of the PADI app intervention and establish preliminary intervention effects. Evaluation of the pre and post PADI-app intervention indicated an improvement in overall knowledge, attitudes to PCC and PAM. After the 3-month PADI app intervention, there was a positive change in women’s perceived benefits of PCC and self-efficacy (self-confidence to use contraception to prevent an unplanned pregnancy and seek PCC). There was also reduction in perceived susceptibility to unplanned pregnancies and complications, and barriers to seeking PCC. Knowledge of PCC, that is, pregnancy planning and risks, as well as PAM improved. These preliminary findings appear to suggest that the PADI app can be used to provide PCC, potentially improve PCC knowledge, attitudes and PAM. Furthermore, the overall app satisfaction rating showed that while participants identified areas for future development of the app, they were satisfied with the app-based PCC intervention.

The findings from the user experience interviews are presented in the next section.
7.7 **Section 2: User experience interviews**

Women’s views and experiences of the PADI app were explored using semi-structured interviews and are presented using a thematic analysis.

7.8 **Demographic profile**

Participants comprised of (n=6) women with DM who participated in the 3-month intervention and agreed to be interviewed (Table 7.12). Semi-structured telephone interviews took place from April to July 2017 and lasted about 20-30 minutes. Participants were geographically dispersed across the United Kingdom, America and Canada. The average age of participants was 31 years, and all had T1DM.

**Table 7.12 Participants descriptive table**

<table>
<thead>
<tr>
<th>No</th>
<th>Identifier</th>
<th>Age (years)</th>
<th>Diabetes mellitus type &amp; duration (years)</th>
<th>Educational qualification</th>
<th>Occupation</th>
<th>Planning a pregnancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>P11</td>
<td>24</td>
<td>Type 1 (&gt;5)</td>
<td>Higher degree (M.Sc or PhD)</td>
<td>Researcher</td>
<td>&gt; 5 years</td>
</tr>
<tr>
<td>2.</td>
<td>P12</td>
<td>36</td>
<td>Type 1 (&gt;5)</td>
<td>First degree</td>
<td>Nurse</td>
<td>&lt; 1 year</td>
</tr>
<tr>
<td>3.</td>
<td>P13</td>
<td>33</td>
<td>Type 1 (&gt;5)</td>
<td>Higher degree (M.Sc or PhD)</td>
<td>Researcher</td>
<td>&lt; 1 year</td>
</tr>
<tr>
<td>4.</td>
<td>P14</td>
<td>32</td>
<td>Type 1 (&gt;5)</td>
<td>Higher degree (M.Sc or PhD)</td>
<td>Town planner</td>
<td>&lt; 1 year</td>
</tr>
<tr>
<td>5.</td>
<td>P15</td>
<td>20</td>
<td>Type 1 (&gt;5)</td>
<td>A levels</td>
<td>Student</td>
<td>&gt; 5 years</td>
</tr>
<tr>
<td>6.</td>
<td>P16</td>
<td>39</td>
<td>Type 1 (&gt;5)</td>
<td>First degree</td>
<td>Administrator</td>
<td>&lt; 1 year</td>
</tr>
</tbody>
</table>

7.8.1 **Findings**

Three main themes were identified from the analysis (described in chapter 5):

- Feasibility and acceptability of the PADI app
- Engagement with the PADI app
- Future development of the PADI app.

All themes had two or more sub-themes as shown in Table 7.13 below.
Table 7.13  Themes and sub-themes

<table>
<thead>
<tr>
<th>Main theme</th>
<th>Sub-theme</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Feasibility and acceptability of the PADI app</td>
<td>Acceptability of the PADI app</td>
</tr>
<tr>
<td></td>
<td>Experiences and behavioural effects of the PADI app</td>
</tr>
<tr>
<td>2. Engagement with the PADI app</td>
<td>Usage</td>
</tr>
<tr>
<td></td>
<td>Factors affecting usage</td>
</tr>
<tr>
<td></td>
<td>• Functionality</td>
</tr>
<tr>
<td></td>
<td>• Personal factors</td>
</tr>
<tr>
<td>3. Future development of the PADI app</td>
<td>Improvement to informational content</td>
</tr>
<tr>
<td></td>
<td>Improvement to blood glucose diary</td>
</tr>
<tr>
<td></td>
<td>Improvement to the general app features</td>
</tr>
</tbody>
</table>

7.9  Feasibility and acceptability of the PADI app

Generally, the PADI app was viewed as an ideal means of providing PCC because of its accessibility and portability. Participants highlighted the scarcity of PCC information for women with DM, and considered the app to be a comprehensive and informative source of PCC which incorporated self-management of blood glucose (SMBG) functions. Participants felt that the PADI app helped to improve PCC knowledge especially regarding folic acid and blood glucose control. The acceptability of the PADI app and subsequent behavioural effects of the PADI app use are explored in more detail below.

7.9.1  Acceptability of the PADI app

Participants’ views and attitudes towards the PADI app were positive. Having the PCC information delivered via a mobile app was perceived as advantageous as women always had their phones with them.

It’s helpful to have it on the mobile phone because usually you have your mobile phone with you wherever you go. [P12, 36 years]

Women (n=5) reported that they preferred the PADI app to traditional leaflets because of the convenience, mobility and portability associated with the app. They acknowledged that leaflets were generally obtained during visits to the GP surgery or diabetes clinics which limited access. Furthermore, those who picked up such leaflets rarely carried them around, hence, having the PADI app available at all times removed these constraints and made it easier for women to access PCC information.

I did like that you can have it with you wherever, because although it’s kind of the same information that you could get at a brochure at the GP’s office, you’re not always going to have that...
brochure with you when you want to refer to something, whereas if it’s on your phone you always have it with you and it’s easy to go and double check and to just have that information on hand wherever you are. [P11, 24 years]

In addition to the informational content, the app also contained a diary for monitoring of blood glucose (BG) levels. Most participants (n=5) felt that it was useful to have a diary within the app that recorded and displayed trends as this was considered beneficial to the management of diabetes, as noted below.

I think it would be very good for monitoring. I mean, I’m very particular. My HbA1C is 6.3, so I monitor quite closely my blood glucose anyway. But I think the blood glucose diary is crucial. [P14, 32 years]

Participants believed that having the PADI app on their phone was of immense benefit especially as it condensed the PCC information and blood glucose diary in a single app within their smartphones. It thus precluded the need to carry a book for logging blood glucose readings which is not only bulky but also inconvenient. This integration was perceived as a strength of PADI app.

I like it. I’ve carried around a book but I either don’t have a pen or my handbag is too small for it or I’ve left it at home and it’s very rare that I leave my phone behind, so it’s always there and I can … always put it [BG readings] in and if I don’t have an internet connection the majority of the information is there for me and I just like the fact that it’s like having all the information in a book but in a tiny place on your phone. [P16, 39 years]

They further reported that the app used a supportive approach to inform women planning a pregnancy about the target HbA1c value and the benefits of having BG levels within the recommended range. One woman reported taking the app along to clinic consultations so that target HbA1c and BG levels could be discussed with HCPs in line with the PADI app PCC checklist.

I did speak to the diabetes team and had the HbA1c taken and then we had a bit of a discussion about it. They were quite blunt about it and it was a little bit kind of scary I guess but they were both telling the truth but they weren’t as nice … but your app kind of made them go, “Oh well that’s the preferred level you need to be at,” not the, ‘You’ve got to be there otherwise you can’t.’ [P16, 39 years]

This participant further noted not feeling very supported during the clinic visit which reinforced the need for the positive language used within the app. Furthermore, as previous experiences with HCPs had left women feeling discouraged, the need for reassurance during PCC and pregnancy was emphasised by participants who reported that the PADI app specifically designed for women with DM made them feel supported.

I think that you feel alone and everyone else who is pregnant without diabetes doesn’t have to worry about all these things, so to have this app is like comforting and inclusive and it’s nice. [P13, 33 years]

Furthermore, the positive intervention language used within the PADI app and the perceived benefits of the app content was reported to appeal to participants. Although PADI is a PCC app, participants noted that they would carry on using it beyond preconception and throughout the duration of their pregnancies due to its useful information and functionality.
It’s got a very good content, I think it would be very beneficial ... it’s something that would be great to have throughout your pregnancy. [P14, 32 years]

Thus, the use of a mobile app as an intervention tool for PCC was perceived as acceptable to women with DM. One woman summed this up by noting that: “Overall, I think it’s a wonderful idea.” [P15, 20 years]

7.9.2 Experiences and behavioural effects

Generally, women found the PADI app content educational and informative. They felt that the app provided detailed PCC information, covered a wide range of topics and provided a sufficient amount of tips and advice. All participants were of the opinion that the app was a good source of PCC information and should be recommended to all women with T1DM as in their experiences some HCPs lacked PCC knowledge.

I loved the about pre-pregnancy planning. I think that as a person with type 1 diabetes you don’t get that. Even the people you go see don’t know that much and ... I think this would be great to give to patients so that they understand. So I definitely loved the information in it. [P13, 33 years]

Overall, I felt that it had all the information I would want [P15, 20 years].

Five participants reported that they were able to learn from the PADI app and felt that it improved their knowledge and awareness of PCC. They felt that improved knowledge in turn reduced any previous anxieties that they had about planning and having a healthy pregnancy.

I’m much more knowledgeable on it, learning about things and being prepared for everything. I can be a little more calm because I know of things. [P13, 33 years]

Women were generally aware of the need to maintain good blood glucose levels in pregnancy, but the rationale and importance of this behaviour was not always clear. The PADI app thus helped participants to understand why optimised BG levels before and during pregnancy were important. It also provided information regarding the risks of poorly controlled DM during pregnancy to both the woman and baby, and signposted users to available resources (such as reputable websites and their own diabetic team) that could be consulted for more information.

Just greater emphasis on blood sugar control, which I knew was an issue but knowing specifically how important it is from the app, it’s definitely made a big impact and knowing what research resources are available to me. [P15, 20 years]

Furthermore, the inclusion of a BG diary facilitated monitoring and allowed participants to reflect on their own behaviour, which was enlightening for some. For example, a woman in the study recognised that she did not always prioritise blood glucose level monitoring and acknowledged that using the PADI app helped to improve this. She was also seeing the benefits of regular SMBG since using the diary to monitor and visualise blood glucose (BG) levels—her blood glucose levels were improving.

Because I think it drops priority for a while and because I’ve been helping you it’s made it come
up to a higher priority and it’s made me think about it more and my levels are coming down, so that’s quite impressive. [P16, 39 years]

Participants reported that the PADI app served as a good source of PCC information and its content could help other women planning a pregnancy stay informed, and adopt behaviours that would increase the likelihood of having a healthy pregnancy and baby. The mere presence of the PADI app on a woman’s phone was reported by one participant to provide the motivation to initiate and continue with healthy behaviours, as noted below:

I think that just having the app and seeing it on my phone would kind of remind me like, yes, I’m taking steps to make sure I’m healthy, my baby is healthy. [P15, 20].

The PADI app thus highlighted the significance of seeking PCC to all participants while providing participants with handy resources and details regarding which HCPs to contact when planning a pregnancy. Participants reported that the app intervention enabled them to recognise the importance of pregnancy planning and involving their healthcare team. Going forward, they reported that they would do things differently by seeking PCC and contacting a HCP about their pregnancy intentions.

I think when I do decide I would like to become pregnant I definitely would seek preconception care. I’d probably go to my GP and look for other resources. Yes, I think the app and being part of this study just opened my mind as to what care is out there and where I can search for more care and more support. [P11, 24 years]

In addition to informing women in the study of the merits of seeking PCC, the PADI app was reported to have facilitated actual engagement with HCPs, especially the diabetes consultant. For example, it encouraged women planning a pregnancy (in less than one year) to take the initiative in order to improve their preconception health by requesting a prescription for 5mg folic acid.

I thought it was very useful actually … Things like about taking the extra folic acid, I was actually showing that to my doctor and said, “Well actually it says that we need the 5mg rather than the normal [4µg]” so I’ve had that prescribed now. [P16, 39 years]

The PADI app was a feasible and acceptable means of providing PCC information that resulted in raised PCC awareness and other behavioural effects. However, despite the acceptance of the PADI app, engagement was moderate and several factors affected usage of the app.

### 7.10 Engagement with the PADI app

#### 7.10.1 Usage

Most of the participants liked the app and its functionalities and all reported that they had used the PADI app to access PCC information. Most reported using it periodically mainly to record blood glucose levels, for example;

So I read everything that you wrote about like the planning … but like the blood glucose monitoring, when you have it everywhere else, to put it somewhere else was just not… I just did not keep up with it. [P13, 33 years]
I only did it maybe once a day but not very often because it was just a lot of clicking that I would have to do to get there. [P15, 20 years]

Women who were more frequent users, and reported using it daily, explained how they found it more convenient to use at a particular time, such as early morning or late evening.

I only put my blood glucose in, in the mornings. [P14, 32 years]

I would generally use it around about teatime. [P16, 39 years]

These findings were reflected in the software log of activity data, which, although was limited, confirmed all study participants had used the PADI app at least once, and that usage varied substantially (range from 1 to 8 sessions/day of use). A number of factors were reported to influence the app usage and these are discussed in more detail below.

7.10.2 Factors affecting usage

Participants cited various factors related to functionality (e.g. usability, SMBG functions and inadequate interactivity) and personal issues (prior knowledge, usefulness, not planning a pregnancy, memory/time issues and competing priorities) that influenced their app usage. The main barrier reported related to the limitations associated with the SMBG function.

7.10.2.1 Functionality factors

Usability of the intervention

The interview findings revealed that all of the (n=6) participants found the PADI app straightforward to download and install onto their mobile phones, as shown in the data extract below.

Yes, it was very easy to download, so that wasn’t a problem at all. [P12, 36 years]

Furthermore, all participants noted that they had no difficulty registering their details (username and password) and subsequently logging into the app, describing the process as “perfect [and] very easy” [P14, 32, UK]. Participants further reported that it was easy to navigate the different sections of the app and generally liked the user interface (UI), noting that it was simple, attractive and intuitive.

Quite easy to use. It looks nice, it was quite self-explanatory. [P16, 39 years]

All participants reported that the PADI app was easy to learn, noting that the simple design of the UI allowed them to easily find information and operate the PADI app. For example, while talking about the organisation of the different components within the PADI app, one participant noted that “the title of different things were quite clear ... it was quite simply laid out” [P12, 36 years].
Another participant agreed with this view and stated: “Yes, it’s a very simple app.” [P13, 33 years]

One participant experienced technical problems with the diary and as a result, was unable to log her readings on one day. However, the majority (n=5) of women had not experienced any technical problems with regards to the PADI app or diary during the study.

There was no problem technically with the application at all. [P15, 20 years]

Majority of participants were pleased with the overall PADI app and its functionalities, and noted that they will be sharing or recommending it to other women with DM.

I think it’s a brilliant app … and anyone I do know I will be recommending it to them. [P14, 32 years]

Self-monitoring of blood glucose (SMBG) functions

Participants reported that they found using the PADI app to input their blood glucose data straightforward and easy. However, the blood glucose diary was in UK units of measurement (mmol/l) and participants from other countries e.g. Canada/USA use mg/dl as their unit of measurement and had to convert their blood glucose readings into mmol/l. One of the participants pointed out that although the diary was simple to use, she struggled with this conversion.

I mean, it wasn’t that it was complicated, it was just that having to convert the units … so it was easy, it was just somewhat time consuming. [P15, 20 years]

Other perceived limitations of the diary affected its use. For example, the blood glucose diary had a graph that displayed trends and a reminder built into the app, but some participants felt that it was still limited in its functionality as it did not have the capacity to log insulin, exercise and carbohydrate intake, and estimate HbA1c. They compared it to their existent diary and reported that it was not as comprehensive in its functionalities, as shown below.

No, because I use a different glucose diary … The diary I use you can log the different foods you eat, you can log exercise, you can log how much insulin or other medications you take and so it’s a bit more comprehensive and so that’s the one I use. [P11, 24 years]

Participants wanted simple and fast functionality with minimum effort on their part and reported that manual entry of BG levels was inconvenient. The diary also lacked the facility to download or email BG readings. Participants reported that they already had to write down numbers for clinic appointments and having to enter their numbers into the app as well was a factor affecting continued usage.

My biggest thing was it was something else to do. I wear a Dexcom already, I have a pump, I upload it and if my provider wants numbers, I have to write those down on their sheets. And then to have another thing, I mean, I did it for two or three days, putting it in the beginning … I felt like it was just double work, like it was already being recorded on my phone, the Dexcom readings were there. So to then record a blood sugar number, what’s the point when I have 24hrs a day of blood sugar numbers recorded? [P13, 33 years]
Furthermore participants’ ownership of more sophisticated technology further affected use of the diary for SMBG. For example, some women already used advanced technology such as continuous glucose monitors (CGMs), BG meters (BGMs) and pumps that displayed and gave them a breakdown of their readings. These were considered primary devices because they read the blood glucose levels directly and indicated when participants were likely to experience hyper or hypoglycaemia. Although the PADI app provided a breakdown of blood glucose readings and worked out average BG levels, it was still considered a secondary device because participants had to manually transfer readings from their primary devices into the app.

_I didn’t feel that it was really beneficial for me because I’m using an insulin pump and my own blood glucose meter does give me a lot of the information and the downloads and the working out of what my average levels are, which times of the day I’m mainly maybe at risk of having high blood sugar … so I have got that already, so I didn’t really feel that the app gave me any additional benefits._ [P12, 36 years]

This made the entry of data time-consuming and a slow process. Furthermore, the diary within the app was also compared to other commercial apps in terms of functionality and comprehensiveness and this determined whether or not participants switched from their existent diary to the app. These participants (n=4) who owned sophisticated blood glucose management devices however acknowledged that if they didn’t already have access to their existing technologies, they would have used the PADI app diary more often. They further acknowledged that the diary would be a useful feature for many women as not everyone had access to such advanced monitoring technologies.

_It depends on the technology that the person has set up. For me, because I have the ability to export my blood sugar data to like an easier application, it would not be helpful for me, but for somebody whose blood sugar meter maybe doesn’t track it or doesn’t export it like that then for sure it would be very helpful._ [P15, 20 years]

This view was supported by two participants who did not own pumps, CGMs or BGMs that recorded their readings, provided a breakdown and showed trends. They thus found the PADI app diary useful and did not mind inputting their glucose readings into the app, as shown below:

_I think it’s really useful … I’m happy to do it manually._ [P14, 32 years]

**Inadequate interactivity**

Furthermore, for participants who were not planning a pregnancy in the near future (more than 1 year) and for whom pregnancy planning was not a priority, the diary was the only feature in the app that they could frequently interact with. Although they reported that they often dipped in and out of the app, the absence of other add-on features, such as a food or medication diary, limited their continued engagement.

_I mean, aside from the [blood glucose] diary, I didn’t really have a reason to look through the information or to use the app very often unless I kind of was flipping through my phone and thought “oh maybe I’ll take a look and see what it says.”_ [P11, 24 years]
7.10.2.2 **Personal factors**

**Prior knowledge and usefulness**

Despite the recognition of the app’s usefulness as an informative resource, two participants who reported being very knowledgeable about PCC either from hearing about it from HCPs from an early age or personal research felt that the app contained generic information that was available elsewhere and therefore was not considered personally useful.

*Personally for me it was just not very beneficial, I felt that a lot of the information I knew already and that’s probably because I have been trying to get pregnant for kind of the last four years, so I had a lot of time to get the information already, so I didn’t really feel I’ve found a lot of new information.* [P12, 36 years]

This view was supported by another participant who had been living with diabetes for twelve years and was already very familiar with PCC information via diabetes team and online resources. Both participants were of the opinion that the PADI app was useful but felt that due to their good PCC knowledge, the app would be of more benefit to other women with DM who were not as knowledgeable, especially people with T2DM and those that are newly diagnosed. Despite having prior PCC knowledge, one participant thought women with DM should take the same dose of folic acid as those without DM. Although the app use helped to correct this misconception, the relevance of the app to less knowledgeable women was maintained.

*I thought the information was useful, I did learn a few things from just reading through the different sections … like the folic acid intake, I didn’t know that we were supposed to take more than non-diabetics … I have always known that in order to have a baby my blood glucose needs to be within a certain range. I’ve always known that having lots of highs and lows can impact the health of my baby. It wasn’t really anything new. But I think for someone that’s newly diagnosed, I think it would have been helpful.* [P11, 24 years]

All participants reported that they had previously received PCC advice from HCPs. However, they reported having inadequate folic acid knowledge, indicating that the information regarding 5mg folic acid dosage for women with DM was clearly not provided by some HCPs. Thus, nearly all participants (n=5) reported that they got to know about this by using the PADI app.

*So about the folic acid, it would never have occurred to me that I needed anything different. It’s one of the main things that I found out about … So it was interesting to know that you need to take more than you generally hear about. It wasn’t something that I had been aware of at all.* [P16, 39 years]

Apart from being informative, participants also found the educational aspect of the app useful because as one participant reported, *for somebody who is already thinking about pregnancy, it focuses the mind.* [P14, 32 years]

Additionally, participants found the links to external resources (i.e. Diabetes UK support forum) very useful as it enabled them to discover and talk to other people in similar situations. This form of social support was reported to allow participants to connect with other women with DM, share their experiences, ask questions and learn from the experiences of others regarding pregnancy planning and pregnancy.
Being able to log in to forums about pregnant diabetics … and be able to hear about other people in the same situations … It’s some of the most useful things I’ve seen … I used it via the app and read some of the things that came up. [P16, 39 years]

The educational aspect of the app was deemed to be comprehensive by all women and most were happy with the PADI app’s content and functionality. Furthermore, links (to websites and videos) were used within the informational content of the app to provide more information about a specific topic. They reinforced the information in the app, and should participants want more information, these links provided easy access to external websites (such as NICE and Diabetes UK). Participants reported using these links to seek additional information, as shown in the data below.

The information was very good and the fact that it’s got links to things was also very good. Rather than having to search it for yourself, you could press the link and go straight there and that was really good. [P16, 39 years]

Not planning a pregnancy

Women who were not planning a pregnancy in the short-term such as in the next one year, did not use the app regularly because they did not perceive accessing the information via the PADI app as a priority during the study intervention, as shown in the quote below.

I’m also not planning pregnancy at the moment, so the information wasn’t really on my mind all the time. [P11, 24 years].

In addition to not planning a pregnancy, participants had to deal with a lot of things on a daily basis, including life in general and the complexity of managing a long-term condition, which caused them to forget to use the app.

I wasn’t actually trying to get pregnant but because of all the other things in life I forgot. [P14, 32 years]

The role of memory and time

Participants reported that the app could easily fit into their day-to-day routine as it did not take up much time. Despite this, they reported that they still did not use the diary to record BG levels immediately after taking their readings because they forgot, or did not have time, as shown in this quote below.

It would be quite easy to fit in if I made sure that I did it. I was struggling a bit to find- find the time’s not quite the right word but I think if I set my mind to it … it would only be another minute when I wasn’t taking my readings … sometimes I forgot and I’d think “oh I don’t have the time now, I’ll do it later on.” [P16, 39 years]

Participants reported that taking the readings using their meters and recording it in the diary often did not occur at the same time, causing them to skip some days or transfer the readings from their meters at a later more convenient time. Time constraint and memory therefore affected the frequency of use.
I definitely missed a lot of days. [P15, 20 years]

It was two or three times a week I would say. I’d sit down every couple of days, maybe occasionally slightly longer and put in the ones from my meter, I’d put them in. [P16, 39 years]

Competing priorities
Other aspects in participants’ lives could influence their engagement with the app. The main commitments such as work and diabetes management interfered with participants’ use of the PADI app and caused them to deviate from using it regularly.

I think I would have used it a lot more if my alarm hadn’t have been going off and I hadn’t been rushing out the door and then just work and then suddenly it was the next day. [P14, 32 years]

It’s very hard as a diabetic when you have to wake up in the morning and you have to remember to do your blood and to do your insulin and that’s on top of all the other stuff going on inside of your head. So it’s another layer that you have to remember. [P14, 32 years]

7.11 Future development of the intervention
An aspect that emerged from the interviews with women within the study was the need for further refinement of the intervention in terms of the PCC information, diary and general app features.

7.11.1 PCC information
Participants noted the usefulness of the information contained in the app and made a number of suggestions for future improvements. They stated that not every woman who downloads the app would have received PCC advice, and therefore would want to find out as much as possible about PCC and diabetes and pregnancy in order to feel more confident before embarking on a pregnancy.

I mean, it’s okay as it is but … I think more would be even better. Someone downloading this app wants as much information as they can, are nervous about their diabetes and their pregnancy and so I think more is good. [P13, 33 years]

On this basis, they provided some suggestions that will further strengthen the app, such as more information on medications to avoid while planning and during pregnancy. They noted that while the app contained the common ones such as antihypertensive, antimalarial and drugs that control cholesterol, it might be helpful to include information on other medicines such as antidepressants as people may be unsure as to their safety for use in pregnancy. One participant noted that she was able to find more information about medications to avoid by using links and resources provided within the app but noted that more information about this within the app would be of immense benefit to women.

I didn’t realise that an antidepressant was going to be an issue and it isn’t necessarily going to be because obviously it’s better if you are not on medication but if you are seriously depressed while you are pregnant then that’s more dangerous than if you are taking the antidepressants … It was nice to find out
that perhaps I ought to look into that and discuss it with the doctor at the very least rather than just stopping it or not knowing about it. [P16, 39 years]

Participants, especially those planning a pregnancy, further reported that there was a general lack of clear direction and information about pregnancy (from healthcare and online resources) especially what women with DM should do when they first find out that they are pregnant. They thus wanted the app to help fill this gap by incorporating a section on steps to take after a pregnancy is confirmed, including who to contact and what the process entailed in order to help simplify the process that might otherwise be confusing for new expectant mothers.

When you find out you're pregnant, what do you do? I think find out your pregnant first steps, contact your GP or something which sounds so stupid but actually as a diabetic they told me to contact the antenatal clinic which I did but there's lots of different people you need to talk to and I didn't know. So I think that would be useful. Or 'think you might be pregnant, contact your GP,' or, 'contact your diabetic team' or what to expect, that kind of thing. [P14, 32 years]

7.11.2 Blood glucose diary

Most participants (n=5) strongly recommended that the BG diary be enhanced and refined in order to reduce user burden and increase efficiency. One of those recommendations pertained to automation of the diary, as shown in the quote below;

It was easy enough. It would be brilliant if you could link it into a sugar monitor or from a Bluetooth sort of monitor or something so that it could automatically go in. That would make it much easier, because that would save so much time. [P16, 39 years]

Participants however recognised the challenge in automatic transfer of BG readings between the diary and the various data collection software and diabetes management technology on the market e.g. BGMs and CGMs.

I think that it could be a lot better integration from the other data collection but I know that that's a big challenge in terms of the software and also the model … I know [it] is a very tall order. [P15, 20 years]

Asides from integration, participants reported that they would have used it more regularly if it had the capacity to log other information pertaining to their daily lives (such as insulin, diet, carbs, mood, exercise or sleep). Rather than using separate apps for these activities, they suggested if this could be done collectively via the PADI app it would make it easier to pick up trends and make adjustments. They also felt that increased flexibility within the diary with regards to download or email facilities might increase engagement and the ability to make notes within the app would be particularly useful.

I think potentially having more ability to log different circumstances within your glucose diary, being able to log information and make notes [about] your GP appointments. [P11, 24 years]

Furthermore, all women in the study reported that adding a free text option within the diary would help to increase the diary's appeal and be of immense benefit even to those already using sophisticated technology to manage their diabetes. They noted that this would aid in their reflection, analysis and management of BG levels.
I mean, one feature that I could see would be of benefit to other people in my situation would be kind of a free text option that you can write this is why it [blood glucose level] might have been high so that a certain blood sugar could have made more sense. I think that’s one of the things that I would have found beneficial. [P12, 36 years]

7.11.3 General app features

Participants suggested further improvement that could be made to the app. They recognised the importance of personalising the app or tailoring it to better meet the needs of women at different stages of the pregnancy planning journey. For example, some women may be planning a pregnancy over the next six months, whereas for others this may be several years in the future. Participants felt that, personalising it from the start would help make the information more relevant to the individual.

Perhaps if you put in how far in the future you want to be pregnant and it brought up more relevant things, that could be a very useful thing, so like if I want to get pregnant in six months then maybe you need to think about folic acid, that kind of feature maybe a good one, or “now’s the time to go and get your HbAC1” But perhaps a reminder to book in to get that done or something like that. [P16, 39 years]

The need for personalisation and increased feedback was supported by another participant who suggested adding more resources on lifestyle modification especially diet and exercise. It was felt that that tailored advice with examples of foods to eat and exercises to do would enable people to better modify their behaviours.

I think everyone knows that you should be active and you should do exercise and you should eat healthy but it might be nice to have some concrete tips on how to do so rather than just saying ‘cut down on this’ or ‘exercise 30 minutes a day’. Saying ‘go for a walk after dinner, for dinner have this and this’ would be more useful. [P11, 24 years]

Furthermore, participants reported that women would benefit from the use of motivational messages (push notifications) that also acted as reminders for pre-pregnancy activities such as folic acid supplementation and HbA1c check. They noted that these motivational messages were especially important because of the challenges women with DM go through with regards to managing DM and, as such would serve both as a source of encouragement and reminder to help keep them on track.

Little notifications of more motivation. But I think that it’s hard, especially during pregnancy. It’s the hardest thing I’ve ever done. I mean, to add to it, I think someone once said to me, “People with diabetes, well type 1 diabetes aren’t looking for more, they are looking for less, for much less.” ... we want less, so that would be like motivation, just doing reminders so that you don’t have to remind yourself, things like that. [P13, 33 years]

Participants felt that apart from the periodic motivational messages, they would also benefit from the use of daily reminders to enter their BG reading and that such reminders were best sent in the morning or evening (when participants entered their readings into the diary). They reported that this would enable them record their readings more regularly and use the app more often.

So my recommendation would be that it should have in the morning a reminder or a notification or some kind of alert to make you think about it, so to enter your blood glucose levels. I think that would be
really helpful … and I think that would be something that I personally would have benefitted quite a bit from. [P14, 32 years]

Other suggestions include adding personal tips from women with DM who have had a baby, ovulation / fertility tracker and a period tracker.

7.12 Summary of key findings

This section has presented the findings from the user experience interviews with six participants (aged 20-39 years). All participants had T1DM, were educated and planning a future pregnancy. Participants’ views and experiences regarding the 3-month PADI app use were explored to ascertain acceptability and factors affecting use.

Overall, participants found the PADI app to be a feasible and acceptable means of providing PCC information. The provision of information via an app made it easy to access PCC while the incorporation of a blood glucose diary reduced the hassle of recording it separately. Participants found the PADI app visually appealing and easy to use, and appreciated the positive language used within the PADI app. The app’s content was viewed as comprehensive, useful and informative while its capacity to serve as a source of support and information from preconception to pregnancy was recognised. Furthermore, there were accounts of positive experiences and behavioural effects including improved PCC awareness, pregnancy planning, willingness to seek PCC before pregnancy and actual engagement with HCPs regarding PCC.

However, participants’ usage of the app was modest and episodic. Engagement with the app was affected by various functionality and personal factors. For example, usability (attractiveness, ease of use and satisfaction) and usefulness facilitated the app usage while limitations of the SMBG function, competing priorities and memory/time constraints had a detrimental effect on app usage. For majority of participants, the main factor affecting regular usage was the limitations of the SMBG function. Suggestions for improvement were made including personalisation, automation of the blood glucose diary, use of reminders, motivational messages and a reflective notepad.
7.2 Software log of activity

This section explores the download, usage and interaction with the app during the intervention period (January-June 2017). The (n=17) women recruited into the study at baseline (pre-intervention) joined at different time points during the intervention period. Although the app was not actively publicised, other users still found and downloaded it. The launch of the app into Google Play (android app store) and iTunes (Apple / iOS app store) following development may be the reason why the app usage log revealed >17 downloads within the intervention period. From January when the recruitment started until June 2017, a total of 38 iOS (n=14) and Android (n=24) users from 11 countries had downloaded and installed the app. Figure 7.6 and 7.7 below show app installation data by country for the two mobile platforms (iOS and Android).

![iOS installations](image)

**Figure 7.6 iOS installations**

Figure 7.6 shows that the (n=14) iOS users who downloaded the app were based in America (n=6) and UK (n=8), and both countries had similar rates of download. The usage log also showed that android users (n=24) across 11 countries downloaded and installed the app within the same intervention period, as shown in Figure 7.7 below.
Figure 7.7 also showed the following number of downloads: UK (n=6), Iran (n=4), India (n=4) and America (n=3). All other (n=7) countries, had one download each.

### 7.2.1 App usage data

Usage data for the android platform was not available due to a limitation with data provided by this platform. Thus, usage data was only provided for the iOS platform. According to the available app logs, while the (n=8) users in the US engaged in one session on average, the (n=6) iOS users in the UK engaged in five sessions on average. Every time a user opened the app, it was counted as a new session. It is possible that the study participants used the app more often than other users, but because data could not be collected for the individual (n=17) participants, usage could not be verified. Moreover, frequency of usage varied substantially amongst users with a range from 1 to 8 sessions/day. The components of the app visited, i.e. informational pages or blood glucose diary, and the duration of sessions could not be determined. The usage data however showed that users in the UK used the app more...
frequently than those in the US, as shown in Figure 7.8 below.

![iOS Sessions data](image)

**Figure 7.8  iOS session data**

Furthermore, because usage data was not available for the android platform, usage sessions could not be compared across platforms. However, some participants may have been more active users of the app than others. Usage log further showed that the app was used intermittently, rather than daily. At the time of data compilation, a total of (n=7) devices in America were used actively, while (n=15) devices in the UK were used actively to access the app (Figure 7.9).

![iOS active devices](image)

**Figure 7.9  iOS active devices data**
Thus, everyone who installed the app used it at least once. The data also showed that there were more active devices being used to access the app in the UK (n=15) compared to the number of users (n=6), indicating that perhaps women were using at least ≥2 mobile devices to access the app.

7.2.2 Summary of key findings
Participants’ use of the app can best be described as episodic with periods of action and inaction. Although data from the app usage log was limited, it corroborated participants’ report regarding engagement with the app. Some of the highlighted factors hindering engagement may have been responsible for the modest use of the app as shown in the usage log. Furthermore, participants in America and Canada reported that they were not able to fully utilise the blood glucose diary due to the burden of converting blood glucose units. This may have been responsible for the low usage sessions amongst users in the US. Nevertheless, participants found the app to be a feasible and acceptable means of providing PCC, with high usability, benefits and user satisfaction rating. Furthermore, the various suggestions for app improvement could improve users’ long-term engagement, usage and interaction with the app. This is especially important as the app is currently being used in 11 (developed and developing) countries.

The discussion of the phase 1 and 2 study findings forms the focus of chapter 8.
8. Chapter 8: Discussion

8.1 Overview
This chapter commences with a discussion of the study findings in relation to the literature. A critical review of the study methodology, strengths and limitations are presented, followed by a critical evaluation of the research process. The study’s contribution to knowledge, methodology and theory are discussed. A number of recommendations and implications for practice are provided, and a conclusion of the main issues is then presented. Each of these topics are discussed in depth in the subsequent sections.

8.2 Discussion of the findings in relation to the literature
The results provide preliminary evidence that the PADI app could be successfully used to provide PCC information to women with DM. Phase 1 study findings highlighted current gaps in service provision and indicated that the PADI app was acceptable to both women with DM and HCPs and was seen as an opportunity to improve the provision of PCC. Phase 2 findings showed that the PADI app was considered a useful and comprehensive source of PCC information by the participants who used it for three months and may help improve knowledge and attitudes to PCC and PAM, however, usage was modest and affected by functionality and personal factors.

A discussion of the key issues identified from the results is presented using the following subheadings: ‘Improving access to PCC,’ ‘Using eHealth to improve PCC behaviours,’ and ‘Acceptability of the PADI app’.

Improving access to PCC
The findings from this study and the literature suggest that current approaches to providing preconception care (PCC) do not meet the needs of women with DM (Holmes et al., 2017; Murphy et al., 2010b; Spence et al., 2010; Nwolise et al., 2016). Service provision was reported to be fragmented and inconsistent, with variability in services across different healthcare settings. Consequently, many women with DM lacked knowledge and awareness of the risks associated with pregnancy and/or the need for careful planning (CEMACH, 2007; Spence et al., 2010; Earle et al., 2017). Furthermore, according to the New Statesman (2018), the UK health system is under immense pressure with demand growing at four percent and funding at only one percent. Inadequate funding for PCC services in primary and secondary care trusts may affect their capacity to provide PCC, and although guidelines (CEMACH, 2007; NICE, 2015; NHS Digital, 2016) recommend annual PCC information be given to all women of childbearing age, this may not be achieved without adequate funding and staff capacity. PCC significantly
improves the pregnancy outcomes of women and the inadequacy in service provision gives cause for concern because organogenesis takes place within the first 6-8 weeks of pregnancy, while teratogenic changes tend to occur before many women realise that they are pregnant (Murphy et al., 2010b; Neff et al., 2014; Egan et al., 2016; van Voorst et al., 2015). Hence, a more innovative and sustainable PCC solution is needed.

Phase 1 participants (HCPs and women) believed that PCC provided via eHealth technology, specifically via a smartphone app, could provide a more flexible and convenient way to access PCC and improve pregnancy planning. eHealth is increasingly being used to transform health service delivery and improve access to care (May et al., 2005; Townsend et al., 2015). It is currently used around the world to prevent and monitor diseases, provide health education and encourage self-management; it has ensured that patients can access healthcare from a variety of locations, not just at the hospital or clinic (WHO, 2011). Although some eHealth technologies (DVDs and CD-ROMs) have been used to provide PCC to women with DM, they are now considered outdated and offer limited scope to women without computers and DVD players (Nwolise et al., 2016; Tripp et al., 2014). Hence, there have been calls for more consideration to be given to contemporary means of providing PCC, such as smartphone apps (Nwolise et al., 2016; Earle et al., 2017; O’Higgins et al., 2014; Hughes et al., 2016). The PADI app, successfully developed during phase 1, was subsequently used in phase 2 to provide consistent and comprehensive PCC available to participants 24/7 and accessible from any geographical location, thereby overcoming issues of access in service provision.

Evidence from this study suggests that the PADI app can be used to support PCC service provision. This is of significance given that traditional PCC services, which rely on face-to-face consultations and/or information leaflets, are hindered by the inherent problems within the current UK health system (Temple et al., 2006; Murphy et al., 2010b; Egan et al., 2016). An increased demand for services combined with staff shortages and delayed or cancelled clinics result in reduced access and/or opportunities to receive care (Health Education England, 2017). This has negative implications for the PCC of women with DM because HCPs may not be available during women’s times of need, as highlighted in this study. The successful use of the PADI app, in phase 2, to provide uninterrupted access to PCC across three countries demonstrates its capacity to meet the PCC needs of women with DM. Hence, the PADI app could help overcome the existent barriers of traditional PCC practice identified in this study, including demand-side (childcare issues, inadequate PCC awareness, lack of pregnancy planning and time constraints) and supply-side barriers (HCP attitudes, busy clinics, inadequate knowledge and fragmented advice), consistent with the literature (Earle et al., 2017; Yehuda et al., 2016; Spence et al., 2010; O’Higgins et al., 2014). The findings of this study also indicate
agreement with the literature (Calvillo et al., 2013; Jurascio et al., 2015) regarding app use to extend the reach of health interventions and overcome problems associated with traditional face-to-face care.

This study has shown that mobile apps are being increasingly used by patients, HCPs and healthcare organisations to access up-to-date information, connect with HCPs and patient groups, and improve health outcomes in line with the literature (WHO, 2012b; Townsend et al., 2015; Silva et al., 2015). eHealth, specifically the smartphone app, is instrumental in making care more accessible, particularly where resources are scarce, and in encouraging individuals to be more actively involved in their healthcare (May et al., 2005; DH, 2012; Townsend et al., 2015). Hence, national and international initiatives (DH, 2012; NHS, 2014; NHS Scotland, 2014; WHO, 2012a, 2012b) support their use for giving patients more control over their health and care, and providing cost-effective patient-centred care. Evidently, healthcare systems need to more fully embrace technological innovations, such as the PADI app, in order to improve PCC accessibility and health outcomes, and lower healthcare costs.

The PADI app, reported by study participants to have increased their awareness of, and signposted them to, PCC information, can be used to reduce the disparities in PCC access. Several studies (CEMACH, 2007; Murphy et al., 2010b; Steel et al., 2015) have recognised that PCC services, mainly located in NHS hospitals, are more accessible to T1DM women receiving care from a multidisciplinary team within specialist diabetes clinics. This disparity has been attributed to inefficiency in the primary—secondary care referral pathway (NHS Digital, 2016) and general practitioners’ inadequate understanding of the importance of PCC for women with DM (Earle et al., 2017). Hence for women with T2DM, fragmented DM and PCC services make it difficult to access PCC; many therefore lack awareness of PCC services or how to access them and as a result conceive without adequate pregnancy preparations, as highlighted in this study and relevant literature (Murphy et al., 2010b; Egan et al., 2015; CEMACH, 2007). As the current care configuration is unlikely to change given the financial crisis facing the NHS, variations and gaps in care could be reduced by maximising eHealth (NHS, 2014) in order to increase the availability of information via smartphone apps.

Improved, flexible and convenient PCC access such as that provided via the PADI app is vital to reducing high-risk pregnancies and resultant healthcare costs. Globally, healthcare systems are struggling with an increased demand associated with the growing burden of chronic diseases including DM (IDF, 2017; New Statesman, 2018). It is evident that the increasing numbers of women with DM of childbearing age who get pregnant, especially young and T2DM women, outstrip current PCC coverage (CEMACH, 2007; Murphy et al., 2010b; Egan et al., 2016). Women of childbearing age increasingly rely on smartphone apps because of their advanced
functionalities (including internet access combined with photos, videos and geo-positioning capacity), mobility, ease-of-use and portability (Eng and Lee, 2013; Silva et al., 2015; Derbyshire and Dancey, 2013; Hebden et al., 2012; Tripp et al., 2014). Apps also have significant advantage over desktop computers, laptops and DVD players. For example, the need to have access to a computer affects intervention uptake and usage, whereas, a smartphone app provides a nearly continuous access between the intervention and patients (Renton et al., 2014; Stiles-Shields et al., 2017). Ninety percent of the time spent on mobile phones is spent on apps, which are preferred over web or computer-based applications (Kollmann et al., 2007; Quinn et al., 2011), making the PADI app a valuable tool for giving more women access to PCC.

Facilitating access to PCC via an app is not without its challenges. These include inequality of access between those with smartphones and those without. However, evidence shows that in developed countries, smartphone use is ingrained in daily life; for example, ninety-one percent of adults in the UK aged eighteen to forty-four own a smartphone (Deloitte Report, 2016). Ownership in developing countries is also increasing rapidly and projected to reach the rates of developed countries by 2021 (Pew Research Center, 2016). This provides evidence for a reverse digital divide, whereby people from low-income populations and resource-poor settings are amongst the fastest growing users of mobile phone technology (Bull, 2011; Donner, 2008). Furthermore, a decline in price has contributed to the unprecedented increase in the number of mobile phone users in both developed and developing countries (Lambert and Littlefield, 2009; WHO, 2011b). This penetration of mobile phones could facilitate access to PCC for women who are unreachable via traditional face-to-face channels, e.g. those from lower socio-economic groups, and developing countries. This access has positive implications for addressing some of the disparities and inadequacies in PCC both in the UK and the wider international community (NHS Digital, 2016; WHO, 2013).

Using eHealth to improve PCC behaviours

In line with the study by Holmes et al. (2012), phase 2 findings indicated that women who received PCC via eHealth were more likely to plan their pregnancy and seek PCC. This finding is supported by Spence et al. (2010) and Earle et al. (2017), who suggest that knowledge and attitudes influence women’s PCC behaviours. Evidence is increasing that contemporary eHealth innovations, aimed at improving PCC knowledge, can successfully change PCC behaviours and improve pregnancy outcomes for women in general. For example Van Dijk et al. (2016), using the Smarter Pregnancy mHealth platform in a sample of 1,275 couples contemplating pregnancy in the Netherlands, observed improvement in nutrition and lifestyle after 6 months. Gardiner et al. (2013) found that seventy-three percent of behaviours that were contemplative, progressed to an action or maintenance stage after women used the Gabby PCC system for
two months. Other PCC interventions include *Healthy Pregnancy 4 All*, in the Netherlands, which uses the *ZwangerWijzer* internet questionnaire to assess risks and modify behaviours (Denktaş *et al.*, 2014). Although the effectiveness of the PADI app in changing behaviours requires further study, preliminary results indicate that the app addressed the key determinants of behaviour change, i.e. knowledge, attitudes and self-efficacy, which, according to Michie *et al.* (2005; 2008), is necessary for a meaningful behaviour change to occur.

Educational interventions, such as the PADI app, are premised on the philosophy of equipping people with the knowledge, skills and confidence to improve their health, and empowering individuals to develop a sense of responsibility over their own health to enable them to practise healthy behaviours. For an individual to engage in healthy behaviours, they need to acquire knowledge because knowledge improves attitude, and attitude (positive or negative) determines the likelihood of behaviour change (Kalua and Nyasulu, 2007; Strecher and Rosenstock, 1997). The PADI app’s capacity to change behaviour was underpinned by the Expanded Health Belief Model (EHBM), and it can be inferred that the PCC knowledge acquired through the PADI app positively influenced attitudes (i.e. improved benefits, self-efficacy, and reduced barriers), which then increased the likelihood of behaviour change. This is supported by Van Dijk *et al.* (2016, 2017), who argue that PCC education provided via mobile technology can improve both health literacy and behaviours. The findings relating to the PADI app are indicative, yet they are consistent with other eHealth PCC studies, which have demonstrated the effectiveness of eHealth technologies in promoting behaviour change (Holmes *et al.*, 2012; Charron-Prochownik *et al.*, 2008, 2013; Fischl *et al.*, 2010).

Health education, which is a recognised prerequisite to improved knowledge and behaviour (Kalua and Nyasulu, 2007; Prestwich *et al.*, 2018), was a core component of the PADI app intervention. Phase 2 results indicated an increase in the overall knowledge related to pregnancy planning, particularly the intake of 5mg of folic acid, lifestyle modification, contraception use, HbA1c target and rationale for blood glucose optimisation. Participants’ knowledge of risks, particularly miscarriage and macrosomia, also improved. Other educational mHealth interventions have reported success in improving reproductive health knowledge and changing women’s risk behaviours. For example, *Smarter Pregnancy* improved folic acid intake and lifestyle (healthy diet, physical activity, smoking and alcohol cessation) in pre-pregnant women (Van Dijk *et al.*, 2016); *Text4two* significantly reduced gestational weight gain in overweight or obese pregnant women by improving self-monitoring and lifestyle (Willcox *et al.*, 2017). In addition, the *Waiting Room* app improved contraception and family planning knowledge (Gilliam *et al.*, 2014), while the systematic review by Chen and Mangone (2016)
highlighted the role of apps in preventing unplanned pregnancy in young women. The PADI app intervention also contributed to an increase in PAM, which researchers (Hibbard and Gilburt, 2014; Rask et al., 2009) have highlighted has a direct relationship with adoption of healthy preventive behaviours, e.g. blood glucose optimisation, as well as adherence to rigorous regimens. Hence, the PADI app has shown promise as a behaviour change instrument.

Phase 2 participants, who used the app, reported involving or being willing to involve their HCPs in pregnancy planning and preconception health checks. This finding supports the argument by Janz et al. (1995) and Fischl et al. (2001) that the ability to make reproductive health decisions and initiate discussions with HCPs constitute key modifying factors that affect women’s intention to seek PCC and plan pregnancies. They are considered motivational cues, which contribute to behaviour change, according to the EHBM (Stretcher and Rosenstock, 1997). This argument is supported by Kalua and Nyasulu (2007), who note that although knowledge influences attitudes, it does not guarantee a desirable behaviour; other modifying factors that enable an individual to engage in healthy behaviours have to be present. The improved interaction between young women with DM and their HCPs in relation to PCC observed in the READY-girls eHealth intervention (Fischl et al., 2010), supports the finding in this study. Hence, the PADI app could facilitate PCC discussion with healthcare professionals, which has positive implications for PCC uptake.

Phase 2 participants also reported feeling supported by the PADI app intervention, and experiencing reduced anxiety, along with improved motivation and confidence to plan their pregnancies. These findings support the qualitative study by McCorry et al. (2012) in that women need to know why pregnancy planning is important and must feel confident that they can effectively plan their pregnancies in order to avoid unnecessary anxiety. Apps are becoming widely accepted as effective tools for empowering patients, changing behaviours and increasing quality of life (DigitalHealth.London, 2017). The systematic review by Zhao et al. (2016) highlighted their role in encouraging healthy behavioural changes in several areas including diabetes, weight and medication management as well as their contribution to general lifestyle improvement. A literature review on the use of technology to empower patients found that health literacy, remote access to healthcare and self-management mechanisms were the most valued means of achieving patient empowerment and behaviour change (Solomon et al., 2012; Calvillo et al., 2013). Bridging knowledge gaps is a vital step towards improving maternal and child health outcomes (Knight-Agarwal et al., 2015); knowledgeable, competent and confident women are more likely to take responsibility for their health and that of their babies-to-be. Hence, the PADI app has the potential to improve pregnancy planning and outcomes in women with DM.
Acceptability of the PADI app

Phase 1 findings suggested that the PADI app intervention would be acceptable and feasible to deliver to women planning a pregnancy. Phase 2 participants similarly felt that there was significant value in using mobile technology to deliver PCC, as they were comfortable accessing PCC via the PADI app, noting that the intervention was both relevant and beneficial to women with DM. Acceptability reflects participants’ views of the intervention’s suitability, appropriateness for addressing the problem and convenience for use in daily life (Sidani and Braden, 2011). In order to ensure that the PADI app was acceptable to the target audience (HCPs and women with DM), a co-design approach was adopted. This involvement of service users and HCPs in intervention design and development enhances the intervention’s acceptability by highlighting the components most acceptable (to the target population) for addressing the identified problem (Sidani and Braden, 2011). A similar approach was used by Tonkin-Crine et al. (2011), who used GPs as co-designers of an online intervention to promote prudent antibiotics prescribing across Europe; the involvement of GPs in the formative stage led to the development of an intervention that was acceptable and successful across five countries. Hence, co-design ensures that participants’ expectations are closely matched to the intervention and promotes the likelihood of success (Steen et al., 2011).

Participants’ input facilitated the successful development of a mobile health intervention that was consistent with, and responsive to, participants’ preferences and needs. Phase 1 participants identified vital design and content features that were used to inform the development of the app, such as efficiency, usefulness, simplicity, relevant content (pregnancy planning, contraception, lifestyle modification and SMBG function) and an attractive user interface. They noted that these features would promote its use in practice. The importance of participants’ input and acceptability of a technological intervention is demonstrated in Greenhalgh et al. (2017), who contrasted the level of uptake between two similar eHealth technologies designed to help relatives, friends and HCPs organise tasks and visits for people with health and care needs. In contrast to the web portal developed based on an employee’s past caring experience, which did not consider the training and ongoing support needs of end users and was used by less than five families, a smartphone app (with linked web portal) developed and piloted with families, took into consideration the various needs of end users during the development stage and as a result was accepted, downloaded and used by over one thousand families. Catwell and Sheikh (2009) concluded that eHealth interventions, which are not acceptable and ‘fit for purpose’, are unlikely to be adopted by HCPs or users and at risk of implementation failure. The acceptability of the PADI app intervention to service users and
HCPs (who will deliver the intervention in practice) is therefore important to its uptake and adoption by users and healthcare organisations.

The study findings suggest that in line with the literature (McLean, 2011; Sidani and Braden, 2011), phase 2 participants accepted the app because they found it simple, informative and useful. The acceptability of the PADI app contributed to the high satisfaction rating and achievement of preliminary intervention effects, such as improved knowledge and attitudes, and self-management ability or PAM. This reflects the argument that while those who view an intervention as unacceptable tend to withdraw from it, participants who accept the intervention rate it favourably, use it and experience its beneficial effects (Hibbard et al., 2009; Kowinsky et al., 2009; Sidani, 2008), which include reduced health service use, costs to the healthcare system and burden to individuals and society (Eckert and Hintze, 2000; Naber and Kasper, 2000). Acceptance of the PADI app by service users is important because it demonstrates that the users considered the app to be useful and worth an investment of their time. As Groshek et al. (2015) pointed out, a HCP’s recommendation of an app is no guarantee that the end user will find it of value. In addition, an intervention that is perceived as providing limited benefits, difficult to understand or fit into normal daily practice would not appeal to HCPs (Murray et al., 2010; Mair et al., 2012). This highlights the importance of HCP and patient input, support and acceptability of the PADI app from the outset.

The early testing of the app (phase 2) provided the opportunity to identify aspects of the PADI app that need improvement in order to enhance the intervention’s acceptability, usage and effectiveness in the future. Guidelines for developing eHealth interventions for behaviour change (Mummah et al., 2016; Whittaker et al., 2012; Yardley et al., 2015) recommend testing technological innovations early, in order to analyse usage behaviour, understand user experiences and highlight any design faults or limitations. This is particularly important in terms of avoiding low-quality and potentially harmful interventions being made available to the public (Mummah et al., 2016; Catwell and Sheikh, 2009). In line with the literature (Krebs and Duncan, 2015; Milward et al., 2017; Scott et al., 2017), phase 2 of this study suggested that despite acceptability and a high user satisfaction rating, the engagement with the app was episodic and affected by personal factors (e.g. pregnancy intention, memory, time and competing priorities) and functionality (e.g. manual data input). Although Dennison et al. (2013) found that users prefer to engage with health apps periodically, an increased engagement through the repeated use of digital health technology, e.g. apps and websites, is associated with improved health outcomes (Hoj et al., 2017; Funk et al., 2010; Strecher et al., 2008). Thus, as highlighted by the phase 2 participants and relevant literature (Short et al., 2015; Chomutare et al., 2011), automation, an improved self-monitoring capacity, notifications and the personalisation of health
apps may be vital for sustaining engagement and realising the optimal effects of the PADI app. For this to be realised, further development is required.

Evidence in this study and the literature (Murray et al., 2011; Mair et al., 2007; Milward et al., 2017; Wu et al., 2017; Zapata et al., 2015) indicates that possible factors affecting the implementation of eHealth technology within the NHS include at the individual level, the cost of the eHealth technology, user acceptance and support of HCPs, and at the organisational level, cost, organisational support and financial viability. For women with DM, cost was also a potential barrier to the PADI app uptake. Cost is a recognised barrier to healthcare in developed and developing countries, whether provided face-to-face or remotely via mobile apps (Jacobs et al., 2011; Fu et al., 2013; Aaltonen et al., 2015; Stiles-Shields et al., 2017). Hence, although ownership of a smartphone was necessary, no cost was associated with the app and it was free to download from Google Play and iTunes stores. This ensured that women in all eleven countries, where the app had been downloaded and used, received the same level of PCC support at no extra cost. Other mHealth studies have also identified the cost of the data package, in addition to internet accessibility, as a barrier to app usage (Stiles-Shields et al., 2017); hence after the initial PADI app download, the information pages did not require an active internet connection and could be accessed in areas without third and fourth generation (i.e. 3G and 4G) mobile broadband internet.

Although this feasibility study did not explore, in detail, the implementation of the PADI app, these preliminary findings form the platform for future work, and proponents (Whittaker et al., 2012; Murray et al., 2010) recommend planning for implementation early. The normalisation process theory (NPT) was used as a framework to guide the app development and study, in order to improve the potential for successful implementation in future. According to Bull (2011), implementation is important because when health promotion interventions reach the target population, even modest effects can translate into a reduction in mortality and morbidity. For example, the preconception counselling DVD implemented across healthcare services in Northern Ireland demonstrated improved maternal and child health outcomes (Holmes et al., 2017). Hence, as the ultimate goal of the PADI app is to improve pregnancy outcomes for women with DM, it is imperative that the PADI app is implemented and normalised into healthcare practice, in order for it to maximise its clinical and public health impact (Pagoto and Bennett, 2013; DigitalHealth. London, 2017).
8.3 Discussion of methodology

Overall, this feasibility study was successful in that each research question was answered (i.e. research question, RQ, 1 was answered in Chapter 2; RQ 2 and 3 were answered in Chapter 6 while RQ 3 to 7 were answered in Chapter 7). The mixed methods research (MMR) approach enabled the use of different data collection methods (i.e. focus group, interviews and questionnaires) in answering the research questions (Chapter 1, section 1.5). The MMR facilitated the collection of data on the views and experiences of women and HCPs regarding PCC, app content, feasibility of the PADI app and women’s experiences of using the app. Data regarding the preliminary effects, i.e. knowledge and attitudes towards PCC and PAM, as well as app satisfaction rating were also collected. The insights gained from the user experience interviews highlighted likely reasons for the variability observed in the app usage and allowed insight into how participants used the app.

The MMR approach used is especially of benefit in mHealth studies, where it is recognised that one method alone is likely to be insufficient to answer the research questions (Whittaker et al., 2012; Mummah et al., 2016). The researcher’s pragmatic approach allowed the incorporation of different research paradigms and approaches to data collection and analysis while researching a multi-faceted and complex technological intervention. Thus, by not taking a post-positivist or constructivist view, more informative, complete and useful research findings were achieved (Johnson et al., 2007; Tashokkori and Teddlie, 2010; Creswell and Plano-Clarke 2011).

Challenges were nevertheless experienced in recruiting women with DM of reproductive age from healthcare settings. The recruitment of patients into the study was initially facilitated by HCPs in three local NHS hospitals. Other studies (Holmes et al. 2012; Earle et al. 2017) also experienced similar difficulties in recruiting women with DM from healthcare settings. However, this method of recruitment proved unsuccessful and there were delays in identifying participants who met the inclusion criteria and were willing to participate. Furthermore, the researcher aimed to recruit women with T2DM from one GP surgery, which was later unable to support the study due to time constraints. The protocol was subsequently revised, and an amendment was submitted for ethical approval, in order to allow the researcher to recruit participants for phase 1 and 2 via social media. Although the amendment was approved by the ethics committee and recruitment via this means was successful, these recruitment challenges caused a five-month delay.
8.3.1 Study strengths

This is the first study to design and explore the acceptability and feasibility of a Preconception and Diabetes Information (PADI) app for women with DM. The content of the PADI app was informed by phase 1 study findings, and incorporated service users and HCPs views. The quality of this process is a strength of the study. The acceptability of the PADI app by women with DM and HCPs, in terms of content and mode of delivery, as a feasible means of providing PCC has positive implications for future PCC delivery.

The PADI app was developed using a systematic approach in line with the recommendations by the MRC (Craig et al., 2008), and mHealth development and evaluation frameworks (Whittaker et al., 2012; Mummah et al., 2016). The exploratory study (phase 1) provided insight into service users' and HCPs' expectations regarding the app, which was developed using an iterative approach. In phase 2, the feasibility study evaluated the data collection tools, overall user satisfaction (rating > 70%) and preliminary intervention effects, while the interviews explored experience, usability and satisfaction. App usage behaviour, which is important for the development of more effective apps (Yardley et al., 2016), was also examined.

Apps that go through iterative development cycles involving patients and HCPs are more likely to be effective (Cai et al., 2013; Mummah et al., 2016). The PADI app development went through two cycles of pre-testing with patients, HCPs, researchers and members of the public before being released for further evaluation. Feedback was obtained from participants throughout the PADI app development to ensure that the final app met users' needs, was easy to use and provided evidence-based guidance. Patients further tested it for three months to establish the app’s feasibility and provided additional feedback regarding their experience and suggestions for future app improvement.

This study used a behavioural theory, the expanded health belief model, as a theoretical framework to underpin the PADI app intervention content in line with recommendations for mHealth studies (Yardley et al., 2015; Baker et al., 2014; Riley et al., 2011; Mummah et al., 2016). Furthermore, NPT was used to guide the feasibility study design and promote the app’s potential for implementation. Many commercially-developed apps do not use behavioural theories or conduct efficacy tests, while researcher-developed apps do not incorporate the expertise of commercial app developers who are more adept at developing attractive apps (Pagoto and Bennett, 2013). This study used both methods via a co-design approach, which resulted in an app that is both potentially effective and attractive.

The completion rate for the PADI app intervention was good at 65%, all (n=17) participants completed the pre-intervention questionnaire, while (n=11, 65%) participants completed the
post-intervention questionnaire. The number of missing responses was low with only one question in the pre-intervention questionnaire having (n=3) missing responses, indicating that the questionnaire was acceptable for measuring demographic, knowledge, reproductive health and self-management status.

Despite challenges with recruitment, nineteen participants (10 women with DM and 9 HCPs) were recruited in phase 1. Seventeen participants were also successfully recruited into the feasibility study, which exceeded the recruitment target (n=12). The log of activity also showed that a total of 38 iOS (n=14) and Android (n=24) users from eleven countries downloaded and installed the app during this time, highlighting international interest. The majority of phase 2 participants reported that they had a good experience and enjoyed participating in the study as it was easy, beneficial, enlightening and timely.

### 8.3.2 Study limitations

While this study contributes to our understanding of the use of mobile phone apps in the PCC of women with DM, there are a number of limitations. The preliminary findings suggest that the PADI app can improve knowledge and attitudes to PCC and PAM, but as a feasibility study the aim was not to detect statistical changes. Hence, the findings are indicative and should be interpreted with caution.

Due to challenges associated with the recruitment of women with DM from healthcare settings, the participants for phase 1 were recruited solely via social media platforms, which may bias the sample to digitally-literate individuals, who would be open and perhaps more likely to use smartphone apps as opposed to the general population of women with DM. Phase 2 participants were mostly recruited via social media and it is possible that the more motivated and highly-educated women responded to the invitation to participate in this study. This may help explain the high rate of participants (88%), who previously reported receiving PCC pre-intervention.

This study was self-funded by the researcher and non-financial incentives (e.g. giving participants an opportunity to contribute to the app development and sharing the study findings with them) were used to promote participation. The use of financial incentives may have aided recruitment, uptake and retention. The financial constraint also limited the type and amount of data that was collected via the software log of activity and as a result, the frequency of app usage for each participant in the study could not be determined.
8.3.3 Critical evaluation of the research process

As a researcher, it is important to reflect on and critically evaluate the research process. Overall, the study was successful in that the study objectives were met, the intervention was acceptable to participants and the majority of participants found the intervention feasible to implement within healthcare. Recruitment was also successful, however, the challenges and delays, particularly during phase 1, meant that the recruitment was not a straightforward or smooth process. Hence, a multi-modal recruitment approach should be employed in future studies. That is, in addition to placing adverts on social media sites and approaching patients during clinic visits, potentially eligible patients in general practices and NHS hospitals should receive a letter of invitation from their HCPs.

Although some concerns have been expressed about the use of MMR and mixing qualitative and quantitative research perspectives within a single study (Greene, 2008; Mertens, 2012), the researcher has demonstrated that the chosen methodology and methods worked well together and were the appropriate choice to address the research topic and answer the research questions. Furthermore, the use of MMR improved the researcher’s time and project management skills because conducting and analysing both forms of data was time and labour-intensive. The large volumes of qualitative and quantitative data had to be carefully transcribed, coded, organised, analysed and interpreted.

This study gives a clear and detailed account of each stage of the research process starting with the intervention design, development of the data collection tools, ethical approval, data collection and app development. At each stage, records of what helped or hindered the process were kept. For example, difficulties and delays were experienced by the researcher in obtaining R&D approvals from the study sites. This highlighted the importance of establishing and maintaining a close relationship with the site gatekeepers, such as R&D managers and the clinical team.

Adherence to the intervention was low and the use of the mobile app was moderate, which support findings from a previous qualitative research study exploring users’ engagement with health apps (Dennison et al., 2013). A solution may be the improvement of the intervention. Suggestions, such as personalisation to make it more relevant to women at various pregnancy planning stages, incorporation of other add-on features to increase interactivity and refinement of the diary may promote engagement in future studies.

During this study, the researcher achieved a steep learning curve. Undertaking research within a clinical setting, in an unfamiliar geographical area and country (having just moved to Surrey for my PhD) were challenging aspects of the research process. However, this study allowed the
researcher to appreciate the complexities of the research process and the experience is one that I have immensely benefitted from. This vital experiential learning will be applied to future research projects.

The project has allowed me to work with HCPs and researchers, and to experience the academic and practical side of developing and testing the feasibility of an mHealth intervention. Working with women with DM has been an interesting and rewarding aspect of the study. I have always been interested in health education and improvement, and during the course of the research, I realised the difference the PADI app intervention could make to the lives of women with DM who are planning a pregnancy. All of these have increased my passion for research in this area.

8.4 Contribution to knowledge, methodology and theory
This section outlines the contribution this study has made to the body of knowledge, methodology and theory, each of which is discussed below.

a. Contribution to knowledge
This is the first study to design and use a smartphone app for the PCC of women with DM and adds to the small body of evidence on the use of eHealth for PCC. Various researchers have called for the development of alternative means of providing PCC, other than face-to-face care (Hughes et al., 2016; Earle et al. 2017) but few studies have explored the use of technology for the PCC of women with DM (Charron-Prochownik et al., 2008, 2013; Fischl et al., 2010; Holmes et al., 2012, 2017). Moreover, none have taken advantage of the ubiquity and acceptance of smartphones among women of reproductive age to develop an app-based intervention tailored specifically to women with DM. The PADI app, an alternative means for providing PCC, which combines PCC information with SMBG functions, was therefore successfully developed and its feasibility and acceptability explored.

This is the first study to include the views and opinions of key stakeholders (i.e. women with DM and HCPs) regarding the desired PCC app content and features. In this study, the input from HCPs and women with DM was specifically used to inform the content of the PADI app intervention so that it addressed current shortfalls in PCC service provision. Participants used the app for 3 months and their feedback provided insight into its functionality and the personal factors that hinder app usage and need consideration in future app development.

This study has enhanced understanding regarding the role of mobile apps for PCC in women with DM and provided insight into their use for promoting PCC awareness, patient activation and
behaviour change. These study findings suggest that knowledge and attitudes to PCC, and PAM can be improved via eHealth technology. This is consistent with the few studies that have used technology to effectively increase knowledge and change behaviours towards PCC (Charron-Prochownik et al., 2008, 2013; Fischl et al., 2010; Holmes et al., 2012).

This study highlights the importance of the co-design approach in the iterative development of mHealth interventions. The study found that it was important for a PCC mobile app to be efficient, affordable, comprehensive, user-friendly, useful and attractive in order to be acceptable to service users and HCPs. This adds to the growing literature in this area. Furthermore, as highlighted in the literature (Yardley et al., 2016), the credibility of the PADI app intervention was enhanced by the professional visual appearance of the app, provision of additional supportive evidence via links and videos, up-to-date content and opportunities to provide additional feedback either via the app or email to the researcher.

This study recruited women from a number of countries, thus highlighting international interest, as issues related to PCC access are not specific to the UK. The diffusion and pervasive nature of mobile phone technology means that interventions, such as the PADI app, can be delivered to women with DM irrespective of geographical locations or demographic factors. mHealth apps have been deemed one of the most effective tools for changing behaviours and improving outcomes and can be scaled up at a relatively low cost compared to face-to-face methods (Zhao et al., 2016). The use of mobile phone technology to improve patients’ health and care is supported by national and international health initiatives (WHO, 2012, 2013; NHS, 2014; UN, 2015).

The study findings have been disseminated in various ways including presentations at national and international conferences. A selection of these conference presentations is presented below:

Faculty of Health and Medical Sciences (FHMS) Festival of Research & Doctoral College Conference, University of Surrey (April/June, 2015). Poster and oral pitch presentation: Planning a holiday or planning a pregnancy: exploring alternative strategies for providing preconception care for women with diabetes.

FHMS Festival of Research, University of Surrey (June, 2016). Poster: Preconception care educational interventions for women with diabetes: a narrative review.


Festival of Research & Doctoral College Conference, University of Surrey (June/July, 2017). Poster: Perceptions of the feasibility of a preconception and diabetes information (PADI) app for women with type 1 or 2 diabetes mellitus.
Three articles have been published in peer reviewed journals and these have supported the wider dissemination of the study and its findings within the field of eHealth and healthcare practice. A copy of each of the articles below can be found in Appendix 15:


b. Contribution to research methodology

A lack of studies using a mixed methods approach in this field was highlighted in Chapter 2, especially in terms of reporting both the effect of eHealth PCC interventions and in-depth patient experience.

This study offers a significant contribution to methodology in this area as it is the first to use a combination of qualitative methods to inform the intervention development, a feasibility study to explore the effect of the PADI app intervention, and qualitative methods to explore the experience of the app use. Additional information regarding app use is also provided via the software log of activity.

The use of mixed methods added rigour and credibility to the study, and enabled the examination of processes and outcomes (Plano-Clarke, 2010; Craig et al., 2008). This facilitated an extensive understanding of the PADI app intervention as well as how it can best be optimised to yield maximum benefit.

c. Contribution to theory

The need for studies to adopt a less clinically-oriented and a more theoretical approach in this area of research was highlighted in Chapter 2. Furthermore, theory-based strategies have been known to produce changes in health behaviour interventions, yet very few studies in the literature have incorporated these into mHealth interventions. Thus, the Expanded Health Belief Model (EHBM), a behaviour change theory, was used to predict and understand the behaviour change mechanism of the PADI app intervention. This theory proposes that behaviour is
influenced by an individual’s attitudes, i.e. favourable or unfavourable evaluative reaction towards PCC, exhibited in their beliefs or intended behaviours (Myers, 1999).

The PADI app intervention, incorporating health education, social support, self-monitoring of blood glucose levels and instructions, contributed to knowledge improvement. Knowledge may have influenced attitudes (including self-efficacy/confidence), which in combination could have altered intention and increased the likelihood of planning a pregnancy and seeking PCC, according to the EHBM. These findings support other PCC studies that have used technology, underpinned by the EHBM, to change behaviours (Charron-Prochownik et al., 2008, 2013; Fischl et al., 2010; Holmes et al., 2012). However, this study makes a valuable contribution to theory in that it is the first study to use the EHBM to understand the mechanism of action of a PCC mobile app for women with DM.

For patients to adhere to adopted behaviours, they need to be activated (Hibbard and Gilburt, 2014), i.e. have the knowledge, skills and confidence to manage their preconception health behaviours. It has been recognised that patients with higher levels of activation are more likely to be engaged in their health, motivated to adopt healthy behaviours and take actions that result in their health promotion (Hibbard and Gilburt, 2014; Mosen et al., 2007; Rask et al., 2009). A similar pattern of behaviour was evident in the results of this feasibility study. Although this study used a small sample, the findings support other PAM research in people with DM which indicates that educational interventions can increase the PAM (Shah et al., 2015; Solomon et al., 2012). The relevance of patient activation to PCC is one that has not been studied in previous PCC research. Hence, this study has made a useful contribution to theory by showing that mHealth PCC has the capacity to increase the PAM, which can help to facilitate the uptake of PCC services with the ultimate goal of improving pregnancy outcomes.

Additionally, the use of normalisation process theory (NPT) in mHealth PCC intervention development is one that has not been previously undertaken. This study has therefore made a contribution to theory in this area by showing that the use of NPT to guide intervention development helped to promote the app’s acceptability and potential for implementation. It also shaped the feasibility study and contributed to the development of a useful and simple intervention that is relevant to service users and HCPs.

8.5 Recommendations

The findings from this study provide insight into the role of the PADI app for PCC, its acceptance, use and feasibility. The results have confirmed and extended knowledge and
understanding in this area. Given the study findings, strengths and limitations, a number of recommendations have been made. These are presented below:

### 8.5.1 Recommendations for future research

1. The current study focused on the development, feasibility and acceptability of the PADI app. In line with the MRC, and mHealth development and evaluation framework (Craig et al., 2008; Whittaker et al., 2012; Mummah et al., 2016), further piloting using an RCT over a longer period of time is needed, followed by an evaluation study to determine clinical effectiveness.

2. Pregnancy planning with an emphasis on optimising glycaemic control before pregnancy reduces the risk of adverse outcomes (Wahabi et al., 2010; Murphy et al., 2010). Hence, in future studies, it would be useful to evaluate the effect of the PADI app intervention on the clinical measures used to monitor diabetes control, e.g. HbA1c, pregnancy planning indicators, e.g. folic acid intake, pregnancy outcomes, in addition to PCC knowledge and attitudes. This would provide evidence of the clinical effect on patient outcomes.

3. The PADI app needs to be further developed to include personalised information in order to improve and sustain engagement, positive behaviour change and outcomes. It would also be useful to explore women’s experiences of using a more personalised PADI app.

4. The app analytics functionality also needs to be optimised to enable it to provide comprehensive app usage data particularly in terms of frequency and duration of app usage, features used as well as the number and type of informational pages visited by each participant.

5. The findings in this study and in the relevant literature (Mulvaney et al., 2011, Milward et al., 2017, Tatara et al., 2013) support the use of automation to reduce user burden, improve clinical outcomes, e.g. HbA1c, and promote compliance and long-term app usage. Hence, the blood glucose (BG) diary should be automated and BG measurements for different countries should be included in order to improve efficiency.

6. T2DM is more prevalent in people from minority ethnic groups, hence, areas with a large representation of ethnic communities should also be targeted to ensure that the sample is more ethnically diverse and balanced in terms of the type of DM. This will ensure that the next version of the PADI app is refined to best meet the needs of women with T1 and T2DM.
8.5.2 Recommendations for practice

1. In order to overcome the inadequacies associated with the traditional model of PCC (i.e. face-to-face and use of leaflets), it is recommended that healthcare organisations that care for women with DM, e.g. NHS hospitals and general practices, consider adopting and integrating technology-based PCC, such as the PADI app (subject to resources, further development and evaluation), into routine healthcare. In addition, national policy-makers should encourage and support this implementation, which is in line with the current government policy on improving patients’ access to information and reducing complications via smartphones and apps (NHS, 2014).

2. Technology-based PCC, such as the PADI app, has the potential to enhance the patient-provider relationship. However, HCPs’ attitudes towards PCC and pregnancy encourage or discourage women from seeking PCC. In order to prevent dissatisfaction and the perceived lack of support towards PCC and pregnancy planning, there is a need for more awareness and training of the HCPs who care for women with DM in relation to PCC, diabetes and pregnancy. In addition, the importance of a supportive approach that focuses on success and the normalisation of pregnancy in women with DM should be emphasised. This could be achieved by reviewing current diabetes education and training, to ensure it is fit for purpose and focuses on positivity.

3. PCC policies, funding and guidelines for women with DM need to be reviewed to take into consideration the increase in the prevalence of DM among women of childbearing age, and pregnancies in younger women and those with T2DM. The PCC referral pathways between primary and secondary care need to be strengthened. This could be achieved by providing additional PCC training to GPs and practice nurses so that they understand the need for PCC especially in the case of women with DM. Furthermore, PCC and contraception responsibility need to be more clearly delineated and communicated to service providers, and PCC services for women with DM, audited to ensure equity in provision and receipt of PCC.

8.6 Conclusions

eHealth is increasingly being used to improve access to healthcare around the world. The findings presented in this thesis demonstrate that a smartphone application is an acceptable way of providing PCC to women with DM and can help overcome current shortfalls in PCC service provision.
Studies using smartphone app to provide PCC to women with DM are scarce; hence, this study has developed and tested the feasibility and acceptability of a preconception and diabetes information (PADI) app, for women with DM. As such it provides a unique contribution to knowledge, which can influence future PCC service delivery and lead to healthy outcomes of pregnancy for women with DM.

Findings from the study showed a high level of interest, acceptance and support from healthcare professionals and women with DM regarding the use of the PADI app for PCC. This is important given that acceptance by women with DM and healthcare professionals, will be key to successful adoption and implementation of the PADI app in routine practice.

Preliminary results also indicate that the PADI app may help improve knowledge, attitudes and behaviours towards PCC, which has positive implications for pregnancy planning and PCC uptake. However, in order to realise the full potential of the PADI app intervention, further development and evaluation is required.
References


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Faculty of Sexual and Reproductive Health Care. UK Medical Eligibility Criteria for Contraceptive Use (UKMEC 2009); London: 2009. Available from:


Hasan, R., Olshan, A.F., Herring, A.H., Savitz, D.A., Siega-Riz, A.M. and Hartmann, K.E.


Appendix 1 Data Extraction Form

1. General Information

| Date form completed  
  (dd/mm/yyyy) |  |
|-------------------|---|
| Report title  
  (title of paper/abstract/report 
  that data are extracted from) |  |
| Publication type  
  (e.g. full report, abstract, letter) |  |
| Study ID (e.g. 01 plus surname of 
  first author and year first full 
  report of study was published 
  e.g. Smith 2001) |  |
| Country in which the study 
  conducted |  |
| Economic level of the country in 
  which the study conducted  
  (e.g. low income, lower-middle 
  income or upper-middle 
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2. Eligibility

| Study Characteristics | Review Inclusion Criteria | Location in text  
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| Decision (with reasons for either 
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| Notes |  |  |

DO NOT PROCEED IF STUDY EXCLUDED FROM REVIEW
3. Population and setting

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<td>controls) if available</td>
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4. Methods

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5. Participants

Provide overall data and, if available, comparative data for each intervention or comparison group.

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### 6. Intervention groups

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<td>Group name (specify whether intervention or control)</td>
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<td>Description of any co-interventions.</td>
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### 7. Outcomes

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### 8. Results and findings

Copy and paste the appropriate table for each outcome, including additional tables for each time point and subgroup as required.

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<td>Subgroup (if any, e.g. age-specific prevalence reporting)</td>
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<td>Results</td>
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<td>Response/non-response rate</td>
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<td>Any other results reported</td>
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<td>No. missing participants and reasons</td>
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<td>Unit of analysis (e.g. by individuals)</td>
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<td>Statistical methods used and appropriateness of these methods (e.g. proportion/%, RR/OR)</td>
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<td>All systematic and random error adjusted? (e.g. confounding)</td>
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<tr>
<td>Whether results weighted? (e.g. Yes/No)</td>
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<tr>
<td>Post-intervention or change from baseline? (for continuous outcomes)</td>
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<td>Notes</td>
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9. Limitations and mitigation strategy

<table>
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<th>Strength</th>
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| Strategies to overcome the limitations. |  |

Notes:

10. Conclusion and other information

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<td>Key conclusions of study authors</td>
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<td></td>
<td>References to other relevant studies</td>
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Notes:
Appendix 2

QUALITY ASSESSMENT TOOL
FOR QUANTITATIVE STUDIES

COMPONENT RATINGS

1 SELECTION BIAS

(Q1) Are the individuals selected to participate in the study likely to be representative of the target population?
1 Very likely
2 Somewhat likely
3 Not likely
4 Can’t tell

(Q2) What percentage of selected individuals agreed to participate?
1 80 - 100% agreement
2 60 – 79% agreement
3 less than 60% agreement
4 Not applicable
5 Can’t tell

RATE THIS SECTION STRONG MODERATE WEAK
See dictionary 1 2 3

1. STUDY DESIGN

Indicate the study design
1 Randomized controlled trial
2 Controlled clinical trial
3 Cohort analytic (two group pre + post)
4 Case-control
5 Cohort (one group pre + post (before and after))
6 Interrupted time series
7 Other specify ____________________________
8 Can’t tell

Was the study described as randomized? If NO, go to Component C.

No Yes

If Yes, was the method of randomization described? (See dictionary)

No Yes

If Yes, was the method appropriate? (See dictionary)

No Yes

RATE THIS SECTION STRONG MODERATE WEAK
See dictionary 1 2 3
3. CONFOUNDERS

(Q1) Were there important differences between groups prior to the intervention?  
   1 Yes  
   2 No  
   3 Can’t tell

The following are examples of confounders:  
   1 Race  
   2 Sex  
   3 Marital status/family  
   4 Age  
   5 SES (income or class)  
   6 Education  
   7 Health status  
   8 Pre-intervention score on outcome measure

(Q2) If yes, indicate the percentage of relevant confounders that were controlled (either in the design (e.g. stratification, matching) or analysis)?  
   1 80 – 100% (most)  
   2 60 – 79% (some)  
   3 Less than 60% (few or none)  
   4 Can’t Tell

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D) BLINDING

(Q1) Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?  
   1 Yes  
   2 No  
   3 Can’t tell

(Q2) Were the study participants aware of the research question?  
   1 Yes  
   2 No  
   3 Can’t tell

RATE THIS SECTION

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E) DATA COLLECTION METHODS

(Q1) Were data collection tools shown to be valid?  
   1 Yes  
   2 No  
   3 Can’t tell

(Q2) Were data collection tools shown to be reliable?  
   1 Yes  
   2 No  
   3 Can’t tell

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See dictionary
F) WITHDRAWALS AND DROP-OUTS

(Q1) Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?
1 Yes
2 No
3 Can’t tell
4 Not Applicable (i.e. one time surveys or interviews)

(Q2) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).
1 80 -100%
2 60 - 79%
3 less than 60%
4 Can’t tell
5 Not Applicable (i.e. Retrospective case-control)

RATE THIS SECTION STRONG MODERATE WEAK
See dictionary 1 2 3 Not Applicable

G) INTERVENTION INTEGRITY

(Q1) What percentage of participants received the allocated intervention or exposure of interest?
1 80 -100%
2 60 - 79%
3 less than 60%
4 Can’t tell

(Q2) Was the consistency of the intervention measured?
1 Yes
2 No
3 Can’t tell

(Q3) Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?
1 Yes
2 No
3 Can’t tell

H) ANALYSES

(Q1) Indicate the unit of allocation (circle one)
community organization/institution practice/office individual

(Q2) Indicate the unit of analysis (circle one)
community organization/institution practice/office individual

(Q3) Are the statistical methods appropriate for the study design?
1 Yes
2 No
3 Can’t tell

(Q4) Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?
1 Yes
2 No
3 Can’t tell
GLOBAL RATING

COMPONENT RATINGS
Please transcribe the information from the gray boxes on pages 1-4 onto this page. See dictionary on how to rate this section.

<table>
<thead>
<tr>
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GLOBAL RATING FOR THIS PAPER (circle one):

1. STRONG (no WEAK ratings)
2. MODERATE (one WEAK rating)
3. WEAK (two or more WEAK ratings)

With both reviewers discussing the ratings:

Is there a discrepancy between the two reviewers with respect to the component (A-F) ratings?

No  Yes

If yes, indicate the reason for the discrepancy

1. Oversight
2. Differences in interpretation of criteria
3. Differences in interpretation of study

Final decision of both reviewers (circle one):

1. STRONG
2. MODERATE
3. WEAK
Quality Assessment Tool for Quantitative Studies Dictionary

The purpose of this dictionary is to describe items in the tool thereby assisting raters to score study quality. Due to under-reporting or lack of clarity in the primary study, raters will need to make judgements about the extent that bias may be present. When making judgements about each component, raters should form their opinion based upon information contained in the study rather than making inferences about what the authors intended.

A) SELECTION BIAS

(Q1) Participants are more likely to be representative of the target population if they are randomly selected from a comprehensive list of individuals in the target population (score very likely). They may not be representative if they are referred from a source (e.g. clinic) in a systematic manner (scores somewhat likely) or self-referred (score not likely).

(Q2) Refers to the % of subjects in the control and intervention groups that agreed to participate in the study before they were assigned to intervention or control groups.

B) STUDY DESIGN

In this section, raters assess the likelihood of bias due to the allocation process in an experimental study. For observational studies, raters assess the extent that assessments of exposure and outcome are likely to be independent. Generally, the type of design is a good indicator of the extent of bias. In stronger designs, an equivalent control group is present and the allocation process is such that the investigators are unable to predict the sequence.

Randomized Controlled Trial (RCT)
An experimental design where investigators randomly allocate eligible people to an intervention or control group. A rater should describe a study as an RCT if the randomization sequence allows each study participant to have the same chance of receiving each intervention and the investigators could not predict which intervention was next. If the investigators do not describe the allocation process and only use the words ‘random’ or ‘randomly’, the study is described as a controlled clinical trial.

See below for more details.

Was the study described as randomized?
Score YES, if the authors used words such as random allocation, randomly assigned, and random assignment. Score NO, if no mention of randomization is made.

Was the method of randomization described?
Score YES, if the authors describe any method used to generate a random allocation sequence.

Score NO, if the authors do not describe the allocation method or describe methods of allocation such as alternation, case record numbers, dates of birth, day of the week, and any allocation procedure that is entirely transparent before assignment, such as an open list of random numbers of assignments.

If NO is scored, then the study is a controlled clinical trial.
Was the method appropriate?
Score YES, if the randomization sequence allowed each study participant to have the same chance of receiving each intervention and the investigators could not predict which intervention was next. Examples of appropriate approaches include assignment of subjects by a central office unaware of subject characteristics, or sequentially numbered, sealed, opaque envelopes.
Score NO, if the randomization sequence is open to the individuals responsible for recruiting and allocating participants or providing the intervention, since those individuals can influence the allocation process, either knowingly or unknowingly.
If NO is scored, then the study is a controlled clinical trial.

Controlled Clinical Trial (CCT)
An experimental study design where the method of allocating study subjects to intervention or control groups is open to individuals responsible for recruiting subjects or providing the intervention. The method of allocation is transparent before assignment, e.g. an open list of random numbers or allocation by date of birth, etc.

Cohort analytic (two group pre and post)
An observational study design where groups are assembled according to whether or not exposure to the intervention has occurred. Exposure to the intervention is not under the control of the investigators. Study groups might be non-equivalent or not comparable on some feature that affects outcome.

Case control study
A retrospective study design where the investigators gather ‘cases’ of people who already have the outcome of interest and ‘controls’ who do not. Both groups are then questioned or their records examined about whether they received the intervention exposure of interest.

Cohort (one group pre + post (before and after)
The same group is pretested, given an intervention, and tested immediately after the intervention. The intervention group, by means of the pretest, act as their own control group.

Interrupted time series
A time series consists of multiple observations over time. Observations can be on the same units (e.g. individuals over time) or on different but similar units (e.g. student achievement scores for particular grade and school). Interrupted time series analysis requires knowing the specific point in the series when an intervention occurred.

C) CONFUNDERS
By definition, a confounder is a variable that is associated with the intervention or exposure and causally related to the outcome of interest. Even in a robust study design, groups may not be balanced with respect to important variables prior to the intervention. The authors should indicate if confounders were controlled in the design (by stratification or matching) or in the analysis. If the allocation to intervention and control groups is randomized, the authors must report that the groups were balanced at baseline with respect to confounders (either in the text or a table).

D) BLINDING
(Q1) Assessors should be described as blinded to which participants were in the control and intervention groups. The purpose of blinding the outcome assessors (who might also be the care providers) is to protect against detection bias.

(Q2) Study participants should not be aware of (i.e. blinded to) the research question. The purpose of blinding the participants is to protect against reporting bias.
E) DATA COLLECTION METHODS

Tools for primary outcome measures must be described as reliable and valid. If ‘face’ validity or ‘content’ validity has been demonstrated, this is acceptable. Some sources from which data may be collected are described below:

Self reported data includes data that is collected from participants in the study (e.g. completing a questionnaire, survey, answering questions during an interview, etc.).

Assessment/Screening includes objective data that is retrieved by the researchers. (e.g. observations by investigators).

Medical Records/Vital Statistics refers to the types of formal records used for the extraction of the data.

Reliability and validity can be reported in the study or in a separate study. For example, some standard assessment tools have known reliability and validity.

F) WITHDRAWALS AND DROP-OUTS

Score YES if the authors describe BOTH the numbers and reasons for withdrawals and drop-outs. Score NO if either the numbers or reasons for withdrawals and drop-outs are not reported.

The percentage of participants completing the study refers to the % of subjects remaining in the study at the final data collection period in all groups (i.e. control and intervention groups).

G) INTERVENTION INTEGRITY

The number of participants receiving the intended intervention should be noted (consider both frequency and intensity). For example, the authors may have reported that at least 80 percent of the participants received the complete intervention. The authors should describe a method of measuring if the intervention was provided to all participants the same way. As well, the authors should indicate if subjects received an unintended intervention that may have influenced the outcomes. For example, co-intervention occurs when the study group receives an additional intervention (other than that intended). In this case, it is possible that the effect of the intervention may be over-estimated.

Contamination refers to situations where the control group accidentally receives the study intervention. This could result in an under-estimation of the impact of the intervention.

H) ANALYSIS APPROPRIATE TO QUESTION

Was the quantitative analysis appropriate to the research question being asked?

An intention-to-treat analysis is one in which all the participants in a trial are analyzed according to the intervention to which they were allocated, whether they received it or not. Intention-to-treat analyses are favoured in assessments of effectiveness as they mirror the noncompliance and treatment changes that are likely to occur when the intervention is used in practice, and because of the risk of attrition bias when participants are excluded from the analysis.
**Component Ratings of Study:**

For each of the six components A – F, use the following descriptions as a roadmap.

**A) SELECTION BIAS**

**Strong:** The selected individuals are very likely to be representative of the target population (Q1 is 1) and there is greater than 80% participation (Q2 is 1).

**Moderate:** The selected individuals are at least somewhat likely to be representative of the target population (Q1 is 1 or 2); and there is 60–79% participation (Q2 is 2). ‘Moderate’ may also be assigned if Q1 is 1 or 2 and Q2 is 5 (can’t tell).

**Weak:** The selected individuals are not likely to be representative of the target population (Q1 is 3); or there is less than 60% participation (Q2 is 3) or selection is not described (Q1 is 4); and the level of participation is not described (Q2 is 5).

**B) DESIGN**

**Strong:** will be assigned to those articles that described RCTs and CCTs.

**Moderate:** will be assigned to those that described a cohort analytic study, a case control study, a cohort design, or an interrupted time series.

**Weak:** will be assigned to those that used any other method or did not state the method used.

**C) CONFOUNDERS**

**Strong:** will be assigned to those articles that controlled for at least 80% of relevant confounders (Q1 is 2); or (Q2 is 1). **Moderate:** will be given to those studies that controlled for 60–79% of relevant confounders (Q1 is 1) and (Q2 is 2). **Weak:** will be assigned when less than 60% of relevant confounders were controlled (Q1 is 1) and (Q2 is 3) or control of confounders was not described (Q1 is 3) and (Q2 is 4).

**D) BLINDING**

**Strong:** The outcome assessor is not aware of the intervention status of participants (Q1 is 2); and the study participants are not aware of the research question (Q2 is 2).

**Moderate:** The outcome assessor is not aware of the intervention status of participants (Q1 is 2); or the study participants are not aware of the research question (Q2 is 2); or blinding is not described (Q1 is 3 and Q2 is 3).

**Weak:** The outcome assessor is aware of the intervention status of participants (Q1 is 1); and the study participants are aware of the research question (Q2 is 1).

**E) DATA COLLECTION METHODS**

**Strong:** The data collection tools have been shown to be valid (Q1 is 1); and the data collection tools have been shown to be reliable (Q2 is 1).

**Moderate:** The data collection tools have been shown to be valid (Q1 is 1); and the data collection tools have not been shown to be reliable (Q2 is 2) or reliability is not described (Q2 is 3).

**Weak:** The data collection tools have not been shown to be valid (Q1 is 2) or both reliability and validity are not described (Q1 is 3 and Q2 is 3).

**F) WITHDRAWALS AND DROP-OUTS - a rating of:**

**Strong:** will be assigned when the follow-up rate is 80% or greater (Q2 is 1).

**Moderate:** will be assigned when the follow-up rate is 60 – 79% (Q2 is 2) OR Q2 is 5 (N/A).

**Weak:** will be assigned when a follow-up rate is less than 60% (Q2 is 3) or if the withdrawals and drop-outs were not described (Q2 is 4).
26 August 2015

Miss Chidiebere Nwolise
Postgraduate research student
University of Surrey
5th Floor, Duke of Kent Building
School of Health Sciences, University of Surrey
GU2 7TE

Dear Miss Nwolise

Study title: Feasibility Study Of A Smartphone Application (App) for the Preconception Care Of Women With Type 1 or Type 2 Diabetes: A Mixed Methods Study

REC reference: 15/EM/0358
Protocol number: N/A
IRAS project ID: 178530

Thank you for your letter of 25th August 2015, responding to the Proportionate Review Sub-Committee’s request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Assistant, Tad Jones, NRESCommittee.EastMidlands-Derby@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the
Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation’s role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" above).

Approved documents

The documents reviewed and approved by the Committee are:
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<th>Version</th>
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<td>Participant information sheet (PIS) [Stakeholder focus group information</td>
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<td>28 July 2015</td>
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<td>sheet]</td>
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<tr>
<td>Participant information sheet (PIS) [Intervention patient information</td>
<td>4</td>
<td>24 August 2015</td>
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<tr>
<td>sheet]</td>
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<tr>
<td>Participant information sheet (PIS) [Patient focus group information</td>
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<td>Participant information sheet (PIS) [Healthcare Professional focus group</td>
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<td>REC Application Form [REC_Form_28072015]</td>
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<td>Research protocol or project proposal [PCC-MA Feasibility Study Project</td>
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<td>Protocol]</td>
<td></td>
<td></td>
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<tr>
<td>Summary CV for Chief Investigator (CI) [Postgraduate Researcher Chidiebere Nwolise CV]</td>
<td>1</td>
<td>28 July 2015</td>
</tr>
<tr>
<td>Summary CV for supervisor (student research) [1st Supervisor]</td>
<td>1</td>
<td>28 July 2015</td>
</tr>
</tbody>
</table>
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance

We are pleased to welcome researchers and R & D staff at our NRES committee members’ training days – see details at http://www.hra.nhs.uk/hra-training/

15/EM/0358 Please quote this number on all correspondence

With the Committee’s best wishes for the success of this project.

Yours sincerely

Mrs Janet Mallett
Chair

Email: NRESCommittee.EastMidlands-Derby@nhs.net

Enclosures: “After ethical review – guidance for researchers” [SL-AR2]
Copy to: Dr Sophie Wehrens

Sarah Martin, Royal Surrey County Hospital
01 September 2015

Confirmation of sponsorship by the University of Surrey

Dear Miss Nwolise,

Study title: Feasibility Study of a Smartphone Application (app) for the Preconception Care of Women with Type 1 or Type 2 Diabetes: A Mixed Methods Study.
NHS REC reference: 15/EM/0358
University of Surrey reference: SPON/2015/003/FHMS

I am writing to confirm that the above study has satisfied the requirements of the University of Surrey Research Integrity and Governance Office. We are pleased to confirm that the University of Surrey, as a recognised Sponsor under the Department of Health’s Research Governance Framework for Health and Social Care, agrees to act as a Sponsor for your study on the basis of the documentation listed in the NHS REC Favourable Ethical Opinion letter of 26 August 2015.

Your study does not require review by a University of Surrey Ethics Committee. Permission to start recruitment is given provided that you comply with the conditions listed in your NHS REC Favourable Ethical Opinion letter and any additional condition letter(s). These conditions include, but are not limited to:

- Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.
- All clinical trials must be registered on a publically accessible database before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

Ongoing sponsorship by the University is further subject to satisfactory reporting of the following to the Research Integrity and Governance Office as well as the NHS REC where they request this:

- Submitting substantial and notifying minor amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Serious Adverse Events and Suspected Unexpected Serious Adverse Reactions
- Progress and safety reports

Miss Chidiebere Nwolise
School of Health Sciences
Faculty of Health and Medical Sciences
- Notifying the end or early termination of the study or extension of the study beyond the expected end date

Please also ensure that you and your study staff are familiar and act in accordance with the University of Surrey's Code on Good Research Practice and the Ethical Principles and Procedures for Teaching and Research.

Yours sincerely,

Dr Sophie Wehrens
Research Integrity and Governance Officer Copy to.

Dr Nicola Carey, Professor Jill Shawe
Appendix 5

Miss Chidiebere Nwolise
5th Floor, Duke of Kent Building
University of Surrey
GU2 7XH

27th January 2016

Dear Miss Chidiebere,

<table>
<thead>
<tr>
<th>Study Title</th>
<th>Feasibility study of A Smartphone Application (APP) for the Preconception Care of Women With Type 1 and Type 2 Diabetes: A mixed Methods Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRAS Number</td>
<td>178530</td>
</tr>
<tr>
<td>Sponsor</td>
<td>University of Surrey</td>
</tr>
</tbody>
</table>

Thank you for submitting details of the above study. On behalf of Surrey and Sussex Healthcare NHS Trust I am happy to advise that NHS permission for this research has been granted subject to the conditions below:

- Completed research passport in place, prior to commencement of the research at Surrey and Sussex Healthcare Trust.
- All the study materials are provided to Dr Field.

NHS permission is granted on the basis described in the NHS R&D application; research protocol; supporting documentation and correspondence with the Trust R&D Office. The documents reviewed are detailed on page 2.

Your contact at the Trust for this project is Dr Benjamin Field, Consultant in Endocrinology and Diabetes, 01737 231877. This study has been agreed on the basis that Dr Field will identify suitable patients for the study and distribute the recruitment study materials.

**Required standards**

All research must be conducted in accordance with the Research Governance Framework to ensure that the research is of a high quality and that the risks, in particular to participants, are effectively identified and managed. As the Chief Investigator, you are required to ensure you and any members of your team are adequately trained and conduct the study in accordance with Research Governance standards; Sponsor, Trust and Ethical approval conditions, Data Protection and where appropriate ICH/GCP standards. Please ensure you co-operate with monitoring and audit activities which may be undertaken by the study Sponsor, Trust or regulatory bodies.

**Changes during the study**

All changes to the protocol, study documentation or study team should be reported to the R&D Office, AD10a, Trust HQ, East Surrey Hospital, Redhill, Surrey RH1 5RH

**Results/Publications**

Please provide a copy of the final report/results to Dr Benjamin Field and the Trust R&D Office.

Yours sincerely,

Anne Shears
R&D manager

Copies to:
Dr Nicola Carey, Senior Lecturer, School of Health Science, University of Surrey,
Prof Jill Allison Shawe, School of Health Science, University of Surrey, j.shawe@surrey.ac.uk
Dr Benjamin Field, Local Collaborator, benjamin.field@sash.nhs.uk
Documents reviewed as part of the approval:
R&D Form: 178530/867940/14/402
Protocol: version2
SSI Form: 178530/873632/6/431/301966/335137
REC: Favorable Opinion letter dated: 26.08.2015
Appendix 1 for R&D approval letter dated: 1st February 2016

R&D Ref: 16DIAN0001

Study Title: Feasibility Study of a Smartphone App for the Preconception Care of Women with Type 1 or Type 2 Diabetes

The following documents have been reviewed as part of the R&D approval.

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol</td>
<td>2.0</td>
<td>24/09/2015</td>
</tr>
<tr>
<td>GP Letter</td>
<td>1.0</td>
<td>24/08/2015</td>
</tr>
<tr>
<td>Letter of invitation to participant (for focus group)</td>
<td>1.0</td>
<td>28/07/2015</td>
</tr>
<tr>
<td>Letter of invitation to participant (for intervention patients)</td>
<td>1.0</td>
<td>28/07/2015</td>
</tr>
<tr>
<td>Participant Consent Form (Intervention patient)</td>
<td>4.0</td>
<td>24/08/2015</td>
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<tr>
<td>Participant Consent Form (Healthcare Professional)</td>
<td>4.0</td>
<td>24/08/2015</td>
</tr>
<tr>
<td>Participant Information Sheet (Intervention Patient)</td>
<td>4.0</td>
<td>24/08/2015</td>
</tr>
<tr>
<td>Participant Information Sheet (Healthcare Professional Focus Group)</td>
<td>4.0</td>
<td>24/08/2015</td>
</tr>
</tbody>
</table>
Investigator Responsibilities

Study Title: Feasibility Study of a Smartphone App for the Preconception care of Women with Type 1 or Type 2 Diabetes: A Mixed Methods Study
Chidiebere Nwolise

The conditions of approval require that the Principal Investigator (PI) meeting the responsibilities listed below. Where the Chief Investigator (CI) is also located at RSCH, the CI must meet both PI and CI responsibilities. All research falls under the requirements of the research governance Framework and Good Clinical Practice and all research conducted at the RSCH must abide by the RSCH R&D policies.

Responsibilities – Chief Investigator (CI)

- Unless urgent safety measures are necessary, the research always follows the protocol agreed by the relevant ethics committee, by the Trust R&D department/s and by the sponsor
- Any substantial amendment- including change of (legal) sponsor- is approved by REC (MHRA) and all hosting R&D
- A Trial Master File is held and maintained to include all with essential documents. TMF must be stored in a secure location with authorised access only.
- CI to ensure that all PI’s have obtained local R&D approval before commencing recruitment or substantial amendment approval before implementing new document versions at their sites
- CI to ensure arrangements are in place for the management of any intellectual property arising from the research and that the findings from the work are open to critical review through the accepted scientific and professional channels, are disseminated promptly and feedback as appropriate to participants
- Periodical Reports/Updates/End of study reports must be submitted by CI; full overview see overleaf

Responsibilities- Principal Investigator (PI)

Investigator Site File (ISF)

- Set up and maintain Investigator Site File (ISF) containing the ‘essential Documents’ as listed by ICH GCP section 8.
- PI’s have obtained local R&D approval before commencing recruitment or substantial amendment approval before implementing new document versions at their sites
- Keep a copy of superseded documents versions (i.e tracking alterations, marked as superseded (dated)
- Procedures (such as SOP’s) are in place to ensure collection is high quality, accurate data and for the integrity and confidentiality of data during processing and storage
- Appropriate arrangements in place to archive the data when the research has finished and to ensure it is still accessible at the request of the inspection and auditing authorities. Study documents and source data must be retained in accordance with the Statutory Instrument.

Participants

- PI ensures research team give priority at all times to the dignity, rights, safety and well-being of participants
- Consent must be received prior to any intervention (e.g before questionnaire, fasting, tests) unless otherwise specified in REC/R&D approved protocol
- Keep screening & recruitment log (eg list patients with date approached, date screened, data recruited/consent; date withdrawn/completed).
- Record participation in patient medical records (if applicable, generate notes for healthy participants)
- Unless the REC have permitted otherwise, inform GP/healthcare team of research participation, keep log in patient notes and retain copy.

Version 1.0 04 Apr 2011
Research Team
- PI must select team as qualified by training and experience
- PI records allocated project tasks in “Delegation of Duties log”; Team member to sign and PI must countersign these duties
- Copy of Staff signed and dated CVs into ISF (update at least every 2 years)
- GCP training updated for all staff at least every 2 years (including prescribing clinicians/admin/lab)
- Document any project specific training or supervisory arrangements in ISF (On training record or file note)
- New staff/PG students: if not RSCH employee, arrange NHS access permission (i.e research passport/letter of access); seek guidance from R&D department.
- PI arranges adequate supervision for new staff/students, (for CTIMP document this is held within the ISF).
- PI’s sick/maternity/annual leave over 4 weeks must be reported to R&D
- PI ensures the research team carry out the study in accordance with the Research Governance Framework and for Clinical trials involving medicines, any conditions as imposed by MHRA.
- PI ensures adequate medical cover is in place at all times, including absences of the PI

Deviations/Breaches of GCP
- All deviations of the protocol, breaches of GCP regulations must be documented and the sponsor and R&D informed in compliance with the protocol. Copies of all documents to be retained in ISF
- Consistent and serious breaches of GCP (endangering participant safety/affecting scientific value) must be reported immediately (sponsor expedites reporting MHRA within 7 days) and R&D must be notified.

Safety Reporting
- Document all Adverse Events in ISF and medical notes
- Escalate the reporting of all serious Adverse Events (SAE, including SAR/SUSAR) to sponsor and hosting R&D; unless certain SAE excluded from escalated reporting by REC/MHRA approved protocol

Amendments – (must be acknowledged by the host R&D before they can be implemented).

Substantial amendments (including but not limited to: changes to protocol such as more/fewer tests/visits; more/fewer participants, changes to contents of PIS/consent from, risk versus benefit changes to Investigator’s Brochure, change of Sponsor, change to quality/supplier of IMP used, adding new research site, change for funding arrangements) must obtain sponsor, REC (if applicable MHRA) and finally R&D approval before implementing them

Urgent Safety measures can be implemented immediately and must be followed by a substantial amendment within 3 days

Non-substantial amendments (editorial changes, contact name/address changes) can be put in place immediately, notify sponsor, REC, R&D and send new document versions.

<table>
<thead>
<tr>
<th>Periodical Reports/Updates/End of study reports</th>
<th>CTIMP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-CTIMP</td>
<td>Only commercially sponsored, worldwide clinical trials CI sends 6 monthly Safety Reports to REC</td>
</tr>
<tr>
<td>CI sends Annual Progress Reports to REC and copy to R&amp;D</td>
<td></td>
</tr>
<tr>
<td>Any safety information, eg SAE is to be included in this progress report using NRES template</td>
<td>CI sends Annual Progress Report to REC and copy to R&amp;D</td>
</tr>
<tr>
<td><a href="http://www.nres.npsa.nhs.uk/applications/after-">http://www.nres.npsa.nhs.uk/applications/after-</a></td>
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</tr>
</tbody>
</table>

Version 1.0 04 Apr 2011
<table>
<thead>
<tr>
<th>ethcal-review/annual-progress-reports</th>
<th>CI sends Annual Safety report to MHRA (Electronically on disk- address see MHRA website), sponsor REC and each R&amp;D department</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CI/Sponsor company arranged any urgent and annual updates to Investigator Brochure (IB) and informs all PI using the same IMP (Investigational Medicinal product)</td>
</tr>
<tr>
<td>End of Study declaration to REC and R&amp;D usually after last patient last follow up visit and no later than 12 months after the end of the study End of Study Report – see REC templates on website.</td>
<td>EudraCT declaration of end of trials form to sponsor/MHRA/REC/R&amp;D within 90 days from end of trial. End of trial must be defined in protocol usually after the last patients last follow up visits</td>
</tr>
</tbody>
</table>

I agree to the terms of the Investigator Responsibilities outlined above

Signed:

Date: 25/01/2016
Dear Chidiebere,

Letter of NHS Permission at ASPH

Full Study Title: Feasibility Study Of A Smartphone Application (App) for the Preconception Care Of Women With Type 1 or Type 2 Diabetes: A Mixed Methods Study.
IRAS Project ID: 178530
REC Ref: 15/em/0358

Thank you very much for submitting your study for R&D review. I am very pleased to inform you that the Director of R&D has approved your study and the R&D office has no objection to your proceeding with this study. However, the R&D Office would highly appreciate to receive final report of your study and any dissemination(s) from this work.

Please make sure you are using the latest version of all documents and are following the latest procedures.

We wish you success with your research!

If you wish to discuss further, please do not hesitate to contact me.

Yours sincerely,

Freda Gomes
R&D Support Manager
E-Mail: Freda.Gomes@asph.nhs.uk

Cc: Prof Jill Shawe, Professor and Lead Maternal & Family Health, University of Surrey
Appendix 5
Appendix 8 – Phase 1

Healthcare Professional Information Sheet

Feasibility study of a smartphone application (App) for the preconception care (PCC) of women with Type 1 or Type 2 diabetes.

My name is Chidi Nwolise and I would like to invite you to take part in a research project that is being undertaken as part of a PhD study at the University of Surrey. Your participation in the project is entirely voluntary. Before you decide to participate it is important that you understand why the research is being done and what it will involve. Please take the time to read the following information carefully. Talk to others about the study if you wish. If there is anything that is not clear, or you would like to know about, please contact me using the contact details provided at the end of this sheet. Thank you for reading this information.

What is the purpose of the study?
Preconception care enables women to prepare themselves to become as healthy as possible before pregnancy and achieve the best outcomes for both themselves and their baby. It involves adopting actions that support a healthier lifestyle such as stopping smoking and decreasing alcohol intake, improving blood glucose levels, taking folic acid (supplements) and using contraception until stable glycaemic control (HbA1c) is attained. Despite this, preconception care services are only accessed by a small number of women. In line with recent changes in technology, smartphone applications (Apps) are increasingly being used to improve health in a number of areas. However, little is known about the use or acceptability of Apps in the preconception care of women with diabetes.

Aim of the study
This study seeks to develop, test and explore the usage of a smartphone application (App) to promote knowledge and awareness of preconception care in women with diabetes.

Why have I been chosen?
You have been chosen because you are a healthcare professional involved in the care of women with diabetes. In order to ensure the mobile App that is developed best meets the preconception care needs of women with diabetes, it is important that a wide range of expert views are sought. The information collected will be used to help inform the development of the App.

Do I have to take part?
No, you do not have to participate. If you decide to participate, you are free to withdraw at any time without giving a reason. If you withdraw from the study, data collected would be used in the study but no further data will be collected or any other research procedures carried out. There will be no impact on your employment status if you decide not to participate.
What will my involvement require?
If you decide to participate, you will be asked to take part in a discussion which will last no more than 1 hour. This will take place at a place and time convenient for you. The discussion will be audio recorded. You will be asked to discuss your views and opinions regarding the use and acceptability of an App for preconception care of women with diabetes, and information that should be included to improve the health outcomes of women and their babies.

What are the possible benefits of taking part?
The discussions will give you an opportunity to contribute to the development of a preconception care mobile App (PCC-MA) for use by women with diabetes, but otherwise you are unlikely to benefit directly from taking part in the study. If you take part, you may be helping to develop an alternative means of providing preconception care information to this high-risk group of women.

Are there any disadvantages or risks in taking part in the research?
It is unlikely that there will be any, I just need a little of your time to discuss issues regarding the content of the preconception care mobile App (PCC-MA).

Will the information you provide be passed on to anybody else?
All information provided will be treated as strictly confidential in accordance with the Data Protection Act 1998. The audio recording from the discussion will only be identified by a unique code number, not by your name, your organisation’s name or the name of the service you provide. Although what you have said may be quoted in study reports and publications, no material from which you or your service could be identified will be published.

What will happen to the results of the study?
The findings will be included in my PhD thesis, presented at conferences and submitted to medical journals for publication. A written report of the study findings will be sent to you at the end of the study. Research data will be securely stored for at least 10 years in line with university policy.

Who has reviewed the project?
The study has been reviewed and received a favourable ethical approval by East Midlands - Derby National Research Ethics Service (NRES).

What if there is a problem with the study?
If you have any concern or complaint about the way you have been dealt with during the course of the study, you can contact the researcher (Chidi Nwolise), the study supervisor (Dr Nicola Carey) or the Patients Advice and Liaison Service (PALS) using the details below.

Contacts for further information
If you are interested in taking part in this study or if you have any questions about it, please contact Chidi Nwolise using the contact details below.

Miss Chidi Nwolise  
(PhD Researcher)  
School of Health Sciences  
Faculty of Health & Medical Sciences

Dr Nicola Carey  
(Supervisor)  
School of Health Sciences  
Faculty of Health & Medical Sciences

Patients Advice and Liaison Service  
(PALS Service)  
Royal Surrey County Hospital  
Egerton Road, Guildford
Thank you for taking the time to read this Information Sheet.
My name is Chidi Nwolise and I would like to invite you to take part in a research project that is being undertaken as part of a PhD study at the University of Surrey. Your participation in the project is entirely voluntary. Before you decide to participate it is important that you understand why the research is being done and what it will involve. Please take the time to read the following information carefully. Talk to others about the study if you wish. If there is anything that is not clear, or you would like to know about, please contact me using the contact details provided at the end of this sheet. Thank you for reading this information.

What is the purpose of the study?
Preconception care enables women to prepare themselves to become as healthy as possible before pregnancy and achieve the best outcomes for both themselves and their baby. It involves adopting actions that support a healthier lifestyle such as stopping smoking and decreasing alcohol intake, improving blood glucose levels, taking folic acid (supplements) and using contraception until stable glycaemic control (HbA1c) is attained. Despite this, preconception care services are only accessed by a small number of women. In line with recent changes in technology, smartphone applications (Apps) are increasingly being used to improve health in a number of areas. However, little is known about the use or acceptability of Apps in the preconception care of women with diabetes.

Aim of the study
This study seeks to develop, test and explore the usage of a smartphone application (App) to promote knowledge and awareness of preconception care in women living with diabetes.

Why have I been chosen?
You have been chosen because you are a woman with type 1 or 2 diabetes, aged between 18-45 years.

Do I have to take part?
It is up to you whether or not to take part in this research. You are free to withdraw from the research at any time and without giving a reason. If you choose to withdraw from the study, data collected would be used in the study but no further data will be collected or any other research procedures carried out. Your decision about this will not affect the standard of care you will receive.

What will happen to me if I take part?
You will be asked to take part in a discussion which will last no more than 1 hour. This will take place at a place and time convenient for you. The discussion will be audio-recorded. You will be asked about your understanding of preconception care, and how diabetes affects pregnancy.
You will be asked about your thoughts and feelings of using an App for preconception care. This information will be used to inform the content and features of the App.

**Will my taking part in the study be kept confidential?**
All information collected during the course of the research will be kept strictly confidential and secured against unauthorised access in accordance with the Data Protection Act 1998. Identification codes will be assigned to the data to protect your anonymity.

**What are the possible benefits of taking part?**
The App is an educational tool that will educate and provide information on preconception care and risks involved in unplanned pregnancies, benefits of pregnancy planning for both the woman and child. Furthermore, if you take part, you will be contributing to the development of a tool that may be of benefit to women with diabetes, to raise awareness of preconception care, educate and aid in pregnancy planning.

**Are there any disadvantages or risks in taking part in the research?**
It is unlikely that there will be any, I just need a little of your time to discuss issues regarding the content of the preconception care mobile App (PCC-MA).

**What will happen to the results of the study?**
At the end of the study, the results will be included in my PhD thesis, published in academic journals and presented at conferences. You will not be identified in any report or publication. A written report of the study findings will be sent to you at the end of the study. Research data will be securely stored for at least 10 years in line with university policy.

**Who is organising and funding the study?**
The study is being organised by the University of Surrey and self-funded by the researcher. You will not be paid for taking part in this study.

**Ethical Review**
The study has been reviewed and received a favourable ethical approval by East Midlands - Derby National Research Ethics Service (NRES).

**What if there is a problem?**
If you have any concern or complaint about the way you have been dealt with during the course of the study or if you have an issue with the care you have received, you can contact the researcher (Chidi Nwolise), the study supervisor (Dr Nicola Carey) or the Patient Advice and Liaison Service (PALS) using the details given below.

**Contacts for further information**
If you are interested in taking part in this study or if you have any questions about it, please contact Chidi Nwolise using the contact details below:

**Miss Chidi Nwolise**
(PhD Researcher)
School of Health Sciences
Faculty of Health & Medical Sciences

**Dr Nicola Carey**
(Supervisor)
School of Health Sciences
Faculty of Health & Medical Sciences

**Patient Advice and Liaison Service**
Royal Surrey County Hospital
Egerton Road, Guildford
Thank you for taking the time to read this Information Sheet.
Phase 2

Intervention Patient Information Sheet

Feasibility study of a smartphone application (App) for the preconception care (PCC) of women with Type 1 or 2 diabetes

My name is Chidi Nwolise and I would like to invite you to take part in a research project that is being undertaken as part of a PhD study at the University of Surrey. Your participation in the project is entirely voluntary. Before you decide to participate it is important that you understand why the research is being done and what it will involve. Please take the time to read the following information carefully. Talk to others about the study if you wish. If there is anything that is not clear, or you would like to know about, please contact me using the contact details provided at the end of this sheet. Thank you for reading this information.

What is the purpose of the study?
Preconception care enables women to prepare themselves to become as healthy as possible before pregnancy and achieve the best outcomes for both themselves and their baby. It involves adopting actions that support a healthier lifestyle such as stopping smoking and decreasing alcohol intake, improving blood glucose levels, taking folic acid (supplements) and using contraception until stable glycaemic control (HbA1c) is attained. Despite this, preconception care services are only accessed by a small number of women. In line with recent changes in technology, smartphone applications (Apps) are increasingly being used to improve health in a number of areas. However, little is known about the use or acceptability of Apps in the preconception care of women with diabetes.

Aim of the study
This study seeks to develop, test and explore the usage of a smartphone application (App) to promote knowledge and awareness of preconception care in women living with diabetes.

Why have I been chosen?
You have been chosen because you are a woman with type 1 or 2 diabetes, aged between 18-45 years. You have also had diabetes for more than 6 months, own a smartphone and have indicated that you are planning a future pregnancy (in the next 5 years) or want children sometime in the future.

Do I have to take part?
It is up to you whether or not to take part in this research. You are free to withdraw from the research at any time and without giving a reason. Your decision about this will not affect the standard of care you will receive. If you choose to withdraw from the study or lose capacity to consent during the study, data collected with consent would be retained and used in the study. No further data will be collected or any other research procedures carried out.
What will happen to me if I take part?
The researcher will answer any questions you may have and if you decide to take part in the study, she will ask you to sign a consent form. During this process you will be asked if you are willing to participate in any of the following:

- Receive a demonstration from the researcher, explaining how to download and use the preconception care mobile App. You will be asked to regularly use the preconception care App by viewing the information on preconception care, diabetes and recording your blood glucose levels in the diary for 3 months. It is anticipated that you will use the App for around 5 minutes a day.
- Completing a questionnaire at the beginning and 3 months later after you have used the App. This should take about 15 minutes to complete each time and include questions about your reproductive health and preconception care. Once complete, please either hand the questionnaire to the researcher or post it back using the stamped envelope provided.
- An optional interview after you have used the App for 3 months. You will discuss your experiences of using the App including its usefulness for preconception care, as well as your ideas of how to improve it with the researcher. This will last no more than 20-30 minutes and will be audio-recorded. You can indicate if you would like to participate in an interview on the consent form.
- Having the researcher look at the data you have entered via the App for research purposes.

You may decide that you are happy to participate in some of these activities but not others. This is OK, just let the researcher know or indicate this on the consent form.

Will my taking part in the study be kept confidential?
All information collected during the course of the research will be kept strictly confidential and secured against unauthorised access in accordance with the Data Protection Act 1998. Identification codes will be assigned to the data to protect your anonymity.

What are the possible benefits of taking part?
The App is an educational tool that will educate and provide information on preconception care and risks involved in unplanned pregnancies, benefits of pregnancy planning for both the woman and child. Furthermore, if you take part, you will be contributing to the development of a tool that may be of benefit to women with diabetes, to raise awareness of preconception care, educate and aid in pregnancy planning.

Are there any disadvantages or risks in taking part in the research?
It is unlikely that there will be any, I just need a little of your time to use the App (periodically for 3 months) and answer some questions. All participants of this study are at low risk of hazards or harm.

What will happen to the results of the study?
At the end of the study, the results will be included in my PhD thesis, published in academic
journals and presented at conferences. You will not be identified in any report or publication. A written report of the study findings will be sent to you at the end of the study. Research data will be securely stored for at least 10 years in line with university policy.

**Ethical Review**
The study has been reviewed and received a favourable ethical approval by East Midlands - Derby National Research Ethics Service (NRES).

**What if there is a problem?**
If you have any concern or complaint about the way you have been dealt with during the course of the study or if you have an issue with the care you have received, you can contact the researcher (Chidi Nwolise), the study supervisor (Dr Nicola Carey) or the Patient Advice and Liaison Service (PALS), using the details given below.

**Contacts for further information**
If you are interested in taking part in this study or if you have any questions about it, please contact Chidi Nwolise using the contact details below.

<table>
<thead>
<tr>
<th>Miss Chidi Nwolise</th>
<th>Dr Nicola Carey</th>
<th>Patient Advice and Liaison Service</th>
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</thead>
<tbody>
<tr>
<td>(PhD Researcher)</td>
<td>(Supervisor)</td>
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<tr>
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<td>Senior Lecturer</td>
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<td>Medical Sciences</td>
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**Thank you for taking the time to read this Information Sheet.**
Appendix 9 – Phase 1

Healthcare Professional Consent Form

Feasibility study of a smartphone application (App) for the preconception care (PCC) of women with Type 1 or 2 diabetes

Name of Researcher: Chidi Nwolise

Please initial each box

- I confirm that I have read and understood the Information Sheet (version 4, 24/08/15) provided for the above study and have had the opportunity to ask questions and have these answered to my satisfaction.

- I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason or affecting my medical or legal rights. If I withdraw from the study, data collected would be retained and used in the study. No further data will be collected or any other research procedures carried out.

- I confirm that I have been given adequate time to consider my participation and freely consent to participating in the study.

- I agree to being involved in a discussion and for these to be audio-recorded and used for research purposes.

- I agree to anonymous quotations (taken from discussion data) to be used in publications.

- I agree to receive a written report of the study findings at the end of the study. This is optional.

  YES
  NO

- I consent to my personal data, as outlined in the accompanying information sheet, being used for this study. I understand that all personal data relating to volunteers is held and processed in the strictest confidence, and in accordance with the Data Protection Act (1998).

- I agree to respect the privacy of other participants in the study.

- I agree to take part in the above study.

_________________________  ______________________  ______________________
Name of Participant  Date  Signature

_________________________  ______________________  ______________________
Name of Person taking consent  Date  Signature

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Phase 1

Patient Consent Form

Feasibility study of a smartphone application (App) for the preconception care (PCC) of women with type 1 or 2 diabetes

Name of Researcher: Chidi Nwolise

- I confirm that I have read and understood the Information Sheet (version 4, 24/08/15) provided for the above study and have had the opportunity to ask questions and have these answered to my satisfaction.

- I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason or affecting my medical or legal rights. If I withdraw from the study, data collected would be retained and used in the study. No further data will be collected or any other research procedures carried out.

- I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the University of Surrey, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

- I agree to comply with any instruction given to me during the study and to cooperate fully with the investigators.

- I confirm that I have been given adequate time to consider my participation and freely consent to participating in the study.

- I agree to being involved in a discussion and for this to be audio-recorded and used for research purposes.

- I agree to anonymous quotations (taken from discussion data) to be used in publications.

- I agree to receive a written report of the study findings at the end of the study. This is optional.

- I consent to my personal data, as outlined in the accompanying information sheet, being used for this study. I understand that all personal data relating to volunteers is held and processed in the strictest confidence, and in accordance with the Data Protection Act (1998).

- I agree to respect the privacy of other participants in the study.

- I agree to take part in the above study.

Please initial each box

Name of Participant: __________________________ Date: ____________ Signature: __________________________

Name of Person taking consent: __________________________ Date: ____________ Signature: __________________________
Phase 2

Intervention Patient Consent Form

Feasibility study of a smartphone application (App) for the preconception care (PCC) of women with Type 1 or 2 diabetes

Name of Researcher: Chidi Nwolise

- I confirm that I have read and understood the Information Sheet (version 4, 24/08/15) provided for the above study and have had the opportunity to ask questions and have these answered to my satisfaction.

- I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason or affecting my medical or legal rights. If I withdraw from the study, data collected would be retained and used in the study. No further data will be collected or any other research procedures carried out.

- I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the University of Surrey, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

- I agree to my General Practitioner being informed of my participation in the study.

- I agree to receiving a demonstration regarding the download and use of the preconception care mobile App.

- I agree to complete 2 questionnaires at the beginning and 3 months after using the mobile App.

- I agree to participate in an interview and for this to be audio recorded, and used for research purposes. Participation in the interview is optional. YES  NO

- I agree to receive a written report of the study findings at the end of the study. This is optional. YES  NO

- I agree to having a researcher look at the data entered via the preconception care mobile App for research purposes.

- I consent to my personal data, as outlined in the accompanying information sheet, being used for this study. I understand that all personal data relating to volunteers is held and processed in the strictest confidence, and in accordance with the Data Protection Act (1998).

- I agree to take part in the above study.

_________________________  _________________________  _________________________
Name of Participant        Date                  Signature
If you are willing to participate in an interview please provide your contact details below

Contact details:

Name ........................................................................................................................................
Address ....................................................................................................................................
................................................................................................................................................
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Postcode ....................................................................................................................................
Home Telephone ......................................................................................................................
Mobile Telephone ....................................................................................................................
Email ..........................................................................................................................................
Appendix 10- Phase 1

Healthcare Professional Schedule
Title of Project: Feasibility study of a smartphone App for preconception care of women with Type 1 or 2 diabetes

1. Introduce self and project. Recap ethical issues such as confidentiality, anonymity, audio-recording of session, obtain consent and signed consent form.

2. Lets talk about preconception care (PCC)

Prompts

What do you think about PCC and diabetes?
What do you think about diabetes and pregnancy?
What is the relevance of PCC to women living with diabetes?
What information do you think these women need to know about PCC?
What information do you think they need to know about pregnancy planning?
What advice would you give on how to minimise pregnancy-related risks?
What are the most important points about diabetes, pregnancy and PCC that women need to be aware of?
Is there any other information you think women with diabetes should be aware of?

3. Lets talk about the smartphone App

Prompts

What do you think about the use of information technology (IT) to promote PCC?
What do you think about the use of a smartphone App for PCC in practice?
What do you think about adding self-monitoring features such as a blood glucose diary to the App?
Do you have suggestions for any other add-ons that may promote self-management?
How frequently should women record their blood glucose readings in the diary?
Do you have further suggestions on components or information you want incorporated in the App?
Phase 1

Patient Schedule

Title of Project: Feasibility study of a smartphone App for preconception care of women with type 1 or 2 diabetes

1. Introduce self and project. Recap ethical issues such as confidentiality, anonymity, audio-recording of session, obtain consent and signed consent form.

2. Lets talk about preconception care (PCC) and diabetes

Prompts

What do you understand about preconception care?
What do know about PCC and diabetes?
What do you know about diabetes and pregnancy?
What do you know about diabetes and folic acid intake?
What do you know about diabetes and family planning/contraception?
If you needed information on PCC, where would you get it?
If you needed information about diabetes and pregnancy, where would you get it?
If you needed contraception/family planning advice, where would you get it?
If you needed folic acid where would you get it?

3. Lets talk about the smartphone App

Prompts

What do you know about smartphone Apps?
What do you think about using an App for preconception care?
What do you think about the title of the App?
How do you think the App in general could be made more interesting?
How do you think the information pages could be made more visually appealing?
What do you think about adding self-monitoring features such as a blood glucose diary to the App and what other features would you like to see included?
Do you have any suggestions about preferred number of times to record blood glucose readings in the diary?
Do you have any other suggestions on how to improve the App?
Phase 2

Title of Project: Feasibility study of a smartphone App for preconception care of women with type 1 or 2 diabetes

Intervention Patient Interview Schedule

1. Introduce self and project. Recap ethical issues such as confidentiality, anonymity, audio-recording of interviews, obtain consent and signed consent form.

2. Let’s talk about your experience of using the smartphone App

Prompts
Can you tell me how you got on with using the App over the last few months?
How did you find navigating the pages and finding information?
What do you think about the content and functionality of the App?
Do you have any suggestions of how the App could be improved?

3. Let’s talk about the use of the App for preconception care (PCC)

Prompts
How did you find using an App for PCC?
How did you find the information on preconception care (PCC)?
How did you find the general information pages, checklists, videos and external links?
Is there any other information that you would have liked included in the App?

4. Let’s talk about the features of the App

Prompts
Can you tell me what you think about the add-on features of the App, such as blood glucose diary?
What was your experience of using the included diary to record your blood glucose?
Would this help you in the management of your diabetes?

5. Tell me about your experience of being in the study

Prompts
How did you find the overall experience of being in the preconception care mobile App (PCC-MA) feasibility study?
Is there anything you would do differently following your participation in the study?
Is there anything that I haven’t asked about regarding the use of the App for PCC of women with diabetes that you think would be helpful?
Appendix 11 – Phase 1 Healthcare Professional interview

Coding Summary By Source

Feasibility study

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And then the other side, a lot of women don’t like every time they come being asked if they are planning to get pregnant, you know. I mean even without diabetes, “oh you know, are you gonna have little ones soon?” and they are like “go away” you know.

Can you imagine having that every time? But kind of unfortunately it’s so important that it has to be mentioned. I think our doctors kind of try and you know just mention it. You know, and kind of say look just give me the nod if we are to go for this but if not, you know the drill. Yeah. So, it’s all a bit complicated but all positive

But yeah the women appreciate not being dragged up to a hospital every 5 minutes. You know the parking here is appalling and you know they’ve got other things going on. Yeah and pregnancy and preconception is supposed to be a lovely healthy time isn’t it, you don’t want to associate it with always being at a hospital, kind of almost gives you the impression that you are ill. Yeah. That’s it really.

I mean to get patient information leaflets done by the hospital, there is so many forms and things you have to do and go through. I must admit we, it sounds awful, it’s something I wanted to do, I wanted to do an up to date information for our ladies but actually having the time to research it, write it and put it through the hospital systems and all that, without being funny there is no chance. No, we are struggling just to see patients at the moment which is when diabetes UK brought out a lovely booklet for gestational diabetes, and actually what I’m trying to do is gather leaflets from all round, that companies have made and we are gonna try and look at them as an antenatal team and see which one we are happy giving out. But again that’s another piece of paper and also the lady’s got to come in and engage with us to get it
Yeah. I think some people don’t tell you they are planning a pregnancy because they don’t want a lecture and the– you know, the Spanish inquisition, sort of thing.

Yeah. A lot of ladies won’t tell people that they are trying for a baby because you don’t know how long it’s going to take, the pressure, you just keep it quiet don’t you? You don’t tell people till you’ve had your 12 weeks scan and everything is ok. I know we are healthcare professionals but there’s got to be an element to that as well. You go to your diabetes team and say oh you are trying for a baby and then you go back a year later and they go “oh you are not pregnant yet?” you know, so yeah.

**Nodes\Accessibility of care or services\Provision of Care**

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It’s so important and generally you know it can be just taking time to get their control good, getting them onto folic acid, you know. Yeah and especially ladies with type 2, younger age and women having babies later. You’ve got the risks that they might be on tablets that they shouldn’t be on for the pregnancy and that’s kind of a key thing.

**Reports\Coding Summary By Source Report**

**Nodes\Accessibility of care or services\Satisfaction in care provided or dissatisfaction**

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It’s so important and generally you know it can be just taking time to get their control good, getting them onto folic acid, you know. Yeah and especially ladies with type 2, younger age and women having babies later. You’ve got the risks that they might be on tablets that they shouldn’t be on for the pregnancy and that’s kind of a key thing.

we’ve had you know— I have been doing antenatal for 5, 6 years maybe and you know we’ve got so many of our type 1’s, type 2’s having healthy beautiful children, several, you know so they are coming back for their second and third pregnancies which is lovely. Yeah, we are very lucky here that we’ve got some midwives that try and pair up with us, you know, see our ladies, so they get a bit of continuity. Yeah.

**Nodes\Accessibility of care or services\Variation in PCC provision**

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and especially with more and more ladies with type 2, you know, now becoming pregnant, we do tend to miss them because they are managed in primary care whereas we are very pregnancy focused. You know, there is all these ladies who aren’t getting that and if a GP rang me and said “oh my lady is type 2, she wants to get pregnant”, I would be like “oh that’s great, when is she coming to have a chat with me?”

You know what I mean, we make ourselves so accessible but kind of it doesn’t happen and the type 2 ladies do tend to have quite poor control when they conceive so you know those first 12 weeks of organ forming can be– you can miss them before the lady realises she is pregnant and then they’ve had awful control, they haven’t had their folic acid, you know, yeah.
But kind of, you want to address the diabetes and you want to address the pregnancy but you also want to combine it because it is the whole package and some ladies are focused just on the diabetes whereas actually they are having this pregnancy and you know that’s the key, that’s what it’s about. The diabetes is important but you know, so it’s not—I guess not purely diabetes-driven, you know kind of linking it back to positive message of you know, yes ladies with pre-existing diabetes are at risk of all these problems you know. I mean it’s still appalling—maternal death, preeclampsia, intrauterine death, still births, you know early miscarriage, but kind of getting the preconception in there you know kind of reduces all the various risks so much. It’s so important and generally you know it can be just taking time to get their control good, getting them onto folic acid, you know. Yeah and especially ladies with type 2, younger age and women having babies later. You’ve got the risks that they might be on tablets that they shouldn’t be on for the pregnancy and that’s kind of a key thing.

but actually hopefully, you know, if you are thinking of getting pregnant you might google things at home first and you know rather than us meeting a lady when she is pregnant but now to get in there with PCC

So you would kind of hope the lady or her partner or someone will be like “well hang on if you are gonna be doing this, do a bit of research” and kind of google, and the internet and apps is the way forward,

and also it’s always about teaching.

You don’t want someone always relying on you to adjust things for them, but you want them to become independent and develop their own knowledge sort of thing.
I guess you must be able to get general apps and things for planning a pregnancy so maybe, I’m assuming I haven’t looked to see what is kind of out there to kind of combine that with the diabetes which I suppose is where you are coming from to kind of fill that gap.

I don’t see why not, even within our hospital, there are so many different groups and people you have to go through. Preconception might be easier because you are talking more about just a certain group of healthcare professionals, the obstetrics and the diabetes, but to be recommended as a hospital you know again I don’t know if it’s the patient safety group or if it would be the information governance team. It probably wouldn’t have to go through infection control but you know. I must admit I wouldn’t know, you know what I mean but there’s got to be various groups and things that it would have to go through and I guess sometimes with a lot of things we seem to trial things in the hospital, get feedback and then kind of launch them. Yeah.

I couldn’t do it professionally except the hospital was happy. Because when I’m sitting in my uniform I am representing the hospital. If I was, you know, down the park and someone didn’t know what I did and you know I was speaking to someone, I might say “oh, there is an app.” But as I say when you’ve got a registration you’ve always got to be careful what you do because you are accountable 24 hours a day and all that. But generally as long as my hospital and my team, antenatal team were happy, I would be happy to, because again it’s helping benefit women.

I guess the way to meet most people would be for the app to be free, you’ve got to put it out there haven’t you?

You know, or, yeah. Or at least very you know what I mean. If the app was £20 pounds, you’d be like no chance, so-

Every hospital is struggling financially. We are leasing resources and various things, so I must admit generally if there is a cost, combined generally it’s- yeah.

Oh definitely, definitely. but apart from that, kind of-- the reason we do this job or we work in a hospital is to make a difference and improve things with people so from that side of things you know people would be interested in everything. It’s just we’ve also got the constraint of, I mean there is a constraint on time, you’ve seen X and I, you know don’t know where to start but also we keep looking at
Kind of the things we’ve gone over to be honest. I never give out a leaflet or anything unless I’ve looked at. This might seem extreme but even the needles we supply, X and I have tested them on ourselves to check because we, not just as a healthcare professional but also as a person you want the best for your patients. So if it provided the information and kind of everything else and the hospital are happy then I’d be happy to have posters up, you know what I mean. You could, kind of, we have a meeting where we meet with the GPs and the diabetes leads in the area, it would be presented there, and kind of everything. If it kind of had the backing you know what I mean, we do our best to use it. 'Cause as I say, it makes sense.

If it say, if it got mixed in with gestational diabetes, sometimes you look at leaflets and it will talk about gestational diabetes and checking for ketones and DKA, and I’m thinking hang on that’s not appropriate— this is the company trying to get more of their ketones strips used. I’m like well actually no, I’m not scaring my ladies by giving them the wrong information. If there was an app, I would download it and have a look at it and make sure I was happy, but if it was relevant and up to date, yeah, I don’t see a problem.

I think it’s a brilliant idea. Easy to access, you know, you’ve got the information there so it’s something you can discreetly look at on your phone. It’s not like you are sitting there with a textbook on diabetes and pregnancy. It’s just something people could look up when they are, you know, commuting on the train, standing in the post office for an hour, they can look at their app which would make it kind of, a lot easier for ladies to look up things. Yeah, I think it would be good. I’ve got an app on geography, I’m trying to improve my knowledge on maps and stuffs but actually having it on my phone, you know what I mean, I must say I can’t remember the last time I did but it’s there and I can just do it. I have got a book of maps somewhere in my house but to go and find it or the time you know, you could play on the app and I don’t quite know how it relates but apps often has quizzes and questionnaires, you know something interactive whereas general leaflets and textbooks don’t and of course the updating bit, for it to be really relevant. I mean NICE guidelines have just updated so that’s kind of put so many things are now wrong— leaflet information out there. Yeah, I think an app is a lovely idea.
there is always the information and support there even if it’s a random time and I guess that comes into your own life as well. You might be looking up something for yourself and it’s not, you know it’s so much easier to do at 10 o’clock at night when you’ve finished for the day than it is you know while you are trying to work and stuff. So I guess it makes it a lot more accessible and probably not so daunting either.

You know, kind of phoning someone up and asking things, things you might think you ought to know can be a bit embarrassing and put you off whereas if you just look it up, you know at least it will give you the confidence when you then go and speak to someone like a healthcare professional. Does that kind of make sense?

If you are that way inclined, brilliant. The fact that we can upload metres nowadays is a god-send because we can literally— you know we have Diasend® and we upload and then we can print graphs, we can print charts and it’s so much better at being visual. You know if you say to a patient well your sugars are high in the morning you know, they might go “well they are low at night” but if you can kind of go well look yeah this is what’s happening and its happening because of this. You know if people can understand why you are suggesting things, then they are much more likely to you know comply or do it.

So kind of from that point of view, brilliant, and if its written down you know you can always refer back to what it says in black and white whereas when you tell people things they only take down 10% or something of what you say and you know, kind of here you might see these ladies you know once or twice or something and you want to get all the information in. We give them so many bits of paper, you know when I start my ladies on insulin and things but I do know, then you’ve got loads of bits of paper to go through whereas an app on your phone or an e-reader or something, it just, it feels easier to do. At least it does for me, you know what I mean, I can literally dip in and out when I’ve got the time rather than thinking, oh I’ve got 10 minutes, oh the paper’s at home. You know it’s generally with you isn’t it, so you can log on wherever you are and I guess kind of a lot of my ladies, it’s not, I mean it is them that’s going through the pregnancy but its them and their partner you know.

The partners are very involved, you know, want to know about their ladies’ diabetes and want to know how it’s going to affect them and their babies. You know it’s– So actually it’s something their partners as well can look at with them which will improve their experience generally.

Then, the ladies could always use various apps and things to track their blood glucose levels you know, record them and you can get meters that do bolus advice, how you calculate your rapid acting insulin, you can get those on phones, you know some people have the blood glucose metre and then the app on their phones, kind of thing and I guess you must be able to get general apps and things for planning a pregnancy so maybe, I’m assuming I haven’t looked to see what is kind of out there to kind of combine that with the diabetes which I suppose is where you are coming from to kind of fill that gap. But apart from that, I guess you’ve got the technology to be able to keep in touch with your nurses and people. A lot of our ladies are busy, you know they are working and raising other kids so being able to do things via email and being able to download the information and send it easily and quickly to us. We are in a very time-constrained world, aren’t we? Everyone’s got so much to do.
I mean at work it’s always the computer, the bleep, faxes, email, things like that. At home the only other things really are things like, I guess various apps on the phone and ipad, things like that. Yeah, I am not very technology-based I am afraid. No. That’s about it.

Apart from that I guess it’s important to cover their general health, checking what medications they are on, their control. You know we meet ladies who aren’t actually monitoring their blood sugars, they might be on metformin monotherapies and just the metformin and generally you don’t test but of course if you are planning a pregnancy, you should be testing and everything, making sure they know what their targets are, know who to contact sort of thing, where they could go for more information, maybe direct them to diabetes UK, or something, somewhere you know is reliable. So diet, meds, general health, what else? I guess the usual prepregnancy information as well because you don’t want people thinking they’ve got to have an app for their diabetes preconcept and an app for preconception generally, you know. So it would be covering things that they just generally should be considering and then having their diabetes side in there as well, like relating it, putting it in and then just the general things

if they have got any problems with their eyes and kidneys they need checking out before they conceive

Yeah and especially ladies with type 2, younger age and women having babies later. You’ve got the risks that they might be on tablets that they shouldn’t be on for the pregnancy and that’s kind of a key thing, we had GP training here the other week and that was kind of a key thing saying, actually yes we’ve got all these wonderful drugs but any woman who could potentially conceive you’ve got to think of that you know and Dr X says you are either on folic acid or you are on the pill, you know [laughter]. Those are your options sort of thing. So, if you are not trying to prevent a pregnancy, in theory you are trying for a pregnancy. Yeah so especially now we tend to put in like ACE inhibitors a lot earlier and things like that, you know. It’s got to be so careful for these women
You want to address the diabetes and you want to address the pregnancy but you also want to combine it because it is the whole package and some ladies are focused just on the diabetes whereas actually they are having this pregnancy and you know that’s the key, that’s what it’s about. The diabetes is important but you know, so it’s not— I guess not purely diabetes-driven, you know kind of linking it back to positive message of you know, yes ladies with pre-existing diabetes are at risk of all these problems you know. I mean it’s still appalling—maternal death, preeclampsia, intrauterine death, still births, you know early miscarriage, but kind of getting the preconception in there you know kind of reduces all the various risks so much.

It’s so important and generally you know it can be just taking time to get their control good, getting them onto folic acid, you know.

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If it started with, you know, ladies with diabetes are more likely to have a still–, you know what I mean, that never goes down well with me because it’s important the ladies know definitely and it’s– but at the same time it’s kind of saying these risks are– can be reduced. It is possible, that’s why we want preconception care and we would look after you during your pregnancy. Ladies with diabetes should be able to enjoy their pregnancies and have a healthy pregnancy just the same as any other lady, yeah. But sometimes you start reading and it’s just all doom and gloom and I think if that’s the first thing you read, you immediately switch off. You think I can’t deal with that, you know, because I mean how would that make you feel? Yeah, so kind of like giving all the information but I guess in a positive way.

So you would kind of hope the lady or her partner or someone will be like “well hang on if you are gonna be doing this, do a bit of research” and kind of google, and the internet and apps is the way forward, definitely, and it’s something that could be advertised in like a poster, up in the GP surgery, you know, do you have diabetes? Are you planning to get pregnant? Look at it. It’s out there kind of thing.
I guess in not so much in our area but if you were looking at it being kind of UK wide, you would also want it in different languages, you know what I mean. Like in the London area, a lot of South East Asian ladies and things and kind of, we find this with some of our things, you know, like the dietary information such as low carbs whereas actually some ethnic groups you know they are very focused on you know different cooking methods.

Like actually I’ve got one lady who has rice all day, but that’s what they do. So we are busy focusing on the evening meal and you are like “what did you have for breakfast?” and she is like “rice” and you are like “rice?” and she says “yes rice.” I have got friends from the Philippines and it’s the same, they have rice for breakfast and you are like, “ok”. So you know my other ladies I’m like “oh change your cereal to low GI, change your bread to brown” and when you are presented with rice, you are like “could you try brown rice?” It’s not like you can substitute it with much else, so yeah kind of there will be some groups that would need it in their own language, maybe some tweaks or even if it was a general app that says, is your diet like this or do you follow a more traditional diet.

That’s where maybe speaking to someone who works with ladies from South East Asia, you know things like that might help sort of thing.

I guess the way to meet most people would be for the app to be free, you’ve got to put it out there haven’t you?

Nodes\Technology-assisted PCC intervention\User engagement

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Relevant up to date information, easy to read language,

Nodes\Technology-assisted PCC intervention\User engagement\Design of PCC-MA

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Relevant up to date information, easy to read language,

you know it’s so much easier to read kind of either bullet points or short paragraphs rather than just an essay, you know. Some people are visual, aren’t they for their learning, so just making it memorable what they are reading.

That’s it really, being updated, not just being put out there but if you are providing information that is kind of, it’s not medical as such but it’s so important, it’s also kind of important to make sure that its updated and if it’s not, to put some info about when it was stopped so at least the women know when it was last updated or they know that things do change so please speak to your healthcare professional. But no that’s about it I think.
### Technology-assisted self-monitoring

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Then, the ladies could always use various apps and things to track their blood glucose levels you know, record them and you can get meters that do bolus advice, how you calculate your rapid acting insulin, you can get those on phones, you know some people have the blood glucose metre and then the app on their phones, kind of thing and I guess you must be able to get general apps and things for planning a pregnancy so maybe, I’m assuming I haven’t looked to see what is kind of out there to kind of combine that with the diabetes which I suppose is where you are coming from to kind of fill that gap.

### Blood glucose diary or log with data visualisation

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I think sometimes people go in, obviously with preconception people go in with good intentions but obviously if like it takes a while to get pregnant or whatever, they can lose interest which is, you know is obviously a bit alarming because especially with diabetics, you need to maintain and check, you need to maintain you know looking after yourself and obviously like supplementations and all things like that.

I am—I have recently charted over to the adolescence clinic from like child, child clinic. I go to the hospital I think once every 6 months to see my consultant and a dietician but I do have contact quite regularly with my diabetes nurse and the dietician. If like I have got any problems with the pump or whatever I just give them a ring and, I pretty much get an appointment that day to go in and sort out any problems.

Well when I was placed on an insulin pump, the consultant— I had like a 3 month review catch up with the consultant and she said that the, the pump was like the best thing to be on when like obviously it comes to like thinking about starting a family and things. But, I don’t know, I don’t know whether it’s because I’m like still a student they think— I haven’t really had any like advice or anything about like conceiving or like leaflets with diabetes or anything on it. My mother is a pharmacist as well so she is obviously like quite aware of the importance of obviously supplementation and things and because I think I am a dietetic student, I’m probably more aware of the importance of diabetes control but like with conception and things, but I have never, I’ve never had any like any particular input from my care team. I’ve never— nothing more than what I have learned myself.
Well, I don’t really know too much about it. I, I know obviously about the importance of like folic acid supplementation because that’s just a topic I’ve just covered now myself in university. I know, I know about like the importance of controlling your blood sugars and having HbA1c of a certain range before conceiving and things but nothing, I don’t really know too much on the subject.

I think for me is probably highlighting how little I know about this area of diabetes. I think maybe it’s different for different people, given perhaps that I’m a student. Maybe my diabetes team don’t look at me as being of childbearing age because I’m still a student, maybe all these things would become more relevant to me in a few years’ time when I graduate you know things like that. But I still think, this conversation today has highlighted to me the importance of knowing things beforehand. I think, I think people need to be aware of preconception advice, maybe not only when they are planning to have – like get pregnant then. Just in general, I think it’s a good thing to know just in general.

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Usually I, I usually google. I google quite a lot of things, I know. Dr Google in all things [laughter]. But, I- If it’s something that’s obviously diabetes-related or affecting my health, I go to the doctor or more specifically to do with my diabetes, I probably phone my nursing team or try and get an appointment with my consultant specifically.

Probably the internet.

Yeah, it’s nice like information is all concentrated in one place. Like I know, like if I’m not sure of what I’m eating and I’m not really sure on like the calories or carbohydrate content of foods, I usually just whip my phone out and have a quick look for that information which is quite handy.
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No, I think—Now I’ve decided to take part in this like study thing with you and discussing it. ’Cause it’s like I’ve thought about it a lot more over the weekend. Like, when you google it and things, there doesn’t seem to be much out there about like preconception especially with diabetes. Because obviously, it’s— it needs to be tightly controlled, you know your blood sugar and things. But there doesn’t seem to be much. I don’t know whether it’s just like the healthcare team I’m with necessarily, but I would have thought that being like a 22 year old female, they would have like warned—like talked more to me about it, and like the importance of it but there doesn’t, doesn’t seem to be much literature and things on that.

Well considering I don’t really have much in—, I have never been told much information on it. Anything really, anything that’s relevant to me, to my age, my condition, the thing, I know people, just getting the message across to people in different ways. But to me, shock tactics work. So like when I realised like, only recently I got spoken to about diabetic retinopathy and things like that and it was only when the message was delivered to me like in a shock [category?]. When you realise you know this can happen to you, then I think, I think that’s the best way, for me personally anyways, it’s the best way to get the message across and relay the importance of it and how things can and things do go wrong with, like obviously an unplanned pregnancy in diabetics.

I think for me is probably highlighting how little I know about this area of diabetes. I think maybe it’s different for different people, given perhaps that I’m a student. Maybe my diabetes team don’t look at me as being of childbearing age because I’m still a student, maybe all these things would become more relevant to me in a few years’ time when I graduate you know things like that. But I still think, this conversation today has highlighted to me the importance of knowing things beforehand. I think, I think people need to be aware of preconception advice, maybe not only when they are planning to have—like get pregnant then. Just in general, I think it’s a good thing to know just in general.

I suppose it would be things like controlling blood sugars, giving up alcohol and things, making sure you’ve got a good diet like folic acid and supplementation and giving up smoking, all the normal things really.

Mainly family planning, I think of like obviously planned pregnancy rather than an unexpected or unplanned pregnancy.
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Nodes\Expertise and knowledge about PCC for women with DM\Facilitators or barriers to PCC-MA acceptance
I think it’s probably the best way to get information across to people like myself who obviously haven’t been informed of like the importance of preconception especially in diabetes. I think if it, if it was like user friendly, not too overpowering but delivers like the main, the key information points needed. Like the absolute importance of supplementation, the importance of blood glucose control, the effect of not having blood glucose control. So, that delivered the key messages in a simple way that was, that got the message across to people who may not be, as, like understand the medical terms. Key importance really. I think it’s a good idea. To get the message out there is better than– to have some understanding is more important than having no understanding.

I think visual aids are a big thing. I think sometimes if apps have too much like detailed information, like, too much words and things that can be quite off-putting. My friend’s mum is trying to get pregnant, she like, keeps track of, like, like through visual ways, she’s got like an app that shows how the baby is developing and things like that and she finds it quite motivating. So she said to me, when you can see what’s going on inside your body through an app is more motivating. Which I think would be a good thing for diabetics, if they can understand– if they can see the baby developing through visual aids, more so than information, I think it keeps people motivated obviously to look after themselves and keeps them interested and on top of like healthcare.

Just that its relevant and easy to use obviously, people don’t want to spend hours at a time putting– inputting information into an app. if it was something that was quick and easy, just simple to use like obviously on the go and things then. Simplicity and ease of use more than anything really.

If it was too expensive, if it was slow running, if it was giving out like too much wordy information, things like that.
Yeah, I use 2 apps mainly- I use my Fitness Pal® to like calculate foods and keep track of what I’m eating. I use the Carb and Cal® app too for obviously when I need to estimate carbohydrate intake.

Yeah, it’s nice like information is all concentrated in one place. Like I know, like if I’m not sure of what I’m eating and I’m not really sure on like the calories or carbohydrate content of foods, I usually just whip my phone out and have a quick look for that information which is quite handy.

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Mainly my phone or my iPad or my laptop.

Well [laughter] I have practically got my phone glued to my hands. When I’m in Uni, I mostly use my laptop and my phone. So yeah, I have always got some sort of device on me. But like, if I need to know, if like something comes to mind that I want to think of, it’s usually my phone that I tend to use.

Yeah, I use 2 apps mainly- I use my Fitness Pal® to like calculate foods and keep track of what I’m eating. I use the Carb and Cal® app too for obviously when I need to estimate carbohydrate intake.
I think I find that mobile apps are more specific to like a certain subject. Like obviously, the Carb and Cal are specific for calculating carbs, my Fitness Pal I use that to track my exercise and obviously what I’m eating and obviously like social media. Like Instagram and things like that, which are more specific. I find apps focus on one area rather than a broad range of things if that makes sense.  

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I think it’s good to obviously include preconception information but then also continuing into the pregnancy because obviously it’s important to plan as a diabetic for pregnancy but also to provide like ongoing support to people and unto the early and later stages of pregnancy.

My mother is a pharmacist as well so she is obviously like quite aware of the importance of obviously supplementation and things...
making sure you've got a good diet like folic acid and supplementation

and because I think I am a dietetic student, I’m probably more aware of the importance of diabetes control but like with conception and things, but I have never, I’ve never had any like any particular input from my care team. I’ve never– nothing more than what I have learned myself.

I know, I know about like the importance of controlling your blood sugars and having HbA1c of a certain range before conceiving and things

I suppose it would be things like controlling blood sugars

giving up alcohol and things

giving up smoking

I like that, because I use them quite regularly and I like that they are easy to use and I know how to work it and things like that. It’s not like very complicated, I know like especially the Carb and Cal it’s got– it’s got a large database, so there is a lot of information in one place rather than going to google for instance to have to search and to find something that’s relevant to what I’m looking for, the Carb and Cal especially uses like pictures and stuff which is easy to visualise. It’s quite user friendly, it’s quite– its suits me for what I need.
No. not really. Sometimes, it can be quite limited in the information. I mean there’s a lot on apps and things but sometimes if you are looking for something a little bit more then you will need to like search, do your search. But generally, for what I use apps and things for is pretty much things that I need.

A wide variety of information available, user friendly, not too much information like no information overload, yes, easy to use. Obviously, I, sometimes I buy apps, but I— yes, and use it and things, as long as it’s not like too expensive I don’t mind paying 2 or 3 pounds for an app if I know I’m going to get good use out of it.

No not really. Just, it’s easy to use, runs well. It’s got the information I need, and it’s all relevant but not too over-powering.

I think visual aids are a big thing. I think sometimes if apps have too much like detailed information, like, too much words and things that can be quite off-putting. My friend’s mum is trying to get pregnant, she like, keeps track of, like, like through visual ways, she’s got like an app that shows how the baby is developing and things like that and she finds it quite motivating. So she said to me, when you can see what’s going on inside your body through an app is more motivating. Which I think would be a good thing for diabetics, if they can understand— if they can see the baby developing through visual aids, more than information, I think it keeps people motivated obviously to look after themselves and keeps them interested and on top of like healthcare.

Yeah, it’s nice like information is all concentrated in one place. Like I know, like if I’m not sure of what I’m eating and I’m not really sure on like the calories or carbohydrate content of foods, I usually just whip my phone out and have a quick look for that information which is quite handy.

I like that, because I use them quite regularly and I like that they are easy to use and I know how to work it and things like that. It’s not like very complicated, I know like especially the Carb and Cal it’s got— it’s got a large database, so there is a lot of information in one place rather than going to google for instance to have to search and to find something that’s relevant to what I’m looking for, the Carb and Cal especially uses like pictures and stuff which is easy to visualise. It’s quite user friendly. It’s quite— it suits me for what I need.
Well considering I don’t really have much in–, I have never been told much information on it. Anything really, anything that’s relevant to me, to my age, my condition, the thing, I know people, just getting the message across to people in different ways. But to me, shock tactics work. So like when I realised like, only recently I got spoken to about diabetic retinopathy and things like that and it was only when the message was delivered to me like in a shock [category?]. When you realise you know this can happen to you, then I think, I think that’s the best way, for me personally anyways, it’s the best way to get the message across and relay the importance of it and how things can and things do go wrong with, like obviously an unplanned pregnancy in diabetics.

I think visual aids are a big thing. I think sometimes if apps have too much like detailed information, like, too much words and things that can be quite off-putting. My friend’s mum is trying to get pregnant, she like, keeps track of, like, like through visual ways, she’s got like an app that shows how the baby is developing and things like that and she finds it quite motivating. So she said to me, when you can see what’s going on inside your body through an app is more motivating. Which I think would be a good thing for diabetics, if they can understand– if they can see the baby developing through visual aids, more so than information, I think it keeps people motivated obviously to look after themselves and keeps them interested and on top of like healthcare.

Maybe like reminders. Like I know of some, if you haven’t used it– an app for a while they give like notifications to like remind you that you know it’s still here, you can still use me sort of thing. I think that’s a good thing to have, to like, because I think sometimes people go in, obviously with preconception people go in with good intentions but obviously if like it takes a while to get pregnant or whatever, they can lose interest which is, you know is obviously a bit alarming because especially with diabetics, you need to maintain and check, you need to maintain you know looking after yourself and obviously like supplementations and all things like that so having reminders and like notifications and things would be a good thing to include.

Personally because I use a handset that comes with my pump, I tend to keep track of my blood glucose and things through that, if there could be a way of maybe like linking the two technologies together. I obviously, when I was first diagnosed, that was 15, 16 years ago or whatever it was, I- we- used to have a diary, and having a diary of pages and pages of numbers had no relevance but like now obviously with the way technology has advanced, on my handset I can see like breakdowns of my blood glucose readings over the last day, weeks, months which is quite handy, because you can see you know how it’s going and have like graphs and pie charts and things which is more handy than obviously pages of useless numbers. I suppose yes, if there was a way of maybe putting like weekly averages in or like daily averages.
with the way technology has advanced, on my handset I can see like breakdowns of my blood glucose readings over the last day, weeks, months which is quite handy, because you can see you know how it’s going and have like graphs and pie charts and things which is more handy than obviously pages of useless numbers. I suppose yes, if there was a way of maybe putting like weekly averages in or like daily averages.

**Nodes\Technology-assisted self-monitoring\Reminders**

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Maybe like reminders. Like I know of some, if you haven’t used it— an app for a while they give like notifications to like remind you that you know it’s still here, you can still use me sort of thing. I think that’s a good thing to have, to like, because I think sometimes people go in, obviously with preconception people go in with good intentions but obviously if like it takes a while to get pregnant or whatever, they can lose interest which is, you know is obviously a bit alarming because especially with diabetics, you need to maintain and check, you need to maintain you know looking after yourself and obviously like supplementations and all things like that so having reminders and like notifications and things would be a good thing to include.
Phase 2 Patient interview

Internals P16

Node

Nodes Engagement with the intervention Adherence

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</thead>
</table>

I had a similar app on an old phone and it’s no longer supported. You’d log in your details of what your scores were, you know what I mean, in a similar way to the app that you’ve got. So I found it quite simple to do, but sometimes I’d forget to put them in, so I’d sit down at the end of the week and put them all in rather than perhaps doing it at the same time, because I wouldn’t always have my phone next to me when I took readings.

Reports Coding Summary By Source Report

<table>
<thead>
<tr>
<th>Classification</th>
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<th>Coverage</th>
<th>Number Of Coding References</th>
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2  CHB  23/08/2017 11:05

I didn’t use it every day, but I would have been able to

3  CHB  23/08/2017 11:06

It was two or three times a week I would say. I’d sit down every couple of days, maybe occasionally slightly longer and put in the ones from my meter, I’d put them in.

4  CHB  23/08/2017 11:07

I would generally use it around about teatime.

5  CHB  23/08/2017 11:08

Sometimes I would use it at the time I took the readings but more often it was around teatime because I’d sit down after I’d driven home from work and just have a bit of a sit down and then I’d sit there and fill it in.

Nodes Engagement with the intervention Barriers to usage

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<th>CHB</th>
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</table>
Sometimes I forgot and I’d think oh I don’t quite have the time now, I’ll do it later on.

I’m not sure. I’m a bit rubbish at it at the moment. I think when I do get pregnant then I will be more motivated to make sure that I’m sticking to targets and things like that.

I had a lot of things going on at the time as well, so it wasn’t quite at the top of my priority list.

I had a wedding to plan, I had the end of my university year to hand in assignments for, I was doing a sponsored swim and I had to fit all these things in and just kind of forgot I guess occasionally.

It wasn’t difficult to use. I would suggest if I’d been more… I’m trying to think of the right word. It wasn’t… Ooh I’ve lost all my words, I’m terribly sorry. It would be quite easy to fit in if I made sure that I did it. I was struggling a bit to find… find the time’s not quite the right word but I think if I set my mind to it, it would be quite easy for it to fit in, it would only be another minute when I wasn’t taking my readings, so.

I had a lot of things going on at the time as well, so it wasn’t quite at the top of my priority list.

I did speak to the diabetes team, yes, and had the HbA1 thing - I can never say that right - taken and then we had a bit of a discussion about it. They were quite blunt about it and it was a little bit kind of scary I guess but they were both telling the truth but they weren’t as nice… nice is not quite the right word but your app kind of made them go, “Oh well that’s the preferred level you need to be at,” not the, ‘You’ve got to be there otherwise you can’t.’ So I just spoke to them.
I didn’t really feel very supported but I guess it was more of a question of I wasn’t at the time saying I’m trying to get pregnant, it was more of a “you’ve got to do this before you can start,” so it wasn’t very supportive at that point.

I like it. I’ve carried around a book but I either don’t have a pen or my handbag is too small for it or I’ve left it at home and it’s very rare that I leave my phone behind, so it’s always there and I can, if I remember, always put it in and it’s always there and if I don’t have an internet connection the majority of the information is there for me and I just like the fact that it’s like having all the information in a book but in a tiny place on your phone.

Quite easy to use. It looks nice, it was quite self-explanatory.

It was quite simple to do. As I said, I didn’t have a lot of motivation to do it straightaway, so occasionally it took me a while, but that’s my fault for not doing it at the time. So I would say it’s easy, I was just making my own life hard.
Quite easy to use. It looks nice, it was quite self-explanatory.

I think I will... I’m trying to think of the words, in general, take better care of me and keep taking readings and trying to take my... just being in better control of my diabetes.

I think it probably did, yes. I think, in a small part is, because I was testing it for you, it made me do it more, but being able to see what it says and it’s actually in front of me rather than having to scroll through on the meter and stuff, it definitely makes me think about it more and the fact that I need to put in the readings might remind me a little bit better to take the readings and things like that.

Because I think it drops priority for a while and because I’ve been helping you it’s made it come up to a higher priority and it’s made me think about it more and my levels are coming down, so that’s quite impressive.

The information was very good and the fact that it’s got links to things was also very good. Rather than having to search it for yourself, you could press the link and go straight there and that was really good.

I thought it was very useful actually. I’m not sure it would be very useful to somebody who was thinking about it five years down the line but maybe six months or a year before it would be better suited than in four or five years because it was all just a ‘ooh I might remember that,’ whereas things like about taking the extra folic acid, I was actually showing that to my doctor and said, “Well actually it says that we need the 5mg rather than the normal,” so I’ve had that prescribed now.
finding out about the other things and being able to log in to forums about pregnant diabetics and see what had to be said because my sugar level is slightly too high than what the doctors are recommending and I just wanted to see what other people had and whether it would be awful if it was one above what they’d asked for or not. Just being able to log in to these forums and be able to hear about other people in the same situations.

I found it very useful actually. I actually sat and read quite a lot of it one night when I couldn’t sleep and found out a lot of things that I perhaps wouldn’t have known before or things like that. So about the folic acid, it would never have occurred to me that I needed anything different. It’s one of the main things that I found out about rather than the actual while I’m pregnant stage because obviously I’m not at that stage yet. So it was interesting to know that you need to take more than you generally hear about. It wasn’t something that I had been aware of at all.

The information was very good and the fact that it’s got links to things was also very good. Rather than having to search it for yourself, you could press the link and go straight there and that was really good.

finding out about the other things and being able to log in to forums about pregnant diabetics and see what had to be said because my sugar level is slightly too high than what the doctors are recommending and I just wanted to see what other people had and whether it would be awful if it was one above what they’d asked for or not. Just being able to log in to these forums and be able to hear about other people in the same situations.

It was, yes. Logging in is not quite the right word but I used it via the app and read some of the things that came up.

I didn’t think any of it was too short, no, and it wasn’t too long and I think the fact that it got links so you could find out more was probably the perfect way for it to be, so if you did want to hear more you could go on and have a look.
I think I will... I'm trying to think of the words, in general, take better care of me and keep taking readings and trying to take my... just being in better control of my diabetes.

**Nodes**

**Future development of the intervention**

**Improvement to app features**

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I don’t think so. I don’t know whether... perhaps if you put in how far in the future you want to be pregnant and it brought up more relevant things, that could be a very useful thing, so like if I want to get pregnant in six months then maybe you need to think about folic acid, that kind of feature maybe a good one, or “now’s the time to go and get your [HbA1c]”. I can’t say it. [Laughs] I get it wrong every time and when I think about it. But perhaps a reminder to book in to get that done or something like that.

| 2  | CHB    | 23/08/2017 11:31 |

Because obviously you need to do different things at different times before you get pregnant and it could become more specific when you actually are or “here are the favourite bits for this time in your journey” I guess is one way to put it.

| 3  | CHB    | 23/08/2017 11:33 |

I don’t... Oh I just thought that maybe there could be a space so you could put in local numbers, for instance, like I’d put in my diabetic consultant’s number or some local places where perhaps I’d need to go, like see the pregnancy team at the hospital or the diabetic nurse, perhaps put their- a space to put notes maybe or contact details for people.

**Nodes**

**Future development of the intervention**

**Improvement to diary**

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It was easy enough. It would be brilliant if you could link it into a sugar monitor or from a Bluetooth sort of monitor or something so that it could automatically go in. That would make it much easier, because that would save so much time, and my monitor is tiny and fiddly and getting to go through the... if you leave it too long it will go back to the beginning again and then you have to scroll through.

| 2  | CHB    | 23/08/2017 11:33 |

I don’t... Oh I just thought that maybe there could be a space so you could put in local numbers, for instance, like I’d put in my diabetic consultant’s number or some local places where perhaps I’d need to go, like see the pregnancy team at the hospital or the diabetic nurse, perhaps put their- a space to put notes maybe or contact details for people.

**Nodes**

**Future development of the intervention**

**Improvement to PCC content**

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<td>23/08/2017 11:24</td>
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</table>

Yes, I think the more commons ones were in there and perhaps a thing to say ‘discuss anything you’re on with the doctor’ would be very useful because I didn’t realise that an antidepressant was going to be an issue. And it isn’t necessarily going to be because obviously it’s better if you are not on medication but if you are seriously depressed while you are pregnant then that’s more dangerous than if you are taking the antidepressants. It was nice to find out that oh well, perhaps I ought to look into that and discuss it with the doctor at the very least rather than just stopping it or not knowing about it.
<table>
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<th>Classification</th>
<th>Aggregate</th>
<th>Coverage</th>
<th>Number Of Coding References</th>
<th>Reference Number</th>
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</table>

I quite enjoyed it actually. I feel like I’ve helped Diabetes UK for instance and helped you and I feel good for having done it and it’s given me more information that I perhaps wouldn’t have looked at. I would have got round to it at some point but because it was in front of me and it was important to be helping you then I’ve looked at it and got all the knowledge I need probably at the right time as well.
Feasibility study of a Smartphone Application (App) for the preconception care of women with diabetes

PATIENT QUESTIONNAIRE

Instructions: Thank you for agreeing to complete this questionnaire. It is designed to assess your knowledge and attitudes to reproductive health and preconception care. The questionnaire will take about 15 minutes to complete. Please answer every question.

To return the questionnaire, either hand it to the researcher who gave it to you or post it back in the envelope provided.

Pre-conception Care Mobile App (PCC-MA)
This section is designed to explore your knowledge about how diabetes affects pregnancy. Please read each statement and mark the option that best describes your opinion. Please respond to all of the questions

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>1. Have you ever discussed how diabetes affects pregnancy with your regular diabetes health care provider? If Yes, please state who you discussed this with.</td>
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</tr>
<tr>
<td>2. Has a health care professional (doctor, nurse, etc) ever told you that you should get special medical care and advice before you become pregnant or plan for a pregnancy? This is called preconception care or pregnancy planning If Yes, please state who told you.</td>
<td></td>
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<tr>
<td>3. Has anyone else (partner, friends, family, colleagues, etc) told you that you should get preconception care (special medical care and advice) before you become pregnant or plan for a pregnancy? If Yes, please state who told you.</td>
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<tr>
<td>4. Has a healthcare professional (doctor, nurse, etc) told you that you should use some type of contraception to prevent a pregnancy? If Yes, please state who told you.</td>
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<tr>
<td>5. Has anyone else (partner, friends, family, colleagues, etc) told you that you should use some type of contraception to prevent a pregnancy? If Yes, please state who told you.</td>
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Please continue questions on next page
### Assuming you are sexually active or think back to when last you were:

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<th></th>
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<th>A little</th>
<th>Somewhat</th>
<th>A moderate amount</th>
<th>A lot</th>
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<tbody>
<tr>
<td>6. How much do/did you worry that you could become pregnant?</td>
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<td>7. How much do/did you worry that you could catch a sexually transmitted infection (eg HIV/AIDS)?</td>
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<td>8. How much do/did you worry that you could develop health problems if you become pregnant?</td>
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<tr>
<td>9. How much do/did you worry that if you become pregnant your baby could develop health problems?</td>
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### When planning a pregnancy:

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<th>Somewhat</th>
<th>A moderate amount</th>
<th>A lot</th>
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<tr>
<td>10. Would having blood sugar levels in the normal range (3.5-7.5 mmol/l) before becoming pregnant improve your chances of having a healthy baby?</td>
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<td>11. Would seeking preconception care (special medical care and advice) improve your chances of having a healthy baby?</td>
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<td>12. How difficult do you think it would be to seek preconception care (special medical care and advice)?</td>
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<td>13. How difficult do you think it would be, to follow the preconception care advice given by a health professional (e.g. attending retinal screening)?</td>
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</table>
How confident am I that I could:

14. Get preconception care (special medical care and advice) before I get pregnant.

15. Change my insulin, medication and diet to keep my blood sugar levels in normal range, even if I am not yet pregnant, but planning a pregnancy.

16. Delay becoming pregnant until my blood sugar levels are within the normal range.

Would you say that getting preconception care (special medical care and advice):

17. Would help you get normal blood sugar levels?

18. Would help you understand how diabetes affects pregnancy?

19. Would help you decide what contraception method to use?

20. Would help you prevent an unplanned pregnancy?

Section 2  
Knowledge of preconception care

This section is designed to assess your knowledge of preconception care (special medical care and advice about pregnancy planning). Please read each statement and mark the option that best describes your opinion. Please respond to all of the statements.

STATEMENT

1. Women with diabetes have very limited choices of contraception

2. Women with diabetes cannot use hormonal contraception

3. All insulin are suitable for use during pregnancy
<table>
<thead>
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<th>STATEMENT</th>
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<th>False</th>
<th>Not sure</th>
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<tbody>
<tr>
<td>4. If you have Type 2 diabetes and are planning to become pregnant you may need to change from tablets to injections of insulin</td>
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<tr>
<td>5. Women with diabetes should take folic acid daily when planning a pregnancy</td>
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<tr>
<td>6. Women with diabetes should take the same amount of folic acid as all other women planning a pregnancy</td>
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<tr>
<td>7. Before becoming pregnant, ideally your HbA1c should be below 6.5% (48.0 mmol/mol)</td>
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<tr>
<td>8. Blood glucose levels before pregnancy can affect the health of the baby</td>
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<tr>
<td>9. High blood glucose levels during pregnancy do not increase the risk of problems for the mother</td>
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<td></td>
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<tr>
<td>10. High blood glucose levels during pregnancy do not increase the risk of problems for the baby</td>
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<tr>
<td>11. Women with diabetes have an increased risk of having a large baby making delivery more difficult</td>
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<tr>
<td>12. Women with diabetes do not have an increased risk of having a baby with birth defects</td>
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<tr>
<td>13. Women with diabetes have an increased risk of miscarriage</td>
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<tr>
<td>14. All over the counter drugs are safe and can be taken by women with diabetes who are planning a pregnancy</td>
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<td>15. Women who are planning a pregnancy should discuss medication use with a healthcare provider</td>
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<td>16. Women who are planning a pregnancy should stop smoking</td>
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<tr>
<td>17. Women who are planning a pregnancy should stop drinking alcohol</td>
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<tr>
<td>18. Women with diabetes have little control over the health of their baby</td>
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<td>19. Chances of a woman having a healthy baby increase as she improves her health prior to conception</td>
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<tr>
<td>20. Women with diabetes can have a healthy baby</td>
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</table>
Below are some statements that people sometimes make when they talk about their health. Please indicate how much you agree or disagree with each statement as it applies to you personally by marking your answer. Your answers should be what is true for you and not just what you think others want you to say.

If the statement does not apply to you, mark N/A (Not Applicable)

<table>
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<tr>
<th>STATEMENT</th>
<th>Disagree strongly</th>
<th>Disagree</th>
<th>Agree</th>
<th>Agree strongly</th>
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<tbody>
<tr>
<td>1. When all is said and done, I am the person who is responsible for taking care of my health</td>
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<td>○</td>
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<tr>
<td>2. Taking an active role in my health care is the most important thing that affects my health</td>
<td>○</td>
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<td>○</td>
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<tr>
<td>3. I am confident I can help or reduce problems associated with my health</td>
<td>○</td>
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<tr>
<td>4. I know what each of my prescribed medicine does</td>
<td>○</td>
<td>○</td>
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<tr>
<td>5. I am confident that I can tell whether I need to go to the doctor or whether I can take care of a health problem myself</td>
<td>○</td>
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<tr>
<td>6. I am confident that I can tell a doctor concerns I have even when he or she does not ask</td>
<td>○</td>
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<tr>
<td>7. I am confident that I can follow through on medical treatments I may need to do at home</td>
<td>○</td>
<td>○</td>
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<td>○</td>
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<tr>
<td>8. I understand my health problems and what causes them</td>
<td>○</td>
<td>○</td>
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<td>○</td>
<td>○</td>
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<tr>
<td>9. I know what treatments are available for my health problems</td>
<td>○</td>
<td>○</td>
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<td>○</td>
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<tr>
<td>10. I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>STATEMENT</td>
<td>Disagree strongly</td>
<td>Disagree</td>
<td>Agree</td>
<td>Agree strongly</td>
<td>N/A</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
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<tr>
<td>11. I know how to prevent problems with my health</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>12. I am confident I can figure out solutions when new problems arise</td>
<td>○</td>
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<td>with my health</td>
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</tr>
<tr>
<td>13. I am confident that I can maintain lifestyle changes, like eating</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
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<tr>
<td>right and exercising, even during times of stress</td>
<td></td>
<td></td>
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</tbody>
</table>

Section 4 General Information

This section is designed to provide some basic information about who took part in the study.

1. What month and year were you born?
   ______ / ______ (Please write month/year)

2. Current marital status
   - [ ] Married/ living with partner
   - [ ] Divorced/ separated
   - [ ] Single (never married)
   - [ ] Widowed

3. Please look down the list starting from the top and tick the first educational qualification you come to that you have (Please tick one box)
   - [ ] Higher degree (M.Sc or PhD)
   - [ ] First degree (B.Sc)
   - [ ] Other diplomas
   - [ ] A / AS / S levels
   - [ ] O level / GCSE/ NVQ
   - [ ] Other academic qualifications
   - [ ] None of these qualifications

4. What is your ethnic group?
   Choose one section from (a) to (e) then tick the appropriate box to indicate your cultural background.

   a) White
   - [ ] British
   - [ ] Irish
   - [ ] Any other White background

   d) Black or Black British
   - [ ] Caribbean
   - [ ] African
   - [ ] Any other Black background
b) Mixed
☐ White and Black Caribbean
☐ White and Black African
☐ White and Asian
☐ Any other mixed background

e) Chinese or other ethnic group
☐ Chinese
☐ Any other

c) Asian or Asian British
☐ Indian
☐ Pakistani
☐ Bangladeshi
☐ Any other Asian background

5. Is English your first language?
☐ Yes
☐ No (Please give details) ________________________________________

6. Diabetes type
☐ Type 1
☐ Type 2

7. How long is it since you were diagnosed with diabetes?
☐ Less than 1 year
☐ 1-5 years
☐ Over 5 years

8. Are you currently employed?
☐ Employed full time/part-time
☐ Student
☐ Full time home-maker
☐ Unemployed

9. Currently considering or planning to have children?
☐ In less than 1 year
☐ In 1-5 years
☐ Over 5 years
☐ Do not know/unsure
☐ Do not want children
☐ My family is complete

10. Have you had any pregnancies that were not carried to term?
☐ Yes
☐ No

If yes, what was the cause? Please tick all that apply
☐ Miscarriage
☐ Ectopic pregnancy (pregnancy in tube)
☐ Still birth (i.e. birth of a baby that is not alive, past 24 weeks’ pregnancy)
☐ Fetal/congenital abnormalities

Please continue on to next page
Please indicate if you would like to receive a summary of the overall results of this survey. Please note that this information will be separated and stored separately immediately upon receipt.

☐ Yes  ☐ No

If yes, please provide your contact details in the space provided

Name ............................................................................................................

Address ........................................................................................................

............................................................................................................

Postcode ......................................................................................................

Email ...........................................................................................................

Thank you for completing this questionnaire, your help with this study is much appreciated.

To return the questionnaire, please hand it back to the researcher who gave it to you or post it back in the enclosed Freepost envelope.
Feasibility study of a Smartphone Application (App) for the preconception care of women with diabetes

PATIENT QUESTIONNAIRE 2

Instructions: Thank you for agreeing to complete this questionnaire. It is designed to assess your knowledge and attitudes to reproductive health and preconception care. The questionnaire will take about 15 minutes to complete. Please answer every question.

To return the questionnaire, either hand it to the researcher who gave it to you or post it back in the envelope provided.

Pre-conception Care Mobile App (PCC-MA)
This section is designed to explore your knowledge about how diabetes affects pregnancy. Please read each statement and mark the option that best describes your opinion. *Please respond to all of the questions*

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Since using the app, have you discussed how diabetes affects pregnancy with your regular diabetes health care provider?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If <strong>Yes</strong>, please state who you discussed this with.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Since using the app, has a health care professional (doctor, nurse, etc) told you that you should get special medical care and advice before you become pregnant or plan for a pregnancy?</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>This is called preconception care or pregnancy planning</em></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If <strong>Yes</strong>, please state who told you.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Since using the app, has anyone else (partner, friends, family, colleagues, etc) told you that you should get preconception care (special medical care and advice) before you become pregnant or plan for a pregnancy?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If <strong>Yes</strong>, please state who told you.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Since using the app, has a healthcare professional (doctor, nurse, etc) told you that you should use some type of contraception to prevent a pregnancy?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If <strong>Yes</strong>, please state who told you.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Since using the app, has anyone else (partner, friends, family, colleagues, etc) told you that you should use some type of contraception to prevent a pregnancy?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If <strong>Yes</strong>, please state who told you.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Please continue questions on next page*
Assuming you are sexually active or think back to when last you were:

<table>
<thead>
<tr>
<th>Question</th>
<th>Not at all</th>
<th>A little</th>
<th>Somewhat</th>
<th>A moderate amount</th>
<th>A lot</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. How much do/did you worry that you could become pregnant?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. How much do/did you worry that you could catch a sexually transmitted infection (eg HIV/AIDS)?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. How much do/did you worry that you could develop health problems if you become pregnant?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. How much do/did you worry that if you become pregnant your baby could develop health problems?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

When planning a pregnancy:

<table>
<thead>
<tr>
<th>Question</th>
<th>Not at all</th>
<th>A little</th>
<th>Somewhat</th>
<th>A moderate amount</th>
<th>A lot</th>
</tr>
</thead>
<tbody>
<tr>
<td>10. Would having blood sugar levels in the normal range (4.0 - 7.5 mmol/l) before becoming pregnant improve your chances of having a healthy baby?</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>11. Would seeking preconception care (special medical care and advice) improve your chances of having a healthy baby?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. How difficult do you think it would be to seek preconception care (special medical care and advice)?</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>13. How difficult do you think it would be, to follow the preconception care advice given by a health professional (e.g attending retinal screening)?</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

*Please continue questions on next page*
This section is designed to assess your knowledge of preconception care (special medical care and advice about pregnancy planning). Please read each statement and mark the option that best describes your opinion. *Please respond to all of the statements*

<table>
<thead>
<tr>
<th>STATEMENT</th>
<th>True</th>
<th>False</th>
<th>Not sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Women with diabetes have very limited choices of contraception</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2. Women with diabetes cannot use hormonal contraception</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>3. All insulin are suitable for use during pregnancy</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>STATEMENT</td>
<td>True</td>
<td>False</td>
<td>Not sure</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
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<td>----------</td>
</tr>
<tr>
<td>4. If you have Type 2 diabetes and are planning to become pregnant you may need to change from tablets to injections of insulin</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>5. Women with diabetes should take folic acid daily when planning a pregnancy</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>6. Women with diabetes should take the same amount of folic acid as all other women planning a pregnancy</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>7. Before becoming pregnant, ideally your HbA1c should be below 6.5% (48.0 mmol/mol)</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>8. Blood glucose levels before pregnancy can affect the health of the baby</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>9. High blood glucose levels during pregnancy do not increase the risk of problems for the mother</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>10. High blood glucose levels during pregnancy do not increase the risk of problems for the baby</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>11. Women with diabetes have an increased risk of having a large baby making delivery more difficult</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>12. Women with diabetes do not have an increased risk of having a baby with birth defects</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>13. Women with diabetes have an increased risk of miscarriage</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>14. All over the counter drugs are safe and can be taken by women with diabetes who are planning a pregnancy</td>
<td>○</td>
<td>○</td>
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</tr>
<tr>
<td>15. Women who are planning a pregnancy should discuss medication use with a healthcare provider</td>
<td>○</td>
<td>○</td>
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</tr>
<tr>
<td>16. Women who are planning a pregnancy should stop smoking</td>
<td>○</td>
<td>○</td>
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</tr>
<tr>
<td>17. Women who are planning a pregnancy should stop drinking alcohol</td>
<td>○</td>
<td>○</td>
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</tr>
<tr>
<td>18. Women with diabetes have little control over the health of their baby</td>
<td>○</td>
<td>○</td>
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</tr>
<tr>
<td>19. Chances of a woman having a healthy baby increase as she improves her health prior to conception</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>20. Women with diabetes can have a healthy baby</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>
Below are some statements that people sometimes make when they talk about their health. Please indicate how much you agree or disagree with each statement as it applies to you personally by marking your answer. Your answers should be what is true for you and not just what you think others want you to say.

If the statement does not apply to you, mark N/A (Not Applicable)

<table>
<thead>
<tr>
<th>STATEMENT</th>
<th>Disagree strongly</th>
<th>Disagree</th>
<th>Agree</th>
<th>Agree strongly</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. When all is said and done, I am the person who is responsible for taking care of my health</td>
<td></td>
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<tr>
<td>2. Taking an active role in my health care is the most important thing that affects my health</td>
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<tr>
<td>3. I am confident I can help or reduce problems associated with my health</td>
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<td></td>
<td></td>
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<tr>
<td>4. I know what each of my prescribed medicine does</td>
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<td>5. I am confident that I can tell whether I need to go to the doctor or whether I can take care of a health problem myself</td>
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<td>7. I am confident that I can follow through on medical treatments I may need to do at home</td>
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<td>10. I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STATEMENT</td>
<td>Disagree strongly</td>
<td>Disagree</td>
<td>Agree</td>
<td>Agree strongly</td>
<td>N/A</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------</td>
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<tr>
<td>11. I know how to prevent problems with my health</td>
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<td>12. I am confident I can figure out solutions when new problems arise with my health</td>
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<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>13. I am confident that I can maintain lifestyle changes, like eating right and exercising, even during times of stress</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

On a scale from 0 [not satisfied at all] to 100 [completely satisfied] how satisfied were you with the overall app?

[ ]

Please list any other suggestions for app improvement

……………………………………………………………………………………………………………………
……………………………………………………………………………………………………………………
……………………………………………………………………………………………………………………

Do you have any additional comments?

……………………………………………………………………………………………………………………
……………………………………………………………………………………………………………………
……………………………………………………………………………………………………………………
……………………………………………………………………………………………………………………

Thank you for completing this questionnaire, your help with this study is much appreciated.

To return the questionnaire, please post it back in the envelope provided.
### Appendix 13 - Full list of suggested app content

<table>
<thead>
<tr>
<th>Content / Frequency</th>
<th>Illustrative Quote</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1. Antenatal Care (HCPs, n=4)</td>
<td>Informing them they have to have more regular check-ups, they’ve got to monitor their fetal movements and everything … Inform anybody if there is anything that is of concern. [HCP2]</td>
</tr>
</tbody>
</table>
| #2. Assessments, Vaccinations & Check-ups (HCPs, n=5) | Type 1 diabetes will require ophthalmic assessments, checking kidney function is also good practice … because it’s an autoimmune condition, and so you want to make sure that they don’t have coexisting underactive thyroid. [HCP5]  
- There are certain tests that you should have. A lot of women don’t know what checks they should be having and obviously if they are not given that information, then that might be quite useful. [P3] |
| #3. Contraception (HCPs, n=3) | You are either on folic acid or you are on the pill, those are your options [HCP7] |
| #4. Diabetes and pregnancy information (HCPs, n=3; women, n=5) | It will be useful if it extended to … when you did become pregnant, that information is quite useful as well … and also its important that there is the general information and then if you needed more information, links to where you can go … so it would be good to have the basics and if you wanted more complicated stuffs, it would link into it. [P9]  
- Making sure that … their diabetes is well controlled and that they are healthy going into pregnancy and that they try and maintain that during the pregnancy, so that they continue to get support from their midwives and the diabetes consultants, so it’s an ongoing process. [HCP4] |
| #5. Frequently asked questions (FAQs, women, n=2) | If you could put frequently asked questions or maybe upload questions and if you had any kind of queries you could look them up in the app … that would be quite useful. [P6] |
| #6. Folic acid supplementation (HCPs, n=6; women, n=3) | A lot of ladies with diabetes need to be on 5mg of folic acid, rather than the 400 microgrammes that is readily available over the counter, so they need to go ask for it be specifically prescribed. [HCP6]  
- Letting people know that they need to start folic acid because … people don’t know this.” [P5] |
| #7. Foods to eat or avoid (HCPs, n=3; women, n=6) | Just the general advice that you will give them about avoiding certain foodstuffs e.g non-pasteurised. [HCP4]  
- If there was anything that I should or shouldn’t eat. I think that changes year on year doesn’t it? I think when I had one of my children, you could eat eggs and when I had the next one, you couldn’t or the other way around. [P3] |
| #8. Good blood glucose control (HCPs, n=8; women, n=5) | I think the main thing is, with diabetes, your control has got to be absolutely optimal in order to achieve a pregnancy in the first place and it’s vital that in order to make sure the baby grows within the right parameters that your blood sugar is kept absolutely perfect and the HbA1c is good throughout the pregnancy. [HCP2]  
- Just to make women aware of the dangers of not keeping their levels within range. [P8] |
| #9. Hypoglycaemia (HCPs, n=3; women (n=2) | I think it’s being clear about the targets pre and post prandially … so it’s having all those, the targets there but then it’s the means to get there but not go too low that you are risking hypos all the time. [HCP8]  
- Positive support around the benefits of maintaining blood glucose levels … hypo risks, obviously I know sort of certainly in the first trimester of pregnancy, you are much more likely to have a lot of hypos. [P7] |
<p>| #10. Lifestyle modification (HCPs, n=7) | They have to know of lifestyles factors that will improve their health status, so avoid things like smoking, excessive alcohol intake, be advised that they take folic acid, yes, healthy diet in general, exercise, so it’s more of health promotion together with their specific medical needs, yeah. [HCP5] |</p>
<table>
<thead>
<tr>
<th>#</th>
<th>Category</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>#11</td>
<td>Medication compliance (HCPs, n=4)</td>
<td>Also making sure that they are taking their medications, to help maintain their sugars within acceptable range. [HCP5]</td>
</tr>
<tr>
<td>#12</td>
<td>Medication review (HCPs, n=5)</td>
<td>Some of the medication does have to be changed because some of the medications they can't take during pregnancy, so things like, the prime one is the ACE inhibitor that they may take for hypertension and renoprotection, and a lot of the hypertension medication, you shouldn’t take during pregnancy, and their insulin requirements may change. [HCP4]</td>
</tr>
<tr>
<td>#13</td>
<td>Obstetric complications (HCPs, n=5)</td>
<td>To be aware that their medical condition puts them at greater risk with the pregnancy and the delivery, there is higher instance of stillbirth, higher instance of having a baby being induced and having a baby early, there is higher instance of overweight babies. [HCP2]</td>
</tr>
<tr>
<td>#14</td>
<td>PCC education (women, n=5)</td>
<td>I think just the awareness and education for women ... There should be more education especially pre-pregnancy and during pregnancy. [P8] I think the educational side because I think it’s not something that I know of personally, it’s not something I know much about. [P1]</td>
</tr>
<tr>
<td>#15</td>
<td>Rapport with HCPs (clinicians, n=8)</td>
<td>An app would be brilliant in saying to them or saying in there that actually there is always someone like me on the end of the phone. [HCP7] And if they have problem, yes they can have someone to talk to. [HCP3]</td>
</tr>
<tr>
<td>#16</td>
<td>Social support (women, n=4)</td>
<td>Letting them know of other people they could talk to ... just trying to get people’s own experiences and advice of what they’ve gone through and how they’ve handled it, and the emotional support as well ... being able to communicate freely and confidentially with other people. [P9]</td>
</tr>
</tbody>
</table>
Appendix 14 – Additional PADI app snapshots

Diabetes is a condition characterised by a high level of glucose in the blood. It occurs when the body does not produce sufficient insulin or there is reduced action of the insulin that is produced. Insulin is responsible for regulating blood glucose levels. It helps the body use glucose for energy. When the overall quantity of insulin produced by the body is inadequate to maintain normal blood glucose levels, this is known as insulin resistance.

Types of diabetes

- Type 1 diabetes: the body produces insufficient or no insulin. This is usually treated with insulin.

- Type 2 diabetes: the body does not properly use the insulin produced and is usually characterised by insulin resistance. It is treated with diet, oral treatment with diet and exercise. Some women may need oral drugs and insulin.

Symptoms

Increased appetite, increased urination, thirst, increased fluid intake, blurred vision, poor wound healing, feeling of tiredness and unease, weight loss, weakness and fatigue.

This app is mainly designed for women who develop diabetes before pregnancy (type 1 or 2) as it is important that these pregnancies are carefully planned. Good diabetes management and planned pregnancy can improve the health of women and their babies.

Women with diabetes can have a healthy pregnancy and baby! Click here to watch Becca’s inspirational video.

You are more likely to have a healthy pregnancy and baby with good medical care and advice before you become pregnant, also known as preconception care. Problems experienced by women with diabetes during pregnancy are often caused by poorly controlled blood glucose levels before and during pregnancy.

High blood glucose levels can cause problems for the baby, especially in the first 8 weeks of pregnancy when organs such as brain, lungs, heart and kidneys develop, because the excess glucose passes from the mother to the baby through the placenta.

You may not realise that you are pregnant until 5 or 6 weeks after conception. This is why it is important that you pay special attention to your health and achieve improved blood glucose levels before you become pregnant.

For more information on diabetes and pregnancy, see Diabetes UK.

High blood glucose levels before and during pregnancy can place extra burden on existing diabetes complications such as retinal (eye) or kidney (renal) problem.

Establishing good blood glucose control before conception and maintaining this throughout pregnancy can reduce the risk of complications to you such as miscarriage, pregnancy-induced hypertension and preterm delivery, and decrease the risk of a still birth, birth defects, or neonatal death.
**Blood glucose management**

When planning to become pregnant, discuss your blood glucose target with your doctor, as well as how often to monitor your blood glucose levels using a blood glucose meter.

The National Institute for Clinical Care and Excellence (NICE) recommend the following blood glucose levels for women with diabetes planning a pregnancy:

- 4-7 mmol/l before meals and 5-9 mmol/l after meals

When you maintain your blood glucose levels as close to the recommended range as possible before and during pregnancy, the risk of birth defects and complications is reduced and almost the same as in women who do not have diabetes.

It is good practice to check your blood glucose levels several times a day for example, before breakfast, an hour after each meal and before driving. If you are treated with insulin, it is also important to check your blood glucose level before going to bed. You can use the blood glucose diary included in this application (App) to record and keep track of both the time and results. This can help you monitor your blood glucose levels. If you have any questions about your test results, speak to a member of your healthcare team.

**HbA1c test**

The HbA1c, known as glycated haemoglobin, provides another way of checking your glucose level to see if you are meeting your targets. The result of your HbA1c test reflects the levels of glucose in your blood over the past 2-3 months. You

**Hypoglycaemia**

When the glucose level in the blood is too low (less than 4mmol/l), this is called hypoglycaemia or 'hypo'. It is usually mild and can be self-managed. It can cause increased heart rate, sweating, headaches and trembling. It can be treated quickly by taking foods or drinks containing sugar such as fruit juice. After taking something sugary, you may need to have a longer-acting 'starchy' carbohydrate food such as a sandwich or a few biscuits. The starch and sugar present in these products can help bring your blood glucose level back to normal (5-9 mmol/l). The best way to avoid hypos is by regular blood glucose measurement. For more information, see [NHS choices (hypoglycaemia: low blood sugar)](https://www.nhs.uk/conditions/hypoglycaemia-low-blood-sugar/).
Contraception

It is important to always use contraception and to use it correctly, until you are ready to get pregnant. With contraception, you can prevent an unplanned pregnancy by delaying conception until your HbA1c is within the level suggested by your doctor or nurse. Although you have the same contraception choices as women without diabetes, they do have different risks and benefits. There are 15 different methods of contraception that you can use:

- **Methods with user failure** depend on you remembering to take them. These are long acting reversible contraceptives (LARC): contraceptive injection, contraceptive implant, intrauterine device (IUD, coil) and intrauterine system (IUS). Others are female sterilisation (tubal occlusion) and male sterilisation (vasectomy).

- **Emergency contraception** is needed if you had unprotected sexual intercourse or there was a failure with your contraception and you do not wish to become pregnant. These include emergency contraceptive pills (i.e. Levonelle and ellaOne) and the emergency IUD. These are effective if Levonelle is taken within 3 days (72 hours) and IUD is fitted or ellaOne is taken within 5 days (120 hours) of the sexual activity or contraceptive failure.

The LARCs are very effective. Your fertility usually returns very quickly when you stop them, except the ‘injection’, where normal fertility may be delayed for a few months. The injection is not always recommended because it may affect your blood fat (lipids). Regular blood tests are recommended if you choose this method. The injection, implant, IUS, IUD, COCP, POP, vaginal ring, patch and emergency contraceptive pills (ellaOne, levonelle) are hormonal contraceptives containing progestogen, estrogen or both.

The combined oral contraceptive pill (COCP) is safe and a good contraceptive choice for women with uncomplicated, well-controlled type 1 or type 2 diabetes. However, it is not advised if you are over 35 years, very overweight with a BMI of more than 30, or have complications affecting your eyes, kidney, heart or nerves. In which case, the other methods may be more suitable for you.

IUS, IUD, COCP, POP, vaginal ring, patch and emergency contraceptive pills (ellaOne, levonelle) are hormonal contraceptives containing progestogen, estrogen or both.

No one method is 100% effective. The success or failure of contraception depends on how you use them, especially user-dependent methods. For more information, see advice on choice of contraceptive method from the Family Planning Association.
**Folic acid** (vitamin B9) is a very important vitamin for you to start taking at least 3 months before and 3 months into your pregnancy to prevent your baby from having birth defects of the brain and spinal cord. To prepare your body for a healthy pregnancy, you should take 5mg folic acid every day. To help you remember to take your vitamins, you can:

- Place them by your toothbrush or on the kitchen counter.
- Take them when you are taking your insulin.

You should ask your doctor or nurse to prescribe you 5mg folic acid as this is a higher dose and is not available to buy over the counter.

Speak to your healthcare team about the use of all medication that you are taking. Your doctor will tell you which, if any medication you may need to change when planning a pregnancy.

- **Diabetes medication:** insulin is considered the main medication of choice in managing type 1 diabetes and also used in the treatment of type 2 diabetes. Some insulins are safe for use in pregnancy. If you are using insulin, you may need to change the type, amount, time and method of use. Oral diabetic drugs are often used as an alternative to insulin in type 2 diabetics such as metformin and sulphonylureas. Metformin is considered safe for use during pregnancy.

- **Other medication:** anti-hypertensives such as Angiotensin Converting Enzyme (ACE) inhibitors, anti-malarials and drugs that control cholesterol, statins are not recommended as they may cause birth defects. If you are on ACE inhibitors or statins, please contact your doctor to discuss other options before conception.

- **Over-the-counter supplements should be avoided and only used when you have discussed with your doctor.**

It is important for you to adopt and maintain a healthy lifestyle such as becoming more active, reducing/stopping alcohol consumption, quitting smoking and eating right, when planning a pregnancy.

- **Exercise**

Physical activity lowers your blood glucose level, blood pressure and cholesterol levels. You should aim for 30 minutes of moderate exercise 5 or more days per week. This can be exercise that makes you slightly out of breath and increases your heart rate such as brisk walking, swimming, gardening, cycling and stair climbing. For more information, see [Diabetes UK](https://www.diabetes.org.uk).

- **Smoking**

Cigarette smoking is not healthy for you and can also be harmful to your unborn baby. If you smoke, wanting to have a baby is a
Lifestyle modification

• Smoking

Cigarette smoking is not healthy for you and can also be harmful to your unborn baby. If you smoke, wanting to have a baby is a good reason to quit. It can increase complications and health problems related to diabetes. It can also delay conception and cause pre-term delivery for you or cause a low birth weight and possible birth defects for the baby. Although it can be difficult to stop, your healthcare team can advise you on options. You can also find a support person or group. For more information, visit www.smokefree.nhs.uk, http://www.quit4life.nhs.uk, or call the NHS smoking helpline on 0800 022 4 332.

• Alcohol intake

Avoid drinking alcohol while trying to get pregnant and throughout pregnancy as this can cause health problems for you and your baby. If you drink, aim to stop immediately if you find yourself pregnant before planned. No known safe level exists for alcohol during pregnancy. Visit the NHS website for more information on alcohol in pregnancy, and tips on cutting down, or call NHS Drinkline for support on 0300 123 1110.

• Diet

As you prepare for pregnancy, it is important that you try to adopt a healthy eating plan as this will help you manage your blood glucose levels. Your doctor or dietician can help you plan your diet. You don’t need a special diet, however it is important to eat a mixed healthy diet such as pasta, bread, rice, pasteurised milk, yoghurt, hard cheese, fruits and vegetables and avoid foods such as liver, unpasteurised and soft cheeses, undercooked meats and eggs, as these may harm the unborn baby. You should also cut down on your caffeine intake including tea, chocolates and some soft drinks. For more information see, Women With Diabetes. For general information on eating a healthy diet, see Diabetes UK.

• Healthy Weight

A healthy body weight is both important before and during pregnancy. Attaining and maintaining a healthy body weight would help to prevent complications during pregnancy, and involves eating healthily and being physically active. The National Institute for Clinical Care and Excellence (NICE) recommends that women with a body mass index (BMI) above 27Kg/m² lose weight before conception. The BMI is a convenient method of assessing your weight and it is your weight in kilograms divided by the square of height in metres. You can talk to your doctor or nurse about ways to reach and maintain a healthy weight. For more information on healthy weight, see NHS choices (what is the BMI?)
### My check-ups

Health problems related to your diabetes can affect or complicate your pregnancy. Some diabetes-related problems can also get worse during pregnancy. Before you get pregnant, ask your doctor or nurse to check the following:

- Average blood glucose level (HbA1c)
- Your vaccinations (these are immunisations/injections to prevent diseases) especially vaccination against rubella, also known as German measles.
- Sexually transmitted infections (STIs) or HIV/AIDS
- Eye disease (retinopathy)
- Kidney disease (nephropathy)
- Nerve damage (neuropathy)
- High blood pressure (hypertension)
- Blood fats (lipids)
- Thyroid function test (blood test to check the function of the thyroid gland)

For more information on preventing complications and staying healthy before pregnancy, see the [NICE Guidelines](#).

### Immunisations/injections to prevent diseases

- Sexually transmitted infections (STIs) or HIV/AIDS
- Eye disease (retinopathy)
- Kidney disease (nephropathy)
- Nerve damage (neuropathy)

### Planning my pregnancy

- I will ensure proper control of my blood glucose level 3 to 6 months before trying to conceive.
- I will plan my pregnancy and use contraception to avoid getting pregnant before I am ready.
- I will adopt a healthier lifestyle and reach a healthy weight before I get pregnant.

### My healthcare team

- I will ensure that I have the right healthcare team (GP, diabetes consultant, diabetes specialist nurses and midwife, dietician).
- I will make regular contact with my healthcare team.

### My blood glucose levels

- I will monitor my blood glucose regularly.
- I will set targets for my daily blood glucose levels with my doctor or nurse.
- I will set a target for my HbA1c level with my doctor or nurse.

### Smoking

- If I smoke, I will quit.
- I will speak to my doctor about quitting.

### My diet plan

- I will take 5mg folic acid supplement daily before I get pregnant. I will continue to take folic acid during the first 3 months of my pregnancy.
My preconception care checklist

- I won't consume alcohol during pregnancy.

My physical activity
- I will speak to my doctor about physical activities I can do and that are safe.
- I will make a plan for regular physical activity and exercise regularly.

My medication
- I will speak to my doctor about my diabetes medication and how to take them correctly.
- I will talk to my doctor about other medication and over the counter drugs that I am currently taking.

Screening
- I will attend retinal screening

Health problems related to your diabetes can affect or complicate your pregnancy. Some diabetes-related problems can also get worse during pregnancy. Before you get pregnant, ask your doctor or nurse to check the following:

- Average blood glucose level (HbA1c)
- Your vaccinations (these are immunisations/injections to prevent diseases) especially vaccination against rubella, also known as German measles.
- Sexually transmitted infections (STIs) or HIV/AIDS
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For more information on preventing complications and staying healthy before pregnancy, see the NICE Guidelines

Planning my pregnancy

- I will ensure proper control of my blood glucose level 3 to 6 months before trying to conceive.
- I will plan my pregnancy and use contraception to avoid getting pregnant before I am ready.
- I will adopt a healthier lifestyle and reach a healthy weight before I get pregnant.

My healthcare team

- I will ensure that I have the right healthcare team (GP, diabetes consultant, diabetes specialist nurses and/midwife, dietician).
- I will make regular contact with my healthcare team.
• I won’t consume alcohol during pregnancy.

My physical activity
• I will speak to my doctor about physical activities I can do and that are safe.
• I will make a plan for regular physical activity and exercise regularly.

My medication
• I will speak to my doctor about my diabetes medication and how to take them correctly.
• I will talk to my doctor about other medication and over the counter drugs that I am currently taking.

Screening
• I will attend retinal screening

Becca’s story “rebels rebal’” is available on the diabetes UK website. You can also visit the site to meet other women with diabetes who share their own views and experiences.

A pregnancy usually has 3 trimesters and many women want to know what to expect during each trimester of their pregnancy and delivery. To find out more about what to expect during pregnancy, delivery and post-delivery, as well as when you attend the joint antenatal-diabetes clinic, visit Women with Diabetes to view the respective videos. Also see, the NICE Guidelines for more information.

Planning your pregnancy is important for you and your baby. Here are a few preconception care tips to help you get started:

• Control your blood glucose before you become pregnant. High blood glucose levels especially in the first few weeks of pregnancy can be harmful to your baby even before you know you are pregnant.

• Maintain your blood glucose level as close to the recommended range as possible before and during pregnancy. This is the most important thing you can do to stay healthy for you and your baby.

• Use contraception to avoid unplanned pregnancy.
Preconception care tips

Planning your pregnancy is important for you and your baby. Here are a few preconception care tips to help you get started:

- Control your blood glucose before you become pregnant. High blood glucose levels especially in the first few weeks of pregnancy can be harmful to your baby even before you know you are pregnant.
- Maintain your blood glucose level as close to the recommended range as possible before and during pregnancy. This is the most important thing you can do to stay healthy for you and your baby.
- Use contraception to avoid unplanned pregnancy.
- Use contraception to avoid unplanned pregnancy.
- Prepare yourself for pregnancy by adopting and maintaining healthy behaviours.
- Take 5mg folic acid.
- Maintain regular contact with members of your healthcare team (GP, diabetes consultant, diabetes specialist nurses and midwife, dietitian) as they can ensure you get the care you need before and during pregnancy.
- Speak to your doctor about any medication or over the counter drug you are using when planning a pregnancy.

FAQs

Q. How much alcohol can I consume?
It is good to reduce or stop your alcohol consumption before pregnancy because no known safe level exists for alcohol consumption during pregnancy.

Q. Can I still take caffeine?
Cutting down on your caffeine intake when planning a pregnancy is good practice as caffeinated drinks may make your diabetes control difficult especially during pregnancy. Studies also show caffeine consumption before pregnancy increases risk of miscarriage.

Q. When should I start taking 5 mg folic acid?
You should start taking 5mg folic acid at least 3 months before and 3 months into your pregnancy to prevent neural tube defects and aid your baby's healthy development. You can ask your doctor or nurse for a free prescription.

Q. How often should I measure my blood glucose level?
Ensuring your blood glucose level is as close to the recommended range as possible before and during pregnancy is the most important thing you can do to stay healthy for you and your baby, as research shows this can prevent birth defects and complications. It is good to measure and record your blood glucose levels regularly and as often as advised by your doctor or nurse.
<table>
<thead>
<tr>
<th>Q. How often should I measure my blood glucose level?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ensuring your blood glucose level is as close to the recommended range as possible before and during pregnancy is the most important thing you can do to stay healthy for you and your baby, as research shows this can prevent birth defects and complications. It is good to measure and record your blood glucose levels regularly and as often as advised by your doctor or nurse. Checking your blood glucose level several times a day can help to prevent low or high blood sugar.</td>
</tr>
<tr>
<td>Q. What are the effects of over-the-counter medications?</td>
</tr>
<tr>
<td>Over-the-counter medications should be avoided when you are planning a pregnancy as they may have different effects depending on the medication. Any medication should only be taken after talking to a doctor or nurse.</td>
</tr>
<tr>
<td>Q. Why do I need contraception?</td>
</tr>
<tr>
<td>Regular use of contraception can help to prevent unplanned pregnancy until your blood glucose level is within the recommended range.</td>
</tr>
<tr>
<td>Q. Why do I need to eat a healthy diet?</td>
</tr>
<tr>
<td>Eating a mixed diet that is low in fat, salt and sugar and rich in fruits and vegetables can help you manage your blood glucose level. Also, eating fresh fruits and vegetables</td>
</tr>
<tr>
<td>Q. Why do I need to eat a healthy diet?</td>
</tr>
<tr>
<td>Eating a mixed diet that is low in fat, salt and sugar and rich in fruits and vegetables can help you manage your blood glucose level. Also, eating fresh fruits and vegetables everyday helps you reduce the risk of heart diseases and maintain good health as they are high in fibre.</td>
</tr>
<tr>
<td>Q. Do I need vaccinations?</td>
</tr>
<tr>
<td>Up-to-date vaccinations are the best defence against diseases. Your doctor or nurse can tell you if your vaccinations are up to date or advise you on what vaccinations to have.</td>
</tr>
<tr>
<td>Q. Why do I need to keep active?</td>
</tr>
<tr>
<td>Keeping active by cycling, gardening and walking can help lower blood glucose, blood pressure and blood fat levels.</td>
</tr>
<tr>
<td>Q. Can I talk to other people with diabetes who have had a baby?</td>
</tr>
<tr>
<td>Getting regular check-ups can help you stay on top of your health. For example, the glycaated haemoglobin (HbA1c) test is another way of checking to see if you are meeting your glucose level targets. Having annual eye and kidney checks are important to keep your eyes and kidneys healthy. Also, checking blood pressure and blood fat (lipid) levels every year can help reduce your risk of developing diabetes complications.</td>
</tr>
<tr>
<td>Q. What support is available to me?</td>
</tr>
<tr>
<td>Your diabetes nurse, GP and/or healthcare team can provide advice and support when you are planning a pregnancy and can also help you achieve your individual targets, be it HbA1c or your daily blood glucose levels.</td>
</tr>
</tbody>
</table>
meeting your glucose level-targets. Having annual eye and kidney checks are important to keep your eyes and kidneys healthy. Also, checking blood pressure and blood fat (lipid) levels every year can help reduce your risk of developing diabetes complications.

Q. **What support is available to me?**

Your diabetes nurse, GP and/or healthcare team can provide advice and support when you are planning a pregnancy and can also help you achieve your individual targets, be it HbA1c or your daily blood glucose levels.

Q. **Can I talk to other people with diabetes?**

Diabetes UK has a support forum where you can interact with other people with diabetes. You can join the community by visiting [The Diabetes UK Support Forum](https://www.diabetes.org.uk/support/forum).
Appendix 15 – Publications
Contraception for women with diabetes: challenges and solutions

Ann Robinson
Chidiebere Nwolise
Jill Shawe

School of Health Sciences, Faculty of Health and Medical Sciences, University of Surrey, Surrey, UK

Abstract: Diabetes mellitus (DM), the most common of metabolic disorders, is a global public health concern. Numbers are rising with 383 million adults currently diagnosed with DM and another 175 million as yet undiagnosed. The rise in cases includes increasing numbers of women of a reproductive age whose reproductive health and contraception need careful consideration. Unintended pregnancy with poor glycemic control at the time of conception increases the chance of adverse pregnancy outcomes including stillbirth, congenital abnormalities, and perinatal mortality. In order to minimize complications, safe and effective contraception is paramount for all women with DM. This is a challenge as women have been found to be reticent to ask for advice, appear to lack understanding of risks, and are less likely to be using contraception than women without DM. The World Health Organization has developed Medical Eligibility Criteria to guide contraceptive choice. Women with DM without complications can choose from the full range of contraceptive methods including hormonal contraception as the advantages of use outweigh any risk. Women with diabetic complications may need specialist advice to assess the risk–benefit equation, particularly in respect of hormonal contraception. Women should be aware that there is no restriction to the use of oral and copper intrauterine emergency contraception methods. There is a need for an integrated approach to diabetes and reproductive health with improved communication between women with DM and their health care providers. Women need to be aware of advice and services and should make their own choice of contraception based on their needs and associated risk factors. Practitioners can offer nonjudgmental guidance working in partnership with women. This will enable discussion of risks and benefits of contraceptive methods and provision of advice dedicated to improving overall health and well-being.

Keywords: diabetes mellitus, gestational diabetes, contraception, education, preconception counseling

Introduction

Diabetes mellitus (DM), the most common of metabolic disorders, is a global public health concern. Three hundred and eighty three million adults are currently diagnosed with DM and another 175 million are estimated to be living with the condition but are as yet undiagnosed. By 2035, numbers are set to increase by 55% with 592 million people becoming affected worldwide. The rise in cases includes increasing numbers of women of reproductive age whose reproductive health and contraceptive needs must be carefully considered as DM has serious implications for pregnancy. It is the most common medical condition complicating pregnancy and affects up to 10% of women of a reproductive age in developed countries.
There are three main types of DM (Table 1). Type 1 DM is an autoimmune, chronic condition occurring in both adults and children, often before 40 years of age, and accounting for \( \sim 10\% \) of cases in adults and \( 98\% \) of cases in children.\(^4\) In type 1 DM, the primary beta cells of the pancreas do not produce insulin resulting in hyperglycemia. The propensity to develop autoimmune diseases, such as diabetes, may be familial. Treatment involves careful glucose monitoring and administration of insulin.

Type 2 DM, accounting for \( \sim 90\% \) of cases in adults and \( 2\% \) of cases in children,\(^4\) is sometimes known as mature onset diabetes. This occurs when the amount of insulin produced by the pancreatic beta cells is insufficient or if the body develops a resistance to the insulin produced. As this condition is often associated with obesity, treatment involves diet and exercise, oral medication, and occasionally insulin. Recently, more cases of type 2 DM have been diagnosed in younger age groups due to increasing obesity.\(^1\)

Gestational DM (GDM) develops during pregnancy in women without previously diagnosed DM. It is caused by increased blood glucose levels in pregnancy and is treated with diet or insulin. GDM usually disappears after pregnancy but women are at risk of developing type 2 DM in the future.

This paper will review some of the challenges for women with DM in relation to contraception and will suggest solutions guided by current evidence.

**Methods**

To update previous searches for new primary research and reviews, we searched MEDLINE (754 articles), PsycINFO (95 articles), CAB Abstracts (451 articles), CINAHL (174 articles), Maternity and Infant Care (49 articles), Web of Science (53 articles), British Nursing Index (35 articles), Embase (150 articles), and ScienceDirect (76 articles) from 2008 to 2015. The following terms were used for MEDLINE and Maternity and Infant Care; these terms were amended for the other databases.


The terms were searched separately and in combination. References given in the listed papers were searched for papers that did not appear on any of the databases searched. The search was limited to studies in the English language. Articles that addressed the issues of contraception use in women with diabetes were qualified for inclusion in the review. The search yielded 1,837 results; most of these were duplicates due to the combination of search terms within the different databases. The titles and abstracts of 1,837 studies were screened, and those articles whose eligibility could not be determined from their titles and abstracts alone were read in full. The full text of 28 studies was read and 17 studies were found to be relevant. The relevant studies included reviews and primary quantitative and qualitative research studies.

**Facing the challenges**

DM can lead to numerous complications with long-term health implications on vascular, neurological, renal, and ophthalmic functions.\(^5\) From a reproductive perspective, poor glycemic control at the time of conception and during pregnancy increases the chance of adverse pregnancy outcomes including stillbirth, congenital abnormalities, and perinatal mortality.\(^6\) Neonates born to women with DM are “five times as likely to be stillborn, three times as likely to die in their first months of life, and twice as likely to have a major congenital anomaly”.\(^7\) The UK Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK (MBRRACE) report\(^8\) highlights other risks associated with diabetes and pregnancy, namely, hypoglycemia and diabetic ketoacidosis, and the importance of preconception advice and glycemic control with an HbA\(_1c\) < 10%.

In order to minimize complications, safe and effective contraception to prevent unintended pregnancy and preconception care is paramount for all women with DM.\(^9\) Monitoring and improving maternal health whilst encouraging adequate inter-pregnancy spacing and the use of effective contraception forms an integral part of pre-pregnancy care.\(^1\) This is a challenge for health care professionals as only half
of the women with DM plan their pregnancies,7 and they can be reticent to ask for advice;10 a US National survey found that women with DM were less likely to be using contraception than women without DM.11

Lack of understanding about the high risks for unplanned pregnancy and diabetes and the need for effective contraception among women with DM is of concern. Cartwright et al12 published findings of an audit involving 100 women attending a diabetic clinic in UK. Findings revealed that two-thirds of women were not able to remember discussing pregnancy or contraception with a health care provider. The most common method of contraception (65%) was the use of condoms and some women were unsure about suitable contraception. Those having had a pregnancy exhibited no additional knowledge regarding risks associated with pregnancy and DM.

Murphy et al11 explored the experiences of women with DM who did not attend pre-pregnancy care in the UK. Twenty-nine pregnant women with type 1 and type 2 DM participated in a qualitative study. Data were collected via semi-structured interviews and coded as part of thematic analysis. Women were found to have difficulty complying with contraceptive advice and the majority were not using reliable contraception prior to becoming pregnant. With regard to preconception health, although some women had experienced previous miscarriage, fetal anomaly, and stillbirth, they had however been reluctant to attend preconception care due to previous negative experiences, becoming pregnant quickly, having concerns relating to fertility, or simply due to practicalities associated with attending services.

The prevalence of DM is rising rapidly in the Middle Eastern countries and the developing world,2 and two studies from Iran have identified low use of contraception by women with DM.14,15 A mixed method cross-sectional study involving 200 women identified many pregnancy-related abnormalities and a lack of confidence in using contraceptives, with many women not using any form of contraception. Similar findings and low use of modern contraceptive methods with women mainly using coital withdrawal method were found in Iranian women with type 2 DM, hypertension, or obesity.15 Although the results of these studies may not be generalizable to different demographic communities, the importance of educating women with DM from all groups of society needs to be emphasized.

The challenge is to support women with type 1 and type 2 DM in making a choice of contraception based on their individual needs and associated risk factors.16 No restrictions for use of any contraceptive apply to women with GDM, but their propensity to develop type 2 DM may need consideration. Young people with unstable DM are of particular concern as they need reliable contraception in order to prevent high-risk unintended pregnancies.

Providing contraceptive solutions
Guidance about contraception needs to be offered holistically and a trusting relationship between practitioner and client is advocated.17 The importance of avoiding unintended pregnancy should be an integral part of diabetes education from adolescence onward discussed by diabetes health care providers.9 Choice of contraception should be made on the preference of the woman and individual risk factors identified such as the presence of vascular, nephropathy, neuropathy, or retinal disease.1,18 Choosing a safe and reliable method of contraception for a woman with DM needs careful consideration and practitioners need to make reference to the WHO Medical Eligibility Criteria for Contraceptive Use18 as outlined in Table 2.

Efficacy must be assured and the chosen method must not induce diabetic-related risks such as thromboembolic and cardiovascular complications.19 Those with poorly controlled diabetes and obese women may need to be targeted as they often fall victim to associated risks by not seeking advice and support.1

Combined hormonal contraception
Combined hormonal contraception (CHC) methods include the administration of estrogen and progestogen. Examples of CHC include combined contraceptive pills, transdermal contraceptive patches, combined vaginal rings, and combined injectable contraception. Historically, women with diabetes were denied CHC due to concerns about the effect on carbohydrate and lipid metabolism.20 Recent data highlight the safety of CHC not only in relation to women with DM without complications, but in not inducing diabetes in otherwise healthy individuals.1,2,10,21

A recent review of evidence1 emphasized that CHC containing less than 35 µg of ethinyl-estradiol did not alter blood glucose concentrations and insulin secretion. In relation to

Table 2 WHO Medical Eligibility Criteria for Contraceptive Use

<table>
<thead>
<tr>
<th>Category</th>
<th>With clinical judgment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Use method in any circumstance</td>
</tr>
<tr>
<td>2</td>
<td>Generally use method</td>
</tr>
<tr>
<td>3</td>
<td>Use of method not usually recommended unless other more appropriate methods are not available or not acceptable</td>
</tr>
<tr>
<td>4</td>
<td>Method not to be used</td>
</tr>
</tbody>
</table>

diabetic retinopathy, macular edema, and nephropathy, there was no increase in risk or acceleration of disease in women taking oral CHC.1,19 The WHO Medical Eligibility Criteria for Contraceptive Use18 states (Table 3) that for any diabetic patient without cardiovascular or microvascular complications, advantages of using the method generally outweigh the theoretical or proven risks, and Category 2 applies for CHC.

The results of a Cochrane review of randomized controlled trials by Visser et al21 was inconclusive in determining whether hormonal contraception affected carbohydrate and lipid metabolism and long-term complications in women with DM. The French Society of Endocrinology expert group,22 however, undertook a comprehensive review of evidence and pathophysiologically data, as to the safe contraceptive options for diabetic women with risk factors, and concluded that from a hormonal perspective extreme caution is recommended as risk factors often do not occur in isolation. Gourdy2 in his review supports this and suggests that CHC with estrogens and progestogen should be avoided whatever their route of administration in women with DM who have microvascular complications such as severe retinopathy (ischemic or proliferative), active macular edema, or nephropathy with persistent proteinuria. In cases of DM complicated by cardiovascular or microvascular disease, the risks of prescribing CHC outweigh any advantages and a WHO Medical Eligibility Criteria (MEC) 3/418 would be awarded.1,2,22 CHC is also unlikely to be suitable for women with risk factors such as smoking, obesity, or hypertension due to increased risk of venous thromboembolism, myocardial infarction, and stroke.17,23

Progestogen oral hormonal contraception
The progestogen-only pill (POP) is regarded as a safe option for women with DM of any age with or without complications.

Table 3 Contraceptive methods and diabetes

<table>
<thead>
<tr>
<th>Condition</th>
<th>CHC</th>
<th>POP</th>
<th>DMPA/NET-EN</th>
<th>IMP</th>
<th>Cu</th>
<th>IUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of gestational diabetes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonvascular disease</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>i. Noninsulin dependent</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ii. Insulin dependent</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ii. Insulin dependent</td>
<td>3/4</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Neuropathy/retinopathy/neuropathy</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other vascular disease</td>
<td>3/4</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

Abbreviations: CHC, combined hormonal contraception; Cu, IUD, copper intrauterine device; DMPA/NET-EN, medroxyprogesterone acetate/Norethisterone enanthate; IMP, implants; POP, progestogen-only pill; IUS, intrauterine system.


Advantages of using the method generally outweigh the theoretical or proven risks (WHO MEC 218). The POP needs to be taken within a daily set time period but compliance is likely to be good if scheduled with routine insulin or oral hypoglycemic medication. Desogestrel has the benefit of inhibiting ovulation in 97% of cases and a 12 hours dosing period,24 and therefore may be a more reliable choice especially for younger people with DM.

Long-acting reversible contraception
Long-acting reversible contraceptives (LARC) are not memory-dependent and have high efficacy, which can make them a good choice for women with DM. Methods include copper intrauterine device (IUD), intrauterine system (IUS), progestogen-only injectable contraceptives, progestogen-only subdermal implants, and combined vaginal ring. The combined vaginal ring has been included under CHC within this review. Despite their safety and effectiveness, LARCS are generally underutilized with only 15.5% of women worldwide using IUDs, and only 3.4% using subdermal implants.25 In the UK in 2008–2009, only 12% of women aged 16–49 years used LARC compared to 25% of women who used COC and 25% whose male partners used condoms.26

Goldstuck and Steyn27 published a systematic review focusing on the efficacy of the IUD and IUS for women with DM. Four hundred and ninety nine articles were screened and seven studies met the inclusion criteria. Analysis resulted in the reassurance that the copper IUD and IUS were suitable for women with type 1 and type 2 DM, although the IUS needed further monitoring from a metabolic perspective in relation to type 2 DM. WHO MEC19 agrees that the IUD is entirely suitable for women with type 1 or type 2 DM with no restriction for use, and the advantages of using IUS generally outweigh the theoretical or proven risks.

A Cochrane review by Visser et al21 focused on evidences from randomized controlled trials relating to hormonal as opposed to nonhormonal contraception in diabetic patients. Results concluded that there was limited evidence relating to the effect of hormonal contraception on diabetes. Although the quality of the data was inconclusive, it identified the POP and the IUS as not being contraindicated for women with DM, whereas the CHC was identified as having a negligible effect on glucose stability.

Progestogen-only injectable contraceptives, such as medroxyprogesterone acetate and norethindrone enanthate, are suitable for women with DM without complications.26 Concerns regarding possible negative effect on lipid
metabolism due to hypoestrogenic effects and reduced HDL levels mean that for women with complications, risk outweighs benefit (MEC 3/4), and POPs would only be administered following specialist advice.\textsuperscript{16} Injectable methods may also cause a possible delay returning to fertility,\textsuperscript{20} which may be unacceptable to women with DM who may prefer to have families as soon as possible before complications of DM arise.

Progestogen-only subdermal implants containing etonogestrel are suitable for women with diabetes, as per WHO MEC guidelines.\textsuperscript{18} Implants release a constant dose of progestogen reducing the potential for metabolic variation and maintaining steady blood-lipid ratios.\textsuperscript{28}

**Barrier and natural methods of contraception**

Barrier methods include a range of contraceptives including diaphragms, cervical caps, as well as male and female condoms. Some involve using spermicide such as nonoxynol-9; however, there appear to be no studies contraindicating the use of spermicide from a diabetic perspective. The decision to use a barrier method comes down to personal acceptability and efficacy; a male condom, for example, is 98% effective with proper use, a female condom 95%, and a diaphragm with spermicide is 92%–96% effective.\textsuperscript{29} Using barrier methods alone may be too unreliable in preventing pregnancy for women with DM, especially if she is trying to lose weight or reduce her HbA\textsubscript{1c} levels.\textsuperscript{26} Male and female condoms may be best used to prevent sexually transmitted infections, in conjunction with a more effective contraceptive such as hormonal methods or IUD.

Fertility awareness methods, although effective for some couples striving for a non-hormonal, more “natural” method of contraception, may not be a suitable choice for women with DM. In healthy women with a regular menstrual cycle and contemporaneous use, natural family planning is rated as being 99% effective.\textsuperscript{29} Women with DM have a potentially increased incidence of erratic menstrual cycles\textsuperscript{20} that may affect efficacy and lead to an increased failure rate.\textsuperscript{31}

**Male and female sterilization**

The failure rate for female sterilization is one in 200 and one in 2,000 for men following a vasectomy.\textsuperscript{29} Since both procedures involve an operative intervention, however, minor, glycemic control needs consideration since it can affect the chances of acquiring a postoperative infection.\textsuperscript{32} In addition, the chances of hypoglycaemia and ketoacidosis occurring, increase post surgery complications.\textsuperscript{33} Guidance from a diabetic physician regarding the safest operative location as well as prophylactic antibiotics are advisable if a couple decides that sterilization is the right choice.\textsuperscript{18}

**Emergency contraception**

Emergency contraception provides all women with additional choice for prevention of pregnancy. The global rate of unplanned pregnancy in 2012 was 53 per 1,000 women aged between 15 years and 44 years.\textsuperscript{24} Emergency contraception may be required for multiple reasons including failure to use a contraceptive correctly and following sexual abuse or rape. Women with DM at risk and not wanting to be pregnant are advised to seek emergency contraception at the earliest opportunity. From a diabetic perspective, there are no contraindications to taking emergency progestogen-only contraceptive pills within the recommended time frame or to the use of the copper-bearing IUD within 5 days of unprotected intercourse or when ovulation is known, no more than 5 days after ovulation.\textsuperscript{13} According to the WHO MEC guidelines,\textsuperscript{18} the benefit of using emergency contraception outweighs the risk, even where there is severe vascular disease.

**Key solutions**

Our review has highlighted that women with DM need to use a reliable method of contraception in order to avoid high-risk unintended pregnancies. Women without complications can choose from the full range of methods that are available;\textsuperscript{18} however, studies have shown that they are less likely to use contraception or to seek advice.\textsuperscript{10,11} To improve pregnancy outcomes, women with DM need to be made aware of fertility and contraception advice services available within both acute and primary care.

Taking the earlier discussions into account, it is of concern that not all women with DM appear to understand the importance of contraceptive and/or preconception well-being from a diabetic perspective. Contraception messages in the diabetic female population need to be reinforced.\textsuperscript{12–15} There is a need for a more integrated approach to diabetes and reproductive health with improved communication between women with DM and their health care providers.\textsuperscript{13} Diabetes health professionals need to discuss contraception with women and referral to a contraceptive specialist for advice may be advisable.\textsuperscript{22,36}

UK guidelines\textsuperscript{16} emphasize that women should choose their own contraceptive method, based on guidelines and taking account of any risks. In order to make appropriate choices, women with DM need to be provided with up-to-date research-based evidence regarding suitable methods.
The effectiveness of barrier methods and oral contraception is often compromised due to inconsistent use,26 and LARC methods, if suitable, will provide better efficacy.26 Women with DM need to plan any pregnancies and use reliable contraception until their diabetic health care provider confirms a satisfactory HbA1c result, ideally below 6.5%.9 Women should be advised to maintain their “fasting blood glucose between 3.5 and 5.9 mmol/L and their 1-hour postprandial blood glucose below 7.8 mmol/L if this is safely achievable”.37 They do, however, need to be aware of the potential risk of hypoglycemic episodes and the appropriate treatment required. Women with an HbA1c level above 86 mmol/mol (10%) are advised not to become pregnant due to associated risks.9 Before discontinuing contraception, a comprehensive drug assessment should be made to review and change medication that is potentially teratogenic, such as ACE inhibitors and certain insulins.9,38 In addition, women should be offered a renal assessment including measurement of microalbuminuria and retinal assessment to exclude progressive disease.9,38

Support and education prior to pregnancy, therefore, benefits by ensuring an optimal pre-pregnancy weight, stabilizing glycemic control, ensuring safety of medication, and providing baseline levels for monitoring retinal and renal functions.9,38 Delay of pregnancy to achieve favorable glycemic control has been found to prevent poor maternal and neonatal outcomes,6 and in most cases, maintaining an optimal inter-pregnancy interval reduces adverse birth outcomes and decreases maternal morbidity from a physical and psychological perspective.39,40

Monitoring and improving health while encouraging adequate use of effective contraception forms an integral part of contraceptive care. Follow-up for women with DM using hormonal contraception is based on routine clinical practice of blood pressure and body mass index measurements, but baseline lipid profiles may need assessment, especially if injectable contraception is used, and blood glucose levels as relevant.19

In conclusion, the prevalence of DM in women of reproductive age is rising. Effective contraception is required in order to prevent unintended pregnancy as uncontrolled glucose levels at conception leads to poor maternal and perinatal outcomes. Contraceptive choices need to be made by women in conjunction with evidence-based research (Table 4). Women with DM without complications have multiple choices for contraception and those with complications may need specialist advice. Communication between health professionals and women with DM needs improving in relation to promoting reproductive health and contraception. A trusting, nonjudgmental approach and a positive relationship are important. This will enable the discussion of risks and benefits of contraceptive methods and provision of advice dedicated to improving overall health and well-being.

Disclosure
The authors report no conflicts of interest in this work.

References

Table 4 Summary of recommendations

| Individualized, specialist contraceptive advice |
| Contraceptive guidance needs to be offered holistically; a trusting relationship between practitioner and client is advocated. |
| Practitioners need to make reference to the WHO Medical Eligibility Criteria for Contraceptive Use. |
| Women should be informed of all methods available including LARC methods which have higher efficacy. |

| Contraceptive choices for women with diabetes |
| Recent data highlight the safety of hormonal contraception in relation to women with DM without complications of cardiovascular or microvascular risk factors. |
| The copper IUD and IUS are suitable for women with type 1 and type 2 DM (MEC 1/2). |
| Injectable contraceptives (medroxyprogesterone acetate) are not contraindicated for healthy diabetic women (MEC 2). Women at risk are recommended that they seek specialist advice (MEC 3). |
| Contraceptive implants are suitable for women with diabetes (MEC 2). |
| Natural and barrier methods of contraception are not contraindicated for women looking for a nonhormonal method of birth control. |
| Male and female sterilization remains an option; however, infection control is paramount and specialist referral is recommended. |
| Emergency contraceptive pills and the copper IUD are suitable for all women with DM to prevent unintended pregnancy. |

| Preconception care |
| Effective contraception is paramount for women exhibiting poor glycemic control. |
| Women with diabetes have increased risks of adverse pregnancy outcomes: Fivefold increased risk of stillbirth, threefold increased risk of perinatal mortality, and twofold increased risk of fetal congenital anomaly. |
| Contraceptive care prior to pregnancy can benefit optimal pre-pregnancy weight, stabilize glycemic control, ensure safety of medication, and provide baseline levels for monitoring retinal and renal functions. Contraception is advised until HbA1c is below 6.5%. Women whose HbA1c level is above 86 mmol/mol (10%) are advised not to get pregnant. |
| Women with DM need to be made aware of fertility advice services available within both acute and primary care. |

Abbreviations: LARC, long-acting reversible contraceptives; DM, diabetes mellitus; IUD, intrauterine device; IUS, intrauterine system; MEC, Medical Eligibility Criteria; WHO, World Health Organization.


Review

Preconception Care Education for Women With Diabetes: A Systematic Review of Conventional and Digital Health Interventions

Chidiebere Hope Nwolise, MSc; Nicola Carey, PhD; Jill Shawe, PhD
School of Health Sciences, Faculty of Health & Medical Sciences, University of Surrey, Guildford, United Kingdom

Corresponding Author:
Chidiebere Hope Nwolise, MSc
School of Health Sciences
Faculty of Health & Medical Sciences
University of Surrey
Fifth Floor, Duke of Kent Building
Guildford, GU2 7XH
United Kingdom
Phone: 44 1483686717
Email: c.nwolise@surrey.ac.uk

Abstract

Background: Worldwide, 199.5 million women have diabetes mellitus (DM). Preconception care (PCC) education starting from adolescence has been recommended as an effective strategy for safeguarding maternal and child health. However, traditional preconception care advice provided by health care professionals (HCPs) within clinic settings is hindered by inadequate resources, suboptimal coverage, and busy clinics. Electronic health (eHealth), which is instrumental in solving problems around scarce health resources, could be of value in overcoming these limitations and be used to improve preconception care and pregnancy outcomes for women with DM.

Objective: The objectives were to: (1) identify, summarize, and critically appraise the current methods of providing PCC education; (2) examine the relationship between PCC educational interventions (including use of technology as an intervention medium) on patient and behavioral outcomes; and (3) highlight limitations of current interventions and make recommendations for development of eHealth in this field.

Methods: Electronic databases were searched using predefined search terms for PCC education in women with type 1 or 2 DM for quantitative studies from 2003 until June 2016. Of the 1969 titles identified, 20 full papers were retrieved and 12 papers were included in this review.

Results: The reviewed studies consistently reported that women receiving educational interventions via health care professionals and eHealth had significantly improved levels of glycosylated hemoglobin (P<.001) with fewer preterm deliveries (P=.02) and adverse fetal outcomes (P=.03). Significant improvements in knowledge (P<.001) and attitudes toward seeking PCC (P=.003) were reported along with reduced barriers (P<.001).

Conclusions: PCC has a positive effect on pregnancy outcomes for women with DM. However, uptake of PCC is low and the use of eHealth applications for PCC of women with DM is still in its infancy. Initial results are promising; however, future research incorporating mobile phones and apps is needed. Clearly, there is much to be done if the full potential of eHealth PCC to improve obstetric outcomes for women with DM is to be realized.


KEYWORDS
preconception care; education; diabetes mellitus; women; review; smartphone; mobile applications; technology

Introduction

Electronic health (eHealth) is transforming health care delivery [1-9] and increasingly being used to promote healthy behaviors in people with diabetes mellitus (DM) [10-17]. eHealth is the cost-effective and secure use of information and communication technologies (ICT) in support of health and health-related fields, including health education, knowledge, and research [1]. eHealth
plays an instrumental role in improving access to health care, particularly where resources are scarce, and encourages individuals to actively connect with health care services [6,18]. eHealth technologies include consumer health informatics, the Internet, and mobile devices [19]. The Internet has emerged as a popular source of health care information that may replace face-to-face consultations, strengthen patient participation, and supplement health care [20].

A recent report on Internet use [21] identified that of the average 5.6 hours spent on the Internet per day, 51% of time was spent accessing it via mobile devices compared with computers or laptops (42%) and other connected devices (7%). By providing individuals with increased access to information anytime and anywhere, eHealth delivered via mobile phones has significant potential to transform health care delivery. Evidence suggests that 90% of the world’s population own a mobile phone, and over a third of the 7.1 billion mobile devices in use are now smartphones [22,24,23-26] that run third-party apps. Apps are programs designed to enhance smartphone functionality and their increased popularity has resulted in proliferation of educational, decision support, and patient monitoring apps [24]. In 2010, over 200 million health apps were downloaded with estimates suggesting that this figure will have risen to 1.7 billion by 2017 [22].

eHealth technologies can be used to maximize preventative health care for people with chronic conditions such as DM. Worldwide 415 million people have DM, of which 199.5 million are women [27]. DM is now of increasing concern in the field of women’s health and the most common preexisting medical condition complicating pregnancy [28,29]. Poorly-controlled DM at conception coupled with unplanned pregnancy is a major contributor to morbidity and mortality including miscarriages, maternal and perinatal death, and congenital malformations [29,30-36]. It is therefore recommended that women optimize their health via preconception care (PCC) [29,36-42]. Women are also encouraged to achieve a target glycosylated level of hemoglobin (HbA1c; average blood glucose level over the past 2-3 months) of <7% before and during the first trimester of pregnancy to reduce obstetric risks [29,36,38-41]. However, less than 50% of women with DM receive PCC advice [34,43,44] with fragmented and suboptimal services being reported [45-47]. As a result, women with DM have insufficient knowledge of the risks associated with pregnancy to themselves or their baby [12,48,49]. International clinical guidelines [29,38-41] recommend PCC education from adolescence for all women with DM as an effective strategy to facilitate behavior change and improve pregnancy outcomes. However, barriers such as inadequate resources, busy clinics, time, and distance to health facilities [48,50] can inhibit and restrict the extent to which women engage in PCC. Hence, eHealth could be of value in overcoming these limitations and extending the reach of health interventions.

While rapid advances in eHealth technology create a new opportunity to improve knowledge and health outcomes, to date there is no extant literature appraising and quantifying the impact of different methods of PCC provision for women with DM. Therefore, a systematic literature review was undertaken to (1) identify, summarize, and critically appraise the current methods of providing PCC education; (2) examine the relationship between PCC educational interventions (including use of technology as an intervention medium) on patient and behavioral outcomes; and (3) highlight limitations of current practice and make recommendations of eHealth in this field.

**Methods**

**Search Strategy**

A systematic approach was used to search the literature for relevant articles. The review was limited to human studies conducted between 2003 and June 2016 to reflect current and emerging trends in design and conduct of PCC interventions for women with DM. The reviewed literature drew on a wide range of evidence. The following databases were searched: Medline, Embase, Web of Science, Maternity and Infant Care, Cumulative Index to Nursing and Allied Health, CAB Abstract, British Nursing Index, PsycINFO, Scopus, Science Direct, and Google Scholar.

The keywords “preconception care,” “education,” “counseling,” “diabetes,” “pregnancy outcomes,” “knowledge,” “behavior change,” “birth defects,” and “women” were used in various combinations when searching the databases (see Multimedia Appendix 1 for full text of search string). Additionally, reference lists of retrieved articles, reviews, and related articles were hand-searched for potentially relevant papers. Emphasis was placed on primary research. No language restriction was applied to the search.

**Study Selection**

The titles, abstracts, and full papers were screened by CHN and checked by NC and JS. Articles were excluded if there was an agreement that the article met 1 or more of the following exclusion criteria: did not contain any human data; contained no original data (ie, was a commentary, meeting abstract, or editorial); population of interest was not women with DM; and did not assess impact of a PCC educational intervention. The search protocol included identification of potentially relevant articles, screening of identified papers based on their titles and abstracts, examination of full text of potentially relevant studies for eligibility, and application of the inclusion criteria to select the studies included in the review. For the study to be included in the literature review, the following inclusion criteria were applied.

- Women of reproductive age with preexisting type 1 diabetes mellitus (T1DM) or type 2 diabetes mellitus (T2DM) not pregnant at the time of the PCC intervention.
- PCC interventions including but not limited to education, advice, or counseling on use of folic acid, insulin therapy, glycemic control, screening for diabetes complications, contraception use, and blood glucose monitoring.
- Comparator was standard care in all studies except the one [12] in which the intervention group also served as the control.
- Studies reporting maternal and neonatal outcomes and knowledge and attitudes toward PCC.
Quantitative studies, that is randomized controlled trials, before and after studies, and observational (cohort, cross-sectional and case control) studies.

Data Abstraction

The data was subsequently extracted by CHN and checked by NC and JS for accuracy and completeness. The reviewers were not masked to the articles’ authors, journals, or institutions.

Quality Assessment

Assessment was initially performed by CHN and results agreed by NC and JS. The quality of reviewed studies was assessed using a modified version of the EPHPP quality assessment tool for quantitative studies which was developed by the Effective Public Health Practice Project (EPHPP), Canada. It contains summary judgments and an accompanying dictionary that increases standardization of the study quality assessment [51,52]. This tool includes items on selection bias, study design, confounders, blinding, data collection, and withdrawals and dropouts. Each of these 6 aspects of quality received a score out of 3 to make up a total score of 18. The studies were given a rating out of 18, and the quality of the evidence was graded as strong (rating>14), moderate (rating 7-13), or weak (rating 1-6).

Synthesis

Meta-analysis of the data was not appropriate because there was great diversity in the interventions, research designs (methodology), and outcome measures. In this review, the main focus was on extracting data on descriptions of interventions (study design, samples, and intervention overviews), outcome measures, and examinations of the effectiveness of interventions. The results are presented as a narrative summary.

Results

Search Results

A total of 1969 articles were identified from the literature search and the titles and abstracts of 864 articles were screened for eligibility. After excluding 844 articles that did not meet the eligibility criteria, 20 full text articles were selected for detailed review, of which 12 met the eligibility criteria (Figure 1).

The 12 included studies evaluated 2 categories of PCC health education delivery in use for women with DM: health education provided by health care professionals (HCPs; n=8) and health education using eHealth technologies (CD-ROMs and DVDs; n=4). Of the included studies, 8 were found to investigate the effect of PCC education on maternal and child health outcomes, whereas 4 focused on use of eHealth technology for PCC of women with DM. Of the 12 included articles, 1 study discussed their findings in 2 articles [53,54]. Hence, 12 articles of 11 studies were included.

Study Characteristics

The summary characteristics of reviewed articles are given in Multimedia Appendix 2. All studies provided face-to-face or eHealth PCC education to women with DM. Women were recruited from specialist and primary care diabetes clinics. Of the included studies, 8 focused on the effect of a PCC intervention on maternal and child outcomes [43,44,53-58] and 4 on improving knowledge and changing attitudes toward PCC [10,11,12,13]. Timing and duration of intervention for some studies was not specified [12,44,55-58]. Follow-up periods ranged from 3 months to 12 years.

All studies were carried out in clinical settings, except one [12], undertaken in women’s homes. Most of the studies were observational [43,44,53-58], with data collected from medical,
pregnancy and birth records, or databases. Of the included studies, 4 [10-13] used previously validated and reliable questionnaires. Although data collection methods were different for the face-to-face and eHealth PCC studies, there was consistency in findings and methods of data collection used within each category. Sample sizes ranged from n=58 to n=680. All studies, except one [12], had a separate intervention and control group. All studies were carried out in different countries (United States, n=3; United Kingdom, n=5; France, n=1; Spain, n=1; Finland, n=1; and Republic of Ireland, n=1), highlighting increased prioritization of PCC for women with DM in these countries. Studies which adopted eHealth for PCC of women with DM were based in either United States (n=3) [10,11,13] or United Kingdom (n=1) [12], perhaps reflecting the increasing use of ICT to support PCC service provision in these countries.

Study Quality

Studies varied with respect to their quality (See Multimedia Appendix 2). Of the included studies, 3 had a rating above 14 [11,13,43] and 9 were rated between 7-13 [10,12,44,53-58]. All studies used appropriate study designs, namely, randomized controlled trials, before and after, and cohort studies but lacked details on blinding and allocation concealment. Although small sample sizes [10,11,12], selection bias [10,12,58], and confounding [12,56,57] were underlying issues of weakness within most studies, these were acknowledged and addressed by the authors.

Findings

Of the included articles, 12 of them reporting on 11 studies (n=12) were grouped into 2 main categories based on their mode of PCC health education delivery: (1) evaluation of PCC education provided by HCPs (n=8) and (2) evaluation of PCC education provided via eHealth technology (n=4).

Evaluation of PCC Education Provided by HCPs

PCC education traditionally provided in clinical settings by health care professionals is associated with positive maternal and child health outcomes. An overview of the interventions, outcome measures, and their effects are described in the following points.

Maternal Health Outcomes

Of the included studies, 2 [56,57] explored the effect of a PCC educational intervention on levels of glycosylated hemoglobin (HbA1c). Boulot et al [56] assigned women with T1DM and T2DM to either an intervention group (n=175) where they received the PCC education before conception, or to a control group (n=360) receiving standard care. Results showed that the educational intervention was effective in enabling more women in the intervention group attain HbA1c <8%. Intervention participants had improved HbA1c in the first trimester with a significantly lower number of women with T1DM (4.3% vs 55%) and T2DM (2.9% vs 27.9%) having HbA1c >8% compared with those in the control group (P<.001). A similar study by Galindo et al [57] in Spain included women with both T1DM and T2DM. The intervention group (n=15) received preconception counseling, whereas the control group (n=112) only presented to medical care when pregnant. Although Galindo et al [57] did not set out to measure the effect of a PCC intervention on maternal HbA1c, the intervention group had significantly improved HbA1c (<7%) compared with those in the control group (P=.02).

Another UK study [53,54] considered the effect of PCC education on maternal HbA1c, spontaneous abortion, preterm delivery, and gestational age at presentation for prenatal care. Statistically significant differences were found in intervention participants who had improved and sustained HbA1c (6.5% vs 7.6%; P<.001) throughout pregnancy, presented earlier for prenatal care (6.6 vs 8.3 weeks; P<.001), less spontaneous abortions (P=.06), and preterm deliveries (P=.02).

Furthermore, 2 other studies [43,44] reported the effects of PCC education on HbA1c, gestational age at presentation for prenatal care, and folic acid intake in women with T1DM and T2DM. During the 3-year study period by Murphy et al [43], women who received a structured education program were assigned to the intervention group (n=181) and those who did not, to a control group (n=499). Women in the intervention group with increased intake of 5mg folic acid before conception (P<.001) had significantly improved HbA1c values (6.9% vs 7.6%; P<.001), and an earlier date of presentation for prenatal care compared with those in the control group (6.7 vs 7.7 weeks; P<.001). The role of PCC education in promoting healthy preconception behaviors and pregnancy planning was also explored by Tripathi et al [44] who assigned women receiving PCC counseling to the intervention group (n=240) and those who did not, to the control group (n=297). Results showed that participants receiving the intervention had significantly improved and sustained levels of HbA1c (≤7% vs >7%) 3 months before conception (P=.002) and during the first trimester of pregnancy (P<.001), higher rates of folic acid intake 3 months before pregnancy (P<.001), and presented earlier for prenatal care (≤8 weeks vs >8 weeks; P=.001).

Additionally, 2 recent studies [55,58] reinforced the benefits of PCC education on HbA1c and pregnancy outcomes. Neff et al [55] assigned women with T1DM to the intervention group where they received health education (n=70) while those in the control group received standard care (n=394). Intervention participants had significant improvements to HbA1c (<7% vs 7.8%; P<.001) and earlier prenatal care presentation (6±2 weeks vs 8±6 weeks; P<.001) compared with those who received standard care. However, the effect on rates of spontaneous abortion or preterm delivery was not found to be statistically significant (P=.12, P=.46 respectively). Kekalainen et al [58] also found statistically significant differences in the intervention group who had improved and sustained HbA1c (7.1% vs 9.1%; P<.001) and reduced adverse pregnancy outcomes (P<.06).

Child Health Outcomes

Boulot et al [56] demonstrated that women with T1DM who received PCC education had significantly lower rates of perinatal mortality and congenital malformation (P<.005) compared to those in the control group. Furthermore, women with DM whose HbA1c was >8% in the first trimester had double the risk of developing adverse fetal outcomes such as perinatal mortality (P<.005), congenital malformation (P<.01), and preterm delivery (P<.005).
Additionally, 5 further studies [43,53,54,57,58] reported similar findings. Temple et al [53,54] found that women who received a PCC educational intervention had significantly reduced risk of adverse outcomes (including malformations, stillbirths, and neonatal death) compared with those receiving standard care ($P = .03$). Similarly, Murphy et al [43] and Kekalainen et al [58] found that the intervention group participants experienced a significant reduction in congenital malformations compared with those in the control group ($P = .009; P = .001$). Galindo et al [57] also found a positive relationship between increase in maternal HbA1c levels (>7%) and the occurrence of fetal malformations. Additionally, Tripathi et al [44] and Neff et al [55] found a significant association between lack of preconception care education and increased risk of adverse fetal outcomes ($P = .03$).

Most studies (n=7) reported low levels of PCC uptake, range 12% [57] to 48.5% [56], amongst women with DM.

**Evaluation of PCC Education Provided via eHealth Technology**

Low levels of PCC uptake among women with DM have elicited interest in use of multimedia technologies such as CD-ROMs and DVDs as an intervention tool for PCC education.

Four studies [10-13] investigated the effect of eHealth technology on knowledge and PCC behaviors. Charron-Prochownik et al [10] developed and used an interactive computer program (CD-ROM) to promote PCC knowledge. Adolescent girls with T1DM were randomized to receive the 3-month CD-ROM intervention (n=37) or standard care (n=16). Significant improvement in knowledge ($P < .05$), perceived benefits ($P = .04$), and reduced barriers to seeking PCC ($P = .01$) were reported in intervention participants. An RCT by Fischl et al [11], which lasted 9 months, similarly used an interactive CD-ROM to deliver PCC health education. Adolescent girls with T1DM were randomized to either the intervention group (n=43) where they watched 2 CD-ROMs, read a book, and met with a nurse for counseling or standard care (n=45). Compared with those receiving standard care, intervention participants had significantly improved knowledge and perceived benefits of PCC ($P < .001$), reduced barriers to seeking PCC ($P < .001$), and increased intention to initiate PCC discussion with health care professionals ($P < .001$). The effect on intention to use contraception was not significant ($P = .10$).

A UK study by Holmes et al [12] aimed to explore whether an educational DVD would improve PCC knowledge and behavior. Women with T1DM and T2DM (n=97) who viewed the contents of the DVD individually in their homes showed a significant increase in perceived benefits and attitudes to contraceptive use ($P < .001$), receiving PCC ($P = .003$), knowledge of pregnancy planning ($P < .001$), and pregnancy-related risks ($P < .001$). Finally, Charron-Prochownik et al [13] assessed the long-term effect (12 months) of an educational DVD on knowledge and attitudes to PCC in adolescent girls with T1DM and T2DM. Participants who were randomized to receive the intervention (n=51) demonstrated a significant increase in PCC knowledge ($P < .001$), and intention to discuss PCC and contraception with health care professionals ($P = .03; P = .003$), compared with those in the control group who received standard care (n=58).

**Discussion**

**Principal Findings**

The reviewed evidence suggests that educationally-based PCC (delivered by health care professionals) is effective in improving maternal and child health. The evidence is consistent across studies, but with few robust controlled studies of PCC educational interventions for women with DM. Studies are generally of moderate quality, with only one assessed as high quality [43]. The inadequacy in traditional PCC education in meeting the needs of women with DM has been widely recognized [43,44,48,56-58], but alternative means of providing PCC remains underresearched. This review highlights the potential capacity of eHealth technologies to help improve coverage and access to PCC.

PCC should ideally be provided to all women with DM [29,34]. However, evidence presented in this review confirms that PCC uptake is still <50% [44,55-57], in line with the low PCC uptake reported in the 2007 confidential enquiry into maternal and child health (CEMACH) in women with DM [34]. Women who do not receive PCC also have poor levels of glycemic control, higher rates of unplanned pregnancy, and adverse pregnancy outcomes [29,30,43,53,54,56-58]. It is therefore worrying that PCC service provision and uptake has not increased at the same rate as the prevalence of DM in women of reproductive age. PCC provided predominantly in a health care setting by a HCP also excludes the 55% (3.1 billion) of the developing world’s population in rural areas who do not have adequate access to health care [59]. PCC provision is therefore almost nonexistent for many women in the developing world who have increased risk of adverse maternal and fetal outcomes [37]. This underlines the shortcoming of traditional PCC practice. We have reached the age of personalized medicine [23]. The growing popularity and effectiveness of eHealth technologies for health promotion in several areas including obesity and smoking cessation [4,15-17,60-62], makes its use in PCC of women with DM timely, warranting further exploration.

eHealth technologies hold great promise in terms of helping to deliver preconception health education that increases knowledge and supports behavior change [10-13]. This review highlights the potential of these technologies to empower women with DM to make informed reproductive health decisions. The ultimate goal is to prevent unplanned pregnancies and reduce adverse maternal and fetal outcomes. Behavioral interventions must reach the target population to achieve success [62]; in this lies a weakness of the reviewed eHealth intervention studies which have used technology that is now dated and offers limited scope to the many women who do not have access to computers and/or DVD players [10-13].

**Challenges of eHealth PCC**

This review highlights that adoption of eHealth in this field is slow and use of ICT for PCC is still very limited. For example, between 2008 and 2016, only 4 studies examined the effect of eHealth PCC using multimedia technology—CD-ROMs and DVDs, with none examining the use of the Internet or mobile phones. Computers or ICT has been used by some reviewed studies to provide health education within clinic settings...
However, people are now proactive in seeking health information and increasingly prefer to do things in the privacy of their homes and in their own time. Developments in technology mean that increasingly health programs can be delivered to people outside the traditional clinic setting, improving access for hard-to-reach populations across the world, as reflected in the recently agreed goals of the United Nations sustainable development plan [63].

The majority of studies (n=11) involved women traveling to clinics to physically receive the PCC educational intervention. However, constraints such as inadequate resources, time, and distance to health facilities have been shown to inhibit women’s ability to adequately access such PCC interventions [48,50], and for many women around the world, this has negative implications for PCC uptake. Furthermore, no studies were carried out in developing countries; reflecting the existent inequality in PCC service provision. Mobile technologies can be used to extend the reach of PCC interventions given that 90% of the world’s population now have access to a mobile phone [25]. Moreover, evidence of a reverse digital divide confirms that low income populations and those living in resource-poor settings are among the fastest growing users of mobile phones [64,65].

Bull [64] argues that if more people can be reached with health promotion interventions then even “modest” effects will translate into greater impact on morbidity and mortality. Contemporary eHealth technologies have the capacity to take an intervention that works on a small scale to a larger audience. From this review, which demonstrates the efficacy of PCC health education, it is apparent that the challenge lies in translating “what works” to a wider audience. We have a unique opportunity to overcome this challenge in eHealth PCC using mobile phones.

Way Forward for eHealth PCC

Mobile phones represent an underutilized resource that could be developed to support eHealth interventions for women with DM. Mobile phone ownership in developed countries has outstripped the population, with an average phone ownership of 1.16 mobile phones per person [25]. In developing countries, mobile communications technology is the fastest growing sector of the telecommunications industry with over a billion mobile phones [65,66]. Smartphones in particular, have the capacity of both computers and the Internet [24]. Their significant advantage over desktop computers, laptops, and DVD players make them a valuable tool for giving more women access to PCC [46]. They offer the opportunity to penetrate a larger population, are easily accessible, technologically advanced, utilize existing features (eg, geo-positioning technology; Internet access with photos, videos, and voice-recording capabilities), are mobile and convenient to use [4,22,23,67].

Many of the advanced functionalities of smartphones are aided by software applications or apps which hold great potential in helping to deliver cost-effective health interventions [4,16,17,22,23,67]. 90% of the time spent on mobile phones is spent on apps and in terms of usability, they are preferred over Web or computer-based applications [14,68]. Incorporating health education interventions into apps could help reduce barriers to adoption and facilitate increased acceptance of the intervention [4,24,69]. The innovative integration of smartphones or apps and PCC health education could help reduce the widespread burden caused by unplanned pregnancies in women with DM.

This is the first review to incorporate the use of eHealth technologies for PCC of women with DM into a discussion of PCC interventions. It highlights the benefits and limitations of each mode of delivery, and recommends use of smartphones and apps for maximizing the impact of future PCC interventions.

Limitations

A number of limitations should be noted. All reviewed studies were conducted in developed countries and their generalizability is limited to the geographical locations and health care settings in which the studies have been conducted. Various research methodologies were used in this review, and study quality was mainly moderate. Methodological weaknesses present in the study designs (small sample sizes, selection bias, confounding, and short follow-up periods) require caution in interpreting the results.

Conclusions

PCC education has a positive effect on pregnancy outcomes for women with DM. However, uptake of PCC is low and the use of eHealth apps for PCC of women with DM is still in its infancy. eHealth apps have the potential to improve access to PCC around the world, particularly in developing countries where women have increased risk of adverse maternal and fetal outcomes. Further research utilizing smartphones and apps is urgently needed as these technologies are increasingly being used around the world to provide health care information and support. Clearly, there is much to be done if full potential of eHealth PCC to improve obstetric outcomes for women with DM is to be realized.

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Authors' Contributions

CHN was responsible for the conception and design, and writing of the manuscript. NC and JS assisted with study design and writing of the manuscript. All authors critically reviewed the manuscript and approved the final version submitted for publication.
Conflicts of Interest
None declared.

Multimedia Appendix 1
Medline Strategy.
[PDF File (Adobe PDF File), 22KB - jmir_v18i11e291_app1.pdf]

Multimedia Appendix 2
Summary characteristics and quality assessment of reviewed articles.
[PDF File (Adobe PDF File), 206KB - jmir_v18i11e291_app2.pdf]

References


http://www.jmir.org/2016/11/e291/


Abbreviations

ACE: angiotensin-converting enzyme
CEMACH: confidential enquiry into maternal and child health
DM: diabetes mellitus
DSN: Diabetes specialist nurse
Hba1c: glycosylated haemoglobin
HCPs: Health care professionals
ICT: Information and communication technology
PCC: preconception care
PNC: prenatal care
RCT: randomized controlled trial
READY-Girls: reproductive-health education and awareness of diabetes in youth for girls
T1DM: type 1 diabetes mellitus
T2DM: type 2 diabetes mellitus

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Exploring the acceptability and feasibility of a preconception and diabetes information app for women with pregestational diabetes: A mixed-methods study protocol

Chidiebere Hope Nwolise, Nicola Carey and Jill Shawe

Abstract

Background: Women with diabetes are at increased risk of adverse maternal and fetal outcomes. Preconception care can improve pregnancy outcomes and is paramount to minimise complications, but, current provision is sub-optimal. Mobile technology, particularly smartphones and apps have the potential to improve preconception care provision but research is lacking in this area. The need to use modern technologies to improve preconception care knowledge and awareness led to the development of a preconception and diabetes information app in Stage A of this study.

Objective: The aim of this paper, Stage B of the study, is to explore the feasibility and acceptability of the Preconception and Diabetes Information app to improve preconception care knowledge and attitudes in women with diabetes, and explore the potential for wider implementation.

Methods: A mixed-methods study design adopting a quasi-experimental approach will assess women's knowledge and attitudes related to preconception care, and level of patient activation (knowledge and confidence for self-management of health) before and after the three-month intervention period. A log of activity will be used to determine engagement with the app and semi-structured interviews will explore women's experiences.

Conclusions: This is the first study to explore the acceptability and feasibility of a preconception and diabetes information app for women with diabetes. The app has potential to change the way preconception care is delivered, improve pregnancy outcomes and be widely implemented both in developed and developing countries. This is important given the considerable shortfalls in current preconception care services in the United Kingdom and around the world.

Keywords

Preconception care, education, diabetes mellitus, women, smartphones, mobile applications, mobile health, technology

Introduction

Diabetes mellitus (DM) has been deemed a global emergency.1,2 Worldwide, 415 million adults have DM and by 2040, this is predicted to rise to 642 million adults.2 There are two main types of DM that affect women before pregnancy: Type 1 (the pancreas does not produce any insulin) and Type 2 (the amount of insulin produced by the pancreas is insufficient or the body develops a resistance to insulin produced).1,2 DM is the most common pre-existing medical condition that can complicate pregnancy creating considerable risks both for mother and child.3–5 Poorly controlled DM together with unplanned pregnancy increases the risk of maternal and fetal complications. In addition to the
increased risk of fetal and maternal death, common complications include miscarriage, birth defects, preterm labour and birth injury, the risks of which can be minimised through preconception care (PCC). This is targeted medical care and advice about pregnancy planning which can improve pregnancy outcomes by increasing knowledge and supporting women to adopt healthy behaviours, e.g. blood glucose monitoring and folic acid use before pregnancy. Clinical guidelines recommend that PCC is provided to all women with DM once they reach adolescence. However, evidence suggests that PCC is hindered by poor implementation of clinical guidelines, provider- and patient-level barriers, and sub-optimal uptake and inadequate knowledge of PCC. These have negative implications for women with DM around the world, especially those in developing countries who are at greatest risk of adverse pregnancy outcomes. There is therefore a need to adopt more innovative approaches to delivering PCC. Evidence suggests that while PCC delivered by multimedia, i.e. compact discs with read-only memory (CD-ROMs) and digital video discs (DVDs) is feasible and effective in raising awareness of PCC in women with DM, these multi-media technologies are now outdated. Consequently they offer limited scope to the many women without access to computers or DVD players who increasingly rely on apps delivered by smartphones to access health information. The smartphone is the most popular mobile device, with over a billion users worldwide. It is technologically advanced, easily accessible, mobile and offers the opportunity to penetrate a larger population. In most developed countries, smartphones are ingrained into daily life while in developing economies, usage is proliferating rapidly and is expected to approach levels seen in developed countries. Most smartphone functionalities are aided by apps (software designed to run on smartphones), and in a recent qualitative study, women with DM suggested development of a PCC app to help convey PCC education, increase knowledge of diabetes and pregnancy and improve PCC uptake.

The increasing availability of health information in easily accessible digital format is rapidly changing the health education and information paradigm. There is some evidence to suggest that apps can help improve women’s knowledge of family planning and contraception and to reduce body mass index (BMI). They have also contributed to healthy behavioural changes in other areas – medication management, diet control, physical activity, lifestyle improvement, smoking cessation and diabetes management. The acceptance, coverage and effectiveness of apps in improving knowledge and enhancing behaviour change, coupled with the need for increased PCC awareness and uptake in women with DM, led to the development of a Preconception and Diabetes Information (PADI) app in Stage A of this study. The PADI app is designed to provide flexible and easy access to information about PCC, blood glucose monitoring and support for women with DM to optimise their health from preconception to early pregnancy. This paper presents Stage B of the study, the primary aim of which is to test the feasibility and acceptability of the PADI app and explore its potential for wider implementation.

Methods

Study design

A mixed-methods study design incorporating several data-collection methods will be used to explore the feasibility of the PADI app for women with Type 1 DM (T1DM) and Type 2 DM (T2DM). A longitudinal quasi-experimental approach with two data collection points, at the beginning and end of three months of app usage (Figure 1), will be used to assess women’s knowledge and attitudes to PCC. The quasi-experiment will not involve an external control group, outcomes will be measured before participants receive the intervention and again after the intervention, and any changes in measurement compared within the individuals over a period of time to determine the impact of the intervention. A log of activity will be used to determine engagement with the app, a simple visual scale will measure satisfaction and semi-structured interviews will explore women’s experiences of app usage.

Conceptual framework

The Normalisation Process Theory (NPT) provides the theoretical basis for this study. The NPT provides a framework that is useful for assessing and enhancing the implementation potential of technological interventions. It addresses the factors for successful implementation and integration of health interventions into routine practice, a process known as normalisation. The four components of the NPT (Table 1) were considered before and during the development of the app, and incorporated into the design of this feasibility study.

Ethical review

Favourable ethical opinion was obtained from United Kingdom National Research Ethics Service (UK NRES) Committee East Midlands-Derby; REC reference 15/EM/0358; IRAS project ID: 178530.
Figure 1. Study flow diagram.

Table 1. Components of the Normalisation Process Theory.

<table>
<thead>
<tr>
<th>Component</th>
<th>Related Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Coherence or sense-making (the meaning the intervention makes to participants)</td>
<td>Is the intervention easy to understand and what benefits will it bring and to whom?</td>
</tr>
<tr>
<td>2. Cognitive participation or engagement (commitment made by participants)</td>
<td>Will the target user groups see it as a good idea and will they be prepared to invest time, energy and work into it?</td>
</tr>
<tr>
<td>3. Collective action (effort invested in the intervention by participants)</td>
<td>How will the intervention affect the work of user groups, will it promote or impede their work, and what effect will it have on health services, e.g. consultation time?</td>
</tr>
<tr>
<td>4. Reflexive monitoring (appraisal of the intervention by participants)</td>
<td>How will users perceive use of the intervention, can users contribute feedback about the intervention, and is there room for the intervention to be improved following user experience?</td>
</tr>
</tbody>
</table>
Recruitment

Participants will be recruited from two National Health Service (NHS) hospitals in the South of England and via social media (i.e. Twitter). Eligible participants who attend the outpatient clinics at the hospitals will be approached by a member of the healthcare team when they come for their clinic appointments and asked if they are willing to speak to a researcher (CHN) about testing the PADI app. A Twitter advert will be sent out inviting eligible participants to contact the study researcher if they are interested in taking part in the study. If participants indicate interest, they will be asked to provide the researcher (CHN) with their contact details. Potentially eligible participants will receive an introduction to the study face to face, by mail or telephone. It will be made clear in all information provided to participants that they do not have to participate in the study and that they can withdraw from the study at any time without prejudicing their care. All potentially eligible participants will be screened for eligibility against the following inclusion criteria:

- Woman of reproductive age (18–45 years) with T1DM or T2DM.
- Diagnosis of diabetes by a healthcare professional for more than six months.
- Currently are not pregnant, but are planning a future pregnancy (in the next five years) or want children sometime in the future.
- Own a smartphone (iOS or Android).

Those who meet the inclusion criteria will be provided with a written participant information sheet (PIS) informing them about the study. They will be given the opportunity to ask questions and written consent to participate in the study will be obtained prior to study commencement. Only eligible participants who provide written informed consent will be enrolled in the study.

Sample

A purposive sample of patients with T1DM and T2DM will be recruited into the study, from two NHS hospitals in the South of England and via social media. For feasibility studies, a sample size of 12 is considered sufficient.35 Participants for the intervention phase will comprise \( n = 15–20 \) women with DM, with attrition (or drop-outs) estimated at 20%.36 Figure 1 provides a flowchart of participants through the study.

Intervention

All eligible participants enrolled in the study will receive the intervention. It is anticipated that participants will utilise the PADI app for at least five minutes a day, 35 minutes a week and seven hours over three months to (1) access preconception information and (2) record their blood glucose level.

PADI app development

A co-design approach was used to develop the PADI app (Figure 2) to help ensure that it met the needs of women and that its content was appropriate and acceptable.37–40 The PADI development team included women with DM (app development working group), healthcare professionals (expert advisory group) and a digital agency (Netsells Ltd).

Content development. The PADI app content was based on a series of focus groups and interviews with the expert advisory group and app development working group, the majority of whose members were supportive of using technology to support PCC. The app content was also informed by previous research in this area (Holmes et al.21) and the findings from a recent systematic review.10

Expert advisory group

The expert advisory group comprised doctors (general practitioner, obstetrician, endocrinologist) and nurses (research and specialist) who suggested including the following information: importance of planning pregnancy and using contraception until stable HbA1c is achieved, pregnancy-related risks for the woman and baby, and general health advice for the preconception period.

App development working group

The app development working group included women of childbearing age with T1DM and T2DM, age range 22–43 years, with and without prior pregnancies. They expressed desire for easily accessible and comprehensive PCC information that was provided using positive and supportive language.

Both groups were of the opinion that the information should extend beyond preconception to include diabetes and pregnancy, particularly what to expect during pregnancy and delivery. They suggested including a blood glucose diary, reminder and graph to help women track and visualise their blood glucose levels in the run up to pregnancy, and wanted a PCC app that was attractive, simple and user friendly.

PADI app design and prototype development. The app design was discussed with the app developer (Netsells), which then created wireframes, a visual
guide representing the skeletal framework of the app. The wireframes were used to detail the app layout, prioritise components and determine how the app screens will link together. They took into account the functionality of the screen, content, layout, app behaviour and sequencing of the app’s function. The output of the wireframe work was then used to create an initial prototype, a design model of the final user interface (UI), which gave the first detailed impression of how the UI or app screens would look and work. The app prototype was designed to provide a series of informational pages and a place to submit and view blood glucose readings by day, week and month. This initial design output, however, highlighted potential usability issues regarding the layout, colours and navigation. The prototype was then revised several times to ensure that the final UI was simple, user friendly and attractive.

**PADI** was developed both in Swift (programming language for iOS) and Java (android development language) in order to run both on Apple’s iOS and Google’s Android platforms. An application programming interface (API) was also developed to allow the storage and retrieval of individual records of information. The API routine connects **PADI** to Netsells’ remote server and along with the creation of user accounts, allows authentication with the data in the database. The API was developed using one of the most popular programming languages for web application backend development, Hypertext Preprocessor (PHP) framework Laravel. The resulting prototype was tested by Netsells in-house to ensure optimal functionality before being released for further testing. The final prototype was presented to a selection of participants (healthcare professionals, women with DM, researchers and members of the public) to test the full

![Diagrammatic representation of PADI app development process.](image)

**PADI**: Preconception and Diabetes Information; **HCPs**: healthcare providers.

*Figure 2. Diagrammatic representation of PADI app development process.*
app functionality for a period of 14 days and provide feedback. The piloting comprised two cycles of feedback and resulted in minor textual changes, modification of the blood glucose diary, and rectification of an error with the graphical display of blood glucose readings. This process was deemed complete when the modifications made were tested by participants and their needs satisfied.

Features of the final PADI app. Screenshots of the final app (Figure 3) show the following features: Planning for pregnancy and blood glucose diary with graphical display and reminder. The core aspects of these features and their purpose within the app are shown in Table 2.

Outcome measures
As a feasibility study evaluating the process and/acceptability of the intervention to users there is no primary outcome measure. The study will explore women’s satisfaction and experiences of using the PADI app, and provide preliminary outcome estimates, i.e. knowledge of preconception care, patient activation measure (PAM) and attitudinal change to PCC. Evaluative semi-structured interviews and log of activity after the three months of app use will seek to explore perceived acceptability, utility and usability of the app.

Data collection
Background information. Information will be collected on participants’ demographics and baseline characteristics. A section containing questions aimed at capturing these background data will be included in the patient questionnaires (Q1) administered on enrolment.

Patient questionnaires. These will be administered at two time points, on enrolment (at baseline) and following
three months of PADI app usage, and will be informed by previously validated tools involving PAM, reproductive health and diabetes instrument (RHAB) and knowledge of PCC. These evaluative questionnaires will be used to compare PAM, knowledge and attitudes to PCC before (pre-) and after (post-)intervention. At the end of the study, participants will be required to repeat the initial questionnaire (but without background information) (Q2).

Software log of activity. This will provide information on the frequency of use of the app for accessing informational pages and for self-monitoring activities, i.e. logging of blood glucose. This will be used to demonstrate uptake/utilisation of PADI’s features. PADI has inbuilt analytics that support collection of these data, which will be stored on a secure server accessible only to the app development company who will then ensure secure transfer to the researcher (CHN) to allow data analysis.

Patient interviews. Semi-structured face-to-face or telephone interviews will be undertaken at the end of the study, 40–60 minutes with the first six to eight participants from the intervention who consent to being interviewed. Interviews will explore their experience of using PADI and from this, common themes will be identified regarding acceptability, impediments to regular usage and suggestions for improvement. The interview schedule (Appendix) was informed by previously published protocols for exploring participant experience of using an app.

| Table 2. Preconception and Diabetes Information (PADI) app feature description. |
|---|---|---|
| **Features** | **Aspects of the feature** | **Purpose** |
| Planning for pregnancy drafted in line with National Institute for Clinical Excellence (NICE) pre-conception care (PCC) guidelines | This feature comprises 13 sections with information on the various aspects of preparing for pregnancy and what to expect during pregnancy and delivery. In addition to textual information, it contains videos and uniform resource locators (URLs) that users can click on to view more information on a specific topic. These URLs take users out of the app and to reliable external websites such as Diabetes UK, NICE guidelines, Family Planning Association (FPA) and womenwithdiabetes.net. PADI app icon will remain at the top of the page and users can use this to navigate back to their current session in the app. | Promote knowledge of PCC and pregnancy planning. |
| Blood glucose diary (represented both in text format and through data visualisation) | Blood glucose (BG) readings throughout the day are recorded. Frequency depends on number of times BG reading is taken and as advised by a healthcare professional. Users are able to select the current time of day from a drop-down menu, e.g. before breakfast. The time of reading is automatically set and users have the option of being reminded to take their next reading before saving the BG reading. The list of entries is then displayed starting with the oldest to the most recent. | To record and keep track of BG reading. |
| Reminders | These are set when a new reading is added. A notification is sent to the user’s phone at their set reminder time. Users have the option to deactivate set reminders by toggling the switch. | Reminder to take BG reading and help keep a regular BG reading schedule. |
| Progress | The inputted BG information is further broken down into daily averages and represented in a graph. BG readings outside recommended PCC target range (4–9 mmol/l) trigger a pop-up feature and highlights the reading. Clicking on the pop-up redirects users to the BG management page within the app. Users can choose how they want their progress displayed, e.g. today, past seven days or 30 days. | To display the user’s progress and help monitor trends. |
Data management and analysis

Microsoft Excel© will be used for the organisation, collation and recording of the quantitative data from each participant. Processing of the questionnaire will be consistent and a clear record of the returned questionnaires will be kept. Each participant will be assigned a number and the same number will be used throughout the study to allow the data on demographic information, knowledge and attitudes to PCC and PAM to be correlated. A coding manual will be developed for each questionnaire and used during the data entry process. The responses will be assigned numerical codes and recorded in the codebook. The data will then be entered into Excel spreadsheets and later imported into SPSS® version 22 for analysis. Descriptive statistics will provide preliminary estimates of key parameters, as recommended for feasibility studies.45,46

Content data from the open questions will be coded by assigning data to categories and then labelling the categories. Qualitative data (interviews) will be analysed using inductive thematic analysis.51 Interviews will be recorded, transcribed verbatim, and anonymised. QSR Nvivo 1052 will be used as a data handling management system for the data collected from the interviews. Nvivo will be used mainly for the advantages it offers in allowing large volumes of data to be handled with speed, preparing conceptual maps of coded data, facilitating exploration of relationships between codes, and aiding interpretation and theorising.33,51,52

Discussion

This paper presents a mixed-methods protocol that is designed to examine the acceptability and feasibility of the PADI app intervention. PADI incorporates both PCC information and self-monitoring of blood glucose (SMBG) functions. PCC education has been widely recommended as an effective strategy to promote PCC knowledge and encourage behaviour change.3,6,13,14,18,53 SMBG is a vital part of managing glycaemic control and optimised glycaemic control is a core component of PCC. Mobile phones have been shown to improve glycaemic control in patients with DM54–56 and the effectiveness of technological innovations in improving PCC knowledge and attitude have been demonstrated.19–22 PADI is designed to improve awareness of PCC and to support women with T1DM and T2DM adopt behaviours that support a healthy pregnancy and baby such as regular blood glucose monitoring, folic acid intake, lifestyle modification and use of contraception until optimum blood glucose levels are achieved.

Health interventions utilising mobile technologies offer many advantages including the potential for wide-scale implementation and dissemination.40 They are also able to penetrate disadvantaged or resource-poor settings including developing countries, thereby expanding the reach of health information to underserved communities in line with the United Nations sustainable development goals.57,58 Successful implementation of a technological innovation, however, requires careful consideration of several factors. For example, an intervention that is perceived as providing limited benefits, difficult to understand or fit into normal everyday practice would not appeal to healthcare professionals or policy makers.34,40 In order to maximise benefit, it is important for technological interventions to be accepted by the target population and normalised into practice.54,40 While a healthcare professional may recommend a smartphone app, it is ultimately up to those concerned to determine if the app is beneficial and worth an investment of their time.59 Therefore, to increase PADI’s potential for wide-scale adoption and implementation, women with DM and their healthcare providers were involved in its design and development, and the NPT framework34 was used to optimise the app development and inform the study design.

This is the first study to test the feasibility of a pre-conception app specifically developed for women with DM. Findings of the study will enhance understanding of the role of apps in PCC of women with DM and provide insight into their use for promoting PCC awareness and behaviour change. It is anticipated that PADI will provide an innovative way of providing more women with DM with information on PCC. This is important given the barriers associated with traditional PCC practice6,12,15,17 and the limited technology that is available to support PCC services.10 Given these limitations, the PADI app has been designed both for Apple iOS and Google Android, the two leading mobile operating systems.60 If this study is successful, it will provide the platform for a larger study to evaluate a potentially feasible and easy-to-implement intervention that can be integrated into healthcare and provide evidence of its effect on patient outcomes. However, for this study participants will be required to download the app onto their own phones and need to own a smartphone to be eligible to participate. Repeated examination of preliminary outcomes within three months may introduce some information bias into the study. Also, being a feasibility study, the sample size for the quantitative phase is quite small, limiting the generalisability of the study findings to other contexts and populations.

Conclusion

The prevalence of DM in women of reproductive age is growing, and improved PCC awareness is urgently
required to reduce poor maternal and perinatal outcomes experienced by women with DM, particularly in low and middle income countries. Mobile technology, mainly smartphones and apps, have the potential to improve PCC and obstetric outcomes for women with DM around the world, but, research is lacking in this area. This is the first study to explore the acceptability and feasibility of a preconception app for women with DM, and the findings will inform the development of a larger study. PADI could be easily integrated into healthcare, scaled up and adapted into a sustainable PCC intervention programme which could be widely implemented, particularly in developing countries where women have the highest risk of adverse pregnancy outcomes. This is important given the considerable shortfalls in current PCC provision around the world and in the United Kingdom.

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References


**Appendix**

*Semi-structured interview guide*

1. **Experience of using the smartphone App**
   - How did you get on with using the App over the last 3 months?
   - How did you find navigating the pages and finding information?
   - Did you have any problems using the app?
   - If you had problems, what were they?
   - Was the app easy to use?
   - Did you use the app regularly e.g. 5 minutes/day?
     - If no, why not.

2. **Use of App for preconception care (PCC)**
   - How did you find using an App for PCC?
   - How did you find the information on preconception care (PCC)?
   - Did you think the links to websites and videos were helpful?
   - Did you use any other PCC services whilst in the study (e.g. GP, other website)?
   - Is there any other information that you would have liked included in the App?

3. **Acceptability of features provided**
   - What do you think of the blood glucose diary?
   - How did you find inputting blood glucose data?
   - Did you use the reminders to record your blood glucose reading?
     - If no, why not.
     - If yes, were the reminders helpful?
   - Did you use the progress feature to monitor trends?
     - If no, why not.
     - If yes, did it help you in your diabetes management?
   - What features did you find useful?
   - Why did you find these features useful?

4. **Satisfaction with the app**
   - What do you think about the overall content and functionality of the App?
   - What did you like about having the PCC information delivered via an app?
   - What did you dislike about having the PCC information delivered via an app?

5. **Feedback**
   - What improvements can be made to the App?
   - Do you think any features could be removed or added to the app?
   - Is there anything you would do differently following your participation in the study?