Quality of Life and Experiences of Treatment in Chronic Leg Ulcers

by

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Summary

Leg ulcers are a chronic wound of the lower leg, prone to high levels of recurrence and associated with poor quality of life (QOL). Whilst a substantial body of literature has investigated the comparative efficacy of various treatments, little research has explored patient’s qualitative experiences of these treatments or their impact on psychological outcomes. This thesis aimed to address this gap in the literature through a systematic review and four empirical studies. Firstly, a systematic review found evidence for a relationship between wound status and QOL in leg ulceration, and revealed that surgical management may be associated with greater improvements in QOL than compression therapy alone. Next, study 1 used a cross-sectional design (n = 159) to explore predictors and mediators of quality of life in individuals with leg ulcers and reinforced this relationship between clinical severity and quality of life, suggesting that negative mood may mediate the relationship between these two elements. Study 2 then employed a longitudinal design (n = 6) to investigate the QOL of individuals undergoing minimally invasive surgical management, observing a significant improvement in emotional elements of disease specific QOL at 6-months post-surgery, but no significant improvements in other aspects of QOL. Study 3 used a qualitative design (n = 11) to explore the experiences of individuals undergoing minimally-invasive surgery. The results highlighted the importance of finding a sense of hope and empowerment not associated with other treatment approaches, and the importance of beliefs surrounding chronicity. Finally, Study 4 also used a qualitative design (n = 21) to explore patients experiences of non-surgical treatment, finding overwhelming feelings of powerlessness and frustration, whilst stressing the redemptive power of good relationships. Overall, the findings of these studies suggest that patient’s experiences of treatment for leg ulcers can be conceptualised in terms of three key themes: ‘notions of chronicity’, ‘impact of relationships’, and ‘hope and agency’. Transcending these themes is the proposal that leg ulcers and their treatment, whether surgical or not, exist in a dynamic system and that that their treatment should therefore be approached holistically.
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Chapter One

Introduction and Literature Review

1.1 Introduction

Leg ulcers are a hard-to-heal wound of the lower leg, and are considered to be a chronic wound when present for more than 6 weeks. They are most often caused by venous disease, but other causes include arterial disease, rheumatoid arthritis and diabetes (Simon, Dix, & McCollum, 2004). As the most common form of leg ulcer, approximately 1% of the UK population will suffer from a venous leg ulcer at some point in their lives (SIGN, 2010). They are known to have a profound effect on patient quality of life, and to impact individual’s lives physically, psychologically and socially (Briggs & Flemming, 2007). Leg ulcers are most commonly treated in the community using various dressings, topical medication, compression bandaging, complimentary medicine and surgical management. Many of these techniques are constantly evolving, and in particular compression bandaging and surgical techniques are prolific areas of research. As a result, there is significant debate in the medical literature regarding the most efficacious method of treatment. From a psychological perspective, whilst much research has examined illness experiences in leg ulceration, little is known of psychological outcomes from treatment, or patients’ experiences of treatment. The central aim of this thesis is to explore the psychological impact and experience of treatment for chronic leg ulceration.

In line with the aims of this thesis, the following review will describe and evaluate existing literature regarding leg ulcer aetiology, leg ulcer treatment, the psychological impact of leg ulcers on the individual, and sense-making in chronic illness. The review will introduce leg ulcers as the central concept in the thesis, providing key definitions and understanding regarding physical elements of the condition. The various treatment modalities used in leg ulcer management will be explored, with particular reference to their rationale, efficacy, and current guidelines for best practice. The review will evaluate existing research regarding living with leg ulcers, their psychological impact, and patient’s experiences of treatment, before examining the wider chronic illness literature and how leg ulcers may be situated within
this literature. This section will explore models of chronic illness and how these have been used to inform our understanding of physical and psychological outcomes. It will explore the various processes that contribute to an individual’s illness trajectory, as well as research into patients’ own experiences of chronic illness and treatment. This section of the review will help to ground the thesis within the established chronic illness literature and existing theoretical framework. Finally, it will present an overall interpretation of the existing literature and how this led to the current thesis. The chapter closes with a detailed description of the thesis aims, scope and structure.

1.2 Leg Ulcers: Aetiology, symptoms and prevalence

A leg ulcer is a hard to heal wound of the lower leg, which may increase in size or fail to heal due to an underlying condition. Venous leg ulcers are the most common form of leg ulcer, with approximately eighty per-cent caused by venous disease (Circulation Foundation, 2015; NHS Choices, 2013). Other causes of leg ulcers include arterial disease, diabetes, and rheumatoid arthritis. Arterial leg ulcers are caused by problems with arterial circulation and account for approximately fifteen percent of leg ulcers, whilst ulcers caused by other underlying conditions, such as diabetes and rheumatoid arthritis, account for approximately five percent of leg ulcers (Taylor, 2008). As the most common form of leg ulcers, this review and the wider thesis will focus on Venous leg ulcers in particular. The practicalities and implications of this will be discussed in more detail later in the thesis.

1.2.1 Venous disease

Venous leg ulcers are caused by an underlying condition, commonly known as ‘venous disease’. In a normal circulatory system, arteries carry oxygenated blood away from the heart and to the rest of the body, and veins return deoxygenated blood from the body towards the heart. Blood is moved around this circulatory system under a careful balance of various pressures, managed by the heart and a series of muscle pumps. For example, when the heart contracts or ‘beats’ this creates pressure and pushes the blood around the system. Within the venous system there are three components: deep veins, superficial veins and perforating veins. Deep veins carry the majority of the blood, are deep within the body and exist under high pressure. Superficial veins are closer to the surface of the body, regulate temperature and exist under low pressure. Perforating veins are responsible for carrying blood through muscle tissue and between these two components. Within each of these veins are a series of one-way (bicuspid) valves,
which act to separate the system into sections. When the blood is not under pressure, these valves prevent any refluxing blood from moving beyond one of these sections (see Figure 1 (A)).

During normal movement the calf muscle pump contracts, the deep veins are compressed and blood is moved up the leg and towards the heart. This change in pressure causes the one-way valves to close in order to prevent blood from falling back down the veins and refluxing away from the heart (Figure 1 (B)). When the pumps relax, the deep veins are empty, pressure drops and the valves are opened, allowing blood to again flow again from the superficial venous system to the deep venous system, before the process starts again. The mechanism of the valves opening and closing is a passive process initiated by reversal of the pressure gradient in the veins. In a competent valve, reflux of 0.5 seconds would be expected in order to initiate valve closure, but reflux of a longer duration is considered to indicate an incompetent valve and clinically significant venous reflux (Meissner, 2005). In individuals with venous disease, one or many of these valves are found to be incompetent. As a result, the valve is not able to close properly and blood is able to reflux back down the vein (Figure 1 (C)).

When present in leg veins, refluxing blood can result in acute inflammation and pressure in the surface veins of the leg (venous hypertension), as the valves fail to protect the low-pressure superficial venous system from the high-pressure of the deep venous system (Etufugh & Phillips, 2007). It is this incompetency in the valves which leads the superficial veins to dilate and varicose – known as ‘Varicose veins’. In individuals with ‘Chronic Venous Insufficiency’, the most severe manifestation of this incompetency, the resulting pressure over time damages tissue and the skin is prone to breaking down. This may be spontaneous or triggered by injury, and results in venous leg ulcers. Due to the presence of this underlying venous disease, leg ulcers have a high recurrence rate. One episode of ulceration has been known to last for between a month and more than a decade (O’Meara, Cullum, & Nelson, 2009).
Venous leg ulcers are the most severe manifestation of venous disease as a result of ‘chronic venous insufficiency’. Less severe disorders of the venous system include telangiectasia (otherwise known as ‘thread veins’ or ‘spider veins’) and varicose veins. Telangiectasia are highly prevalent in the general population and widely thought to be harmless, whilst varicose veins are also a result of underlying venous disease and generally considered less serious than active leg ulcers (NHS, 2014). The severity of venous disorders is classified using the ‘CEAP’ system, created by the American Venous Forum in 1994 and revised in 2004 (Eklof et al., 2004; Porter & Moneta, 1995). Using this system, venous disorder can be classified according to clinical disease class (C), the aetiology of the disorder (E), anatomic location of the disorder (A), and pathophysiology (P). Whilst a full assessment might include all four
factors of this system, the ‘clinical disease class’ is the most commonly used element of this classification system, and this can be interpreted as follows:

- **C₀** - No visible signs of venous disease
- **C₁** - Telangiectasia (otherwise known as ‘thread veins’ or ‘spider veins’)
- **C₂** - Varicose veins
- **C₃** - Oedema
- **C₄** - Changes in skin colour (due to pigmentation, eczema, lipodermatosclerosis or atrophie blanche)
- **C₅** - Healed venous ulcer
- **C₆** - Active venous ulcer

As demonstrated by the CEAP classification system, individuals with venous disorders may experience different symptoms dependent on the severity of their condition. This condition may be classified as symptomatic or asymptomatic, and the classification system is an active process whereby individuals may occupy different classes at different times (Eklof et al., 2004). An ulcer is considered ‘active’ if there is a “full thickness defect of the skin” (p.1250; Eklof et al., 2004), and these are typically found between the mid-calf and the ankle. Ulcers can vary greatly in size, depth and colour and people may have multiple ulcerations on one or both legs. As indicated by the CEAP classification, ulcers are often accompanied by a swelling of the legs (oedema) and changes in skin colour. This change in colour may appear as a ‘brownish stain’, as a result of hemosiderin deposits, and often this is one of the first symptoms individuals notice in a developing leg ulcer. Another possible manifestation of venous disease is lipodermatosclerosis, which presents as a severely narrowed ankle and swollen calf. This is sometimes referred to as ‘champagne leg’ because of its resemblance to an inverted champagne bottle, and it can be a very painful condition (Etufugh & Phillips, 2007).

As with many chronic illnesses, the symptoms associated with venous leg ulcers may vary dependent on the individual. Patients with various levels of venous disease may experience feelings of heaviness, itching and aching legs (Kelechi, Johnson, &
Venous ulcers are also widely acknowledged to be associated with pain, discharge from the ulcer and a profound impact on patient quality of life (Briggs & Flemming, 2007). Pain is suggested to be a particularly prevalent and dominant issue for individuals with leg ulcers (Persoon et al., 2004), and up to 85% of patients report experiencing pain as a result of their ulcers (Heinen, van Achterberg, op Reimer, van de Kerkhof, & de Laat, 2004). This pain, alongside swelling and restricted ankle movement, is often believed to result in reduced mobility and this in turn is associated with social isolation and depression. The amount of exudate from leg ulcers can also be particularly distressing for individuals, as well as the odour often associated with this discharge (Rich & McLachlan, 2003). The psychological implications of these symptoms and the leg ulcer itself will be discussed in more detail later in the review (see section 1.4.1).

1.2.2 Diagnosis
A number of non-invasive diagnostic assessments are used to investigate leg ulcers and determine their underlying cause. Upon presentation, it is recommended that an individual with a suspected venous leg ulcer should be asked for a full medical history, with particular reference to prior deep vein thrombosis, treatment for varicose veins and prior surgery. They should be assessed for symptoms of venous disease including oedema, joint mobility lipodermatosclerosis and atrophie blanche (SIGN, 2010). An initial assessment would then include a resting Ankle Brachial Pressure Index (ABPI), commonly known as a ‘Doppler test’. This is a hand-held machine used to measure the competency of arteries, by comparing the systolic blood pressure in an individual’s ankle to the systolic blood pressure in their arm (NICE, 2015). The ABPI is used as a primary diagnostic assessment in many clinical settings, to ascertain whether an ulcer has a venous, arterial or mixed aetiology. This investigation produces an ‘ABPI index’, which according to a set of commonly used thresholds may indicate normal arterial functioning (>0.85), or moderate (≤0.85) to severe (≤0.5) arterial disease (Ghauri, Nyamekye, Grabs, Farndon, & Poskitt, 1998a). This assessment can be conducted by many healthcare practitioners who have received the appropriate training, including district and practice nurses, and thus it is an accessible assessment technique for use in the community. The ABPI is an important element of the assessment process, as any underlying arterial disease is an important consideration in considering an individual’s treatment pathway. It is not, however, suitable for use with individuals who have a
In order to investigate and diagnose venous disease, this primary ABPI assessment may be followed by a dupplex ultrasound (DUS) assessment. This is considered the ‘gold standard’ non-invasive investigation for chronic venous disease (Wittens et al., 2015) and may be conducted by a qualified vascular technologist. DUS is a validated and highly accurate method of investigating vascular anatomy and functionality (Ghauri, Nyamekye, Grabs, Farndon, & Poskitt, 1998b; Magnusson, Nelzén, Risberg, & Sivertsson, 2001), and its accuracy may be improved even further by the inclusion of colour flow imaging (Wittens et al., 2015). With the use of ultrasound it is possible to gather anatomical information, flow visualisation and compressibility. By applying pressure to various areas of the legs (provocation manoeuvres), it is possible for the individual performing the investigation to measure the direction of flow, vein patency and valve competency (Mendoza & Lattimer, 2014). As a result of the ABPI and DUS diagnostic tests, a venous, arterial, mixed or alternative aetiology can be determined, and an individual may be given a ‘CEAP’ classification, as discussed in the previous pages. Following this diagnosis, the appropriate treatment pathway can be identified (see Section 1.3 for further discussion of treatment and management).

1.2.3 Prevalence

Significant issues have been encountered establishing the prevalence of venous leg ulcers in the UK and worldwide. Each method of calculating prevalence is said to have its own pitfalls and thus may be an over or under estimation. Whilst this could be the case for many conditions, it is suggested to be particularly difficult in venous leg ulcers due to difficulty in validating a diagnosis for research purposes (Nelzen, 2008) and the reportedly large number of patients who may not be aware of their ulcer’s aetiology (Van Hecke et al., 2013). Despite these difficulties, overall prevalence of venous leg ulcers is estimated to be approximately 1% of the population, and point prevalence (i.e. the amount of individuals with an open ulcer at any one time) is believed to be approximately 0.1-0.3% of the population. When examining those over the age of 65 years, overall prevalence is suggested to rise to 3% and point prevalence is suggested to rise to 1%. These figures are suggested to be relatively stable across countries (Nelzen,
and little difference is seen between prevalence in men and women (Wittens et al., 2015).

Many risk factors have been investigated in association with chronic venous disease, and these represent an ongoing debate in the literature. Age is suggested to be one of the most important of these risk factors, with individuals over the age of 70 thought to be more than 23 times more likely to have a healed or open venous leg ulcer (Wittens et al., 2015). Obesity is also believed to be a risk factor for venous leg ulcers, although the relationship appears complex, with a higher BMI associated with greater risk of skin changes and ulceration but not necessarily associated with a higher risk of venous reflux (Danielsson, Eklof, Grandinetti, & Kistner, 2002). Many correlational studies suggest an association between a family history of venous disease and increased risk, although no genetic basis for this correlation has been identified to date (Wittens et al., 2015). Further suggestions for risk factors include occupations involving prolonged standing, although evidence surrounding this remains controversial (Etufugh & Phillips, 2007).

1.2.4 Summary
In summary, leg ulcers may be caused by venous disease, arterial disease, rheumatoid arthritis, diabetes and other underlying factors; however, venous ulcers represent 80 per cent of leg ulcers and will be the focus of this thesis. They are caused by underlying venous disease, and are the most serious manifestation of this disease. They have a significant impact on patient quality of life, and dominant symptoms include pain, discharge and limitations to mobility. Venous leg ulcers effect approximately 1% of the UK population, and are more common in the elderly and those with a family history of the condition. Diagnosis may be performed using the Ankle Brachial Pressure Index and a Colour Duplex Ultrasound assessment, and their severity classified using the ‘CEAP’ classification system. Appropriate diagnosis is fundamental to the treatment of venous leg ulcers and this will be explored in more detail in the following section.

1.3 Leg Ulcers: Treatment
Treatment for venous leg ulcers may be separated into compression treatment, advanced wound dressings, various surgical techniques and alternative treatments. A significant literature exists surrounding the rationale, use and efficacy of each of these treatment modalities and debate remains as to the best treatment pathway. Within this literature,
common outcome measures include healing time, healing rate, recurrence rate, and quality of life. Each of these treatment modalities and the relevant research findings will be discussed here, alongside clinical guidelines on evidence-based practice and effective treatment pathways.

1.3.1 Compression therapy

Compression therapy is used in the treatment of leg ulcers to manage venous hypertension and reduce venous stasis (Simon et al., 2004; Wittens et al., 2015). Compression is applied through the use of stockings or layered bandages, and may be applied at varying degrees or graduated up the leg. Stockings may be elastic or non-elastic, short-stretch, long-stretch, or intermittent pneumatic, whilst bandages may be applied in 2-layer or 4-layer systems. These treatment regimens are able to reduce pressure in the venous system and increase lymphatic drainage (reducing Oedema), by compressing the superficial and deep veins of the leg and improving function of the calf muscle pump (Etufugh & Phillips, 2007; Wittens et al., 2015). Applied by nurses, compression therapy is widely used in the treatment of venous leg ulcers and the most commonly used system in the UK is believed to be four-layer bandaging (O’Meara et al., 2009). It is often recommended that compression therapy is combined with limb elevation, as this is believed to reduce the oedema often associated with venous disease and venous leg ulcers, as well as improving microcirculation in the affected legs (Kelechi et al., 2015). Studies have found that 30 minutes of leg elevation per day may be a protective factor for leg ulcer recurrence (Finlayson, Wu, & Edwards, 2015) and compression therapy is also recommended for long-term use in order to prevent ulcer recurrence, via the use of graduated-compression elastic stockings. This is recommended as a life-long prevention strategy, as the stockings are able to moderate many of the mechanisms of venous disease (Etufugh & Phillips, 2007).

In order to determine whether compression therapy aids in the healing of venous leg ulcers it is necessary to compare it to treatment without compression. A recent Cochrane review examined the existing literature (O’Meara et al., 2009) and identified seven relevant randomised controlled trials (RCTs) to answer this question. The review concluded there is evidence to suggest that healing time for venous leg ulcers was reduced with compression treatment, compared to treatment with dressings alone or usual care, although it should be considered that those receiving compression treatments may also be benefiting from a higher level of staff expertise and this may have
influenced patient outcomes (O’Meara et al., 2009). With this in mind, the second research question in O’Meara et al.’s review focused on differences between various compression therapy systems. With a multitude of systems available it is unclear which of these, if any, is most effective. After examining evidence from single-component, multi-component, adjustable and stocking based systems, it was concluded that healing outcomes are more improved with multi-component systems than with single-component systems. Systems using elastic bandages were suggested to be more effective than inelastic bandages, and four-layer bandages were found to be more cost-effective than multi-component systems using short-stretch bandages. Results from trials comparing tubular compression with compression bandages, and four-layer bandaging with paste bandaging systems were unclear, whilst no differences were found between single-layer systems, paste bandages and adjustable compression boots. Again, the influence of staff expertise is relevant to this question, and it was suggested that the efficacy of some compression bandage systems may depend greatly on the expertise of those applying them (O’Meara et al., 2009). In line with this suggestion, some have proposed that treatment would benefit from use of the form of compression with which the practitioner is most competent and the patient is best able to tolerate (Wittens et al., 2015). Suggestions such as these emphasise the importance of patient-centred care, as they consider the patient’s opinion and tolerability of the treatment, in addition to potential medical outcomes.

1.3.2 Dressings and advanced wound dressings

Wound dressings may be applied underneath, or in lieu of, compression therapy. They come in various forms and may improve comfort, control exudate and maintain a moisture balance in the affected area, whilst ultimately aiming to improve healing. The most basic wound dressings consist of a simple non-adherent dressing, with the aim to protect the wound from other elements of treatment. More advanced dressings have various specialised qualities in terms of exudate and moisture, whilst anti-microbial dressings include an additional element to prevent infection. Although a surgical procedure, skin grafting may also be considered a ‘biological’ dressing.

Advanced wound dressings include: hydrocolloid, hydrogel, foam and alginate dressings. All of these dressing types are specially designed to absorb exudate from the surface of the wound whilst also providing a moist wound environment, however, a Cochrane review concluded that current evidence does not suggest any of these dressing
types are more effective than simple non-adherent dressings when used beneath compression (Palfreyman, Nelson, Lochiel, & Michaels, 2006). These findings are supported by additional reviews, focusing solely on Alginate and Foam dressings, which also found them to be no more or less effective than non-adherent dressings (O’Meara, Martyn-St James, & Adderley, 2013; O’Meara & Martyn-St James, 2013). All three Cochrane reviews highlight the paucity of good quality evidence in this area, suggesting that trials often suffered from small sample sizes, short study durations and poor reporting. Palfreyman et al. (2006) suggest that in the absence of high-quality evidence, treatment decisions may be based on practitioner and patient preferences, as well as the cost of dressings. This reflects similar conclusions to those found in the compression bandaging literature.

Anti-microbial dressings aim to prevent infection, or reduce the bioburden of wounds, through the use of antimicrobial agents incorporated into the dressing (Leaper, 2012). Two common examples of these dressings include silver and honey-impregnated dressings; however, there is limited research evidence to support either dressing type. Anecdotal evidence, along with some preliminary in vitro trials, suggest that honey may have antimicrobial properties and facilitate wound healing, and has therefore also been used to impregnate dressings for venous leg ulcers. A randomized clinical trial comparing honey-impregnated dressings with usual care, however, did not find any benefit to the use of honey-impregnated dressings and in fact noted an association between these dressings and undesired adverse events (Jull, Walker, Parag, Molan, & Rodgers, 2008). In a Cochrane review of topical honey treatment for wounds, Jull, Rodgers, & Walker (2008) conclude that the current evidence does not suggest honey-impregnated dressings significantly improve leg ulcer healing when compared to hydrogel dressings or usual care. An additional review of silver-containing foam dressings evaluated the evidence presented in three RCTs and also found no current evidence to suggest silver-containing dressings should be used with venous ulcers (Vermeulen, van Hattem, Storm-Versloot, and Ubbink, 2007). As such, current research evidence does not provide a basis from which to recommend antimicrobial dressings.

Biological skin grafting is also considered a type of advanced wound dressing, and these are sometimes used in order to stimulate wound healing in particularly hard-to-heal venous leg ulcers. Skin grafts may use the patient’s skin, bioengineered skin or animal skin to cover the debrided wound. A systematic review of the current evidence
investigating skin grafting for the treatment of leg ulcers found that bilayer artificial skin aided in the healing of significantly more ulcers than dressings alone (Jones & Nelson, 2005). Conclusions could not be provided regarding other skin graft types, however, national clinical guidelines suggest that at this point not enough is known about skin grafting and its effects to provide recommendations on its use (SIGN, 2010).

1.3.3 Adjunctive treatments
A number of adjunctive treatments have also been developed in the treatment of venous leg ulcers. These include: the use of antibiotics and antiseptics, hyperbaric oxygen therapy, therapeutic ultrasound, and electromagnetic therapy and larval therapy.

As an open wound, venous leg ulcers are prone to infection and bacterial colonisation, which may delay healing (O’Meara, Al-Kurdi, Ologun, & Ovington, 2010). In order to tackle this problem systemic antibiotics, topical antibiotics and topical antiseptics are often used in the treatment of venous leg ulcers; however, a recent Cochrane review suggests that this may not be an appropriate adjunctive treatment. Exploring the results of forty-five RCTs, O’Meara et al. (2010) suggest that, whilst Cadexomer iodine (a topical antiseptic) may be beneficial for wound healing, no current evidence supports the use of systemic antibiotics in the treatment of venous leg ulcers. Further research is required to investigate the use of other topical antiseptics and antibiotics, whilst the authors recommend that systemic antibiotic treatments are used in the case of clinical infection only. This is in line with current guidelines for avoiding bacterial resistance to antibiotics.

Hyperbaric oxygen therapy (HBOT), therapeutic ultrasound (TUS) and electromagnetic therapy (EMT) have all been suggested to improve the healing of venous leg ulcers, although good quality research evidence is suggested to be lacking with regards to the efficacy of each of these treatments. Whilst HBOT has been found to contribute to improved healing in diabetic foot ulcers in the short term, the same effect could not be established in long-term measures and further rigorous research is required to investigate this treatment in venous leg ulcers (Kranke et al., 2015). No reliable current evidence suggests that TUS may lead to shorter healing times in venous leg ulcers (Cullum, Al-Kurdi, & Bell-Syer, 2008), and further good-quality research is required to establish the role of EMT in the healing of venous leg ulcers (Aziz & Cullum, 2006).
Larval therapy has also been suggested to aid in the healing of venous leg ulcers through debridement of the affected area, although few research studies have investigated the effectiveness of this treatment. Larval therapy involves the use of live maggots to remove dead, damaged or infected tissue from the ulcer site, in order to improve healing in the remaining tissue. Whilst alternative debridement techniques exist, larval therapy is believed to provide a cost-effective method with minimal effect on healthy tissue (Parnés & Lagan, 2007). A randomised controlled trial comparing larval therapy to standard hydrogel debridement and found that whilst the rate of healing was not significantly improved in the ‘larval therapy’ group, larval therapy was significantly quicker at debriding the affected area compared to the hydrogel group (Dumville et al., 2009). Compared to other debridement techniques, however, larval therapy is suggested to be significantly more painful for patients and as a result was not recommended for routine use (Dumville et al., 2009).

1.3.4 Superficial venous surgery

Individuals with superficial venous insufficiency may also be offered surgical interventions to treat the underlying venous disease causing the ulceration (Etufugh & Phillips, 2007). Traditionally this required a general anaesthetic and invasive open surgery, specifically saphenofemoral or high ligation and stripping of the incompetent veins. These procedures would involve tying a ligature around the affected vein, and removing this through an incision in the skin. Whilst these classical techniques are believed to be effective at healing the leg ulcer and are still used in some patients (Bello & Scriven, 1999), more recently minimally invasive surgical techniques have been developed in order to treat the veins under local anaesthetic and with less complications (Kelechi et al., 2015). Such minimally invasive techniques include Ultrasound Guided Foam Sclerotherapy (UGFS) and Endovenous thermal ablation (EVTA).

Ultrasound Guided Sclerotherapy involves injecting the affected veins with chemical agents in order to damage the interior surface, cause a clot and trigger the body’s natural defences to remove the damaged vein. Whilst this procedure can be performed with liquid or foam-based chemicals, foam has been found to be a more effective sclerosant for this procedure. In a similar process, heat may also be used to damage the interior surface of the veins, and this is done using Endovenous Thermal Ablation (EVTA) techniques. A laser-fibre (Endovenous Laser Ablation; EVLA) or radiofrequency catheter (Radiofrequency Laser Ablation; RFA) is inserted into the vein,
local anaesthetic is injected around the vein and then the instrument is removed whilst emitting energy to thermally damage the vein wall (Wittens et al., 2015). As with sclerotherapy, the body’s natural defences then remove the damaged vein. Due to their minimally-invasive nature and use of local anaesthetic, foam sclerotherapy and endovenous thermal ablation may be more suitable for elderly or frail patients than classical surgical techniques (Wittens et al., 2015).

Traditional superficial venous surgery, foam sclerotherapy and EVLA have all been found to be effective in healing chronic leg ulcers (Bello & Scriven, 1999; Kulkarni et al., 2013; Navarro, Min, & Bone, 2001). When compared to compression therapy alone, studies have suggested that healing rates are similar in surgical treatment versus compression alone (Howard et al., 2008), however, recurrence rates have been found to be lower for surgical treatment after 1, 2, 3 and 4 years (Barwell et al., 2000; Barwell et al., 2004; Gohel et al., 2007). When comparing surgical techniques, however, significant debate exists in the literature and research continues to investigate their relative merits. A meta-analysis conducted by Van den Bos, Arends, Kockaert, Neumann, & Nijsten (2009) suggested that in the treatment of varicose veins minimally invasive surgical techniques were as effective as stripping, and recommend that EVLA was more effective. No similar meta-analysis has been performed examining the relative efficacy of these treatments for leg ulcers, and the rapid evolution of these techniques and the instruments used makes comparison difficult. Recurrence is an important outcome when comparing treatments, not least because it can have a significant impact on patient quality of life. It is estimated that recurrence rates twelve-months post treatment are between 26-69%, depending on many factors including treatment modality (Nelson, Bell-syer, Cullum, & Webster, 2000). Whilst compression therapy may counteract some of the faulty mechanisms brought about by venous disease, surgical techniques aim to address the underlying venous disease causing the ulcer, and thus recurrence rates are a key measure of their efficacy.

1.3.5 Clinical guidelines for treatment
Several clinical guidelines for treatment have been published in recent years, put together by organisations such as the European Society for Vascular Surgery (ESVS) and the National Institute for Health and Care Excellence (NICE). These guidelines aim to provide evidence-based clinical recommendations for practitioners and patients, and the most recent guidelines were assembled by the ESVS in 2015 (Wittens et al., 2015).
These guidelines synthesise existing research on clinical presentation, diagnosis, and treatment of chronic venous disease, including chronic leg ulcers. In the current set of guidelines, some of the primary recommendations are as follows:

- The CEAP classification system should be used in chronic venous disease assessment
- Evaluations of patients with chronic venous disease should utilise both a general and disease-specific measurement tool
- Duplex ultrasound should be used as a primary diagnostic assessment of chronic venous disease
- Wound dressings and compression therapy may be used to promote wound healing for leg ulceration, whilst options for surgical interventions should also be explored and offered to the patient
- If superficial venous surgery is performed (including Endovenous thermal ablation and Sclerotherapy), compression is recommended post-surgically
- Leg elevation and maintenance of mobility should be considered in order to encourage healing
- Endovenous thermal ablation (EVTA) is recommended as a primary option in the case of superficial venous incompetence
- Foam Sclerotherapy is recommended in order to treat superficial venous incompetence in frail or elderly patients, or those not suitable for EVTA

Although these guidelines are based on current research evidence and the clinical experience of 30 contributors, the authors acknowledge that research and technology development in this area moves swiftly and guidelines are updated as regularly as the committee deem necessary (Wittens et al., 2015).

An alternative set of guidelines is provided by the Scottish Intercollegiate Guidelines Network (SIGN, 2010), synthesising the available evidence in a similar manner to the ESVS guidelines, whilst narrowing their focus to chronic venous leg ulcers in particular. With similar recommendations, the SIGN guidelines recommend the use of basic non-adherent dressings, high compression multicomponent bandaging, and continued use of compression therapy after healing in order to prevent recurrence. In addition, these guidelines recommend that venous leg ulcers are treated in a specialist clinic, in order to provide optimal treatment to patients (SIGN, 2010)
Also produced to guide the assessment and management of chronic venous disease in the UK are the NICE guidelines for ‘Varicose veins: diagnosis and management’ (NICE, 2013). Whilst not addressing the treatment of chronic venous ulcers explicitly, these guidelines recommend that individuals with recurrent varicose veins, external symptoms of venous disease, an active venous leg ulcer, or a healed venous leg ulcer are referred to a specialist vascular service. Assessment is recommended using a duplex ultrasound, and for those with confirmed varicose veins EVLA, RFA, Foam sclerotherapy and more invasive surgical solutions are recommended as suitable interventional procedures. These guidelines are not, however, specific to chronic venous leg ulcers and there is some confusion between these and the Clinical Knowledge Summaries also provided by NICE (NICE, 2015). For this reason many patients and professionals look to the guidelines provided by professional organisations for guidance.

1.3.6 Summary
Treatment for venous leg ulcers includes compression, advanced wound dressings, adjunctive treatments and superficial venous surgery. A significant literature, and many high-quality Cochrane reviews, have been dedicated to the efficacy of these interventions in terms of healing rates, speed of healing and recurrence. This evidence suggests that compression therapy is an effective method of treatment for healing leg ulcers when compared to no compression treatment. Little evidence supports the use of advanced wound dressings, and therefore basic non-adherent dressings are recommended for use underneath compression. Minimally-invasive surgical interventions aim to address the cause of the ulcer through treatment of the underlying venous disease, and results suggest that recurrence rates for these surgical interventions are significantly better than compression bandaging alone. However, critics of the existing literature suggest both arms of many clinical trials show improvement due to the high quality of care provided during research, which is not always evident in the community (Guest, Gerrish, Ayoub, Vowden, & Vowden, 2015). Synthesis of these findings into clinical guidelines have provided a number of clear recommendations for practice, including the primary recommendation that all individuals with a chronic venous leg ulcer are referred to a specialist vascular service for further diagnostic assessment.
1.4 Leg Ulcers as a chronic Illness

Venous leg ulcers are considered to be a chronic illness by the medical profession, and thus can be seen within the context of this psychological literature. These are illnesses which are persistent in duration, require increased use of health care services and introduce functional limitations to an individual’s life which may impact on their day-to-day functioning (de Ridder, 2004; Kaptein et al., 2003; Moss-Morris, 2013). Chronic illnesses are responsible for the deaths of approximately 38 million people each year, and most can be separated into four distinct categories: cardiovascular diseases, cancers, chronic respiratory diseases and diabetes (World Health Organisation, 2015). Leg ulcers fall into the category of cardiovascular disease. Research into leg ulcers as a chronic illness has predominantly focused on health outcomes, psychological impact and quality of life, with additional attention to the impact on caregivers and the interaction between physical and psychological outcomes. This review will explore these areas in the following sections.

1.4.1 Psychological impact

Much research has been conducted exploring patient experience of living with leg ulcers and it is suggested that the effects can be separated into three domains; physical, social, and psychological (Briggs & Flemming, 2007). Physical effects include symptoms, such as pain, weeping from the wound, odour, infection, and limited mobility. These symptoms then appear to have a subsequent impact on social and psychological elements, restricting a patient and causing isolation, for practical or psychological reasons. Whilst leg ulcers most commonly occur in older people and so poorer physical health or limited social activity might not be uncommon, research has shown that the social isolation experienced by those with leg ulcers is more than in an equivalent healthy elderly population (Wissing, Ek, & Unosson, 2002). In addition, when matched with age and gender equivalent controls, individuals with leg ulcers have been found to experience significantly greater levels of depression, poorer quality of life, and less perceived social support, whilst also utilising less coping strategies than their healthy counterparts (Moffatt, Franks, Doherty, Smithdale, & Steptoe, 2009).

A review of the literature exploring the impact of leg ulcers on daily life highlighted negative psychological impact as one of the most pervasive factors in this research area (Persoon et al., 2004). Studies demonstrate that leg ulcers can result in higher levels of depression and anxiety, loss of will power, lower self-confidence, and
lower self-esteem (Douglas, 2001; Green, Jester, McKinley, & Pooler, 2013; Persoon et al., 2004). The recurrent nature of leg ulcers leads to feelings of helplessness and hopelessness (Persoon et al., 2004), whilst body image may become a central focus for those living with leg ulcers (Ebbeskog & Ekman, 2001). Individuals with leg ulcers report body image concerns, in terms of how others perceive physical symptoms of leg ulceration, as well as having to alter the clothes they normally wear due to the compression bandages used in treatment (Chase, Melloni, & Savage, 1997; Ebbeskog & Ekman, 2001; Hyde, Ward, Horsfall, & Winder, 1999; Rich & McLachlan, 2003; Tabolli, Tinelli, & Guarnera, 2007).

Briggs & Flemming (2007) suggest that pain is a particularly dominating element of patients’ experiences with leg ulcers, and this has been reported in a multitude of qualitative and quantitative studies (Chase et al., 1997; Douglas, 2001; Green et al., 2013; Hyde et al., 1999; Palfreyman, 2008; Rich & McLachlan, 2003; Walshe, 1995). Pain control is believed to be a marginalised but important aspect of care (McMullen, 2004), which is likely to also impact on patients’ psychological wellbeing. Several reviews of the literature suggest that patients with leg ulcers have significantly poorer quality of life (Gorecki et al., 2009; Herber, Schnep, & Rieger, 2007; Maddox, 2012; Persoon et al., 2004), and a case-control study has suggested this is particularly poor in terms of energy, mobility, sleep and pain (Moffatt et al., 2009). Cross-sectional research has suggested an association between poor health related quality of life and higher levels of pain or non-healing ulcers (Hareendran et al., 2005), as well as larger ulcer size and longer ulcer duration (Hopman, Vandenkerkhof, Carley, Kuhnke, & Harrison, 2014). Similarly, those whose ulcers are healed or showing signs of healing have been found to report better quality of life on quantitative measures (Kahn et al., 2004; Tennvall & Apelqvist, 2000).

As a chronic condition where leg ulcers may take years to heal and recurrence is high, quality of life is thought to be an important outcome measure (Anand, Dean, Nettleton, & Praburaj, 2003). However, its measurement is also a complex and highly debated area, in venous leg ulcer research and the wider field of health psychology. When using quantitative methods to investigate quality of life, an important dichotomy exists between generic health-related quality of life (HRQOL) measures and disease-specific measures. In a review of thirty-one quality of life measures and their use with venous leg ulcer patients, Palfreyman, Tod, Brazier, & Michaels (2010) suggest that
generic instruments are more widely used and allow comparison with healthy populations. These generic measures have the advantage of remaining relevant if patients’ ulcers heal, whereas some disease-specific measures do not. Disease specific instruments, however, have proven more sensitive to a change in a patient’s condition and may be more relevant to patients’ symptoms, as they are designed specifically for use with leg ulcers. These disease-specific measures are able to distinguish between leg ulcer related factors and a patient’s general health status or co-morbidities, and may lead to a deeper understanding of HRQOL in the patient group (Iglesias, Birks, Nelson, Scanlon, & Cullum, 2005). In order to gain optimal results, authors have suggested future studies combine a generic QOL measure and a disease-specific QOL measure when working with venous leg ulcer patients (Howard & Davies, 2001; Smith et al., 2000). Whilst research must be mindful not to fatigue participants with too many measures, this combination is thought to combine the advantages of both methods.

1.4.2 Interaction with physical outcomes

Not only is the psychosocial impact of leg ulcers important for psychological wellbeing, but studies suggest that it may also be important for patients’ physical outcomes. In particular it is argued that psychological stress may have an impact on wound healing, and this is supported by a recent systematic review and meta-analysis (Walburn, Vedhara, Hankins, Rixon, & Weinman, 2009). Walburn et al.’s (2009) review examined twenty-two papers and found a significant negative association between stress and wound healing, with a medium effect size. They suggest that this association should be considered with the same seriousness as age and diabetes when discussing factors that influence wound healing. Exploring leg ulcers in particular, Cole-King & Harding (2001) found that higher levels of depression and anxiety were associated with delayed healing. Those who demonstrated higher levels of anxiety were found to be approximately eight times more likely to also suffer from delayed leg ulcer healing, than those without this level of anxiety. Cole-King & Harding (2001) suggest that this relationship may be a direct biological effect or an indirect consequence of factors such as self-neglect and poor sleep quality; however, this study does not indicate causation and thus it is unclear whether delayed wound healing may in fact be leading to higher levels of depression and anxiety.

Research has also reported that healed ulcers lead to significant improvements in quality of life measures (Charles, 2004; Franks et al., 1999; Franks, Moffatt,
Doherty, Smithdale, & Martin, 2006), although the sustainability of this change is uncertain and research by Franks et al. (2006) suggests patients may return to previous levels of pain and energy when studied over a longer time-period. Whilst questions remain about the causality involved in these associations, this body of literature demonstrates the important relationship between physical and psychological outcomes.

The relationship a patient has with their practitioner also appears to be strongly linked to participant outcomes. Patients are reported to have confidence and satisfaction in the community nurses who often treat them (Hopkins, 2004; Walshe, 1995), and many studies suggest that a personable approach to patient care and an environment that encourages good patient socialisation can have a positive influence on patients healing and their psychosocial wellbeing (Douglas, 2001; Edwards, Courtney, Finlayson, Shuter, & Lindsay, 2009; Van Hecke & Grypdonck, 2011). Communication appears to be an important element, as Brown (2005) discusses potential improvements in patients adherence if they are aware of the aetiology of their leg ulcer and the reasons behind the treatment approach. In addition, research by Bodenheimer, Lorig, Holman, & Grumbach (2002) stresses the importance of finding out what a patient believes to be their most important problem before designing a self-management programme; further emphasising the importance of good communication. Whilst elements such as pain, infection and dressings are routinely attended to during treatment, Hyde et al. (1999) suggest that attention by community nurses to the more complex or subtle psychosocial issues that patients are struggling with could greatly improve quality of life associated with ulceration. Unfortunately, whilst many community nurses may already put this into practice, others may feel their service is limited by practicalities of time and patient numbers (Chamanga, 2014).

### 1.4.3 Caregiver impact

The psychological impact of leg ulcers is not just limited to those individuals with leg ulcers, as anecdotal and research evidence has suggested there is also a significant psychological impact on those who care for them (Douglas, 2001). This is consistent with other chronic conditions, where caregiver burden is a major area of study. Whilst many caring behaviours, such as preparing meals for someone, may be considered a normal aspect of familial relationships, caregivers are defined by the extraordinary and unpaid nature of their assistance; for example, bathing or aiding in medical care (Schulz & Quittner, 1998). There is a large economic value for this endeavour, saving money
for the National Health Service and for individuals who otherwise may have to pay for private care. As the ageing population increases this economic value is likely to also increase (Bastawrous, 2013), however the adoption of such a role is likely to impact on the daily life of the caregiver and the care recipient. This has led to a large body of research investigating what has been identified as ‘caregiver burden’. Definitions of this burden differ, but it is suggested that this is comprised of objective and subjective components, and may be interpreted effectively within the stress theory and role theory literature (Bastawrous, 2013).

Early research into caregiving primarily utilised descriptive accounts to investigate the impact of care giving on the carer, and examined the relationships between the illness severity of care recipients and the impact on the caregiver. There is thought to be a moderate relationship between these two variables, however longitudinal research has revealed this relationship is not as simple as first thought (Schulz & Quittner, 1998). Many studies have investigated the mediating factors involved in care giving impact, and Williamson, Shaffer, & Schulz (1998) found a relationship between activity restriction, depression, resentment, and symptoms severity in caregivers to people with Cancer. They also found that adaption to the caregiver role was particularly related to past mutual communal behaviour. Those who had shared a great deal of communal behaviour before the care giving dyad developed, for example spouses or those who lived with the care-recipient, appeared to have most difficulty in adapting to the caregiver role. The stability of such mediating factors was examined by Vedhara, Shanks, Anderson, & Lightman (2000) in their study of spousal caregivers of people with dementia. At 3 and 6 month intervals they found that stress could be predicted by reactive coping and self-appraisal, anxiety could be predicted by reactive coping and self-appraisal, and depression could be predicted by reactive coping, proactive coping, and self-appraisal. In addition, at 6 months, anxiety was predicted by seeking social support. Whilst studies suggest that informal caregiving is associated with poor health (Legg, Weir, Langhorne, Smith, & Stott, 2013), it appears the relationship is not as simple as greater illness severity indicating greater impact on the caregiver.

It is important to note that the impact of care giving on the care recipient and the caregiver are likely to differ between illnesses, as Bastawrous (2013) suggests that the type of care required and the pathway to care giving are likely to differ greatly. The
onset of illness may influence preparation and coping mechanisms, and the inclusion of mortality may drastically alter the feelings surrounding care giving. Whilst dementia, HIV, and leg ulcers could all be classed as chronic conditions, they all have a very different aetiology, symptomology, and care pathways. As described by Wight (1998), caring for someone with AIDS is often accompanied with worries about mortality and illness progression. In addition, illness may be the result of a life event. Positive HIV status or AIDS may have been the result of intravenous drug use or extramarital sex, and these circumstances surrounding the onset to care giving may affect the relationship between carer and care-recipient. Equally, people with dementia or Alzheimer’s may require more emotional and cognitive support from the caregiver, whilst venous leg ulcers have a distinct set of care giving routines surrounding dressings and wound care. These unique elements of illness and care requirement will influence the care giving experience, and thus research should investigate the effects of specific illness, as well as comparing outcomes across conditions.

Whilst a significant literature has developed surrounding caregiver impact in other conditions, little research appears to have investigated the role of caregivers in leg ulcers in particular. Nabuurs-Franssen, Huijberts, Nieuwenhuijzen Kruseman, Willems, & Schaper, (2005) explored the health-related quality of life of 153 caregivers of individuals with diabetic foot ulcers, and concluded that caregiver’s quality of life was significantly diminished if the individual they cared for had a persistent leg ulcer, in comparison to a healed leg ulcer. This was particularly the case for the emotional and mental summary scores of the measure, indicating a significant correlation between individuals with ulcers and caregivers on these elements of quality of life. Whilst diabetic and venous leg ulcers share some similarities, for example in terms of limited mobility, differences in aetiology and treatment may affect the generalisability of these findings to a venous leg ulcer population. Tabolli, Tinelli, & Guarnera (2007) also explored ulcers of various aetiologies in their exploration of the relationship between patient health status and caregiver impact. Investigating eighty patients, 45% of whom had a venous leg ulcer, Tabolli et al. (2007) suggest that caregivers who lived with the patient or had to reduce their working hours scored higher on the measure of emotional burden. They found that caregiver’s level of emotional burden was similar to other chronic diseases, such as neurological and respiratory diseases, although this was lower than caregivers of individuals with cancer. Caregivers ‘problems in social involvement’
score was higher in ulcers than in cancer patients, and it is suggested that these issues with social involvement may be due to the problems caused in the relationships between caregiver and patient. This study did not find that caregivers education level, age of patient, ulcer characteristics or living with the patient were statistically significant predictors of high emotional burden. The only predictor of emotional burden identified by Tabolli and colleagues was age of caregiver, with caregivers over the age of 50 found to be more than 3 times likely to suffer a high emotional burden. The authors suggest that caregiver burden in chronic leg ulceration is an important area of study, but that their work appears to be the only investigation in this area thus far. It is therefore unclear whether an improvement in patient health status may lead to improvements in caregiver impact, whether this may change through the course of treatment, or the importance of caregiver-patient relationship quality.

In an unusual study examining care giving from the care-recipients perspective, Newsom & Schulz (1998) examined the complexity of care-recipients negative reactions. Whilst much research assumes that receiving care has only positive elements, Newsom & Schulz (1998) interviewed 228 care-recipients with cardiovascular health problems who were married and living with their spouse. They asked participants about their health functioning, and their mental health, and asked them to complete various psychological measures. Findings suggest that care-recipients negative reactions to care giving were common and predicted by factors including lower perceived control, higher fatalism, and lower self-esteem. This is an important area of research, as whilst health related quality of life research is prolific, little has been investigated with regards to receiving informal care provision. In addition, the negative reaction of care-recipients is likely to have an effect on caregivers and influence their perceptions of care giving.

Research has also investigated the application of various social and psychological theories to the experience of caregivers. Such use of theory and conceptual frameworks were scarce in early research (Deeken, Taylor, Mangan, Yabroff, & Ingham, 2003), potentially leading to a lack of rationale for the procedures and measures used (Bastawrous, 2013). However, many researchers now suggest a more macro approach and that research examines caregivers within a wider theoretical framework in order to aid progression in the field (Bastawrous, 2013; Clair, Fitzpatrick, & Gory, 1995). Frameworks include, for example; the stress process model (Goode, Haley, Roth, & Ford, 1998), psychosocial resource model (Clair et al., 1995), and social
exchange theory (Call, Finch, Huck, & Kane, 1999). The stress process model (Pearlin, Mullan, Semple, & Skaff, 1990) draws on Lazarus’ stress-appraisal-coping model (Lazarus, 1966; in Deeken, Taylor, Mangan, Yabroff, & Ingham, 2003), and focuses on the relationship between stressors, the care giving experience, and the caregiver’s self-concept. The model suggests that caregivers undergo a process of adaptation to their role, influenced by: background and contextual factors, caregiving stressors, mediating factors and caregiving outcomes (Quinn, Clare, & Woods, 2009). As such, it suggests that care giving burden is an outcome variable resulting from situational stressors and the level of burden each carer experiences is modified by their individual psychosocial factors and coping strategies (Deeken et al., 2003). A key investigation into the relationship between caregiver impact and various psychosocial factors, utilising the stress-process model, was carried out by Goode, Haley, Roth, & Ford (1998). They examined how carer’s psychological status changed over time, and identified factors that mediated these changes. Using a sample of carers of people with dementia, Goode et al. (1998) found that psychosocial resource variables (such as stressfulness appraisals and social support) were protective for dementia caregivers at one-year follow-up, and caregiver’s psychological status did not necessarily worsen in line with the health of those that they care for. Rather, a carers initial resource levels were predictive of their health over time; with initial scores on approach coping and social support measures deemed particularly protective.

Caregiver-patient relationships are also an important element of the experiences of both care receiver and caregiver. These may influence the impact of caregiving on both parties and it has been suggested that research should focus on the quality of this relationship and its determinants, rather than focusing solely on caregiver burden (Nele Spruytte, Van Audenhove, Lammertyn, & Storms, 2002). Interpretations of the stress-process model suggest that the quality of the caregiver-patient relationship could be seen as both a background factor and a potential stressor in caregiver’s role adaptation, whilst a good relationship may be seen as a mediator (Quinn et al., 2009). This body of work as a whole emphasises the ways in which relationship quality can help us to understand more about the process of caregiver impact and the wellbeing of both individuals in a caregiver-patient dyad. It also illustrates the complex nature of relationships and their investigation, particularly when exploring this from the point of view of multiple individuals; suggesting this is an important element of future research.
1.4.4 Summary
Leg ulcers are known to have a profound effect on the quality of the life of the individual. Research has found individuals with leg ulcers experience more depression, anxiety, social isolation and mobility issues than their healthy counterparts, as well as lower levels of self-confidence and self-esteem. Not only important for patients’ psychological wellbeing, studies suggest there is also a strong link between this and physical outcomes. Caregivers of individuals with leg ulcers may also experience social and emotional problems as a result of this care, whilst the caregiver-recipient relationship may also be an important factor in the caregiver’s experience. Leg ulcers, however, do not only impact upon an individual’s psychological state in terms of quality of life but also in terms of issues such as sense making, adjustment, coping, the patient’s own illness experience and their satisfaction with their care. These issues will now be considered within the context of leg ulcers as a chronic illness.

1.5 Sense making
A key consideration of chronic illness research is how individuals make sense of their experiences, and this may be considered in terms of three key areas. Firstly, a large body of psychological literature has focused on how individuals with chronic illness cognitively represent their disease and the resulting health behaviours, and a series of models have been developed that aim to predict variation in such behaviour. Secondly, research has explored the process of adjustment to chronic illness and the many psychological elements that this encompasses, including: acceptance, coping, social support, and many others. Finally, research has investigated the patient’s own experience of chronic illness and its associated treatment, as well as developing practical recommendations for how healthcare professionals may use this information to increase patient satisfaction and improve patient outcomes. This section of the review will explore each of these areas in turn, drawing on well-established models and theoretical frameworks, as well as current research and debates in the literature. Whilst the review will take a broad spectrum approach looking at models that reach across illnesses, the relevance of each of these elements to chronic leg ulceration will also be explored. This review will draw upon Leventhal’s common-sense model of illness representations (Leventhal, Meyer, & Nerenz, 1980), Lazarus’s stress-coping model (Lazarus & Folkman, 1984), Taylor’s theory of cognitive adaptation (Taylor, 1983) and Moss-Morris’ working model of adjustment to chronic illness (Moss-Morris, 2013).
This review will focus on these four models in particular due to their relevance to the research area, as well as their ability as a whole to encompass many elements of patients’ experiences. Leventhal’s common-sense model of illness representations may be seen as one of the earliest models to move away from a biomedical model of illness, exploring patient’s own beliefs about illness and how these might influence their behaviour. Lazarus and Folkman’s stress coping model also describes a psychosocial approach to illness experience, but built on earlier models to explore how such cognitions may influence adjustment and how psychosocial variables may mediate these relationships. Both models may be seen as outcome focused, viewing illness as a trigger and providing structure to quantitative exploration. As much of the existing literature surrounding leg ulcers maintains a biomedical focus, these models are thought to be the most appropriate in initial explorations of a more psychosocial model. In contrast, Taylor’s theory of cognitive adaptation and Moss-Morris’ working model of adjustment may be seen as focusing more on the process of sense-making, with more of an emphasis on the role of personal and background factors in the illness experience. As a whole these four models allow a detailed exploration of chronic illness, each encompassing different elements of the patient’s experience.

### 1.5.1 Illness representations

Individuals with a chronic illness are thought to hold ‘illness representations’ (also known as illness cognitions, perceptions or beliefs) in order to organise their knowledge regarding various elements of their illness. This might include how a condition is caused, its typical symptoms, how serious it is and its progress over time. These representations allow us to organise knowledge about a condition in our memory and form mental models to guide behaviour and decision-making. It is this influence on health related behaviours that makes the accuracy of illness representations critically important, and which make them central to the study of health and illness (Cameron & Moss-Morris, 2004). As a result, many models have been developed in order to use elements of these illness representations, and other associated concepts, to predict health behaviour.

The Common Sense Model of Illness Representations was developed by Leventhal and colleagues as a result of extensive research exploring response to health threats, self-regulation and illness perceptions (CSM, Leventhal et al., 1980). The CSM suggests that individuals are problem-solvers, and that illness may be approached in the
same way as other problems in order to employ successful coping strategies. Upon interpretation of a health threat, the CSM suggests that individuals form common-sense representations of illnesses, which are made up of cognitive representations and emotional representations of the illness. These representations, combined with an individual’s motivation to maintain their self-representation, lead to a coping response and an appraisal process whereby this coping response is assessed. Cognitive illness representations are made up of five components - identity, timeline, cause consequences and control - and it is these components, alongside emotional representations, which lead individuals to form action plans and a coping strategy. Coping strategies may also be seen to fall into the five components of illness representations in terms of the element of illness that they address. The model is described as self-regulatory due to its non-linear nature, as individuals might move between the stages (interpretation, coping and appraisal) until self-regulation is achieved (Leventhal, Brissette, & Leventhal, 2003; Leventhal, Leventhal, & Contrada, 1998).

Significant research support exists for the CSM, and a meta-analysis conducted by Hagger & Orbell (2003) sought to synthesise this research in order to investigate associations between coping behaviours and illness cognitions. Hagger & Orbell (2003) found that the use of avoidance and emotion based coping strategies were significantly correlated with perceptions of a strong illness identity. They found a significant positive relationship between perceptions of illness control/curability and psychological wellbeing, whilst a significant negative relationship was found between control/curability and psychological distress. Illness consequences, timeline and identity were found to be significantly negatively correlated with psychological wellbeing and social functioning. Hagger and Orbell (2003) concluded that theoretically predictable relations between illness cognitions, coping and outcomes were present, and thus provided significant support for the common sense-model of illness representations. In comparison, very little research investigating chronic leg ulceration appears to have utilised the Common Sense Model. One of the only examples of its use can be found in studies by Van Hecke et al. (2013). In their findings regarding perceptions of venous leg ulcers, Van Hecke et al. (2013) suggest that patients’ perceptions of Leg Ulcers influenced their help-seeking behaviour, in line with Leventhal’s model. When patients’ perceptions were of an acute illness, Van Hecke et al. suggest that patients may have underestimated their role in treatment, demonstrating the influence of illness
perceptions on behaviour. In another study by Van Heke et al. (2011), a behavioural intervention for adherence to treatment is developed on the basis of illness representations influencing adherence, however, the Common Sense Model did not appear to have been explicitly drawn upon in its design. This demonstrates the applicability of the model to this area of research, however, its use thus far has been limited and this is representative of a wider lack of health psychology input in this area of research.

There has been a long-conceptualised relationship between illness representations and behaviour, demonstrated by the evolution of models such as the Health Belief Model (HBM, Rosenstock, Strecher, & Becker, 1988) and the Theory of Planned Behaviour (TPB, Ajzen, 1991). The CSM has taken this further by allowing the exploration of relationships between emotional outcomes and illness representations. For example, research drawing upon the CSM has suggested that severity of illness is not necessarily related to emotional representations, but emotional response may be affected by beliefs regarding the consequences of illness, whether the illness is believed to follow a cyclical timeline and whether an individual feels they have control. Findings such as these suggest an important role for patients’ illness representations in patient adjustment to chronic illness, and reinforce the power of the CSM, the importance of illness representations and the relationship between these representations and patient outcomes. In addition, illness specific findings are thought to enable the development of appropriate psychological interventions to aid individuals in their adjustment to a chronic condition.

In light of the above results, some would argue that Leventhal’s common-sense model is more closely linked with the processes of adjustment and coping in chronic illness than its predecessors. As discussed, the common-sense model suggests that illness representations are combined with an individual’s motivation to maintain their self-representation in the face of illness, and are in turn used to guide coping strategies. As successful adjustment is believed to require the use of coping strategies, Leventhal’s model may also be considered an explanation of adjustment (Brownlee, Leventhal, & Leventhal, 2000). However, although highly relevant, models such as Leventhal’s CSM were not developed for the purpose of explaining adjustment to illness and are complimented by models developed specifically to explain these processes; these will be considered in the following section. With regards to leg ulcers, Leventhal’s model
has been scarcely utilised in the study of chronic leg ulceration and patient sense-making; used only in a small number of studies investigating patient perceptions and adherence. This reflects a wider paucity of psychological models in the literature surrounding leg ulcers and limited involvement of health psychology theory. Whilst many studies have explored the psychological impact and quality of life of individuals with leg ulcers, these have predominantly focused on descriptive elements of the experience, and the mediating role of psychological factors has largely been neglected.

1.5.2 Adjustment, acceptance and appraisal

Adjustment is commonly defined as ‘a response to a change in the environment that allows an organism to become more suitably adapted to that change’ (p. 1154; Sharpe & Curran, 2006). Within health psychology, successful adaptation is often measured in terms of wellbeing, low negative affect and levels of functioning (Stanton, Revenson, & Tennen, 2007), and many models of adjustment have been developed in order to make sense of this process. One of the most commonly discussed of these models is Taylor’s theory of cognitive adaptation (Taylor, 1983), which emphasises the role of acceptance and perceptions of control in adjustment (De Ridder, Geenen, Kuijer, & Middendorp, 2008). Taylor proposes three themes that an individual is motivated to employ when faced with a threatening event, these are: searching for meaning, regaining mastery and enhancing self-esteem. Within the psychology literature meaning is believed to consist of two components, finding order and finding purpose. Whilst a negative life event might disrupt an individual’s perspective on the world, seeking meaning is thought to allow the event to become congruent with existing beliefs and increase feelings of control (Sharpe & Curran, 2006; Thompson & Janigian, 1988). Taylor argues that by using positive illusions an individual is able to understand the significance of the event, how they might gain control over the situation and how any damage to their self-esteem might be recovered; resulting in a return to normal psychological functioning and successful adjustment. These positive illusions involve adoption of a positive view on a situation, and a series of research studies have demonstrated the ability of these illusions to be protective of both mental and physical health (Taylor, Kemeny, Reed, Bower, & Gruenewald, 2000).

Whilst Taylor’s model emphasises the role of illusions in the process of coping with threatening events, Lazarus and Folkman’s model of stress and coping provides an alternative conceptualisation of this process (Lazarus & Folkman, 1984). The stress-
coping model suggests that when confronted with a source of external stress, an individual’s level of adjustment will depend on their appraisal of the stressor, the coping strategies they employ and subsequent appraisal of these coping strategies. It is this combination of coping strategies and appraisal that is the focus of the stress-coping model, and which Lazarus and Folkman suggest determines successful adjustment.

Appraisal is not limited to assessing the effectiveness of the coping strategies, but begins upon presentation of the stressor and continues throughout the process in order to monitor the situation and the individual’s level of control (Walker, Jackson, & Littlejohn, 2004). Although the stress-coping model has received some criticism – for example, the model is suggested not to explore the role of an individual’s personal resources and background factors in their coping response - it is widely believed to have been one of the most influential models in the study of adjustment (De Ridder, 1997).

Within the caregiving literature in particular, the stress-process model has been developed from Lazarus and Folkman’s original stress-coping model in order to explore caregiving impact. As discussed earlier in the review (see section 1.4.3), this stress-process model suggests that adjustment to caregiving is influenced by background and contextual factors, caregiving stressors, mediating factors and caregiving outcomes (Quinn et al., 2009).

Although models of adjustment such as the theory of cognitive adaptation and the stress-coping model may differ in the factors they emphasise, many common themes may be seen running through them. For example, many of these models incorporate elements such as coping, appraisal, and meaning, and a large body of research has been built around the relationship between these components and adjustment. In addition, the concept of ‘acceptance’ is commonly believed to underlie many of these models, with the assumption that this is the desirable end point for the adjustment process (Telford, Kralik, & Koch, 2006). Acceptance has been linked to positive effects on psychological outcomes for individuals with conditions such as chronic pain (McCracken, 1998) and chronic fatigue syndrome (Van Damme, Crombez, Van Houdenhove, Mariman, & Michielsen, 2006), and it has been suggested that acceptance might be particularly useful in situations where direct action is inhibited by a lack of situational control (David & Suls, 1999). Several authors have, however, questioned the usefulness of acceptance when working with chronic illness. Telford et al. (2006), for example, suggest that clinicians should avoid focusing on acceptance at
the neglect of individuals personal illness narratives, as by doing so they may neglect the wider social context that a patient’s illness exists within. Similarly, Paterson (2001) writes of a ‘shifting-perspectives model’ of adjustment, whereby a person’s perspective on their chronic illness is a more useful indicator of their psychological state than traditional concepts of acceptance. Although the suggestion that acceptance is not a useful concept in chronic illness may be controversial, such discussions around individualised narrative-driven care are reflective of holistic approaches to chronic illness and some would argue that the two approaches are not necessarily mutually exclusive.

Whilst the above models and their constituent parts have been widely employed to explore adjustment in chronic illness, a recent article by Moss-Morris (2013) has highlighted the limitations of the research area and existing models. It is suggested that definitions of adjustment differ between authors and disciplines, and that no consistent definition exists. Within the chronic illness literature, Moss-Morris (2013) argues that adaptation may be illness specific, it may be considered a process rather than an end point, and that how an individual reacts to negative affect may be more relevant than its presence. Although considerable research has explored the utility of models such as the stress-coping paradigm, it is suggested that there has been considerable inconsistency in the outcome measures used to test such models. It is argued that the models can predict little overall variance in adjustment and therefore do not allow understanding of adjustment as a whole. In order to address these limitations and identify factors that both encourage and hinder adjustment, Moss-Morris (2013) proposes a new working model of chronic illness. This working model suggests that adjustment is a process of response to illness stressors, influenced by personal, social and environmental factors. The model separates illness-specific factors into ‘critical events’ and ‘chronic stressors’, suggesting that the aim of adjustment when faced with critical events is to return to equilibrium, whilst the aim for chronic stressors is to maintain equilibrium; incorporating a new level of complexity into definitions of adjustment. Depending on the personal, social and environmental factors present, an individual may successfully or unsuccessfully adjust to illness stressors, specifying various cognitive and behavioural factors that are likely to be present in either outcome. Successful adjustment may be measured via the impact of illness on an individual’s roles and relationships, high levels of positive affect, and low levels of distress.
As an emerging perspective, few research studies have utilised the new working model put forward by Moss-Morris (2013) or tested its ability to predict successful adjustment; however, a more immediate test of the model may be in its ability to aid progress within this research area and encourage a more multifaceted conceptualisation of adjustment. Whilst this new model demonstrates a more complex, chronic-illness specific approach to adjustment, unless it is adopted in the manner in which it is intended there is a danger that it too could suffer the same limitations as it levies at its predecessors. In addition to criticisms surrounding heterogeneity in the measures used and the limited amount of variance they have been able to predict, other criticisms of the work in this area have focused on the sample populations investigated. Denise De Ridder et al. (2008) suggest that the majority of research in this area has been conducted with white middle-class populations and little research has been carried out within low-socioeconomic status or ethnic minority groups. It appears that future development in this research area may focus not only on the ability of models to accurately predict outcomes, but also on the quality and consistency of this research. Once again, research regarding leg ulcers has largely focused on the descriptive elements of experiencing leg ulceration and no research appears to have utilised models of acceptance, adjustment or appraisal in order to investigate these processes.

1.5.3 Experiences of illness

Research has explored chronic illnesses in terms of illness representations, adjustment, acceptance and appraisal, and it is evident from these discussions that patients’ experiences of illness are also an important influence on the physical and psychological health of the patient. As a result, a significant body of cross-disciplinary literature has emerged to explore patients’ experiences of chronic illness. Such studies of illness experience have explored both specific illnesses and chronic illness as a whole and, whilst some studies have utilised quantitative methods, the majority of research in this area has been qualitative. A meta-study of this qualitative literature by Thorne et al. (2002) suggests that the focus within psychology is often on the psychological implications and processes associated with chronic illness, and that the majority of these studies approach illness experience from a social constructionist epistemology. In contrast, Thorne and her colleagues found that sociologists tended to focus on the structures associated with chronic illness, and those working in applied health sciences were more likely to approach research from a practice perspective. Such differences
provide a diverse and rich literature base, which is hoped to more fully represent the patient’s beliefs; however, it is also important to maintain an awareness of these potential differences when exploring the literature in order to appreciate how the researcher’s perspective may have influenced their results. Qualitative exploration of the illness experience has allowed in-depth insight into the lived experiences of many patients with chronic illness, in a way that some would suggest quantitative investigations could not.

When examining the illness experiences literature, Thorne et al. (2002) suggest that certain illnesses are more often researched than others. Cancer, diabetes, asthma, and cardiomyopathy are particularly well-researched, whereas other conditions that affect a similar proportion of the population have not received the same attention, as can be seen in chronic leg ulceration. This is not to say that there is not heterogeneity amongst the research, and this is evident in studies of cancer where research can be seen to investigate a wide variety of cancer-types and the experiences of specific populations. For example, Banning & Tanzeem (2013) specifically explored the experiences of Pakistani women with breast cancer. Although they identified themes which find resonance with cancer and breast cancer more generally, such as positive illusions and an impact on wellbeing, they also found culturally specific factors; specifically the stigma surrounding Breast cancer in Pakistan and beliefs from the wider community that cancer was communicable. Studies such as this also allow investigation of the differences and population-specific experiences that exist within a condition.

In contrast, many studies have also explored experience of illness as a whole, often investigating a particular phenomenon or high-interest group rather than a specific condition. For example, research exploring chronic illness experiences across diagnoses has allowed investigation of other health-related factors, and multi-morbidities in particular have been identified as an influential factor in the illness experience. As a growing number of individuals are living with multi-morbidity, Markle, Attell, & Treiber (2014) sought to investigate the experiences of ‘middle-aged’ individuals managing multiple chronic illnesses. They examined the online blog posts of ten individuals in North America and identified issues with identity and giving up paid employment as particularly challenging, reflecting concepts of ‘premature social aging’ (Singer, 1974). In a similar study conducted in the UK, Morris, Sanders, Kennedy, & Rogers (2011) suggest that multi-morbidity highlights the importance of shifting
priorities between multiple conditions over time. Whilst multiple illnesses were not always considered to be more of a burden to participants, this ability to deal with fluctuations and to shift priorities accordingly was an important factor in the illness experience. Research exploring themes across conditions also allows investigation of specific experiences or research groups. For example, Fox et al. (2011) explored the experiences of junior doctors who had experienced significant illness, finding that this group may delay help-seeking due to the pressure of their working conditions and the influence of their job on their perceptions of illness. As a result, the authors were able to make recommendations regarding support procedures. This demonstrates a specific research question where the aim of the study focuses on the sample being recruited, rather than a common illness, and the importance that these results can have.

An alternative approach is demonstrated by a critical review of the literature surrounding chronic illness and adolescence (Taylor, Gibson, & Franck, 2008). By synthesising twenty studies investigating adolescents with chronic illness, Taylor et al. (2008) were able to identify seven common themes that were important to these young people regardless of their specific diagnosis. Their conclusions demonstrated a desire for normality by adolescents and recommended that adolescents are treated according to their individual needs and experience, but with a focus on ‘wellness’. Findings such as these demonstrate the value of synthesising studies across illnesses and the insight this can give into a particular population. However, there are also disadvantages to this method. Studies investigating experiences of chronic illness across the general population often utilise a convenience sample, which can be prone to recruitment bias, and some would suggest this approach is not able to identify some of the more nuanced experiences of specific illnesses. It could also be argued that whether a study is conducted with a specific illness group or across chronic illness should be led by the research question and there is a place for both approaches within research; therefore, emphasising the importance of a literature which utilises both approaches.

1.5.4 Experiences of treatment

Experiences of illness are not just limited to explorations of living with the illness day-to-day, but have also explored the specific experiences surrounding treatment for chronic illness. Whilst themes identified in the experience of illness may also be relevant to treatment experiences, studies explicitly exploring experiences of treatment are able to provide a detailed insight into the processes and implications of
treatment. Experiences of treatment might be investigated in a general sense, asking participants about treatment they are already receiving as part of their overall illness experience (Lempp, Hatch, Carville, & Choy, 2009). Alternatively, studies might be investigating a specific treatment; for example, home haemodialysis for renal failure (Cases, Dempster, Davies, & Gamble, 2011), walking as a treatment for intermittent claudication (Galea Holmes, Weinman, & Bearne, 2015) or awake craniotomy for brain tumours (Howie, Bambrough, Karabatsou, & Fox, 2015). Other studies have investigated specific elements of treatment, such as transition from hospital to home (Rodham, Boxell, McCabe, Cockburn, & Waller, 2012) or adjustment to work following cancer treatment (Grunfeld & Cooper, 2012). Equally, experiences of treatment are not limited to medical interventions, as demonstrated by Mathias, Parry-Jones, & Huws (2014) and their exploration of patient experiences with an acceptance based pain-management programme. Although previous quantitative research had evaluated the effectiveness of such interventions, this qualitative study was able to explore the processes underlying the intervention. Through six semi-structured interviews with patients, Mathias et al. (2014) were able to identify the components patients saw as ‘active ingredients’ in the treatment, as well as representing their experience and making recommendations for future practice. This demonstrates an important strength of these studies, as investigations of treatment experiences are often able to generate highly grounded practical recommendations for clinical practice, as well as offering explanations of patient behaviour, exploring psychological processes and representing the patient voice.

Although a prolific area of research in chronic illness, experiences of treatment have been scarcely explored for leg ulcers in particular. Considering the variety of treatments offered to individuals with leg ulcers and the psychological impact of the condition, such research could provide a valuable insight into the implications of various treatment pathways. Many qualitative studies have explored the psychological impact of living with leg ulcers and within their analyses themes may relate to the treatment experience; however, the focus of these studies on illness experience suggests that interview questions did not specifically explore treatment experience and the researcher may not have specifically followed up comments made regarding treatment. One element that has emerged from research investigating patients’ experiences of leg ulcers is suggested reasons for processes underlying adherence to treatment. A review
of such studies was undertaken by Van Hecke, Grypdonck, & Defloor (2009), as the authors aimed to explore reasons for non-adherence to compression treatment in individuals with venous leg ulcers. Van Hecke et al. (2009) suggest that this is an underexplored area with potential to influence treatment practices, and as a result of their review they suggest adherence is influenced by psychosocial elements, patient factors, treatment regimens and interpersonal relationships.

Whilst healthcare professionals attribute much non-adherence behaviour to patient-related factors and at times may blame the patient, Van Hecke et al’s review highlights the multidimensional nature of adherence and the importance of understanding how a patient’s individual situation is likely to influence their behaviour. From a patient’s perspective, non-adherence was described as relating to poor information provision, pain from treatment and confusion (Van Hecke et al., 2009). The researchers took this review further in their own investigation of non-adherence to leg ulcer treatment, developing a nursing intervention to improve adherence with the information already known from the literature (Van Hecke, Verhaeghe, Grypdonck, Beele, & Defloor, 2011). They used qualitative interviews to explore patient and clinician’s perspectives on this intervention and suggested that central to adherence behaviours were trust, self-efficacy, and personal barriers; with a particular emphasis on the trust that patients placed in clinicians.

Further research suggests that adherence may also be influenced by patient’s knowledge of their condition and the treatment that they have been recommended. Van Hecke et al. (2013) conducted interviews with fifteen individuals with venous leg ulcers, and suggest that many individuals are not aware of the underlying cause of their venous leg ulcer, or why this underlying cause may have led to their condition. Similarly, patients were not aware of the rationale behind their treatment pathway or their own role in treatment. The authors draw on Leventhal’s common sense model of illness representations (Leventhal, Meyer, & Nerenz, 1980) and argue that this lack of understanding and knowledge of their condition may influence their behaviour with regards to treatment. The studies discussed above illustrate the role of patients’ illness cognitions and trust in clinicians in adherence behaviour, and the value of understanding these experiences in order to inform interventions accordingly.
Another important element of the treatment experience identified in leg ulceration is trust in clinicians and patient-clinician relationships. Throughout the treatment process patients have contact with many different clinicians, including: general practitioners, practice nurses, district nurses, tissue viability nurses, surgeons, dermatologists, and various consultants. Briggs & Flemming (2007) conducted a synthesis of qualitative research into living with leg ulceration, and suggest that patient-professional relationships are a common theme brought up by patients. Whilst a good relationship with nurses was seen to provide therapeutic value and continuity of care, a poor relationship was characterised by a lack of trust and understanding. As seen above, this poor relationship may have a knock on effect for adherence to treatment, as well as encouraging patients to seek out alternative treatment options (Douglas, 2001). Patients descriptions of living with a leg ulcer highlight the importance of continuity-of-care and relationships with nurses (Green et al., 2013), whilst researchers emphasise the importance of confidence in healthcare professionals (Hopkins, 2004; Walshe, 1995).

Referring to primary care more generally, Bodenheimer et al. (2002) discuss the importance of designing treatment pathways in terms of what the patient believes to be their most important problem, emphasising a person-centred approach to treatment. These findings as a whole demonstrate the insight that can be gained from qualitative research into the experience of living with leg ulcers and particular they highlight the processes underlying adherence to treatment, the importance of relationship with clinicians, and the organisation of treatment provision. Research specifically investigating experiences of treatment could expand upon this research and provide greater insight into treatment experience in particular.

1.5.5 Summary

To summarise, venous leg ulcers are an example of a chronic condition and thus may be viewed within the context of the existing chronic illness literature. The number of individuals living with chronic illness is likely to increase as we continue to see an ageing population, and, with a higher prevalence in the elderly, this is also likely to be the case for leg ulcers. Psychological research is aiding our understanding of how individuals think about and adjust to chronic illnesses, and a number of models have been developed to conceptualise these processes. This review has focused on Leventhal’s common-sense model of illness representations (Leventhal, Meyer, & Nerenz, 1980), Taylor’s theory of cognitive adaptation (Taylor, 1983), Lazarus’s stress-
coping model (Lazarus & Folkman, 1984) and Moss-Morris’ working model of adjustment to chronic illness (Moss-Morris, 2013). These specific models have been focused on due to their significant evidence base and their relevance to chronic illness. Whilst limitations of these models have been discussed extensively in the literature, it is their ability to propagate valid and reliable research that ultimately appears to determine their longevity. Their role seems, however, to have been widely ignored in the literature surrounding leg ulcers and this is thought to reflect the limited involvement of psychologists in this area. Although a significant body of research has explored the impact of living with leg ulcers on patient quality of life, many of these studies have utilised qualitative methods, and psychological models of sense-making and adjustment have largely been neglected.

Research regarding patients’ experiences of illness and treatment add further to our understanding of specific chronic illnesses, as well as chronic illness as a whole. Qualitative methods in particular have aided in the understanding of the processes underlying these experiences, and are often able to provide practical recommendations for clinical practice. However, whilst much is known about patients experiences of living with leg ulcers, little research has explored patients’ experiences of leg ulcer treatment in particular. Patients’ experiences of treatment have primarily been explored as an artefact of illness experience research; however, this has borne some valuable conclusions regarding processes of adherence in particular. Further research in this area would benefit from explicitly exploring patients’ experiences of treatment, including specific treatment modalities. Models of chronic illness may be useful in aiding our understanding of this condition and its treatment, and this review has written in particular support of the relevance of the Stress-coping model and the Common Sense Model of Illness Representations for the investigation of venous leg ulcers.

1.6 Aims of the current research
This review of the existing literature has described and explored the aetiology, prevalence and clinical presentation of leg ulcers, their treatment, and their impact on wellbeing. Research suggests that leg ulcers can have a significant impact on quality of life, and this can be seen in the context of literature on chronic illness. A significant body of research has investigated the impact of living with leg ulceration; however, this has largely focused on traditional health outcomes and individuals experiences of living with chronic leg ulceration. There has been little exploration of predictors of health-
related quality of life, and limited use of psychological models within this body of literature.

Within treatment for leg ulceration a dichotomy appears to be emerging between surgical and conservative treatment approaches, and this reflects an underlying difference in approach to treatment. Whilst conservative treatment methods aim to heal the leg ulcer and prevent future ulceration via compression therapies, surgical management aims to address the underlying cause of the leg ulcer with the hope of a longer-term resolution. Although a significant body of research continues to explore the safety and efficacy of emerging techniques, little is known of the psychological impact of treatment. Similarly, there has been no research exploring patients’ experiences of treatment.

It is, therefore, clear that a gap exists in the literature regarding the impact of chronic leg ulceration on quality of life, the psychological impact of treatment, and patient experiences of various treatment modalities. By drawing upon the existing chronic illness literature, these issues can be considered in terms of illness representations, adjustment and patient experiences. In particular, this thesis will draw upon Leventhal’s Common Sense Model of illness representations (Leventhal et al., 1980) and Pearlin’s Stress-process model (Pearlin et al., 1981) as an initial framework for investigation. Patients’ wellbeing will be explored quantitatively as a dynamic process, whereby health related quality of life may be predicted by clinical and demographic variables, as well as psychosocial variables such as social support and mood. A similar framework will be utilised to investigate how this psychological wellbeing may alter over a period of surgical management; whilst, as an exploratory area of study, qualitative methods will allow the in-depth investigation of patients’ experiences of treatment. In light of this, the aims of this thesis are:

- To assess the impact of minimally-invasive surgical treatment for leg ulceration on patient quality of life
- To assess the impact of minimally-invasive surgical treatment for leg ulceration on patients’ psychosocial outcomes
- To assess the role of psychosocial factors in exploring patient quality of life
- To explore the experiences of individuals undergoing conservative treatment for leg ulceration
To explore the experiences of individuals undergoing minimally-invasive surgical treatment for leg ulceration

These aims will be addressed in the current thesis through one systematic review and four empirical studies.

1.7 Thesis outline

In order to achieve the above aims this thesis will be presented in seven chapters. The structure of the thesis, and the content of these chapters, is as follows.

Chapter 2
Chapter two presents a systematic review of the literature, exploring the comparative impact of conservative versus surgical treatment on patient quality of life.

Chapter 3
Chapter three presents findings from a cross-sectional investigation into predictors and mediators of quality of life in individuals with chronic leg ulcers.

Chapter 4
Chapter four involved using a longitudinal quantitative study to assess the psychological impact of minimally-invasive surgical management of venous leg ulceration up to 6 months post-surgery.

Chapter 5
Chapter five presents a qualitative semi-structured interview study of patients’ experiences of minimally-invasive surgical treatment for venous leg ulcers.

Chapter 6
Chapter six explores patients’ experiences of non-surgical treatment for chronic leg ulceration, through a qualitative semi-structured interview study.

Chapter 7
Finally, chapter seven draws upon each of the previous six chapters in order to synthesise the findings, and provide a general discussion and conclusion of the thesis. Clinical implications and recommendations are also presented.
1.8 Methodological note

1.8.1 Leg ulcer aetiology
This thesis will primarily focus on venous leg ulcers due to their higher prevalence rates and their suitability for surgical management. However, as many patients are believed not to be aware of a causal explanation of their leg ulcers (Van Hecke et al., 2013), participants were not primarily selected on the basis of aetiology and empirical studies will also include participants with non-venous or mixed aetiology. The implications and relevance of this factor will be discussed in more detail where appropriate.

1.8.2 Caregiving impact
Due to the literature surrounding caregiver impact in chronic illness, and the limited research exploring this issue with relation to chronic leg ulceration, this thesis had initially aimed to recruit carers into all empirical studies. This was intended to allow exploration of the psychological impact and experiences of caregivers, but also the interaction between caregiver and patient outcomes. Unfortunately it became clear during data collection that this would not be possible due to challenges with recruitment. It became apparent that individuals with leg ulcers did not consider those around them to occupy the role of a ‘carer’, and similarly those who did provide ‘informal care’ did not consider themselves as ‘carers’. This is an interesting phenomenon in itself and an issue reflected in the literature, as it is suggested that individuals often only identify with the term ‘carer’ after being identified as such by researchers, charities and the healthcare profession, and that those providing informal care are less likely to use this term independently (O’Connor, 2007; Ugalde, Krishnasamy, & Schofield, 2012). This effect may be particularly pronounced in the leg ulcer population, as a chronic condition with few associated charities and support groups; this is in great contrast to conditions such as Dementia or Multiple Sclerosis. Those care-charities that were contacted regarding recruitment echoed this sentiment, suggesting that they had little awareness of leg ulcers or any clients who supported individuals with leg ulcers. As a result, an alternative study on the notion of care was considered for inclusion in the thesis; however, due to the same recruitment issues this study was also deemed unfeasible. The implications for this are considered further in the Discussion section of this thesis (see ‘Chapter 7 – General discussion’).
Chapter Two

The comparative impact of conservative treatment versus superficial venous surgery for the treatment of venous leg ulcers: a systematic review of the impact on patient quality of life

2.1 Overview
The first chapter of this thesis provided a thorough review of the literature in this area, including an introduction to the various methods used to treat leg ulcers and the relevant literature regarding treatment outcomes. Until this point several systematic reviews had compared the biological outcomes of various treatment methods, however, no review had focused on the psychological outcomes of treatment. This systematic review aimed to evaluate the comparative impact of conservative treatment versus Superficial Venous Surgery on leg ulcer patients’ quality of Life.

2.2 Introduction
Venous leg ulcers are commonly treated in the community with compression bandaging or advanced wound dressings, however, ulcers often take a long time to heal and recurrence rates are high (Herber et al., 2007). More recently developed treatment methods include surgical interventions, such as superficial venous surgery, and these aim to address the underlying cause of the venous leg ulcers. Results of the ESCHAR trial, a prominent multi-centre randomised controlled trial comparing surgical and conservative treatments, suggest that while no significant differences were found between healing rates in ‘superficial venous surgery and compression’ versus ‘compression alone’ (p=.73), a significant difference was found in recurrence rates at 4 years (p<.01) and more ulcer free time was observed after 3 years in the surgical group (p=.007) (Gohel et al., 2007). Results such as these suggests that this surgery may be effective at healing venous leg ulcers, as well as reducing rates of recurrence (Howard et al., 2008).

Whilst a significant body of research has focused on the healing and recurrence rates in newly developed surgical treatments, the comparative impact of this surgery on patient quality of life remains unclear. Although several review articles have included the impact of treatment on patient quality of life in reviews of comparative effectiveness, their results regarding quality of life are often inconclusive. One such review (Valle et al., 2014) investigated the comparative effectiveness of various advanced wound dressings versus compression bandaging alone, including biological and quality of life outcomes. The authors drew some cautious conclusions about the differential impact on healing, but were unable to provide any conclusions about the impact on quality of life due to scarcity and heterogeneity of research regarding this outcome measure. A second review examined the comparative effectiveness of surgical interventions aimed at treating underlying venous pathology (Malas et al., 2014). Similarly, however, only two studies included in their review had collected data on quality of life and once again no conclusions were offered regarding this outcome measure. As the primary outcomes examined in these reviews were medical, their inclusion criteria were strict with regards to these clinical elements (Malas et al., 2014; Valle et al., 2014). This was necessary for the focus of their reviews, to determine those articles with best clinical and research practice; however, few of these studies were found to include quality of life outcomes.

In light of existing reviews and literature, the aim of this systematic review was to investigate the comparative impact of bandaging/compression treatments and superficial venous surgery for venous leg ulcers on patient quality of life. The present systematic review was conducted with a psychological focus, and aimed to expand the inclusion criteria to allow a wider spectrum of studies to be examined and enable conclusions to be drawn regarding the impact of such interventions on quality of life. Such a review was thought to be necessary as the literature varies widely in many aspects, including the populations studied, outcomes investigated and research designs employed. A systematic review of this nature allows a coherent narrative of the existing literature, providing insight into the impact of various treatments on quality of life and suggesting ways in which future research might build upon the existing literature. This review focused on quality of life as the primary outcome measure, differentiating it from other similar reviews in this area.
In order to investigate the comparative impact of bandaging/compression treatments and superficial venous surgery for venous leg ulcers on patient quality of life, and guided by existing literature, this review focused on three hypotheses:

1. Both bandaging/compression treatments and superficial venous surgery for venous leg ulcers will lead to improvements in patient quality of life

2. Patients’ quality of life will be impacted to differing extents depending on treatment type

3. Patients’ quality of life will be influenced by wound status

2.3 Methods

2.3.1 Aims
This systematic review aimed to evaluate the comparative impact of bandaging/compression treatments and superficial venous surgery on venous leg ulcer patients’ Quality of Life.

2.3.2 Design
A systematic search of three electronic databases was completed in May 2014 to identify relevant research studies. A comprehensive search strategy was developed and utilised with PsycInfo, Medline and CINAHL electronic databases. Search terms within this strategy included: ‘Venous leg ulcer*’, treat*, intervention*, compression, surg*, ‘quality of life’, QOL, and HRQOL. An electronic alert was set-up to notify the researcher of newly published search results and this continued until August 2014.

2.3.3 Study selection
The following criteria were employed when reviewing potential articles for inclusion in this review:

1. Articles must contain original data; therefore no review articles were included.

2. Articles must include quantitative methods; studies with a mixed-methods design were included if the quantitative data was presented separately from the qualitative data and had been statistically analysed.
3. Participants must have had leg ulcers, specifically venous leg ulcers. If participant’s ulcers were of a mixed aetiology, at least 50% of participants in the study must have had venous leg ulcers.

4. Studies must have investigated the effect of a either a bandaging/compression based treatment or superficial venous surgery, with the aim of healing/curing the venous leg ulcer. Interventions aimed only at, for example, reducing pain or improving adherence to another treatment were excluded.

5. Studies must have explicitly measured patients’ ‘quality of life’ or ‘health related quality of life’, either at multiple time points or in multiple conditions.

Two-hundred and six articles were initially identified in the search and underwent ‘title review’. This initial screening excluded 113 articles for irrelevance or ineligibility according to the inclusion criteria (see Figure 2). Abstracts of the remaining 93 articles were subsequently reviewed, at which point a further 65 articles were excluded due to irrelevance or ineligibility. Full text articles were obtained for the remaining 28 studies, at which point 15 were excluded due to violation of the inclusion criteria and 13 were included in the review. Once a final list of eligible studies had been identified, reference lists of these articles were hand-searched for relevant studies and a further 3 articles were identified and obtained as a result. Therefore, a total of 16 articles were included in this review.

Various tools for assessing the quality of these studies were explored, however, the paucity of research in this area meant that each of these existing tools was found to be prohibitively restrictive. As one of the primary aims of this review was to explore the breadth of existing literature, it was decided that all identified studies should be included but that the review should also include comment on the quality of reporting and methodology in the featured studies (see sections 2.4.4 and 2.5).

2.4 Results
For a descriptive summary of all sixteen studies included in the review, see Table 1.

2.4.1 Participants
Sample size in the included studies ranged from 30 to 383 participants, with a mean of 161 participants in each study. All studies included a combination of men and women. The mean age of participants in the included studies ranged from 61.75 to 75.15 years.
old, with a mean of 64.38 years old across fifteen of the sixteen reviewed studies; one study did not provide sufficient data to be included in these mean age calculations (Clarke-Moloney, O’Brien, Grace, & Burke, 2005).

Of the twelve studies that provided data on participant’s ulcer duration, the mean duration of ulceration ranged between 2 and 109 months, with a mean duration across these studies of 13 months. Mean ulcer size was reported by nine studies, this ranged from 410 mm$^2$ to 2650 mm$^2$, with an average of 1030.9 mm$^2$ across the studies. Fourteen studies reported participants with venous leg ulcers only, whilst two studies

![Flow chart to demonstrate review progression and article exclusion](image)

*Figure 2. Flow chart to demonstrate review progression and article exclusion*
reported participants with a combination of venous and mixed venous-arterial/mixed aetiology (Jull et al., 2008; Zamboni et al., 2003).

Seven of the sixteen included studies were conducted in the UK (Charles, 2004; Franks & Moffatt, 2001; Franks et al., 2004; Franks, Moffatt, & Ellison, 1999; Guest et al., 2003; Loftus, 2001; Michaels et al., 2009), two in Australia (Finlayson et al., 2014; Weller, Evans, Staples, Aldons, & McNeil, 2012) and two collected data across multiple countries (Harding, Vanscheidt, Partsch, Caprini, & Comerota, 2014; Moffatt et al., 2008). Studies were also conducted in Argentina (Brizzio, Amsler, Lun, & Blättler, 2010), Ireland (Clarke-Moloney et al., 2005), Canada (Harrison et al., 2011), New Zealand (Jull et al., 2008) and Italy (Zamboni, et al., 2003).

2.4.2 Interventions
Nine studies investigated the comparative effectiveness of various types of bandaging, compression therapy, or advanced wound dressings. These included; compression therapy versus bandaging (Brizzio et al., 2010), 3-layer bandaging versus inelastic compression (Weller et al., 2012), 2-layer bandaging versus 4-layer bandaging (Moffatt et al., 2008), 4-layer bandaging versus regular bandaging (Clarke-Moloney et al., 2005), 4-layer bandaging versus compression hosiery (Finlayson et al., 2014), 4-layer bandaging versus Short-Stretch bandaging (Franks et al., 2004; Harrison et al., 2011), a comparison of two generations of 4-layer bandaging (Franks et al., 1999) and a study investigating adaptive compression therapy (ACT) versus 4-layer bandaging (Harding et al., 2014). This review also includes two studies examining advanced wound dressings, including a comparison of honey infused dressings and compression bandaging (Jull et al., 2008) and silver donating dressings versus regular low adherence dressings (Michaels et al., 2009).

Three studies examined the effects of superficial venous surgery versus compression bandaging (Guest et al., 2003; Loftus, 2001; Zamboni et al., 2003).

Two studies did not compare multiple interventions, but instead aimed to examine quality of life outcomes as a result of treatment in general. In these studies, high compression bandaging (Franks & Moffatt, 2001) and short-stretch compression bandaging (Charles, 2004) were used.
<table>
<thead>
<tr>
<th>Authors</th>
<th>Inte. method(s)</th>
<th>Study design</th>
<th>Follow-up period</th>
<th>Quality of Life (QOL) measure(s)</th>
<th>QOL data reported</th>
<th>Hypothesis 1: QOL improvements as a result of treatment</th>
<th>Hypothesis 2: Differences in QOL improvements between treatments</th>
<th>Hypothesis 3: Relationship between QOL and Wound status outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brizzio, Amsler, Lun, &amp; Blättler (2010)</td>
<td>1: Low-strength compression stockings 2: Traditional bandages</td>
<td>Randomised controlled trial (n=55)</td>
<td>13 weeks</td>
<td>CIVIQ (Spanish version) - measured at 0, 4, 8 and 13 weeks.</td>
<td>Mean? ✓ SD? ✓ p-value? ✓ Effect size? ∗</td>
<td>.</td>
<td>No significant differences were found between treatments (p&gt;.05).</td>
<td>Physical (p=.001), social (p=.02) and psychic (p=.003) dimensions of QOL had significantly improved in healed patients; but not unhealed patients. Pain (p&lt;.001) and the CIVIQ total score (p&lt;.001 healed, p=.03 unhealed) significantly improved in both healed and unhealed participants.</td>
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<tr>
<td>Charles (2004)</td>
<td>Short-stretch bandages.</td>
<td>Non-randomised controlled trial. Data compared with age-equivalent norms (AEN). (n=65)</td>
<td>12 weeks</td>
<td>SF-36 - measured at study entry, and either study exit (12 weeks) or upon complete wound closure.</td>
<td>Mean? ✓ SD? ✓ p-value? ✓ Effect size? ∗</td>
<td>Statistically significant improvements were found in patient reports of bodily pain (p&lt;0.001), social functioning (p&lt;0.005), mental health (p&lt;0.011), and the health transition score (p&lt;0.001) between study entry and exit.</td>
<td>.</td>
<td>In those patients whose ulcers healed, four domains of QOL (bodily pain, vitality, social functioning and mental health) improved significantly between entry and exit. In those patients whose ulcers did not heal, only bodily pain significantly improved between entry and exit.</td>
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<tr>
<td>Clarke-Moloney</td>
<td>1: Four-layer compression</td>
<td>Randomised controlled</td>
<td>Six weeks</td>
<td>SF-36 and CIVIQ - measured at entry</td>
<td>Mean? ∗ SD? ∗</td>
<td>.</td>
<td>4-layer bandaging group participants</td>
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<tr>
<td>Study &amp; Year</td>
<td>Type of Bandaging</td>
<td>Study Design</td>
<td>Sample Size</td>
<td>Duration of Treatment</td>
<td>Main Outcomes</td>
<td>Control Group</td>
<td>Statistical Analysis</td>
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<td>O'Brien, Grace, &amp; Burke (2005)</td>
<td>Bandaging</td>
<td>Randomised controlled trial (n=200)</td>
<td>and after six weeks of treatment in patients whose wound remained unhealed.</td>
<td>p-value? ✓ Effect size? ✗</td>
<td>Continuation of usual care</td>
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<td>Finlayson et al. (2014)</td>
<td>Four-layer compression bandaging</td>
<td>Randomised controlled trial (n=103)</td>
<td>Twenty-four weeks</td>
<td>QL Index, Geriatric Depression Scale and MOS Pain Severity Scale - measured at baseline, 12 weeks and 24 weeks.</td>
<td>Mean? ✓ SD? ✓ p-value? ✓ Effect size? ✓</td>
<td>No significant improvements were found in QL Index scores (p=0.223), however, improvements were found in the Geriatric Depression Scale scores (p=0.035) and MOS Pain scores (p&lt;0.001).</td>
<td>No significant differences were found between treatment groups (p&gt;0.05).</td>
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<tr>
<td>Franks &amp; Moffatt, (2001)</td>
<td>High compression bandaging</td>
<td>Non-randomised controlled trial (n=383)</td>
<td>Twelve weeks</td>
<td>Nottingham Health profile (NHP) - measured upon study entry and exit</td>
<td>Mean? ✓ SD? ✓ p-value? ✓ Effect size? ✗</td>
<td>Quality of Life was found to improve significantly in all domains of the NHP after 12 weeks of treatment (p&lt;0.009).</td>
<td>Significant differences between participants with unhealed and healed ulcers were found in the domain of bodily pain (p=0.004).</td>
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<tr>
<td>Franks et al (2004)</td>
<td>‘Generic four-layer bandaging system’</td>
<td>Randomised controlled trial (n=156)</td>
<td>Twenty-four weeks</td>
<td>Nottingham Health profile (NHP) - measured at baseline, at</td>
<td>Mean? ✓ SD? ✓ p-value? ✓ Effect size? ✓</td>
<td>The total patient group reported statistically significant differences in HRQOL between the two treatment groups</td>
<td>Participants with unhealed ulcers showed no significant differences in any of the NHP domains</td>
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<tr>
<td>Study</td>
<td>Description</td>
<td>Methodology</td>
<td>Timepoints</td>
<td>Outcomes</td>
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<td>Franks, Moffatt, &amp; Ellison (1999)</td>
<td>Old vs. new generation four-layer bandage system</td>
<td>Randomised controlled trial (n=232)</td>
<td>Twenty-four weeks</td>
<td>No significant differences were found between treatment groups (p&gt;0.34). Differences were found between healed and unhealed participants on bodily pain (p=0.023) and sleep (p=0.007) domains of the NHP.</td>
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<td>Guest et al. (2003)</td>
<td>Four-layer bandaging vs. superficial venous surgery and four-layer bandaging</td>
<td>Randomised controlled trial (n=76)</td>
<td>Twenty-four weeks</td>
<td>No significant differences were found between groups at any timepoint using the CCVUQ (p&gt;0.05). Patients with healed ulcers at 24 weeks reported significantly better HRQOL than participants whose ulcers had not healed (p&lt;0.05).</td>
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<td>Harding, Vanscheidt, Partsch, Caprini, &amp; Comerota (2014)</td>
<td>Adaptive Compression Therapy (ACT) device vs. four-layer bandaging system</td>
<td>Randomised controlled trial (n=90)</td>
<td>EuroQoL 5D measured at baseline and study completion</td>
<td>Multi-variable linear regression modelling predicted final QOL scores, suggesting a significantly higher index score for ACT than 4-layer bandaging (0.1025, p=0.0375). Multi-variable linear modelling predicted that patients with healed ulcers would have a higher index score than patients with unhealed ulcers (0.1774, p=0.004).</td>
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<td>Harrison et al. (2011)</td>
<td>Four-layer bandaging vs. short</td>
<td>Randomised controlled trial</td>
<td>Twelve weeks</td>
<td>No significant differences were detected between...</td>
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<tr>
<td>Study</td>
<td>Description</td>
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<td>Measurements</td>
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<td>Jull, Walker, Parag, Molan, &amp; Rodgers (2008)</td>
<td>1: Honey impregnated dressings and compression bandaging 2: Usual care (including compression bandaging)</td>
<td>Randomised controlled trial (n=368)</td>
<td>SF-36, EuroQoL5D, and Charing Cross Venous Ulcer Questionnaire - measured at 12 weeks only.</td>
<td>Effect size? × No significant differences between groups at 3-months post baseline, on the mental component summary (p=0.335) or the physical component summary (p=0.675).</td>
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<td>Loftus (2001)</td>
<td>1: Four-layer bandaging 2: Superficial venous surgery.</td>
<td>Non-randomised trial (n=30)</td>
<td>EuroQol 5D and author created measure - measured at pre-treatment, and four and twelve weeks post-treatment.</td>
<td>Mean? ✓ SD? × p-value? ✓ Effect size? × Quality of life improved significantly for both groups (surgery p=0.001, bandaging p=0.019). No significant differences were found between treatment groups at 12 weeks (p=0.67).</td>
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<td>Michaels et al. (2009)</td>
<td>1: Silver-donating dressings 2: Non-silver low adherence dressings.</td>
<td>Randomised controlled trial (n=213)</td>
<td>EuroQol 5D and SF-6D - measured at 1, 3, 6, and 12 months.</td>
<td>Mean? ✓ SD? × p-value? × Effect size? × No significant differences were found between those whose ulcers healed and those whose ulcers persisted.</td>
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<tr>
<td>Moffatt, et al. (2008)</td>
<td>1: Two layer bandaging system 2: Four layer bandaging system</td>
<td>Randomised controlled 8-week crossover trial (n=83)</td>
<td>Cardiff Wound Impact Schedule – measured at baseline, time of crossover and study exit</td>
<td>Mean? ✓ SD? ✓ p-value? ✓ Effect size? × Two-layer bandaging was associated with significantly larger improvements in the 'physical symptoms and daily living scores of the QOL measure' (p&lt;0.05) - no other significant differences</td>
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<tr>
<td>Study</td>
<td>Treatment 1</td>
<td>Study Design</td>
<td>Duration</td>
<td>Outcome Measure</td>
<td>Statistical Analysis</td>
<td>Results</td>
<td>Conclusion</td>
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<td>Weller, Evans, Staples, Aldons, &amp; McNeil (2012)</td>
<td>1: Three layer bandaging treatment</td>
<td>Randomised controlled trial (n=45)</td>
<td>Twelve weeks</td>
<td>SF-36 and Cardiff Wound Impact Schedule - measured at baseline and end of treatment.</td>
<td>Mean? ✓ SD? ✓ p-value? ✓ Effect size? ✓</td>
<td>No statistically significant differences were found between the two treatment groups (p&gt;0.13).</td>
<td>Participants whose ulcers healed had significantly higher scores on the ‘mental component summary’ of the SF-36 than those whose ulcers did not heal (p=0.02).</td>
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<tr>
<td>Zamboni et al. (2003) - plus erratum (Zamboni, Ciscno, et al., 2003)</td>
<td>1: Minimally invasive surgical haemodynamic correction of reflux (CHIVA)</td>
<td>Randomised controlled trial (n=47)</td>
<td>SF-36 - measured at baseline and conclusion of the study (3 years).</td>
<td>Statistically significant improvements were found in QOL across all eight measured QOL elements in the surgical treatment group and four elements in the compression group.</td>
<td>Statistically significant improvements were found in 4+ domains of QOL for each treatment group (p&lt;0.05).</td>
<td>Statistically significant differences were found between the two groups in five of the measured elements: role-physical limitation, vitality, social functioning, role-emotional limitation, and mental health.</td>
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</table>
2.4.3 **Quality of Life Measures**

Generic Health Related Quality of Life measures included the Short Form-36 (n=6) (Charles, 2004; Clarke-Moloney et al., 2005; Guest et al., 2003; Jull et al., 2008; Weller et al., 2012; Zamboni et al., 2003), Short Form-12 (n=1) (Harrison et al., 2011), ShortForm-6D (n=1) (Michaels et al., 2009), the EuroQol-5D (n=4) (Harding et al., 2014; Jull et al., 2008; Loftus, 2001; Michaels et al., 2009), Nottingham Health Profile (n=3) (Franks & Moffatt, 2001; P. Franks et al., 1999) and Quality of Life Index (n=1) (Finlayson et al., 2014).

Specific ulcer or wound related Quality of Life measures included the Cardiff Wound Impact Schedule (n=2)(Moffatt et al., 2008), the Chronic Venous Insufficiency Questionnaire (n=1) (Brizzio et al., 2010), the Charing Cross Venous Ulcer Questionnaire (n=2) (Guest et al., 2003; Jull et al., 2008) and an author created measure (n=1) (Loftus, 2001).

Five studies combined one or more ‘generic’ quality of life measures with a ‘specific ulcer-related’ quality of life measure (Clarke-Moloney et al., 2005; Guest et al., 2003; Jull et al., 2008; Loftus, 2001; Weller et al., 2012), one study utilised two different generic Quality of Life Measures (Michaels et al., 2009) and the remaining ten studies used a single generic or specific Quality of Life Measures.

### 2.4.4 Quality of data reporting

The quality of data reporting across the included papers varied, with most reporting p-values but variation in the mean values, standard deviations and effect sizes reported (see Table 1). Extensive heterogeneity was observed across the included articles, including heterogeneity of treatment method, measurement tools and time points utilised. Therefore, meta-analysis was deemed inappropriate in line with Cochrane recommendations regarding meaningful pooling of outcomes and comparable treatments (Hopman et al., 2014), and a detailed systematic review was conducted.

### 2.4.5 Hypothesis one: Both treatments for venous leg ulcers will lead to improvement in patient quality of life

Eight studies suggested that all investigated treatments lead to improvements in overall QOL regardless of treatment type (Charles, 2004; Finlayson et al., 2014; Franks & Moffatt, 2001; Franks et al., 2004; Guest et al., 2003; Loftus, 2001; Zamboni et al., 2003). This included compression therapy, 4-layer bandaging, 3-layer bandaging, short-
stretch bandaging, advanced wound dressing, and superficial venous surgery. These results lend support to the hypothesis that treatment itself may lead to improvements in patient quality of life, regardless of type.

Eight studies did not provide sufficient information to contribute to this hypothesis (Brizzio et al., 2010; Clarke-Moloney et al., 2005; Harding et al., 2014; Harrison et al., 2011; Jull et al., 2008; Michaels et al., 2009; Moffatt et al., 2008; Weller et al., 2012). Many of these studies did not clearly report whether treatment had significantly improved from baseline in individual treatment groups, and sufficient data was not included for the reviewers to make these calculations. Other studies did not collect data at multiple time points and therefore could only investigate whether quality of life differed between groups post-treatment.

2.4.6 Hypothesis two: Patient quality of life will be impacted to differing extents depending on treatment type

Nine studies found no statistically significant difference in post-treatment quality of life scores between treatment groups. This included eight studies comparing various types of bandaging and advanced wound dressings (Brizzio et al., 2010; Finlayson et al., 2014; Franks et al., 1999; Harrison et al., 2005; Jull et al., 2008; Michaels et al., 2009; Weller et al., 2012) and one study comparing quality of life as a result of superficial venous surgery versus standard bandaging (Loftus, 2001). All nine of these studies found that quality of life was improved in both treatment conditions, but that no significant differences existed between the treatment groups.

Five studies did find statistically significant differences in quality of life scores between treatment groups. Three of these studies compared various types of bandaging, concluding that: 2-layer bandaging led to significantly larger improvements in ‘physical symptoms’ and ‘daily living’ elements of quality of life than 4-layer bandaging (Moffatt et al., 2008), four-layer bandaging led to better reported outcomes in ‘physical activity’, ‘social functioning’ and ‘global index’ domains than usual bandage-based care (Clarke-Moloney et al., 2005) and adaptive compression therapy (ACT) was suggested to predict a significantly higher quality of life index score when compared with four-layer bandaging (Harding et al., 2014). Two of these five studies investigated superficial venous surgery alongside compression therapy, compared to compression therapy alone, and found that the surgical group reported significantly better quality of life in
more domains of the questionnaires post-treatment than the compression-only group (Guest et al., 2003; Zamboni et al., 2003).

Two studies did not compare treatment types, instead examining changes in quality of life within one treated group over multiple time points (Charles, 2004; Franks & Moffatt, 2001).

2.4.7 Hypothesis three: Patient quality of life is influenced by wound status

Of the sixteen articles included in this review, nine articles analysed data for differences in quality of life dependent on wound status. One study found no statistically significant differences in quality of life between participants with healed and unhealed leg ulcers as a result of the intervention (Michaels et al., 2009), however, eight studies found significant differences in at least some domains of quality of life (Brizzio et al., 2010; Charles, 2004; Franks & Moffatt, 2001; Franks et al., 1999; Guest et al., 2003; Harding et al., 2014; Weller et al., 2012). These latter eight studies concluded that various domains of quality of life had significantly improved in participants whose leg ulcers had healed, whilst those with unhealed ulcers reported comparatively smaller improvements.

Two additional articles (Clarke-Moloney et al., 2005; Zamboni et al., 2003) suggested that significant differences in Quality of Life between treatment groups may be due to healing rates, although they did not statistically analyse data for differences dependent on wound status. One of these studies found that surgical treatment was associated with significant improvements in more QOL domains (p<0.05) and improved healing rates than compression treatment (Zamboni et al., 2003). This led the authors to suggest an association between wound status and quality of life. In addition, a second study found that participants treated with four-layer bandaging experienced higher healing rates, and significantly improved QOL in physical activity related and social functioning domains of quality of life measures (p<0.006) (Clarke-Moloney et al., 2005). This was compared to those treated with usual care bandaging, and these authors also suggested differences may be due to wound status. Whilst these two articles did not run separate statistical analysis to investigate whether or not differences in quality of life were dependent on wound status, they do suggest in discussion of the results that this may have been the case.
Five studies did not present analysis on the relationship between wound status and quality of life (Finlayson et al., 2014; Harrison et al., 2011; Jull et al., 2008; Loftus, 2001; Moffatt et al., 2008). The authors of these articles were contacted for clarification or additional data. Four replied that they had no additional data or publications whilst one provided a further article. This article provided further insight regarding predictors of HRQOL in people with chronic leg ulcers, but did not, however, contribute to the specific hypotheses addressed by the current paper (Hopman et al., 2014).

2.5 Discussion
The aim of this systematic review was to evaluate the comparative impact of bandaging/compression treatments and superficial venous surgery on venous leg ulcer patients’ Quality of Life. Sixteen papers were identified for inclusion in this review, however, they displayed considerable heterogeneity in intervention, study design and measurement tools used. This factor, as well as a paucity of detailed data, meant that a meta-analysis was not deemed appropriate and instead a detailed systematic review was conducted. Of the three hypotheses examined by this review, there appears to be support for all three.

The first hypothesis in this review suggested that both conservative and surgical treatment for venous leg ulcers would lead to improvements in patient quality of life. From the results of this review, it does appear that treatment itself may lead to improvements in patient quality of life, regardless of treatment type, with eight of the sixteen studies included in this review suggesting that all investigated treatments led to improvements in quality of life. The remaining eight studies were unclear on this point and none concluded that treatment had no impact on quality of life.

The second hypothesis in this review suggested that patient quality of life would be impacted to differing extents dependent on treatment type, and evidence was also found to support this hypothesis. Whilst nine of the fourteen studies that compared interventions found no significant difference in participant’s quality of life scores between treatments, these results depended greatly on the treatment types being compared. Results suggest that many of the compression or bandaging based treatments for venous leg ulcers may have an equivalent impact on patient quality of life, as only three of eleven studies (27.27%) found differences in quality of life outcomes between types of bandaging. In contrast, two of the three studies that investigated superficial
venous surgery found significant differences in the QOL of those treated with surgery and compression therapy (versus compression therapy alone). These results lend cautious support to the hypothesis that patient quality of life is impacted to a differing extent dependent on treatment type, with greater improvements observed in patients undergoing superficial venous surgery.

The third hypothesis, that patient quality of life is influenced by wound status, was also supported by the results of this review. Findings regarding wound status and quality of life suggest that this may be an overarching factor when examining the effect of treatment type on patient quality of life. These conclusions are in contrast to some authors, who have suggested that good quality wound care and management may be more important to patient QOL than wound status (Charles, 2004).

Examining this review in the context of existing literature offers some explanation for these findings. Firstly, the finding that all treatment led to improvements in quality of life, regardless of treatment type, is likely to echo the findings of the third hypothesis – that patient quality of life is influenced by wound status. Although debate exists regarding the comparative recurrence rates in conservative and surgical management, a substantial evidence base suggests that both treatments are effective in healing an active venous ulcers, thus it follows that all treatments explored in this review would lead to some improvement in wound status and in turn quality of life. This finding supports existing literature linking clinical severity and quality of life (Hareendran et al., 2005), although it is suggested that other factors may also play a role in patient wellbeing. It must also be considered that the treatment received by participants in research studies may be superior to that received by individuals treated in the community, and thus the results of these studies reflect the outcomes of best practice (Guest et al., 2015).

With regards to the second hypothesis, research regarding other conditions has suggested that surgery might have a differential effect on QOL due to the nature of undergoing a surgical procedure (Criddle, 1993). Such research suggests that healing from surgery involves active participation and evolving beyond the condition, allowing patients to seek purpose and independence (Criddle, 1993). Such a transition may not normally be possible for leg ulcer patients, due to the longevity and immobilisation of the condition (Chase et al., 1997); however, surgery may allow a more definite
transition for patients and a shift in the way they perceive their illness. This is just one potential explanation for the results, however, further research is required to explore the mechanisms behind any change in quality of life due to treatment type.

2.5.1 Limitations
Whilst every effort was made to identify all relevant articles, through design of the search strategy and further hand-searching of relevant articles’ reference lists, potential for missed articles remains and this may have influenced the conclusions of this review. Publication bias is not anticipated to have affected the results, as many studies reported non-significant results regarding quality of life outcomes; this may be because quality of life was often not a primary outcome measure in these articles. Although only English language studies were included in the review, no studies were excluded on the basis of language, so this is not expected to have influenced the results.

It must be considered that the average age of this population implies that a number of comorbidities may be present in participants. This adds complications for researchers in determining the effect of ulceration on QOL from the effect of other comorbidities and should be considered when interpreting results. However, this also emphasises the importance of utilising disease-specific measures in this population when measuring QOL and this should be considered when designing future research. Equally, research is often conducted with ‘hard to heal’ ulcer populations, as indicated in this review by the average ulcer duration of 13 months and average ulcer size of 10cms across the included papers. This may be due to availability of sample population, suitability for treatment methods or increased motivation to participate in research. Those with ‘hard to heal’ ulcers are likely to suffer a considerably larger impact on their QOL and this factor should be considered when considering the clinical implications of this review and other research in this area.

It is believed that a meta-analysis would have added to the strength of this review, however, this was not considered possible by the authors due to the heterogeneity of the included articles and the absence of detailed data available. Articles differed greatly in the type of surgery, type of compression device, measures and time points investigated; and this heterogeneity led to the inclusion of articles investigating either conservative or surgical treatment, due to the scarcity of articles directly comparing the two methods.
2.5.2 Future recommendations

Whilst this review highlights the importance of wound status, the influence of treatment alone indicates a more complex psychological mechanism than a direct link between healing and patient wellbeing. The effect of treatment on QOL may be mediated by multiple factors and future research would benefit from the development of a model of treatment effect on Quality of Life; quantifying the contribution of healing, treatment type and other mediating factors. Future research might also look at the effect of recurrence rates on QOL, as it has been suggested that recurrence is the factor that differentiates superficial venous surgery from other treatment modalities. It is possible that the lower recurrence rates in surgical treatment and the psychological process of recovery from surgery (Criddle, 1993) may improve QOL above other treatment types, as they remove the expectation of the leg ulcer returning and transform the illness from chronic to acute. This expectation of recurrence is compared by some authors to being in remission from cancer and remaining vigilant for its return (Chase et al., 1997). This relief from the expectation of leg ulcer recurrence, however, may only be applicable if the patient is informed of the lower recurrence rates associated with superficial venous surgery and if this is incorporated into their health beliefs. Future research would also benefit from careful consideration of control group design and increased homogeneity in study design and outcome measures. This would facilitate future meta-analyses and synthesis of data.

2.6 Conclusions

This systematic review aimed to evaluate the comparative impact of bandaging/compression treatments and superficial venous surgery on the Quality of Life of venous leg ulcer patients. The results suggest that all treatment improves patient quality of life to some extent, regardless of treatment type. Wound status plays an important role in the extent of improvement, with greater ulcer healing leading to significantly improved quality of life outcomes. Type of bandaging did not appear to influence quality of life outcomes, however, studies investigating surgical treatment appeared to demonstrate improved quality of life compared to compression bandaging alone. These differences are suggested to be due to the nature of undergoing a surgical procedure and the active participation required in this process, although further research is required to establish the validity of this theory. Overall the results of this review
provide a synthesis of the literature not previously available and suggest possible directions for future research.
Chapter Three

Study 1: A cross-sectional investigation into predictors and mediators of quality of life in chronic leg ulceration

3.1 Overview
A systematic review of the literature was presented in chapter two, which evaluated the comparative impact of conservative treatment versus superficial venous surgery on venous leg ulcer patients’ quality of life. Whilst the review explored quality of life as a treatment outcome, the present chapter aims to explore predictors of quality of life in individuals with chronic leg ulceration, as well as the mediating role of psychosocial factors. Little existing research has explored patients’ experiences of leg ulcers using psychological theory and no research appears to have drawn upon such theory to explore quality of life. The present study frames leg ulcers within the chronic illness literature, exploring clinical, demographic, psychosocial, and care factors from a psychological perspective.

3.2 Introduction
Leg ulcers are known to have a profound impact on a patient’s psychological wellbeing, and are associated with higher levels of depression and anxiety, loss of will power, lower self-confidence, and lower self-esteem (Douglas, 2001; Green et al., 2013; Persoon et al., 2004). The quality of life of individuals with leg ulcers has been investigated both qualitatively and quantitatively, with studies demonstrating poorer quality of life in individuals with leg ulcers compared to their peers (Moffatt et al., 2009). Existing research has primarily investigated clinical and demographic predictors of quality of life; however, a lack of consensus appears to exist within the findings. Whilst one quantitative study of over 400 patients suggested that larger ulcer size, longer ulcer duration, and more pain were associated with poorer general quality of life (Hopman et al., 2014), in another investigation ulcer severity was found to significantly predict disease-specific quality of life in leg ulcer patients, but not general quality of life (Kahn et al., 2004). Similarly, whilst Hopman et al. (2014) suggested that younger age may be associated with poorer quality of life in individuals with leg ulcers, a contrasting study suggests that patients who are older, experience more pain and have unhealed ulcers may report particularly poorer QOL (Hareendran et al., 2005). Such
conflicting findings in the literature may reflect the use of different measures or sampling differences, but require clarification in order to further our understanding of quality of life in this condition.

Whilst there has been significant exploration of patient quality of life within the existing leg ulcer literature, there has been little use of psychological theory or models to inform this research. Although clinical and demographic variables are often explored as predictors of quality of life, no previous research has investigated the role of psychosocial variables or explored these in relation to whether an individual receives informal care. These ‘psychosocial variables’ include constructs such as social support, depression, anxiety, and general psychological wellbeing. In contrast, the relationship between psychosocial variables and quality of life has been explored in many other chronic conditions, such as cancer (Parker, Baile, De Moor, & Cohen, 2003) and chronic obstructive pulmonary disease (COPD; Anderson, 1995; Blinderman et al., 2009), and psychological models of adaptation to illness would suggest this relationship is an essential element of investigations. For example, Lazarus’ stress-coping model (Lazarus & Folkman, 1984) has been used to conceptualise the sense-making processes surrounding chronic illness and explore predictors of quality of life. The stress-coping model argues that adjustment to illness is influenced by an individual’s appraisal of the stressor, the coping strategies they employ and subsequent appraisal of these coping strategies. Whilst the primary focus of this model is the influence of coping styles of adaptation to illness, this process is thought to also be influenced by situational stressors and psychosocial factors, and thus these elements could be said to mediate the relationship between the condition and adaptation. These elements are particularly pertinent to leg ulceration in light of the impact leg ulcers can have on an individual’s mood and psychological state. An example of this model being applied to chronic illness can be seen in Anderson’s (1995) study of COPD, whereby researchers explored the mediating role of psychosocial factors in the relationship between demographic and clinical variables and health-related quality of life. Their findings supported the role of psychosocial factors as mediators, particularly self-esteem, depression and social support and support the utility of the stress-coping model in other chronic conditions.

As discussed in Chapter One, such psychological models have demonstrated significant success in their conceptualisation of chronic illness and thus warrant further investigation within the context of leg ulceration. Whilst predictors of quality of life
have been explored extensively in other conditions, studies of chronic leg ulceration have so far focused on the experiences of individuals living with leg ulceration and little work has been conducted drawing upon health psychology theory. Application of Lazarus and Folkman’s (1984) stress-coping model to the study of leg ulceration would allow investigation of psychosocial factors as mediators in the relationship between clinical factors and quality of life, and provide insight into the processes influencing patient adaptation to this condition.

Another key area of research into chronic illness, and one that has been underexplored in leg ulceration, is the impact of the condition on caregivers. It is suggested that caregivers of those with a persistent leg ulcer may have a lower quality of life (Nabuurs-Franssen et al., 2005), and report particularly high levels of emotional burden if living with the patient or having to reduce their working hours in order to care for them (Tabolli et al., 2007). Little is known, however, about the perspective of cared-for individuals. In chronic illness more generally it is thought that negative reactions to caregiving are common (Newsom & Schulz, 1998), however, little research has explored the perspective of the cared-for individual in leg ulceration and no research has explored the association between care status and other clinical, demographic and psychosocial variables in individuals with leg ulcers. Of particular interest in the caregiving literature is the influence of relationship quality between carer and cared-for individual, and this has been explored across chronic illness generally (Hui, Elliott, Martin, & Uswatte, 2011; Iecovich, 2011), in dementia specifically (Quinn et al., 2009; Nele Spruytte et al., 2002) and in the case of chronic mental illness (Spruytte et al., 2002). It is suggested that relationship quality may be seen as an influential factor in adaptation to caregiving; however, it remains unclear whether relationship quality may also be linked to patient quality of life, whether the conclusions of existing research readily apply to leg ulceration or how relationship-quality may influence the relationship between social support and quality of life.

As discussed, whilst existing literature has established that living with a leg ulcer can have a significant impact on patient quality of life, research studies have primarily focused on describing this impact in relation to clinical and demographic variables. Several inconsistencies have been established in research findings, and no existing research has drawn upon psychological models or investigated the influence of psychosocial variables on quality of life. Although a limited amount of research has
investigated the role of carers in chronic leg ulceration, there has been no research into the relationship between care status and patient quality of life or the influence of relationship-quality in leg ulcers.

3.2.1 Aims
The current study aims to explore predictors of health related quality of life in a cross-sectional sample of individuals with leg ulcers, with a focus on psychosocial and care-related variables. Using Lazarus and Folkman’s (1984) stress-coping model as a framework, this study will also explore the mediating role of psychosocial variables in the relationship between clinical severity and quality of life.

3.3 Methods
3.3.1 Design
This study used a cross-sectional questionnaire design. The main independent variables were demographics, clinical aspects (such as ulcer duration and healing status), psychosocial variables (such as social support and mood) and care-related variables (such as relationship quality, informal care provision and perceived caregiving impact). The outcome variables were general quality of life, disease-specific quality of life and pain.

3.3.2 Recruitment
This study aimed to recruit individuals who have previously had, or currently have, leg ulcers. Participants were recruited through advertising with various charities and social media. An advertisement was placed on ‘The Leg Ulcer Charity’ website, and corresponding social media page, and recruitment materials were sent to relevant charities and community groups asking them to pass information onto their members. In order to take part, potential participants were required to meet inclusion criteria, including: to be aged over 18, to have given informed consent, to have a good understanding of written and spoken English, and to either currently have or to have previously had a leg ulcer(s).

3.3.3 Measures
Participation took place via online survey or postal questionnaire. The online survey was hosted on the University of Surrey website, whilst participants wishing to take part via post were sent a participation pack with a freepost envelope, so that they may return
their consent form and questionnaire free of charge. A large print version of the questionnaire was available upon request. Participants were asked to complete a number of questionnaire measures regarding demographic, clinical, psychosocial, care and quality of life constructs. See Table 2 for details of these measures (see Appendix D for examples of these questionnaire measures).

Table 2. Detailed description of questionnaire measures

<table>
<thead>
<tr>
<th>Construct</th>
<th>Measure</th>
<th>Source</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographic variables</td>
<td>Demographic information</td>
<td>Author constructed.</td>
<td>Demographic questions regarding participant’s age and gender.</td>
</tr>
<tr>
<td>Clinical variables</td>
<td>(Adjunct to demographic questionnaire)</td>
<td>Author constructed</td>
<td>This is an author constructed questionnaire, with questions regarding participant’s current ulcer status and treatment history. This includes: the cause of their leg ulcer, current treatment method, whether the patient has undergone surgery for their ulcer, duration of time with leg ulcer, and number of times the ulcer has recurred. In addition, the participant is asked whether they receive informal care, and what this care involves (eg. practical care, personal care, etc).</td>
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<tr>
<td>Quality of life variables</td>
<td>Single-Item Health-Related Quality of Life</td>
<td>Idler and Kasl (1995) Public domain</td>
<td>This is a single-item measure of Health Related Quality of Life, asking participants to rate their current overall health as ‘Very good’, ‘Good’, ‘Okay’, ‘Poor’ or ‘Very Poor’. Measures such as this correlate highly with longer composite measures, and demonstrate good long-term predictive abilities of morbidity and mortality (Idler &amp; Kasl, 1995). On this measure, a larger score indicates worse Quality of Life.</td>
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<tr>
<td></td>
<td>Charing Cross Venous Ulcer Questionnaire.</td>
<td>Smith et al. (2000) Permission obtained</td>
<td>This is a 20-item questionnaire, designed to capture how patients’ lives are impacted by the presence of a leg ulcer. Responses load onto four health related factors; social interaction (6</td>
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</table>
from author. items), domestic activities (4 items), cosmesis (5 items), and emotional status (5 items). An additional item measures the amount of pain the participant experiences due to the ulcer (see variable below). This questionnaire has been previously found to have good internal consistency (Cronbach $\alpha = .93$), test-retest stability ($r = .84$), and sensitivity to change (Smith et al., 2000). Within this sample, an average value was calculated for every participant on each subscale, all had Cronbachs $\alpha > .81$. From these subscales, an average score was calculated for each participant. On this measure, a larger score indicates worse Quality of Life.

<table>
<thead>
<tr>
<th>Ulcer-related pain</th>
<th>Charing Cross Venous Ulcer Questionnaire (Single item)</th>
<th>Smith et al. (2000)</th>
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<td></td>
<td>Permission obtained from author.</td>
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This is a single item from the Charing Cross Venous Ulcer Questionnaire, asking participants to respond to the question “I have pain from my ulcer” on a scale of 1-5 (with 1 representing ‘none of the time’ and 5 representing ‘all of the time’). For the purposes of analysis, this item of the questionnaire was treated as a separate variable. On this measure, a larger score indicates worse Quality of Life.

**Psychosocial variables**

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<td></td>
<td>Public domain.</td>
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The PANAS consists of two 10-item mood scales, designed as brief reliable measures of mood. The scale asks participants to rate, on a scale of 1-5, how often they have felt various emotions in the specified time period. The scales are widely used and a recent study suggests that, whilst the two scales do not appear to be independent, each scale has a Cronbachs $\alpha$ of >.84 (Crawford & Henry, 2004). Within this sample, both subscales had high reliability. The Positive subscale had Cronbachs $\alpha = .92$, and the Negative subscale had Cronbachs $\alpha = .90$.

<table>
<thead>
<tr>
<th>Social Medical Outcomes</th>
<th>Sherbourne &amp; Stewart</th>
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<tr>
<td></td>
<td>The MOS Social Support Survey is a 19-item self-administered survey,</td>
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</table>
Study Social Support Survey (MOS-SSS) (adapted) (1991). Public domain. designed to measure social support in patients with chronic conditions. The measure shows stability over time and reliability, with Cronbach’s alpha of >.91 (Sherbourne & Stewart, 1991). As a result of participant feedback, this measure was reduced to contain only the emotional, tangible and positive social interaction subscales; reducing the measure to 11 items for the purposes of this study. The scale was found to have high reliability, Cronbach’s $\alpha = .95$.

### Care variables

<table>
<thead>
<tr>
<th>Carer-Patient relationship Quality</th>
<th>Quality of Carer-Patient relationships Scale</th>
<th>Spruytte, Van Audenhove, &amp; Lammertyn (2000)</th>
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<tbody>
<tr>
<td>This 14-item measure is intended to measure the quality of the relationship between patient and caregiver, with two subscales: ‘Warmth and affection’ and ‘Conflict and criticism’. The value of this instrument lies in its measure of both warmth and critique in a relationship, and its suitability for use in both romantic and non-romantic relationships. It has been found to have sufficient internal consistency (Spruytte et al., 2000) and demonstrated good reliability within this sample. On the Conflict and criticism subscale, Cronbach’s $\alpha = .73$. On the Warmth and affection subscale, Cronbach’s $\alpha = .93$.</td>
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<tr>
<th>Perceived caregiving impact.</th>
<th>Perceived Caregiving Impact.</th>
<th>Author constructed.</th>
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<tr>
<td>This measure asks participants to report to what extent they believe that caregiving has an impact on their caregiver’s daily life (if applicable). Responses are given on a 7-point Likert scale, from ‘no impact’ to ‘significant impact’.</td>
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### 3.3.4 Choice of quality of life measures

As discussed in Chapter One, quality of life measurement is a highly debated area of research, and a dichotomy has emerged between generic health related quality of life (HRQOL) measures and more disease-specific quality of life (QOL) measures. As there are benefits to the use of each measure, much of the research in this area uses both a generic and disease-specific HRQOL measure in order to capture both elements, and
this approach has been recommended when exploring the experiences of individuals with leg ulcers (Howard & Davies, 2001; Smith et al., 2000). Generic HRQOL measures previously used in the leg ulcer literature include the Medical Outcomes Study Short Form 36 (SF-36) (Ware & Sherbourne, 1992), the Short Form 12 (Ware, Kosinski, & Keller, 2013), the EuroQol (EQ-5D) (EuroQol Group, 1990), the McGill Pain Questionnaire (Melzack, 2005), and the Nottingham Health Profile (NHP) (Hunt, McEwen, & McKenna, 1985). The SF-36 has been used extensively in the leg ulcer literature (Armstrong, Lavery, Wrobel, & Vileikyte, 2008; Charles, 2004; Nabuurs-Franssen et al., 2005; Valensi, Girod, Baron, Moreau-Defarges, & Guillon, 2005; Walters, Morrell, & Dixon, 1999) and has been used as a comparison tool when developing new disease-specific measures (Smith et al., 2000). Equally the SF-12 and EQ-5D are recommended as suitable measures of health related quality of life in this population, and Iglesias et al. (2005) suggest that their brevity compared to some disease specific measures may increase response rates and quality of data collected.

Although not widely used with leg ulcer populations, single-item measures of health related quality of life have also been used extensively in the literature and have been found to correlate highly with composite measures (Idler & Kasl, 1995). Such single-item measures are believed to be simpler to complete and place a lesser burden on the individual completing the measure. In comparison to multi-item scales, single-item quality of life measurements have demonstrated good validity and test-retest reliability; although it is suggested that their use is dependent upon appropriateness to the research question (De Boer et al., 2004). Such brevity in measurement is particularly important when combining a general QOL measure with a disease-specific measure of HRQOL.

Examples of disease specific measures commonly used with leg ulcer patients include The Hyland (Hyland, Ley, & Thomson, 1994), the Charing Cross Venous Ulcer questionnaire (CCVUQ) (Smith et al., 2000), the VEINES-QOL/Sym (Lamping, Schroter, Kurz, Kahn, & Abenhaim, 2003), and the Venous Leg Ulcer Quality of Life questionnaire (Hareendran et al., 2006). All have shown good reliability and validity, but focus on slightly different elements of the patient experience. In a recent review of disease-specific measures, Gonzalez-Consuegra & Verdu (2011) stress the importance of pain to venous leg ulcer patients quality of life and recommend the use of the CCVUQ due to its appropriateness to the patient group and its psychometric
characteristics. The CCVUQ is also highly correlated with the SF-36 and has been found to be responsive to healing (Smith et al., 2000). Therefore, considering the existing literature and the above factors, the CCVUQ (Smith et al., 2000) and a single-item measure of general HRQOL were selected for use in this study.

3.3.5 Procedure
Each participant was given an information sheet (see Appendix A) prior to participation, and was encouraged to contact the researcher if they had any questions regarding the study. Participants were asked to read and sign a consent form if they wished to continue (see Appendix B), before completing the questionnaire measures. Total participation time for each participant was estimated to take 20-30 minutes, and all participants were asked whether they wished to take part in any future research on a similar topic. After completing the questionnaire measures, all participants were asked to read a debrief sheet (see Appendix C) and were again encouraged to contact the researcher if they had any questions or wanted any further information about the research.

3.3.6 Ethical considerations
This study received a favourable ethical opinion from the NHS Research Ethics Committee South Central Berkshire B (see Appendix E), and the University Ethics Committee at the University of Surrey (see Appendix F). To ensure informed consent was gained from all participants, an information sheet described the aims and procedures of the study, how data would be used and participant’s right to withdraw (see Appendix A). Participants were reassured that all their data is confidential and participation is completely voluntary. Participants were asked to read this information before deciding whether or not to complete the questionnaire, and to sign a consent form if they wish to proceed. All participants were given debrief information after completing the questionnaires, either as part of the online survey or in their postal pack and were asked to read this information after participation (see Appendix C). This debrief sheet included information on sources of further support and the contact details of the researchers should participants have any further questions or wish to withdraw from the study.

3.3.7 Data analysis
Data was analysed using SPSS for windows, Version 21.0, as follows:
• Describing demographic, clinical, and care-related variables using descriptive statistics;
• Exploring relationships between health-related quality of life and clinical and demographic variables (age, gender, duration, recurrence, healing status, treatment type), using Kruskal-Wallis tests, Mann-Whitney U tests, and tests of correlation;
• Exploring relationships between psychosocial variables (social support, positive mood, negative mood) and clinical and demographic variables (age, gender, duration, recurrence, healing status, treatment type), using Kruskal-Wallis tests, Mann-Whitney U tests, and tests of correlation;
• Comparing differences between cared-for and non-cared-for individuals on clinical, demographic and psychosocial variables using ANOVA, Kruskall-Wallis tests, T-tests and Mann-Whitney U tests;
• Assessing the relationship between type of informal care received and health related quality of life, relationship quality and perceived caregiving impact using Kruskal-Wallis tests;
• Investigating whether clinical and psychosocial variables (social support, positive mood, negative mood, care status) are predictive of health related quality of life (general, disease-specific and ulcer-related pain) using Multiple Regression analysis.
• Investigating whether psychosocial variables (social support, positive mood, negative mood) mediate the relationship between clinical variables and disease-specific health related quality of life using Mediation analysis.

3.4 Results
3.4.1 Data screening
Data was screened for outliers and assumptions of normality. Skewness and kurtosis values were calculated for all variables. Age, general health-related quality of life (general HRQOL), social support, negative mood, and negative relationship quality were found to meet the assumptions of normality. Disease-specific quality of life (disease-specific QOL), positive mood, positive relationship quality, overall relationship quality, recurrence, duration and healed status did not meet the assumptions of normality. Missing values were assessed on an individual measure-by-measure basis,
with participants excluded for individual questionnaire measures if they had missing responses for >50% of composite items. When a participant had answered more than 50% of the composite items for that measure, missing items were replaced with the mean value of the answered items for that particular scale and participant. One hundred and sixty questionnaire responses were received; however, one participant was excluded due to significant missing data across clinical, demographic and psychosocial variables.

3.4.2 Sample and demographic information

One hundred and fifty-nine participants were included in analyses. Participants ranged in age from 19 to 92 years old ($M = 61.04$, $SD=15.25$). Of those who took part, 45.3% were male and 54.7% were female, and 23.9% of participants had previously undergone surgery for leg ulceration. Mean duration of leg ulcers was 69.75 months ($n=156$, $SD=115.52$, range 1-723), which is approximately 5-6 years. Mean number of times that leg ulcers had recurred was 3.36 ($n=142$, $SD=6.93$, range 0-40). Participants were asked to complete questions regarding other clinical elements of their leg ulcers; including current healing status, current treatment, and cause. Participants were asked questions regarding the social support they receive, including whether or not somebody provided ‘informal care’ for them and whether this care was considered to include ‘emotional support only’, ‘practical support only’ or ‘both practical and emotional support’. Details of clinical severity and informal care provision are shown in Table 3.

Table 3. Descriptive statistics – demographic, clinical and care variables

<table>
<thead>
<tr>
<th>Measure</th>
<th>Category</th>
<th>Number of participants (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current healing status $(n=159)$</td>
<td>Unhealed</td>
<td>95 (59.7%)</td>
</tr>
<tr>
<td></td>
<td>Healing</td>
<td>32 (20.1%)</td>
</tr>
<tr>
<td></td>
<td>Healed and expect to return</td>
<td>17 (10.7%)</td>
</tr>
<tr>
<td></td>
<td>Healed and don’t expect to return</td>
<td>15 (9.4%)</td>
</tr>
<tr>
<td>Current treatment $(n=159)$</td>
<td>None</td>
<td>26 (16.4%)</td>
</tr>
<tr>
<td></td>
<td>Compression</td>
<td>81 (50.9%)</td>
</tr>
<tr>
<td></td>
<td>Bandages</td>
<td>26 (16.4%)</td>
</tr>
<tr>
<td></td>
<td>Oral medication</td>
<td>2 (1.3%)</td>
</tr>
</tbody>
</table>
Topical medication 4 (2.5%)
Other 20 (12.6%)

| Cause (n=159) |  
|---------|---|
| Venous | 39 (24.5%) |
| Arterial | 1 (0.6%) |
| Mixed | 5 (3.1%) |
| Diabetic | 4 (2.5%) |
| Rheumatoid | 1 (0.6%) |
| Trauma | 8 (5%) |
| Other | 14 (8.8%) |
| Don’t know | 87 (54.7%) |

Informal care (n=158) None 68 (42.8%)
Emotional only 18 (11.3%)
Practical only 24 (58.2%)
Both emotional and practical 48 (30.2%)

Examples of free-text responses given when participants indicated ‘Other’ for the cause of their leg ulcer included: ‘Antiphospholid syndrome’, ‘Oral contraceptives’, ‘Behcets syndrome’ and ‘Lupus’. Examples of responses given when participants indicated ‘Other’ for treatment included ‘Turmeric and sugar’ and ‘Hyperbaric oxygen therapy’.

### 3.4.3 Differences in quality of life by clinical and demographic variables

Kruskal-Wallis tests, Mann-Whitney U tests, and Spearman’s correlations were used to investigate the differences in quality of life by demographics (age, gender) and clinical variables (ulcer duration, healing status, recurrence, treatment type). Quality of life was measured in terms of disease-specific quality of life (QOL), ulcer-related pain, general health-related quality of life (HRQOL).

#### 3.4.3.1 Disease-specific quality of life

3.4.3.1.1 Demographic variables

Disease-specific QOL in women ($Mdn = 3.32$) was found to be significantly worse than in men ($Mdn = 2.93$), $U = 2340$, $z = -2.17$, $p = .029$, $r = -.18$. A significant correlation was also found between age and disease-related QOL ($r = -.245$, $p = .001$), with disease-specific QOL reported to be better in older participants. However, when healing status is controlled in the relationship between age and disease-specific QOL, no
significant semi-partial correlation was found ($r = -.133, p = .06$). No significant association was found between disease-specific QOL and duration ($r = .014, p = .431$) or recurrence ($r = .10, p = .120$); and no significant difference was found in disease-specific QOL dependent upon treatment type ($H(5) = 5.984, p = .308$). No significant differences were found in disease-specific QOL between participants who had ($Mdn = 3.01$) or had not ($Mdn = 3.19$) previously had surgery for leg ulcers ($U = 1694, z = -1.33., p = .18, r = -.10$). Therefore, although women were found to have significantly worse quality of life than men, no significant differences in quality of life were found due to treatment type or previous surgery and no associations were found between disease-specific quality of life and age or ulcer duration.

3.4.3.1.2 Clinical variables

Significant differences were found in disease-specific QOL, dependent upon healed status ($H(3) = 34.46, p < .001$). Mann-Whitney tests were used to investigate this further. As a Bonferroni correction was applied, all p-values are reported at a significance level of .0167. These tests revealed significant differences in disease-related QOL between individuals who report having an ‘unhealed’ ($Mdn = 3.59$) or ‘healing’ ($Mdn = 3.00$) ulcer ($U = 881.5, p < .001$). However, no significant differences were found between ‘healing’ ($Mdn = 3.00$) and ‘healed and expect to return’ ($Mdn = 2.28$) ($U = 163, p = .04$), or between ‘healed and expect to return’ ($Mdn = 2.28$) and ‘healed and do not expect to return’ ($Mdn = 2.25$) ($U = 87, p = .981$). This suggests that the difference in disease-specific quality of life is specifically between individuals with ‘unhealed’ and ‘healing/healed’ ulcers; with those who have ‘unhealed’ ulcers reporting poorer disease-specific quality of life.

3.4.3.2 Ulcer related pain

3.4.3.2.1 Demographic variables

Significant associations were found between ulcer-related pain and age ($r = -.22, p = .007$), and between ulcer-related pain and duration ($r = .2, p = .02$); however, when healing status was controlled for in both relationships, no significant semi-partial correlation was found ($Age, r = -.08, p = .34$) ($Healed status, r = .11, p = .17$). No significant association was found between ulcer-related pain and recurrence ($r = .11, p = .20$).
3.4.3.2.2 Clinical variables
Significant differences in ulcer-related pain levels were found to be dependent upon healed status \( (H(3) = 32.41, p < .001) \), and Mann-Whitney tests were used to investigate this further. As a Bonferonni correction was applied, p-values are reported at a significance level of .0167. These tests revealed significant differences in ulcer-related pain between individuals who report having an ‘unhealed’ or ‘healing’ ulcer \( (U = 920, p = .001) \), and individuals who report having ‘healed and expect to return’ and ‘healed and do not expect to return’ ulcers \( (U = 30, p = .005) \). However, no significant differences were found between individuals with ulcers that were ‘healing’ or ‘healed and expect to return’ \( (U = 226.00, p = .74) \).

3.4.3.3 General health-related quality of life

3.4.3.3.1 Demographic variables
General HRQOL in women \( (Mdn = 3) \) was not found to be significantly different to general HRQOL in men \( (Mdn = 3), U = 2932.00, z = -.73, p = 0.47, r = -.06 \). No significant differences were found in general HRQOL between participants who had \( (Mdn = 3) \) or had not \( (Mdn = 3) \) previously had surgery for leg ulcers, \( U = 2245, z = -.23, p = .82, r = -.02 \). Therefore, general health-related quality of life was not found to differ according to demographic or clinical variables.

3.4.3.3.2 Clinical variables
No significant association was found between general HRQOL and healed status \( (p = .25) \), age \( (r = -.07, p = .18) \), duration \( (r = .000, p = .50) \), or recurrence \( (r = -.09, p = .13) \). No significant differences were found in general HRQOL dependent upon treatment type \( (H(5) = 3.10, p = .69) \).

3.4.3.4 Summary
General health-related quality of life did not appear to differ according to any of the clinical or demographic variables included in this analysis. In contrast, disease-specific quality of life was found to be worse in women and individuals with ‘less healed’ ulcers, and ulcer-related pain was found to be worse in participants who reported an ‘unhealed’ ulcer.
3.4.4 Differences in psychosocial variables by clinical and demographic variables

Kruskal-Wallis tests, Mann-Whitney U tests, and Spearman’s correlations were used to investigate the impact of demographic (age, gender) and clinical (ulcer duration, healing status, recurrence, treatment type) variables on psychosocial variables, in terms of social support, positive mood and negative mood.

3.4.4.1 Social support

3.4.4.1.1 Demographic variables

A significant positive association with a small effect size was found between age and social support \( (r = .17, p = .03) \), with older participants reporting more social support. No significant differences were found in social support between men \( (Mdn = 3.45) \) and women \( (Mdn = 3.45) \), \( U = 2812.00, z = -.32, p = .75, r = .03 \).

3.4.4.1.2 Clinical variables

No significant association was found between social support and healed status \( (r = .13, p = .10) \), duration \( (r = -.13, p = .12) \) or times recurred \( (r = -.01, p = .92) \). No significant differences were found in social support dependent upon treatment type \( (H(5) = 2.36, p = .80) \).

3.4.4.2 Positive mood

3.4.4.2.1 Demographic variables

A significant positive association and a small effect size was found between age and positive mood \( (r = .26, p = .001) \), with older participants reporting more positive mood. No significant differences in positive mood were found between men \( (Mdn = 26.25) \) and women \( (Mdn = 24.62) \), \( U = 2519.50, z = -1.06, p = .29, r = -.09 \).

3.4.4.2.2 Clinical variables

Significant differences were found in positive mood, dependent upon healed status \( (H(3) = 15.785, p = .001) \). Mann-Whitney tests were used to investigate this further. As a Bonferonni correction was applied, all p-values are reported at a significance level of .013. These tests revealed no significant differences in positive mood between individuals who report having an ‘unhealed’ \( (Mdn = 21.71) \) or ‘healing’ \( (Mdn = 25.5) \) ulcer \( (U = 1054.00, p = .05) \), no significant differences between ‘healing’ \( (Mdn = 25.5) \) and ‘healed and expect to return’ \( (Mdn = 31.00) \) \( (U = 173.5, p = .36) \), or between
‘healed and expect to return’ (Mdn = 31.00) and ‘healed and do not expect to return’ (Mdn = 34.5) (U = 73.00, p = .27). A significant difference was found between individuals who reported that their ulcers were ‘unhealed’ (Mdn = 21.71) or ‘Healed and don’t expect to return’ (Mdn = 34.5) (U = 216.50, p < .001). This suggests that the difference in positive mood is specifically between individuals with ‘unhealed’ and ‘healed and don’t expect to return’ ulcers; with those who have ‘healed’ ulcers, which they don’t expect to return, reporting significant higher levels of positive mood.

A significant positive association and a small effect size was found between positive mood and recurrence (r = .18, p = .04); with participants whose ulcers had recurred less times reporting higher levels of positive mood. No significant association was found between positive mood and duration of ulcers (r = .13, p = .11), and no significant differences were found in positive mood dependent upon treatment type (H(5) = 6.11, p = .30).

### 3.4.4.2 Negative mood

#### 3.4.4.2.3 Demographic variables

A significant negative association and a medium effect size was found between age and positive mood (r = -.45, p < .001), with older participants reporting less negative mood. A marginally significant difference was found in negative mood between men (Mdn = 22.95) and women (Mdn = 26.15), U = 2272.50, z = -1.97, p = .049, r = -.16; with women reporting higher levels of negative mood than men.

#### 3.4.4.2.4 Clinical variables

Significant differences were found in negative mood, dependent upon healed status (H(3) = 14.283, p = .003). Mann-Whitney tests were used to investigate this further. As a Bonferroni correction was applied, all p-values are reported at a significance level of .013. These tests revealed significant differences in negative mood between individuals who report having an ‘unhealed’ (Mdn = 26.67) or ‘healing’ (Mdn = 23.00) ulcer (U = 971.50, p = .01); however, no significant differences were found between ‘healing’ (Mdn = 23.00) and ‘healed and expect to return’ (Mdn = 16.00) (U = 146.00, p = .08), or between ‘healed and expect to return’ (Mdn = 16.00) and ‘healed and do not expect to return’ (Mdn = 13.50) (U = 84.00, p = .52). A significant difference was also found between individuals who reported that their ulcers were ‘unhealed’ (Mdn = 26.67) or ‘Healed and don’t expect to return’ (Mdn = 13.50) (U = 246.00, p < .001). This suggests
that differences in negative mood are specifically between individuals with ‘unhealed’ or ‘healing’ ulcers, and ‘unhealed’ and ‘healed and don’t expect to return’ ulcers; with those who have ‘unhealed’ ulcers reporting significantly lower levels of negative mood.

No significant association was found between negative mood and duration of ulcers \((r = .02, p = .78)\) or recurrence \((r = -.032, p = .72)\). No significant differences were found in negative mood dependent upon treatment type \((H(5) = 2.71, p = .75)\).

### 3.4.4.3 Summary

These results indicate that women have significantly higher levels of negative mood than men; whilst older participants were found to report higher levels of positive mood, lower levels of negative mood and more social support. Lower levels of negative mood were associated with more healed ulcers, and higher levels of positive mood were associated with both more healed ulcers and less recurrence. No association was found between negative mood and ulcer recurrence, and neither positive mood, negative mood nor levels of social support were associated with duration of ulcer.

### 3.4.5 Differences by informal care provision

Differences by the provision of informal care were analysed in terms of dichotomous care status (no informal care versus informal care) and care type (emotional only, practical only, both practical and emotional) using an Independent t-test and Mann-Whitney tests.

#### 3.4.5.1 Care status

There was no significant association between whether or not participants received informal care and gender \(\chi^2 (1) = .95, p = .34\). Similarly, no significant differences were found in age between those who receive informal care \((Mdn = 61.00)\) and those who do not receive informal care \((Mdn = 66.00)\), \(U = 2972.00, z = -.31, p = .78, r = -.02\).

Independent t-tests were performed to explore the differences between individuals who do or do not receive informal care on measures of general HRQOL and negative mood. On average, participants receiving informal care reported poorer general HRQOL \((M = 2.86, SE = .12)\) than participants not receiving informal care \((M = 2.47, SE = .10)\). This difference was significant \(t(156) = -2.53, p = .01\) with a small sized effect, \(r = .20\). Participants receiving informal care were also found to report higher levels of negative mood \((M = 26.22, SE = 1.04)\) than participants not receiving
informal care ($M = 22.60$, $SE = 1.18$). This difference was also significant $t(147) = -2.30, p = .03$, with a small sized effect, $r = .19$. However, when disease-specific quality of life was controlled in the relationship between negative mood and care status, no significant partial correlation was found ($r = -.02, p = .83$).

Mann-Whitney tests were used to explore differences between individuals who do or do not receive informal care on measures of disease-specific QOL, ulcer duration, healed status, positive mood, social support and relationship quality. Results of these tests are reported in Table 4.

*Table 4. Differences by care status*

<table>
<thead>
<tr>
<th>Measure</th>
<th>No informal care</th>
<th>Informal care</th>
<th>U</th>
<th>z</th>
<th>p</th>
<th>r</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease-specific quality of life *</td>
<td>$Mdn = 2.62$</td>
<td>$Mdn = 3.48$</td>
<td>$U = 1559.50$</td>
<td>$z = -4.80$, $p &lt; .001$,</td>
<td></td>
<td>$r = -.39$</td>
</tr>
<tr>
<td>(n=154)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ulcer duration</td>
<td>$Mdn = 30.00$</td>
<td>$Mdn = 22.50$</td>
<td>$U = 2259.50$,</td>
<td>$z = -1.44$, $p = .15$,</td>
<td></td>
<td>$r = -.012$</td>
</tr>
<tr>
<td>(n=156)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Healed status *</td>
<td>$Mdn = 1.00$</td>
<td>$Mdn = 1.00$</td>
<td>$U = 2474.00$,</td>
<td>$z = -2.33$, $p = .02$,</td>
<td></td>
<td>$r = -.18$</td>
</tr>
<tr>
<td>(n=159)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive mood</td>
<td>$Mdn = 24.00$</td>
<td>$Mdn = 24.00$</td>
<td>$U = 2611.50$,</td>
<td>$z = -.45$, $p = .65$,</td>
<td></td>
<td>$r = -.04$</td>
</tr>
<tr>
<td>(n=150)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social Support *</td>
<td>$Mdn = 3.18$</td>
<td>$Mdn = 3.64$</td>
<td>$U = 2284.00$,</td>
<td>$z = -2.03$, $p = .04$,</td>
<td></td>
<td>$r = -.16$</td>
</tr>
<tr>
<td>(n=153)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relationship quality</td>
<td>$Mdn = 57.00$</td>
<td>$Mdn = 56.00$</td>
<td>$U = 2180.50$,</td>
<td>$z = -.06$, $p = .96$,</td>
<td></td>
<td>$r = -.005$</td>
</tr>
<tr>
<td>(n=138)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Significant at $p<.05$
3.4.5.2 Care type

For the 90 participants who reported receiving informal care, responses were also coded by type of care: ‘emotional only’, ‘practical only’, or ‘both practical and emotional’. No significant differences in general HRQOL were found between individuals receiving different types of care, $F(2, 87) = 1.68, p = .193$. Similarly, no significant differences were found in disease-specific QOL, dependent upon type of care ($H(2) = 1.33, p = .52$). There was also no significant effect of care type on social support, $F(2, 84) = 1.05, p = .36$, or negative mood, $F(2, 82) = 1.00, p = .37$. Similarly, no significant differences were found in duration of ulcers, healed status, social support, positive mood, relationship quality or perceived caregiving impact. Results of these tests are reported in Table 5.

Table 5. Differences by care type

<table>
<thead>
<tr>
<th>Differences between individuals according to care type</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ulcer duration (n=88)</td>
<td>$H(2) = .211, p = .90$</td>
</tr>
<tr>
<td>Healed status (n=90)</td>
<td>$H(2) = 2.24, p = .33$</td>
</tr>
<tr>
<td>Positive mood (n=84)</td>
<td>$H(2) = 3.65, p = .16$</td>
</tr>
<tr>
<td>Social Support (n=87)</td>
<td>$H(2) = 2.76, p = .25$</td>
</tr>
<tr>
<td>Overall relationship quality (n=86)</td>
<td>$H(2) = 2.49, p = .29$</td>
</tr>
<tr>
<td>Perceived caregiving impact (n=68)</td>
<td>$H(2) = 1.406, p = .50$</td>
</tr>
</tbody>
</table>

*Significant at $p<.05$

3.4.5.3 Summary

As a whole, these results demonstrate that individuals who received informal care reported on average poorer disease specific quality of life, poorer general quality of life and higher levels of negative mood; however, they also reported higher levels of social support and a higher level of healing than individuals not receiving informal care. Care type was not associated with any differences in clinical, demographic or psychosocial variables.

3.4.6 Clinical, demographic, care and psychosocial variables as predictors of quality of life

Hierarchical multiple regression analyses were used to investigate whether clinical, demographic, care and psychosocial variables significantly predicted quality of life in individuals with leg ulcers. A blocked method was used, with clinical and demographic
variables (age, gender, duration of ulcers, and healed status) entered into Block 1. Psychosocial and care-related variables (social support, negative mood, positive mood and care status) were entered into Block 2. Separate analyses were performed with ‘general HRQOL’, ‘disease-specific QOL’ and ‘ulcer-related pain’ as the dependent variables. Data was checked for outliers, collinearity, independent errors, random normally distributed errors, homoscedasticity, linearity and non-zero variances for each analysis; all assumptions were satisfied and no cases were excluded from analysis.

3.4.6.1 Predicting general health-related quality of life

Results from the first hierarchical multiple regression, exploring predictors of ‘general HRQOL’ are shown in Table 6. For block 1, the model was not found to significantly predict general HRQOL ($F (5, 137)= 1.27, p =.234$). For block 2, only positive mood ($t (134) = -4.36, p <.001$) and care status ($t (134) = 2.11, p =.04$) were significantly predictive of general HRQOL. Social support ($t (134) = -0.03, p =.98$) and negative mood ($t (134) = 0.49, p =.63$) were not predictive. This model accounted for 16% of the variance ($F (9, 133) = 4.01, p <.001$).

Table 6. Hierarchical multiple regression for 'general health related quality of life'

<table>
<thead>
<tr>
<th>Block 1</th>
<th>B</th>
<th>SE B</th>
<th>β</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant</td>
<td>2.88</td>
<td>0.41</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>0.14</td>
<td>0.16</td>
<td>.07</td>
<td>.39</td>
</tr>
<tr>
<td>Age</td>
<td>-0.001</td>
<td>0.01</td>
<td>-.02</td>
<td>.80</td>
</tr>
<tr>
<td>Duration</td>
<td>0.00</td>
<td>0.001</td>
<td>-.02</td>
<td>.85</td>
</tr>
<tr>
<td>Healing status</td>
<td>-0.18</td>
<td>0.09</td>
<td>-.18</td>
<td>.04*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Block 2</th>
<th>B</th>
<th>SE B</th>
<th>β</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Constant</td>
<td>2.60</td>
<td>0.69</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>0.19</td>
<td>0.15</td>
<td>.10</td>
<td>.20</td>
</tr>
<tr>
<td>Age</td>
<td>0.002</td>
<td>0.01</td>
<td>.04</td>
<td>.68</td>
</tr>
<tr>
<td>Duration</td>
<td>0.00</td>
<td>0.001</td>
<td>.05</td>
<td>.57</td>
</tr>
<tr>
<td>Healing status</td>
<td>0.03</td>
<td>0.09</td>
<td>.03</td>
<td>.77</td>
</tr>
<tr>
<td>Social support</td>
<td>-0.002</td>
<td>0.07</td>
<td>-.002</td>
<td>.98</td>
</tr>
<tr>
<td>Positive mood</td>
<td>-0.04</td>
<td>0.01</td>
<td>-.42</td>
<td>&lt;.001**</td>
</tr>
<tr>
<td>Negative mood</td>
<td>0.01</td>
<td>0.01</td>
<td>.05</td>
<td>.63</td>
</tr>
</tbody>
</table>
This indicates that individuals who report poorer general health-related quality of life are more likely to have an informal carer and to report lower levels of positive mood. General health-related quality of life was not significantly predicted by clinical and demographic variables.

### 3.4.6.2 Predicting disease-specific quality of life

Results from the second hierarchical multiple regression, exploring predictors of ‘disease-specific QOL’ are shown in Table 7. For block 1, healed status ($t(136) = -0.44, p < .001$) was significantly predictive, whilst age ($t(136) = -0.15, p = .05$), gender ($t(136) = -1.13, p = .26$) and duration ($t(136) = 1.57, p = .12$) were not predictive; this accounted for 25.1% of the variance ($F(5, 135) = 10.39, p < .001$). For block 2, healed status remained significantly predictive ($t(132) = -3.55, p = .001$), whilst duration ($t(132) = 1.99, p = .049$), social support ($t(132) = -2.03, p = .045$), negative mood ($t(132) = 4.79, p < .001$), and care status ($t(132) = -4.09, p < .001$) were also found to be significantly predictive of disease-specific QOL. Positive mood was not found to be significantly predictive ($t(138) = -0.82, p = .41$). This model accounted for 48.1% of variance ($F(9, 131) = 18.07, p < .001$).
### Table 7. Hierarchical multiple regression for ‘disease-specific quality of life’

<table>
<thead>
<tr>
<th></th>
<th>B</th>
<th>SE B</th>
<th>β</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Block 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constant</td>
<td>4.49</td>
<td>0.34</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>-0.15</td>
<td>0.14</td>
<td>-.08</td>
<td>.26</td>
</tr>
<tr>
<td>Age</td>
<td>-0.01</td>
<td>0.01</td>
<td>-0.15</td>
<td>.05</td>
</tr>
<tr>
<td>Duration</td>
<td>0.001</td>
<td>0.001</td>
<td>-0.12</td>
<td>.12</td>
</tr>
<tr>
<td>Healing status</td>
<td>-0.42</td>
<td>0.07</td>
<td>-.44</td>
<td>&lt;.001**</td>
</tr>
<tr>
<td><strong>Block 2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Constant</td>
<td>2.28</td>
<td>0.52</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>-0.05</td>
<td>0.11</td>
<td>-0.03</td>
<td>.64</td>
</tr>
<tr>
<td>Age</td>
<td>0.001</td>
<td>0.004</td>
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<td>Duration</td>
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<td>0.000</td>
<td>0.12</td>
<td>.049*</td>
</tr>
<tr>
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<td>0.07</td>
<td>-0.25</td>
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</tr>
<tr>
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<td>0.06</td>
<td>-0.14</td>
<td>.045*</td>
</tr>
<tr>
<td>Positive mood</td>
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<td>0.01</td>
<td>-0.06</td>
<td>.41</td>
</tr>
<tr>
<td>Negative mood</td>
<td>0.04</td>
<td>0.01</td>
<td>0.39</td>
<td>&lt;.001**</td>
</tr>
<tr>
<td>Care status</td>
<td>0.49</td>
<td>0.12</td>
<td>0.27</td>
<td>&lt;.001**</td>
</tr>
</tbody>
</table>

*Note: Adjusted $R^2 = .25$ for Block 1 (p<.001), Adjusted $R^2 = .48$ for Block 2 (p<.001).*

*p < .05  **p<.001

This indicates that individuals who report poorer disease-related quality of life are more likely to have higher levels of negative mood and lower levels of social support. These individuals are also more likely to have an unhealed ulcer, to have had their leg ulcer for a longer duration and to have identified an informal carer.

#### 3.4.6.3 Predicting ulcer-related pain

Results from the third hierarchical multiple regression, exploring predictors of ‘ulcer-related pain’ are shown in Table 8. For block 1, healed status ($t(133) = -6.31$, $p < .001$) was significantly predictive, whilst age ($t(133) = -0.41$, $p = .68$), gender ($t(133) = 0.78$, $p = .44$) and duration ($t(133) = 1.39$, $p = .17$) were not predictive. The model accounted for 24.4% of the variance ($F (4, 133) = 12.05$, $p < .001$). For block 2, healed status remained significantly predictive ($t(129) = -5.19$, $p < .001$), whilst negative mood ($t(129) = 2.96$, $p = .004$), and care status ($t(129) = 2.55$, $p = .01$) were also found to be
significantly predictive of ulcer-related pain. This model was able to account for 34% of variance ($F(8, 129) = 9.83, p < .001$). Social support ($t(129) = -1.61, p = .11$) and positive mood ($t(129) = -0.63, p = .53$) were not found to be significantly predictive.

**Table 8. Multiple regression to explore predictors of ulcer-related pain**

<table>
<thead>
<tr>
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<th>B</th>
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<th>β</th>
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<tr>
<td>Constant</td>
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<td></td>
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<tr>
<td>Gender</td>
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<tr>
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<td>.69</td>
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<td>-.50</td>
<td>&lt;.001**</td>
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<tr>
<td><strong>Block 2</strong></td>
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<tr>
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<td></td>
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<tr>
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<tr>
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<td>0.01</td>
<td>.07</td>
<td>.36</td>
</tr>
<tr>
<td>Duration</td>
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<td>0.001</td>
<td>.10</td>
<td>.19</td>
</tr>
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<td>-.42</td>
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</tr>
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<td>Positive mood</td>
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<td>0.01</td>
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<tr>
<td>Negative mood</td>
<td>0.03</td>
<td>0.01</td>
<td>.27</td>
<td>.004**</td>
</tr>
<tr>
<td>Care status</td>
<td>0.45</td>
<td>0.18</td>
<td>.19</td>
<td>.01**</td>
</tr>
</tbody>
</table>

*Note: Adjusted $R^2 = .24$ for Block 1 (p<.001), Adjusted $R^2 = .34$ for Block 2 (p<.001).*

This indicates that individuals with higher levels of ulcer related pain are likely to report higher levels of negative mood. Individuals with higher levels of ulcer-related pain were also more likely to receive informal care and to have unhealed ulcers.

**3.4.6.4 Summary**

In summary, multiple regression analyses were used to investigate clinical, demographic, psychosocial, and care variables as predictors of general, disease-specific and pain-specific HRQOL. The results of these analyses suggest that poorer general quality of life is significantly predicted by lower levels of positive mood and identification of an ‘informal carer’. In contrast, disease-related quality of life is
significantly predicted by higher levels of negative mood, lower levels of social support, lower levels of ulcer healing and identification of an ‘informal carer’. Ulcer-related pain is significantly predicted by higher levels of negative mood, lower levels of ulcer healing and identification of an ‘informal carer’.

3.4.7 Relationship quality as a mediator in the relationship between Social support and Quality of Life

Mediation analyses were performed to investigate whether the quality of the relationship between caregiver and care-recipient mediated the relationship between social support and quality of life. This analysis was performed in SPSS using the PROCESS command (Hayes, 2013). As recommended by Field (2013), BCa bootstrapped confidence intervals based on 1000 samples were used for indirect effects.

*Note: A higher score on the General HRQOL measure indicates worse QOL.

3.4.7.1 General health-related quality of life (HRQOL)

There was no significant direct effect of social support on general HRQOL in this analysis; however, there was a significant indirect effect of social support on general HRQOL, through relationship-quality, $b = -.19$, BCa CI [-.35, -.03], $p = .008$, and a medium sized effect was found, $k^2 = .16$, BCa CI [.03, .27]. The model suggests an indirect effect of social support on general quality of life, through the quality of the caregiver-receiver relationship (see Figure 3). This indicates that as social support increases relationship quality improves, and this in turn leads to improvements in general HRQOL.

![Diagram](Figure 3)

**Figure 3. Model of Social support as a predictor of General HRQOL, mediated by Relationship quality**
3.4.7.2 **Disease-specific quality of life**

In contrast to the findings above, a direct effect was found between social support and disease-specific quality of life ($b = -.22, p = .03$), but there was found to be no significant indirect effect of social support on disease-specific QOL through relationship-quality, $b = -.05$, BCa CI [-.20, .11], $p = .48$. (See Figure 4. Model of Social support as a predictor of Disease-specific QOL, mediated by Relationship quality).

These findings suggest that social support has a direct effect on disease specific quality of life.

**Figure 4. Model of Social support as a predictor of Disease-specific QOL, mediated by Relationship quality**

3.4.7.3 **Summary**

Social support was found to have a significant indirect effect on general HRQOL through relationship-quality; thus, improvements in social support are associated with an increase in relationship quality, and a subsequent increase in general HRQOL. No significant mediation effect was found when investigating the same variables with relation to disease-specific quality of life, although social support was found to be significantly associated with disease-specific QOL via direct effects.

3.4.8 **Psychosocial variables as mediators in the relationship between Clinical severity and Quality of Life**

Clinical severity was found in earlier analyses to significantly predict disease-specific QOL, in particular healed status (see section 3.4.3.1). Mediation analyses were performed to further investigate whether psychosocial variables mediated this relationship between healed status and disease-specific quality of life. This analysis was
performed in SPSS using the PROCESS command (Hayes, 2013). As recommended by Field (2013), BCa bootstrapped confidence intervals based on 1000 samples were used for indirect effects.

The results showed an indirect effect of healing status on disease-specific QOL, through negative mood, $b = -0.18$, Ca CI $[-0.29, -0.09]$, $p < .001$ (see Figure 5). This indicates a negative relationship between healing status and disease-specific QOL (ie. individuals with ulcers that are more healed experience better disease-specific QOL), mediated by negative mood. It appears that negative mood decreases as healed status improves, and disease-specific QOL worsens as negative mood increases. No significant mediation effects were found for positive mood ($p = .98$) or social support ($p = .48$).

![Diagram](image)

**Figure 5. Model of healed status as a predictor of disease-specific QOL, mediated by psychosocial variables**

### 3.4.8.1 Summary

Mediation analyses suggest that there is an indirect effect of healed status on disease-specific QOL, through negative mood. This indicates that the relationship between clinical severity (healed status) and disease-specific QOL may be explained by higher levels of negative mood.
3.5 Discussion

This study aimed to draw upon models and principles of health psychology theory in order to explore predictors of health related quality of life in individuals with leg ulcers and the mediating role of psychosocial variables. Demographic, clinical, psychosocial and care variables were examined in relation to pain-related, general and disease-specific quality of life. The main findings of this study reinforce the role of clinical and demographic factors in patient quality of life and highlight the importance of psychosocial factors in adaptation to leg ulceration. Relationship quality was found to mediate the relationship between social support and disease-related quality of life, and a mediating role was also found for negative mood in the relationship between clinical severity and disease-related quality of life. These results will be discussed in more detail below, with regards to existing research and psychological theory.

Differences in QOL were found between men and women, with women in the present study found to report significantly worse disease-related quality of life than men. It is suggested that this difference reflects wider QOL differences found amongst those with cancer (Hagedoorn, Buunk, Kuijer, Wobbes, & Sanderman, 2000), heart failure (Riedinger et al., 2001) and across the elderly population more generally (Orfila et al., 2006a). In these studies, women have consistently been found to report worse health-related quality of life than men, with various schools of thought suggesting the phenomena could be due to differences in socialisation and illness perceptions between the two genders. Orfila et al. (2006) explored these differences and specifically whether they were a product of reporting patterns or observable differences in health status amongst older women. Their findings suggest there are in fact observable differences in health status between men and women, with older women demonstrating more functional limitations and a higher prevalence of chronic conditions than male participants. The results from the current study further support these gender differences in HRQOL, suggesting that women with leg ulcers experience a more profound impact on their quality of life than men. The differences identified in this study, however, could also relate to the particular limitations that leg ulcers place on daily life. The measure used to quantify disease-related QOL features questions regarding impact on activities of daily life, including domestic and social activities, and it is possible that the women included in this sample were more likely to take part in these activities prior to ulceration.
The findings of this study also indicate that those individuals with an unhealed leg ulcer reported poorer disease-related quality of life than those whose ulcer is healing or healed. These findings support the existing literature (Hareendran et al., 2005; Kahn et al., 2004), and find this to be the case regardless of the perceived likelihood of recurrence. Whilst it was predicted that those with currently unhealed ulcers would report worse disease-related QOL, expectations of recurrence were also expected to be associated with worse disease-related QOL due to previously reported levels of hyper-vigilance accompanying such expectations (Chase et al., 1997). It is unclear whether the lack of effect found in this study was due to a genuine lack of difference, or whether the measure used was not sufficiently sensitive or suited to detecting this change. Similarly no significant differences in levels of positive or negative mood were found between those whose ulcer was ‘healed and expect to return’ or ‘healed and don’t expect to return’, further supporting the lack of observed differences between the two groups.

With regards to care, although no differences were found between participants receiving different types of care, patients receiving informal care were found to report: worse general HRQOL, worse disease-specific QOL, more unhealed ulcers, and higher levels of social support. Whilst it is not possible to determine causation in this relationship, it is suggested that individuals who report worse general and disease-specific QOL may be more likely to require informal care due to functional limitations. A similar explanation may be suggested regarding the relationship between receiving care and having more unhealed ulcers. The relationships between informal care and higher levels of social support, however, are less clear. Whilst it is possible that those receiving informal care feel more social support from those around them due to this provision, it may also be that those who received more social support prior to leg ulceration were more likely to be offered support when they became unwell. Equally the observed results could be a product of identification, with those who report higher levels of social support or lower levels of negative mood also more likely to consider someone around them to be an informal carer. Unfortunately it is not possible to determine from the current data which of these explanations is more likely, nor whether those individuals who identify lower levels of social support are more likely to receive higher levels of more formal support from local healthcare provision or private companies.
Previous research has highlighted the importance of relationship quality in the adaptation of caregivers (Hui et al., 2011; Quinn et al., 2009; Spruytte et al., 2002), and whilst the causation behind some of the above findings is ambiguous, this study does enable us to explore relationship-quality as a potential mediator between social support and quality of life. Although no effect was found with regards to disease-specific quality of life, relationship-quality was found to significantly mediate the relationship between general HRQOL and social support. These findings suggest that an improvement in general HRQOL as levels of social support increased may be partially explained by relationship-quality. These findings reflect previous research that has identified relationship-quality as an influential factor in adaptation to caregiving, and may extend these conclusions to suggest relationship-quality is also an important factor in patient adaptation to illness. The presence of this effect in general QOL but not disease-specific HRQOL may relate to the nature of the social support provided, as those who report higher levels of social support may also experience more comorbidity, and thus this relationship may be more pertinent to HRQOL in general than leg ulceration specifically. This has important implications for psychological interventions and the attention paid to the relationship-quality in informal caregiving, the clinical implications of which are discussed below (see section 3.5.2).

Investigating further the predictors of quality of life, multiple regression analyses suggest that poorer general quality of life is significantly predicted by identification of an ‘informal carer’ and lower levels of positive mood. Poorer disease-related quality of life is also significantly predicted by identification of an ‘informal carer’, as well as higher levels of negative mood, lower levels of social support, and lower levels of ulcer healing; whilst higher levels of ulcer-related pain are, once again, significantly predicted by identification of an ‘informal carer’, as well as higher levels of negative mood, and lower levels of ulcer healing. In contrast to the existing literature, age was not found to be predictive of general, disease-specific or pain-specific QOL (Hareendran et al., 2005; Hopman et al., 2014), but taken as a whole these results indicate that poorer QOL is predicted by identification of an informal carer, lower mood and currently unhealed ulcers. These findings support existing literature suggesting there is a positive relationship between clinical severity and QOL (Hareendran et al., 2005), as well as research suggesting this is specifically the case for disease-specific QOL (Kahn et al., 2004). As above, these findings could be explained...
via the functional limitations that often accompany worsened clinical severity, and this impact is more sensitively measured in the disease-specific QOL questionnaire. Ulcer duration was not, however, found to predict QOL in the same manner, perhaps suggesting that healed status is a more impactful element of clinical severity for patients than ulcer duration.

Regression analyses in the current study enable some interesting observations with regards to mood. It was found that general HRQOL is associated with lower positive mood but not higher negative mood, whilst the opposite pattern is found in disease-specific QOL. It could be argued that this indicates distinct underlying processes, with poorer general HRQOL causing a suppression of positive affect and poorer disease-specific QOL particularly aggravating negative affect. Both these findings, and the differential effect of clinical severity on general and disease-specific QOL, require further investigation to explore the processes underlying these results, but they appear to suggest differences between the factors that influence general and disease-specific QOL. This reinforces the importance of collecting data on multiple QOL constructs (Howard & Davies, 2001), as well as utilising psychological theory and models to carefully consider what other data may be required to explore these patterns in more detail.

Using Lazarus and Folkman’s (1984) stress-coping model as a framework, mediation analyses were used to investigate the role of psychosocial variables as mediators between clinical ulcer severity and quality of life. This analysis suggests the relationship between clinical severity (healed status) and disease-specific QOL may be partially explained by negative mood; while positive mood and social support were not found to be mediators. These results indicate that the extent to which an individual is able to adapt to leg ulceration is influenced by psychosocial factors, specifically negative mood. Whilst this relationship was predicted, it was also expected that social support and positive mood would be identified as mediating factors in this relationship. Considering these results with relation to other findings in this study, it is suggested that positive mood and social support have been found to relate more to general QOL than disease-specific QOL in the experiences of individuals with leg ulcers. As noted above, this could be due to the suppressive effect that poor general HRQOL appears to have on positive affect, whilst disease-specific QOL appears to play an aggravating role in negative affect. In terms of social support, it is suggested that reported levels of social
support are not solely related to leg ulceration, and those with a poorer general QOL may also experience more comorbidity. Overall, this finding demonstrates the applicability of the stress-coping model to the experiences of individuals living with chronic leg ulceration, suggesting that psychosocial factors may indeed mediate the relationship between the condition and adaptation. Although the present study found only negative mood to play a role in this process, this provides a basis for future research to extend the model and investigate a wider framework of illness beliefs, demographic and clinical factors, psychosocial factors, and coping. As discussed below (see section 3.5), this study was limited by the number of psychosocial variables investigated; however, these findings demonstrate the potential utility of such a model and reinforce the importance of using psychological theory to inform research in this area.

3.5.1 Strengths and limitations
The primary limitation of this study is its reliance on correlational analyses, allowing no causal inferences to be made from findings; however, the results presented do allow for investigation of a previously unexplored subject and development of hypotheses for future research. This study included a limited number of psychosocial variables due to practical constraints experienced during data collection. It is believed that inclusion of additional psychosocial constructs (such as coping, self-esteem and anxiety) would have been beneficial, allowing for further investigation and exploration of psychological theory; however, the inclusion of these measures was believed to introduce an unacceptable level of participant fatigue to the study and significant participant drop-out. For this reason, the number of psychosocial variables included in the study was restricted.

Although also available by post, the majority of participants responded to the questionnaires online and this may have led to a younger sample than is typical of this population. It is often suggested that volunteer samples are influenced by the characteristics of those participants more likely to take part, and this may have been the case in the present study. A more motivated volunteer sample in this population could be said to experience a worse quality of life or clinically worse leg ulceration, and thus are motivated to seek out information related to their condition on the internet; subsequently finding and completing this questionnaire study. Whilst this could be seen as a limitation of the study, it could also be argued that this allows investigation of
those who are most affected by leg ulceration and may also most benefit from the clinical implications of results.

3.5.2 Clinical implications

Psychological interventions may focus on the social support and relationship quality of those individuals who are receiving informal care. The findings of this study suggest that a good relationship with an informal carer may mediate the relationship between social support and general quality of life, and thus support for carers and facilitation of good relationships between caregivers and care-receivers may have benefits for both individuals. The mediating role of negative mood in the relationship between clinical severity and disease-specific quality of life could also be targeted through psychological interventions; as interventions addressing psychosocial factors (such as counselling, talking therapies or cognitive behavioural therapy) may have an important impact on how an individual is able to adapt to their condition.

3.5.3 Future recommendations

Whilst this study has provided a preliminary investigation into the role of psychosocial variables in leg ulcer patients’ quality of life, there is scope for a considerable amount of future work in this area. These findings support the utility of the stress-coping model in the study of chronic leg ulceration, as well as chronic illness more widely. Psychosocial factors are suggested to mediate the relationship between clinical factors and adaptation; however, the results are not able to provide a definitive conclusion regarding the causality of events. Further research is required in order to establish the directionality and causal links between the investigated factors, as well as further exploring the role of coping and coping styles in chronic leg ulceration.

Future research could extend the approach used in this study to investigate the role of more psychosocial variables in the relationship between clinical and demographic variables and patient quality of life. As discussed above, existing literature suggests that concepts such as coping, self-esteem and anxiety may also play an important role in process of adaptation to chronic illness, and future research should include a wider range of psychosocial variables to fully test these hypotheses. In order to further explore the utility of the stress-coping model in leg ulceration, future research could also include a measure of patient beliefs surrounding their condition, such as the
Illness Perceptions Questionnaire (Moss-Morris et al., 2002; Weinman, Petrie, Moss-Morris, & Horne, 1996) and explore a more complete model of coping and appraisal.

Although ‘healing status’ was believed to act as an effective measure of clinical severity in this study, future research could also consider the use of the CEAP classification system, as a widely recognised and objective measure of severity (Eklof et al., 2004; Kahn et al., 2004; Porter & Moneta, 1995). This would, however, require studies to be run in cooperation with a specialist vascular service in order to provide the appropriate expertise, thereby threatening the representativeness of the sample in terms of the wider leg ulcer population and their varied treatment pathways. It is recommended that future studies use both a general and disease-specific quality of life measure, as suggested in previous research (Howard & Davies, 2001; Smith et al., 2000), as results were found to differ between these two dimensions. One possible explanation for these differences is the influence of comorbidities, and it is recommended this is also captured and explored in future research. The findings from this study demonstrate the potential for the stress-coping model to be a valuable framework for understanding adaptation to chronic leg ulceration, and future research utilising the model could greatly extend this understanding.

3.5.4 Conclusions
The aim of this study was to draw upon psychological theory to investigate the predictors of quality of life in individuals with chronic leg ulceration and the mediating role of psychosocial factors. Whilst previous research had explored the influence of clinical and demographic factors on patient quality of life in chronic leg ulceration, no previous research had utilised psychological theory to explore this area. The findings of this study reinforce the role of clinical and demographic factors in patient quality of life, supporting the importance of clinical severity for general, disease-specific and pain-specific elements of patient quality of life. This study also identified mood, social support and informal care as important psychosocial predictors of patient quality of life, whilst negative mood was found to mediate the relationship between clinical severity and disease-specific quality of life. These findings support the inclusion of psychosocial variables in future investigation of predictors of quality of life, and support the utility of the stress-coping model in the study of chronic leg ulceration (Lazarus & Folkman, 1984). In addition, social support was found to have an indirect effect on general quality of life through relationship quality, supporting previous findings in caregivers and
suggesting important implications for possible intervention. Overall, the results of this study stress the importance of psychosocial factors in adaptation to chronic leg ulcers, highlight the importance of relationship quality in caregiver-recipient relationships and outline areas for future research to further test the utility of the stress-coping model and psychosocial variables in this condition.
Chapter Four

Study 2: An investigation into the impact of minimally-invasive venous surgery on patient quality of life: a quantitative longitudinal study

4.1 Overview
Chapter Three (Study 1) presented an investigation into the impact of chronic leg ulceration on patient quality of life, and highlighted the importance of psychosocial factors, such as mood and social support, in the experience of those with leg ulcers. This study was, however, a cross-sectional investigation of patient experience and thus did not investigate the impact of treatment on these outcomes. The importance of the treatment process to patient quality of life was discussed in Chapter One, and explored further through the systematic review detailed in Chapter Two. Whilst existing literature into chronic illnesses suggests treatment experiences are an important factor in adaptation to illness and psychosocial outcomes, there has been no research exploring these themes with regards to leg ulceration. In addition, the findings of the systematic review highlighted the lack of research regarding the impact of minimally-invasive surgical treatment on patient quality of life. In light of those findings, this study aims to use a longitudinal design explore the impact of minimally-invasive surgical treatment on patient quality of life and psychological wellbeing.

4.2 Introduction
Minimally-invasive venous surgery is an umbrella term for various surgical techniques developed in recent decades to address superficial venous incompetence, providing less invasive alternatives to traditional open venous surgery. These procedures include Endovenous Thermal Ablation (EVTA) and Ultrasound Guided Foam Sclerotherapy (UGFS) and are often performed under local anaesthetic (Kelechi et al., 2015), using heat or chemical solutions to damage the interior surface of the vein and trigger the body’s natural defences to remove it (Wittens et al., 2015). These minimally-invasive procedures are associated with fewer complications than classical techniques, and their less invasive nature makes them particularly suitable for more elderly or frail patients (Kelechi et al., 2015). When compared to compression therapy alone, minimally-invasive surgery is thought to result in similar healing rates (Howard et al., 2008), but
significantly lower ulcer recurrence rates at 1, 2, 3 and 4 years (Barwell et al., 2000; Barwell et al., 2004; Gohel et al., 2007). One of the largest randomised controlled trials comparing the two treatment modalities estimated that four-year recurrence rates in compression therapy alone are approximately 56%, whilst in patients receiving both minimally-invasive surgery and compression therapy these rates were found to be 31% (Gohel et al., 2007). Although there is ongoing debate in the literature as to the efficacy of various treatment modalities, evidence such as this appears to highlight the longer-term benefits of surgical treatment in terms of physical outcomes.

Previous research has predominantly investigated outcomes of treatment in terms of healing rates and ulcer recurrence, with some exploration of quality of life outcomes (Howard & Davies, 2001; Tollow et al., 2016). Typically studies include a 3-6 month follow-up period and compare various types of compression or bandaging therapy, surgical management, or surgical management versus compression therapy. Studies in this area provide valuable information regarding the efficacy of various treatment techniques and allow the development of best practice, however, some authors have also highlighted the potential lack of ecological validity in these studies; suggesting that the standard of treatment delivered in clinical trials may not be representative of what is available in the community (Guest et al., 2015). This could be said to reflect a disjoint between discussions of treatment in the literature and the reality of patient’s treatment experiences. Whilst many studies include clinical measures of ulcer severity, no research appears to have included a patient perspective on physical outcomes, nor does there appear to have been any investigation of the relationship between physical outcomes and psychosocial or quality of life outcomes. Health psychology theory would suggest this is a fundamental element of research, due to the role of illness representations in coping, adaptation and behaviour (Leventhal et al., 1980; Moss-Morris et al., 2002). In contrast to traditional biomedical models, sense-making models of chronic illness, such as the Common Sense Model of Illness Representations (Leventhal et al., 1980), put emphasis on the role of psychosocial elements such as patient perceptions in physical health; therefore, it is important that treatment outcomes not only include measures of quality of life, but also a focus on the patient’s perspective of their treatment.
As discussed in Chapters One and Two, whilst the psychological impact of leg ulcers is often studied, psychological outcomes from leg ulcer treatment are scarcely measured and difficult to compare across studies. Systematic reviews and meta-analyses frequently compare healing rates and other medical outcomes of various treatment modalities, but studies including quality of life outcomes have often been excluded from analyses or deemed not sufficient in quantity for conclusions to be drawn. As a result of this gap in the literature, Chapter Two of this thesis completed a systematic review comparing quality of life outcomes in conservative treatment modalities versus minimally-invasive venous surgery (Tollow et al., 2016). This review drew upon sixteen studies, comparing quality of life outcomes as a result of treatment, and concluded that surgical treatment methods may lead to greater improvements in patient quality of life when compared to compression bandaging alone. This review also highlights, however, the paucity of research available regarding patient quality of life outcomes, the poor quality reporting of many studies and the enduring focus of this research area on physical outcomes. Research exploring the psychosocial impact of treatment in this area is scarce, with quality of life outcomes often ignored or poorly reported. The review stressed the importance of future research in investigating the psychosocial outcomes of such treatment and the underlying processes driving these outcomes.

Drawing together this body of research, it appears that whilst medical outcomes from minimally-invasive surgical treatment continue to be extensively explored, psychosocial and quality of life outcomes from treatment are less clear. A systematic review of the literature suggests minimally-invasive surgical treatments may have a positive impact on quality of life beyond that of compression therapy alone; however, further research is required to investigate the impact of treatment on psychosocial and quality of life outcomes, as well as how this may be related to patients’ perceptions of physical outcomes.

4.1.1 Aims

In light of this existing literature, the current study aimed to explore the impact of minimally-invasive surgical treatment for chronic leg ulcers on clinical, psychosocial and quality of life outcomes. It investigated the experience of patients from the point of surgical assessment to six months post-surgery, and explored whether any changes in psychosocial and quality of life outcomes were also associated with patients’ beliefs.
regarding clinical outcomes. In particular the study focused on clinical outcomes (i.e. patients’ perceived healing status of their ulcer), psychosocial outcomes (i.e. mood and social support) and quality of life (i.e. general health-related quality of life, disease-specific quality of life and pain). Please note that the study originally aimed to explore the role of carers’ experiences in patient outcomes but due to poor rates of recruitment this aim was removed (see 4.1.2).

4.3 Methods

4.1.2 Design

This was a quantitative longitudinal questionnaire study, seeking to investigate the impact of minimally-invasive venous surgery for leg ulceration on patients and their carers. Data was collected from each participant at five time points over a period of approximately seven months (see Figure 6).

Figure 6. Time point progression throughout the study

4.1.3 Recruitment

Participants were recruited from a private medical clinic in Guildford, due to the limited availability of this treatment on the NHS. Patients were sent recruitment information upon booking an initial Leg Ulcer assessment appointment at the clinic, inviting them to
take part and informing them of what this would involve. The researcher then attended
this initial appointment and introduced the study to potential participants. If participants
were interested in taking part they were asked to read and sign a consent form and
complete the first stage of the questionnaire study. Patients were also asked whether
they received informal care from anyone, and whether the individual providing this care
would also like to take part in the study. In order to take part, potential participants were
required to meet inclusion criteria, including: to be aged over 18, to have given
informed consent, to have a good understanding of written and spoken English, and to
either have a leg ulcer(s), to have previously had a leg ulcer(s), or to care for someone
who either currently has or has previously had a leg ulcer(s). Prior to onset of the study
it was estimated that the clinic treated approximately 30 patients per year who met the
inclusion criteria for this study. In line with this the aim was to recruit 45 patients over
an 18 month period. However, although all patients were approached (n=20), this
turned out to be much lower than anticipated. Of these (n=20), 12 individuals
consented to participate (60%), with 8 corresponding carers agreeing to participate.
Participants were invited to take part in the duration of the study, regardless of whether
they (or the individual they care for) proceeded to receive treatment at the clinic. Five
patients and five carers withdrew from the study through the course of data collection,
due to illness (n=2), death (n=2) or personal circumstances (n=6); resulting in a final
sample of seven patients and three carers.

4.1.4 Measures
Participants were first asked to identify whether they were a patient or a carer, before
being asked to complete a number of questionnaire measures. These measures were
available via online survey or paper questionnaires; however, all participants opted to
take part via paper questionnaire. At each time point participants were sent a
questionnaire pack with a freepost envelope, so that they may return their participation
pack free of charge. Participants were asked to complete a number of questionnaire
measures regarding demographic, clinical, quality of life and psychosocial constructs.
See Table 9 for details of these measures (see Appendix D for more details of these
questionnaire measures and Appendix H for the carer-specific measures).
Table 9. Details of questionnaire measure (all measures were collected at each time point)

<table>
<thead>
<tr>
<th>Construct</th>
<th>Measure</th>
<th>Source</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographic variables</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demographic information</td>
<td>Demographic questionnaire</td>
<td>Author constructed</td>
<td>Demographic questions regarding participants age and gender.</td>
</tr>
<tr>
<td><strong>Clinical variables</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical variables</td>
<td>(Adjunct to demographic questionnaire)</td>
<td>Author constructed</td>
<td>This is an author constructed questionnaire, with questions regarding participant’s current ulcer status and treatment history. This includes: the cause of their leg ulcer, current treatment method, whether the patient has undergone surgery for their ulcer, duration of time with leg ulcer, and number of times the ulcer has recurred. In addition, the participant is asked whether they receive informal care, and what this care involves (eg. practical care, personal care, etc).</td>
</tr>
<tr>
<td><strong>Quality of life variables</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General health-related quality of life.</td>
<td>Single-Item Health-Related Quality of Life</td>
<td>Idler &amp; Kasl (1995)</td>
<td>This is a single-item measure of Health Related Quality of Life, asking participants to rate their current overall health as ‘Very good’, ‘Good’, ‘Okay’, ‘Poor’ or ‘Very Poor’. Measures such as this correlate highly with longer composite measures, and demonstrate good long-term predictive abilities of morbidity and mortality (Idler &amp; Kasl, 1995). On this measure, a larger score indicates worse Quality of Life.</td>
</tr>
<tr>
<td>Disease-specific quality of life.</td>
<td>Charing Cross Venous Ulcer Questionnaire.</td>
<td>Smith et al. (2000) Permission obtained from author.</td>
<td>This is a 20-item questionnaire, designed to capture how patients’ lives are impacted by the presence of a leg ulcer. Responses load onto four health related factors; social interaction (6 items), domestic activities (4 items), cosmesis (5 items), and emotional status (5 items). An additional item measures the amount of pain the participant experiences due to the ulcer (see variable below). This questionnaire has been previously</td>
</tr>
</tbody>
</table>
found to have good internal consistency (Cronbach $\alpha = .93$), test-retest stability ($r = .84$), and sensitivity to change (Smith et al., 2000). Within this sample, an average value was calculated for every participant on each subscale. From these subscales, an average score was calculated for each participant. On this measure, a larger score indicates worse Quality of Life.

<table>
<thead>
<tr>
<th>Ulcer-related pain</th>
<th>Charing Cross Venous Ulcer Questionnaire (Single item)</th>
<th>Smith et al. (2000)</th>
<th>Permission obtained from author.</th>
</tr>
</thead>
</table>

This is a single item from the Charing Cross Venous Ulcer Questionnaire, asking participants to respond to the question “I have pain from my ulcer” on a scale of 1-5 (with 1 representing ‘none of the time’ and 5 representing ‘all of the time’). For the purposes of analysis, this item of the questionnaire was treated as a separate variable. On this measure, a larger score indicates worse Quality of Life.

### Psychosocial variables

<table>
<thead>
<tr>
<th>Mood.</th>
<th>Positive and Negative Affect Scales (PANAS).</th>
<th>Watson et al. (1988).</th>
<th>The PANAS consists of two 10-item mood scales, designed as brief reliable measures of mood. The scale asks participants to rate, on a scale of 1-5, how often they have felt various emotions in the specified time period. The scales are widely used and a recent study suggests that each scale has a Cronbachs $\alpha$ of &gt;.84</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social support.</td>
<td>Medical Outcomes Study Social Support Survey (MOS-SSS) (adapted)</td>
<td>Sherbourne &amp; Stewart (1991).</td>
<td>The MOS Social Support Survey is a 19-item self-administered survey, designed to measure social support in patients with chronic conditions. The measure shows stability over time and reliability, with Cronbachs alpha of &gt;.91 (Sherbourne &amp; Stewart, 1991). As a result of participant feedback, this measure was reduced to contain only the emotional, tangible and positive social interaction subscales; reducing the measure to 11 items for the purposes of this study.</td>
</tr>
</tbody>
</table>
### Care variables

| Carer-Patient relationship Quality | Quality of Carer-Patient relationships Scale | Spruytte, Van Audenhove, & Lammertyn (2000) | This 14-item measure is intended to measure the quality of the relationship between patient and caregiver, with two subscales: ‘Warmth and affection’ and ‘Conflict and criticism’. The value of this instrument lies in its measure of both warmth and critique in a relationship, and its suitability for use in both romantic and non-romantic relationships. It has been found to have sufficient internal consistency (Spruytte et al., 2000). |

| Perceived caregiving impact. | Perceived Caregiving Impact. | Author constructed. | This measure asks participants to report to what extent they believe that caregiving has an impact on their caregiver’s daily life (if applicable). Responses are given on a 7-point Likert scale, from ‘no impact’ to ‘significant impact’. |

### Carer-specific variables

| Objective caregiving information. | Relationship to Patient and Objective Caring Information. | Researcher constructed. | This is a 3-item measure of objective caregiving. Carers were asked to characterise their relationship to the patient (eg. spouse, daughter, son), whether they occupy any other significant roles (eg. Paid work, caring for someone else), and how much time they estimate they spend caring for the patient per week. |

| Subjective caregiving impact. | Caregiving Appraisal Scale (adapted) | Lawton, Klevan, Moss, Rovine, & Glicksman (1989) | This 15-item measure has been adapted from the original Caregiving Appraisal Scale, to ensure relevance and brevity for the intended sample. The ‘burden’ and ‘satisfaction’ subscales of the scale have been retained. |

### 4.1.5 Procedures

The first time-point was completed at a patient’s initial assessment appointment with The Whiteley Clinic. For some participants who wished to complete the questionnaire at home, or if the researcher was unable to attend this appointment, patients were
invited to take part in the study by post. Participants were able to choose whether they wished to take part at subsequent time-points via online survey or postal questionnaire. If participants chose to take part in the study online, then they were emailed with a link to the online survey when they reached the appropriate time-points. This survey was hosted on the University of Surrey website. If participants chose to take part in the study via post, then a postal participation pack and a freepost envelope were sent to each participant when they reached the appropriate time points. Total participation time at each time-point took approximately 30 minutes for each participant.

After completing the questionnaires at the first time point, participants were given a unique participant identifier. This number allowed them to withdraw their data from the study, should they wish to, as well as allowing the researchers to link together responses from each participant over the different time-points. All participants were be reassured that all their data is confidential, and all participants were given debrief information at each time-point, either as part of the online survey or in their postal pack (see Appendix C). This debrief information included details of sources of further support and the contact details of the researchers should they have any further questions or wish to withdraw from the study. Participants were made aware that they could request a further verbal debrief, in which case they may contact the researcher, who would telephone the participant to provide a verbal debrief (in addition to the written process).

4.1.6 Ethical considerations
This study received a favourable ethical opinion from an NHS Research Ethics Committee (see Appendix E), and the University Ethics Committee at the University of Surrey (see Appendix F). Participants were sent an information sheet (see Appendix G) at the time of booking their assessment appointment, allowing them approximately 2-4 weeks to consider participation in the study before attending their appointment. At this appointment, participants were asked to confirm they had read the information sheet or to read it at the appointment, before agreeing to take part in the study and signing a consent form (see Appendix B). These procedures were to ensure informed consent was gained from all participants. At each time point, including this initial appointment, it was stressed to participants that they could withdraw from the study at any point without giving a reason. Participants were reassured that participation was confidential, as well as anything they disclosed in the course of taking part, and that they would not
be identifiable from any material published as a result of this study. All participants were provided with debrief information after completing the questionnaire, at every time point, including information on the purpose of the research, sources of further support and the contact details for the researchers should participants have any further questions or wish to withdraw from the study.

It was agreed that if participants disclosed experience of poor clinical practice, or expressed complaints regarding any of the treatment they received, then the researcher would advise them on their options should they wish to take this complaint further. If this complaint was regarding treatment at the clinic then the researcher would provide further information regarding the clinic complaints procedure. If this complaint was regarding treatment outside of the clinic where the study was based then the researcher would provide further information regarding NHS Patient Advice and Liaison Services (PALS). The availability of such information was also stated on all information sheets, so that participants may also have requested this information at any time without disclosing a specific complaint or event.

4.1.7 Analytic plan
Data was analysed with SPSS for windows, Version 21.0, as follows:

- To describe demographic, clinical, and care-related variables using descriptive statistics;
- To investigate changes in each outcome measure over time (pain, general QOL, disease-specific QOL, positive mood, negative mood, social support and relationship quality), using Freidman’s ANOVA and appropriate post-hoc tests;
- To explore correlations between physical outcomes (healed status and pain) and psychosocial outcomes (general QOL, disease-specific QOL, positive mood, negative mood and emotional/domestic/cosmetic/social subscales of disease-specific QOL), using Kendall’s tau correlations.

4.4 Results

4.1.8 Data screening
As in Chapter 3, missing values were assessed on an individual measure-by-measure basis, with participants excluded for individual questionnaire measures if they had missing responses for >50% of composite items. When a participant had answered more
than 50% of the composite items for that measure, missing items were replaced with the mean value of the answered items for that particular scale and participant. With a final sample of seven patients and three carers, only one patient-carer dyad had not undergone surgical management, and thus was excluded in order to enable analysis of a homogenous sample.

4.1.9 Sample and demographic information
Six patients and two carers completed all five time-points in this study, with all six patients undergoing surgical management for leg ulceration. Participants ranged in age from 51 to 79 years old ($M = 70.5$, $SD = 10.2$). Five of these six individuals were female (83.3%), and all participants had most recently undergone compression therapy in order to treat their leg ulcers. Mean ulcer duration prior to treatment was 82.5 months ($SD = 109.3$, range 2-240) and the mean number of times that ulcers had recurred was two ($SD = 4.5$, range 0-10); however, the majority of participants reported less than three years ulcer duration prior to treatment and the majority reported that this was their first leg ulcer. Details of this demographic information are shown below in Table 10.

Table 10. Participant demographic information

<table>
<thead>
<tr>
<th>Participant</th>
<th>Age (years)</th>
<th>Gender</th>
<th>Ulcer duration prior to treatment (months)</th>
<th>Recurrence</th>
<th>Prior treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>79</td>
<td>Female</td>
<td>2</td>
<td>0</td>
<td>Compression therapy</td>
</tr>
<tr>
<td>2</td>
<td>71</td>
<td>Female</td>
<td>7</td>
<td>0</td>
<td>Compression therapy</td>
</tr>
<tr>
<td>3</td>
<td>51</td>
<td>Female</td>
<td>240</td>
<td>10</td>
<td>Compression therapy</td>
</tr>
<tr>
<td>4</td>
<td>75</td>
<td>Female</td>
<td>6</td>
<td>0</td>
<td>Compression therapy</td>
</tr>
<tr>
<td>5</td>
<td>70</td>
<td>Female</td>
<td>36</td>
<td>0</td>
<td>Compression therapy</td>
</tr>
<tr>
<td>6</td>
<td>77</td>
<td>Male</td>
<td>204</td>
<td>20</td>
<td>Compression therapy</td>
</tr>
</tbody>
</table>

4.1.10 Changes in clinical outcome measures across time
At each of the five time-points participants were asked to report their beliefs regarding the cause of the leg ulcer, as well as their assessment of healing status. Participant’s beliefs regarding the cause of the ulcer at each of the five time points can be seen in Table 11.
Table 11. Participant perception of ulcer cause throughout treatment

<table>
<thead>
<tr>
<th>Participant</th>
<th>Time point 1</th>
<th>Time point 2</th>
<th>Time point 3</th>
<th>Time point 4</th>
<th>Time point 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Don’t know</td>
<td>Venous</td>
<td>Venous</td>
<td>Venous</td>
<td>Venous</td>
</tr>
<tr>
<td>2</td>
<td>Venous</td>
<td>Venous</td>
<td>Venous</td>
<td>Venous</td>
<td>Venous</td>
</tr>
<tr>
<td>3</td>
<td>Venous</td>
<td>Venous</td>
<td>Don’t know</td>
<td>Venous</td>
<td>Venous</td>
</tr>
<tr>
<td>4</td>
<td>Don’t know</td>
<td>Don’t know</td>
<td>Don’t know</td>
<td>Don’t know</td>
<td>Don’t know</td>
</tr>
<tr>
<td>5</td>
<td>Venous</td>
<td>Venous</td>
<td>Venous</td>
<td>Venous</td>
<td>Venous</td>
</tr>
<tr>
<td>6</td>
<td>Don’t know</td>
<td>Don’t know</td>
<td>Don’t know</td>
<td>Poor</td>
<td>Poor</td>
</tr>
</tbody>
</table>

As seen above, three of the six participants suggested that before their initial assessment appointment at the clinic they did not know the cause of the leg ulcer, whilst the other three participants suggested their ulcer had a venous aetiology. Over the course of the study, one participant consistently reported not knowing the cause of their ulcer, another reported this was due to ‘poor circulation’, and the remaining participants all believed their ulcer to be caused by venous disease by the final time point. It is assumed that all participants included in the study had a leg ulcer of venous aetiology in order for them to have undergone minimally-invasive venous surgery as treatment. This suggests, therefore, that although the majority of participants were aware of the underlying cause of their ulcer, some participants remained who were not aware of this underlying cause up to six months after surgical intervention.

When reporting healing status, participants were asked to select one of four options: ‘Unhealed’ (4), ‘Healing’ (3), ‘Healed, but expected to return’ (2) and ‘Healed and don’t expect to return’ (1). Of the six participants, four indicated that they believed their ulcer to be ‘unhealed’ at baseline, and two indicated their ulcer was ‘healing’. At Time point 2 (at the time of surgery), only two participants changed this assessment – moving from ‘unhealed’ to ‘healed but expected to return’, and from ‘unhealed’ to ‘healing’. By Time point 5 (six months post-surgery), four participants believed their ulcer to be ‘Healed and don’t expect to return’, one believed their ulcer was ‘Healed but expected to return’ and one participant believed their ulcer remained as ‘Healing’ (see Figure 7 for a case-by-case analysis).
These results suggest that all participants observed some improvement in the healing status of their ulcer over the measured time period (up to six months post-surgery). This is suggested to represent a significant change over time, $\chi^2(4) = 14.9, p = .01$. Step-down follow-up analysis suggested that healed status at Time points 1, 2 and 3 was significantly worse compared to Time points 4 and 5; however, no significant differences were found between these earlier time points ($p = .22$). This suggests that a significant difference in perceived healing status was observed between individuals prior to and after twelve-weeks post-surgery.

4.1.11 Changes in quality of life, psychosocial and care-related outcome measures across time

Friedman’s ANOVA tests were used to investigate changes in health-related quality of life (general, disease-specific and pain-specific), psychosocial outcome measures (positive mood, negative mood, social support) and care variables (relationship quality) between the five investigated time-points.

4.4.4.1 General health-related quality of life

Participants were asked to report their general health-related quality of life on a five point scale, from ‘Very poor’ (1) to ‘Very good’ (5). All participants reported their health as ‘okay’, ‘good’ or ‘very good’ at Time point 1, and limited changes were seen.
in these scores through the course of treatment (see Figure 8 for a case-by-case analysis).

![Figure 8. General HRQOL across time](image)

This apparent lack of change is reflected in statistical analyses, with no differences found in participants general HRQOL between time points, $\chi^2(4) = 3.30, p = .53$.

### 4.4.4.2 Disease-specific quality of life

Disease-specific quality of life was measured as an overall mean score (1-5, with a higher score indicating a larger impact on QOL), as well as individual subscales: emotional, domestic, social and cosmetic. Whilst many participants did report an overall improvement in their disease-specific quality of life through the course of treatment (see Figure 9 for a case-by-case analysis), participant’s overall disease-specific QOL was not found to significantly change over the five measured time points, $\chi^2(4) = 4.93, p = .32$. 

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When explored in terms of individual subscales, however, results were found to differ. No significant differences were observed across the five time points on the social ($\chi^2(4) = 4.28, p = .39$), domestic ($\chi^2(4) = 2.11, p = .74$) and cosmetic ($\chi^2(4) = 5.21, p = .28$) subscales; however, significant differences were observed in the emotional subscale of the disease-specific QOL measure over the five measured time points, $\chi^2(4) = 11.18, p = .03$ (see Figure 10 for a case-by-case analysis).

![Figure 9. Disease-specific QOL across time](image)

![Figure 10. Disease-specific QOL across time (Emotional subscale)](image)
Step-down follow-up analysis suggested that the ‘emotional’ subscale of participant’s disease-specific quality of life at Time point’s 4 and 5 was significantly better compared to Time points 1, 2 and 3; however, no significant differences were found between these earlier time points \( (p = .23) \). This suggests that a significant difference in emotional disease-specific quality of life was observed between participants prior to and after twelve weeks post-surgery.

4.4.4.3 Pain-specific quality of life

Participant’s ulcer-related pain was investigated using a single-item measure, on a scale of 1-5, with a higher number indicating worse ulcer-related pain. Whilst many participants reported an overall reduction in ulcer-related pain over the course of treatment (see Figure 11 for a case-by-case analysis), no significant differences in pain-specific quality of life were found over the five measured time points, \( \chi^2 (4) = 7.73, p = .09 \).

![Figure 11. Pain-specific quality of life across time](image)

4.4.4.4 Mood and social support

No significant changes were observed in participant’s positive \( (\chi^2 (4) = 2.70, p = .64) \) or negative mood \( (\chi^2 (4) = 4.26, p = .40) \) across the five time points (see Figure 12 and Figure 13). Similarly, no significant changes in participant’s reported social support \( (\chi^2 (4) = 3.05, p = .58) \) or relationship-quality \( (\chi^2 (4) = 1.87, p = .75) \) were observed across the five time points.
The above results indicate no observed changes in General QOL, pain-specific QOL and disease-specific QOL across time. Significant changes were observed on the ‘emotional’ subscale of disease-specific QOL; indicating a significant improvement on this subscale after twelve-weeks post-surgery. No significant changes were observed in positive mood, negative mood, social support or relationship-quality across the five time points.

4.1.12 Relationships between changes in clinical outcomes, and quality of life and psychosocial outcomes

A series of Kendall’s tau correlations were used to investigate relationships between clinical outcomes and changes in quality of life and psychosocial outcomes. For each variable a change value between Time point 1 and Time point 5 was calculated. The results of these correlations can be seen in Table 12.
Table 12. Correlations between clinical outcomes and psychosocial/quality of life outcomes

<table>
<thead>
<tr>
<th></th>
<th>Disease-specific QOL</th>
<th>General QOL</th>
<th>Negative mood</th>
<th>Positive mood</th>
<th>Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healing status</td>
<td>Corr. Coeff. ($r$)</td>
<td>.39</td>
<td>.33</td>
<td>.00</td>
<td>-.24</td>
</tr>
<tr>
<td></td>
<td>Sig. ($p$)</td>
<td>.30</td>
<td>.40</td>
<td>1.00</td>
<td>.66</td>
</tr>
<tr>
<td>Pain</td>
<td>Corr. Coeff. ($r$)</td>
<td>.55</td>
<td>.07</td>
<td>.80</td>
<td>.92</td>
</tr>
<tr>
<td></td>
<td>Sig. ($p$)</td>
<td>.13</td>
<td>.84</td>
<td>.13</td>
<td>.07</td>
</tr>
</tbody>
</table>

Similar analyses were conducted with healing status, pain, and all four subscales of disease-specific QOL (see Table 13).

Table 13. Correlations between clinical outcomes and disease-specific QOL subscales

<table>
<thead>
<tr>
<th></th>
<th>Emotional subscale</th>
<th>Cosmetic subscale</th>
<th>Domestic subscale</th>
<th>Social subscale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healing status</td>
<td>Corr. Coeff. ($r$)</td>
<td>.39</td>
<td>.59</td>
<td>.55</td>
</tr>
<tr>
<td></td>
<td>Sig. ($p$)</td>
<td>.30</td>
<td>.18</td>
<td>.15</td>
</tr>
<tr>
<td>Pain</td>
<td>Corr. Coeff. ($r$)</td>
<td>.55</td>
<td>.32</td>
<td>.69</td>
</tr>
<tr>
<td></td>
<td>Sig. ($p$)</td>
<td>.13</td>
<td>.45</td>
<td>.06</td>
</tr>
</tbody>
</table>

These findings demonstrate no statistically significant correlations between change in healing status and change in disease-specific QOL (plus subscales), general QOL, pain, negative mood or positive mood. Similarly, no statistically significant correlations were found between changes in pain and changes in disease-specific QOL (plus subscales), general QOL, negative mood or positive mood. A marginally significant positive correlation was observed between pain and positive mood, as well as pain and domestic quality of life. This suggests that those who reported a larger reduction in pain levels may also report a larger increase in positive mood and improvement in domestic aspects of quality of life. All the above results, however, must be treated with caution due to the small sample sizes involved.

Some would argue that in a sample of six participants the use of Null Hypothesis Testing and $p$-values is not appropriate, and instead the focus should be on the effect sizes ($r$) observed (Field, 2013). In this case, large effects were observed between many of the physical and psychosocial variables. In particular improvements in disease-specific QOL, general QOL and pain were associated with improved healing status, and improvements in disease-specific QOL, negative mood and positive mood.
were associated with improvements in pain. Similarly large effects were observed between changes in all subscales of disease-specific QOL and clinical outcomes, suggesting that reports on all subscales of disease-specific QOL were found to improve as healing status and pain improved between Time points 5 and 1.

4.4.5.1 Summary
To summarise, whilst correlations between clinical outcome measures and psychosocial outcome measures suggest no significant relationships were observed between the two, large effect sizes were observed between many of these measures. These results suggest that as leg ulcer’s heal and pain levels reduce, psychosocial variables such as mood and disease-specific QOL may improve. These results must, however, be treated with caution as the small sample sizes involved in these calculations mean that the statistical tests employed are substantially underpowered and thus only tentative conclusions can be drawn.

4.5 Discussion
This study aimed to explore the impact of minimally-invasive surgical treatment for chronic leg ulcers on clinical, psychosocial and quality of life outcomes, and to explore whether any changes in psychosocial and quality of life outcomes were also associated with patients’ beliefs regarding clinical outcomes. The results of this study suggest that all participants observed some improvement in perceived clinical outcomes, with significant changes in ulcer healing reported between twelve and eighteen weeks post-surgery. This demonstrates a positive change in terms of participant’s own perception of their ulcer, and supports previous findings regarding the efficacy of surgical management (Gohel et al., 2007). Whilst previous studies have relied on objective measures alone, this finding demonstrates that patients also perceive a positive change in the clinical status of their ulcer as a result of surgical management.

All participants received surgical treatment aiming to address underlying venous disease, however, only four out of six participants identified the cause of their ulcer as ‘venous disease’ at six months post-surgery. This echoes the findings of Van Hecke et al. (2013), who suggest that many individuals are not aware of the underlying cause of their ulcer or attribute this instead to events which lead to the initial wound. From a psychological perspective this could be said to have important implications for illness representations, as Leventhal’s Common Sense Model (Leventhal et al., 1980)
describes perceived cause of illness as an important contributor to patients’ illness representations. An individual’s perception of their leg ulcer aetiology may in turn influence their health related behaviours, such as when they seek help or who they seek help from. It may also influence their perceptions of treatment, particularly their expectations of the time taken to treat and the expected outcome of treatment. For these reasons, it could be argued that a medically correct perception of the ulcer’s cause is an important element of high-quality treatment and something that should be considered in the treatment pathway of all patients.

Although positive improvements were observed in the individual scores of many participants’ outcome measures, statistically significant changes across the five time points were observed only in the emotional element of disease-specific quality of life. No significant changes were observed in general quality of life, pain-specific quality of life and overall disease-specific quality of life. Similarly, no significant changes were observed in positive mood, negative mood, social support or relationship-quality across the five time points. A significant change was observed in the emotional-subscale of disease-specific QOL and, in line with perception of healing, this change was thought to be located between twelve and eighteen weeks post-surgery. These findings suggest that treatment may have had a positive impact on disease-specific quality of life, as the emotional subscale of this measure includes items such as: ‘I spend a lot of time thinking about my ulcer’, ‘My ulcer has put a strain on my personal relationships’ and ‘I feel depressed because of my leg ulcer’. This subscale could therefore be considered to encompass elements such as ulcer-related anxiety and depression, which were found to improve over the five investigated time points. This improvements cannot, however, be conclusively attributed to surgical management, and it is possible that the process of treatment itself, regardless of modality, was beneficial to patients’ emotional wellbeing.

Treatment by a specialist consultant could be said to raise participant’s confidence regarding their prognosis and reduce some of the ulcer-related anxiety that they are experiencing. This could be particularly pertinent in a private medical clinic, where the amount of time that each patient spends with the consultant and other medical staff is likely to be higher. The mechanisms behind these changes and patients perceptions of treatment requires further research before any definitive conclusions may be drawn.

In contrast to the above findings, general quality of life and pain-related quality of life were not found to significantly improve across time, suggesting a difference
between the impact upon these variables and participant’s emotional wellbeing. This could be seen to reflect findings from the previous chapter, where there was not found to be a strong association between general quality of life and disease-specific quality of life. As discussed, this may suggest that participant’s perception of their general health-related quality of life is not as closely associated with their disease-specific quality of life as might be expected. This could be because leg ulcers have not had a strong influence on how these individuals view their health in general, it might be due to participant’s interpretation of the question or a stoical attitude to their general health, or equally it might be that the generalised nature of the question was not sensitive to change over time. This too would benefit from further research, and in particular qualitative methods may allow a more in-depth exploration of these beliefs.

Relationships between patients’ perceptions of clinical outcomes and their reported psychosocial and quality of life outcomes were also explored. Although no significant correlations were observed, the small sample size included in this study means that the tests used were underpowered and thus tests of significance may be considered unreliable; leading to increased risk of a Type 2 error. Large effect sizes were observed in many of the tested relationships, suggesting there may be a relationship between perceived clinical outcomes and quality of life outcomes. In particular, large effect sizes and marginally significant results were observed in the relationship between pain and positive mood, and between pain and the domestic subscale of disease-specific quality of life. This indicates that as pain decreases participants reported improvements in positive mood and in their ability to carry out domestic tasks. In addition, it appears that as ulcer healing improved, as did disease-specific quality of life, general quality of life, and pain; and as pain decreased there was an improvement in disease-specific quality of life and negative mood. These findings suggest a relationship between improvements in quality of life and patients’ perceptions of clinical variables; however, they must also be treated with caution due to the small sample sizes involved. As a preliminary exploration, these findings support the need for inclusion of both clinical and quality of life variables in future research; both to investigate the impact on these distinct outcome measures and the relationships between the two.
4.1.13 **Strengths and limitations**

The current study is limited by its small sample size, and therefore all statistical findings must be treated with caution. Initial plans were to investigate a significantly larger group of participants, but unfortunately this was not possible due to problems with recruitment and a significant participant attrition rate. As a result, original plans for statistical analysis were not possible and non-parametric alternatives were used. The lack of control group in this study means that the observed impact of treatment cannot be attributed to surgery specifically and further research is required to explore these hypotheses across various treatment modalities. Many of the limitations in this study can be attributed to issues with recruitment, and unfortunately this was a disadvantage of recruiting participants from a private healthcare provider; as our sample population was vulnerable to changes in market forces. Although some might argue that recruiting from a private healthcare provider limits the representativeness of the sample, this was not thought to be a problem in this study due to the limited availability of the procedure in the NHS. Subsequent research should consider recruiting from NHS providers in order to represent the experiences of a larger population and overcome some of the recruitment issues encountered in the present study. This might be achieved through collaboration with several NHS trusts or across multiple research sites.

The strengths of this research predominantly lie in its novel approach to treatment outcomes in chronic leg ulceration. Whilst the small sample size limits the conclusions that can be drawn from this study alone, this is the first study to include a detailed investigation of psychosocial and quality of life outcomes from surgical treatment, and to include patients’ own perceptions of clinical outcomes. This study has demonstrated the viability of the measures used, and provides recommendations for future research that may be used to extend this work (see 4.1.14). The conclusions presented here provide some preliminary trends and are hoped to stimulate further research in this area.

4.1.14 **Future recommendations**

The results of this study support the inclusion of psychosocial and quality of life measures in future investigations into the efficacy of various treatment modalities, demonstrating the differing influence of surgical treatment on various elements of quality of life. For this reason, it is recommended that future research should include measures of disease-specific quality of life and general health-related quality of life, as
well as psychosocial variables such as mood and coping. If this study were to be repeated it is recommended that a substantially larger sample should be recruited for analysis and that patients receiving various treatment modalities are recruited, in order to compare outcomes between surgical and non-surgical management. Future research may also benefit from including both an objective and subjective measure of clinical severity at each time point (such as ulcer size or time to healing), so that this may be compared to patients’ perceptions and used as an additional clinical variable. This would allow investigation of the relationship between objective and subjective outcome measures of clinical outcomes, in addition to exploring the extent to which each of these measures relates to quality of life. Models of illness representations, such as Leventhal’s Common Sense Model (Leventhal et al., 1980), suggest the overriding importance of patient perceptions to adaptation to illness and research of this nature would allow further investigation of these mechanisms.

The results of this study also suggest a number of qualitative research avenues that could be further explored. For example, many studies have suggested that patients are not aware of the underlying cause of their leg ulcer. A qualitative investigation of these beliefs and how these have influenced patients’ behaviour or beliefs about treatment would allow for a richer understanding of these processes and appropriate points for intervention. Similarly, results from this study and the previous chapter suggest a disjoint between disease-specific QOL and general QOL, with individuals reporting a generally good overall health-related quality of life. Further qualitative investigation may benefit from exploring this in more depth; investigating how participants interpret this single-item question and how chronic leg ulceration influences their perception of their overall health. In addition, quantitative analyses do not allow in depth investigation of patient treatment experiences or the psychological processes underlying reported treatment outcomes. As such, investigations into the patient experience of both surgical and conservative treatment will be explored in the following chapters (Chapters Five and Six).

4.1.15 Clinical implications
The clinical implications of this study are also limited due to the small sample size; however, some preliminary recommendations can be made. The results of this study suggest that patients’ disease-specific quality of life, whilst potentially linked to clinical outcomes, may not be wholly explained by changes in physical health. It is therefore
suggested that clinicians consider outcomes from treatment in terms of both physical changes and psychosocial changes. Attention should be paid not only to what is considered an improvement based on objective measures of wound healing, but also to what each individual considers a clinically significant improvement for them. Although this study demonstrates significant changes in emotional quality of life after surgical treatment, no statistically significant changes were observed in domestic, cosmetic or social aspects of quality of life. It is suggested that the importance of each of these elements to an individual patient should be considered when determining the most appropriate treatment pathway, in order to provide a holistic approach to care and address individual patient’s expectations from treatment. Whilst based on the findings of the current study, these recommendations do not apply exclusively to surgical management, but to all methods of treatment for chronic leg ulceration.

The findings of this study support previous research suggesting many patients are not aware of the underlying cause of their leg ulcer. As discussed above, this could have important implications for patients’ health-related beliefs and behaviours, as well as their perceptions of treatment. This has important clinical implications and suggests the need for intervention at the point of diagnosis to sensitively discuss the patient’s perception of cause and address any misconceptions that they might have.

4.1.16 Conclusions
In conclusion, minimally-invasive venous surgery is a relatively recently developed surgical treatment for venous leg ulcers, which demonstrates equivalent healing times and lower recurrence rates than treatment using more conservative compression therapy (Gohel et al., 2007). The current study aimed to investigate the impact of this treatment on clinical, psychosocial and quality of life variables, as well as the relationship between them. Statistically significant changes in emotional aspects of disease-specific quality of life were observed over the course of six months post-surgery, although no other statistically significant changes in psychosocial or quality of life variables were observed. All participants reported improvements in ulcer healing, and there appeared to be a relationship between these physical changes and changes in participants reported quality of life. Due to the small sample sizes involved, all results should be treated with caution; however, this study may be considered a preliminary investigation, providing a basis for many future research opportunities in this area. It is suggested that future research could extend the current study, including both objective and subjective
measures of clinical outcomes, a comparison of multiple treatment modalities and a larger sample. Qualitative research methods should also be used to further investigate some of the trends identified, exploring how patients’ beliefs regarding the cause of their leg ulcer may influence their behaviour and conducting a more in depth investigation of patients’ treatment experiences.
Chapter Five

Study 3: Patients’ experiences of minimally invasive surgery for leg ulceration: a qualitative study

5.1 Overview
The thesis thus far has presented a systematic review exploring the comparative impact of conservative versus surgical management for leg ulcers on quality of life, a cross sectional investigation of quality of life predictors in individuals with leg ulcers, and a longitudinal cohort study of individuals undergoing superficial venous surgery for venous leg ulceration. As a whole these studies have stressed the value of including psychosocial and quality of life variables in the investigation of leg ulceration and treatment, suggesting a differential impact of various treatment modalities on patient quality of life and advocating further exploration of patients’ beliefs and experiences regarding treatment. Therefore, the present study aims to explore patients’ experiences of Superficial Venous Surgery for the treatment of venous leg ulcers, using qualitative methods to gain an in depth insight into patients experiences and beliefs regarding this treatment pathway.

5.2 Introduction
A substantial literature exists on the impact of Leg Ulcers on individual’s daily lives. Leg Ulcers have been found to impact individuals physically, socially and psychologically, with a particular emphasis on the associated pain (Briggs & Flemming, 2007). Clinicians often report lower health related quality of life in these patients (Franks & Moffatt, 2006), and research suggests that individuals with leg ulcers score lower on tests of everyday function than their peers (Wissing et al., 2002). Studies also demonstrate that leg ulcers can result in higher levels of depression and anxiety, loss of will power, hopelessness, lower self-confidence, and lower self-esteem (Douglas, 2001; Green, Jester, McKinley, & Pooler, 2013; Persoon et al., 2004), and as a result treatment for leg ulcers may be considered as important for the patient’s psychological wellbeing as it is for physical health.

Treatment for leg ulcers falls into two main groups: conservative treatment and surgical treatment. Conservative treatment encompasses compression bandaging, advanced dressings and other similar non-invasive treatment approaches. Surgical treatment used to focus predominantly on ‘vein stripping’ procedures, but has moved towards more minimally invasive procedures in the last decade, such as Endo Venous Laser Ablation and Foam Sclerotherapy. A vast body of literature exists comparing the biological outcomes of these treatment modalities, such as healing speed and recurrence rate; however, data regarding psychological or quality of life outcomes is limited and of varying quality (Malas et al., 2014; Valle et al., 2014). As described in Chapter 2, a systematic review of the quantitative literature suggests that it is possible that all treatment improves patient quality of life to some extent, regardless of the type of treatment, but that surgical treatment may lead to improved quality of life outcomes compared to compression bandaging alone (Tollow et al., 2016). The mechanisms underlying this relative improvement in quality of life remain unclear, although this may be due, not only to the outcomes of surgery being more prolonged, but also to the nature of the processes involved in undergoing surgery (Criddle, 1993). In particular, whilst the ongoing routine of dressings and bandaging offers a temporary solution, as a novel and more intrusive intervention surgery may offer patients the hope of a potential shift away from their illness towards permanent healing, even if this permanence has yet to be proven (Tollow et al., 2016).

This explanation finds reflection in research drawing upon a notion of mastery central to key health related constructs such as a health locus of control, self-efficacy and perceived control (Bandura, 1997; Taylor, 1983; Wallston, Wallston, & DeVellis, 1978). It is also in line with studies across a number of different chronic conditions which illustrate a role for sense making in the adjustment to illness (Hagger & Orbell, 2003; Jopson & Moss-Morris, 2003; Leventhal et al., 1998), and reflects research indicating that investment in any procedure may produce better outcomes (Heinrich, Ogden, & Patel, 2014; Totman, 1976). To date however, there has been no in depth exploration of patients experiences of this treatment. Such an exploration is important as surgical management of leg ulcers has the potential to offer a significantly different psychological experience for those who undergo this treatment pathway.
5.2.1 Aims

The present study aimed to explore the experiences of individuals who had undergone Superficial Venous Surgery for the treatment of leg ulcers. It is hoped that such research will provide insight into the patient perspective of treatment, and provide recommendations for future clinical practice and research. Qualitative methods were employed due to the exploratory aim of the study and in order to ground the findings in participants lived experiences.

5.3 Methods

5.3.1 Design

This was a qualitative semi-structured interview study, analysed using Thematic Analysis (Braun & Clarke, 2006). A qualitative approach was believed to be most appropriate in order to collect rich in-depth accounts of participant’s experiences, not restricted by quantitative measures.

Participants were asked to complete a telephone interview, rather than a face-to-face interview, in an effort to encourage honest discussion and to ensure participants were as comfortable as possible throughout the interview process. Discussions of treatment experience may be a sensitive topic for participants, especially if they wish to express any negative sentiment regarding their experiences. Leg ulcers are also known to impact an individual’s mobility and to cause individuals significant amounts of pain (Persoon et al., 2004), as well as impacting on individual’s self-esteem and body image (Douglas, 2001; Ebbeskog & Ekman, 2001; Flaherty, 2005). It was believed that participants engaging in a face-to-face interview might be concerned with self-presentation, providing hospitality to the researcher, or continuing with the interview despite distracting levels of pain. In addition, Pearce, Thøgersen-Ntoumani, & Duda (2013) discuss the issues associated with an interviewer being of significantly different age and experience to the participant, and the barriers this may introduce to honest disclosure. As the researcher was a young woman in her twenties, it was thought this could be an issue for the present research study if face-to-face interviews were employed. In contrast, telephone interviews were hoped to encourage openness and ensure participants comfort as far as possible, and were believed to be a more appropriate data collection method. As a result, all participants were initially invited to take part in a telephone interview, although face-to-face interviews were offered to
participants as an alternative when telephone interviews were thought to be inappropriate; for example, due to hearing difficulties.

5.3.2 Recruitment
Prospective participants were recruited from The Whiteley Clinic, a private medical clinic in Guildford, Surrey. One hundred and eleven previous patients of the clinic were invited by post to take part in a telephone interview, all of whom had undergone superficial venous surgery for the treatment of leg ulcers between 6 months and 12 years previously. Fifty-one of these prospective participants were sent an additional recruitment invite via email.

Participants were required to meet the following inclusion criteria:

- To be aged over 18.
- To have given informed consent.
- To have a good understanding of written and spoken English.
- To have undergone venous surgery for the treatment of leg ulcer(s).

5.3.3 Procedure
Upon expressing an interest in taking part in the study, prospective participants were given further information about the procedure involved in the interview and invited to arrange a time for the interview to take place. Ahead of the interview, participants were sent an information sheet (see Appendix I), a consent form (see Appendix J) and a written copy of debriefing information via post (see Appendix C). Participants were encouraged to contact the researcher if they had any questions, wished to rearrange the interview or no longer wished to take part.

In the case of telephone interviews, the interviewer conducted the interview from a private room on the University campus. They arrived at the room ahead of the scheduled interview, to ensure the room was available and to set-up the audio-recording equipment. A notice was fixed to the door of the room, notifying those passing that an interview was taking place and requesting that this was not disturbed. The researcher then phoned the participant at the pre-arranged time and on their preferred telephone number.
In the case of face-to-face interview, the interviewer travelled to the home of the participant for a pre-arranged date and time. Portable audio-recording equipment was set-up in a suitable room, ensuring that the safety of the researcher and the participant was high priority at all times. In order to further ensure researcher safety, a nominated contact was made aware of the interview location and the expected finishing time, with appropriate lone-working precautions in place.

Participants were first asked whether the pre-arranged time was still suitable to conduct the interview, and whether they had read and understood the information sheet. The researcher answered any questions that the participant had, and explained the interview process, including: the ability to take breaks during the interview, the importance of notifying the interviewer if they felt at all distressed or uncomfortable during the interview, and their right to withdraw from the interview at any time without providing a reason. Participants were told that the researcher was not restricted on time, so they should feel free to talk for a long as they wish, and it was checked that they were happy for the interview to be audio-recorded. Participants were then asked to answer some demographic questions (see Appendix K) and the audio-recording was begun. Interviews were recorded using a High Quality portable digital audio recording device.

The interviewer’s questions were guided by the interview schedule (see Appendix L), departing from this when appropriate. This interview schedule covered three main topics: experiences of diagnosis (‘When did you first notice the leg ulcers?; Who diagnosed the ulcers? When?’), experiences of treatment (‘Could you tell me about your experience of surgery?’; ‘How did you feel after surgery?’), and support from others (‘What kind of support did you receive from other people when your leg ulcers first started?’; ‘How did you feel about this support?’). Upon completion of the interview schedule, participants were asked if there was anything further they wished to add, anything they wished to stress as particularly important or any reflections on the process. The researcher then stopped the audio-recording and verbally debriefed the participant. Participants were asked if they had any further questions and thanked for their time.
5.3.4 Analysis method
Data was transcribed verbatim and analysed using ‘Thematic Analysis’ (Braun & Clarke, 2006). This method was chosen due to the exploratory nature of the study and the focus on patient experience, allowing analysis of themes across the dataset. Thematic analysis was believed to allow representation of both pragmatic and more interpretive aspects of the data, and was approached from a realist/essentialist epistemology, suggesting that the language used by participants accurately reflects their meanings and experiences. An inductive data-driven approach to analysis was adopted - ‘guided by a careful analysis of what is in the data’ (Howitt, 2010, p.184) - in comparison to a theory-led approach, which may choose to base the initial coding on a particular theory or set of research questions (Braun & Clarke, 2006).

5.3.5 Analysis process
The analysis process was conducted in five steps, based on guidance by Braun & Clarke (2006) and Howitt (2010). These were: ‘data familiarisation’, ‘initial coding generation’, ‘searching for themes’, ‘reviewing and refining themes’ and ‘theme definition and labelling’.

5.3.5.1 Data familiarisation
All interviews were conducted and transcribed by the researcher, providing opportunity for initial data familiarisation. During the transcription process interviews were played and transcripts read through repeatedly to ensure accuracy of transcription, adding further to the familiarisation stage. This process allowed the researcher to gain a detailed knowledge of the data set and an overall feeling for patterns or themes that may be present.

5.3.5.2 Initial coding generation
A detailed initial coding process was conducted to indicate important or interesting elements of the data. All initial codes were noted in the left margin of the transcripts, and lists of initial codes were compiled. This process was repeated for each interview transcript.

5.3.5.3 Searching for themes
Once initial codes had been generated for all transcripts, the researcher began to look for broader themes and patterns in these codes. Discussions about these initial codes and themes were conducted between researcher and supervisor, exploring their content,
their conceptual meanings and considering further abstractions. A number of thematic maps were generated throughout this stage of analysis, in order to further develop themes and consider their overall structure in relation to each other. At the end of this stage, a set of tentative themes and subthemes had been produced, with a view to change and refine these conclusions in the next stage of analysis.

5.3.5.4 Reviewing and refining themes
In order to ensure themes were fully grounded in the data, a set of tentative themes and subthemes produced thus far were considered against the original transcripts. Transcripts were examined with regards to data that supported these initial themes and data that remained unrepresented. At this stage, themes were disregarded, divided, combined and generated to more appropriately fit the data set, and another set of thematic maps evolved with the analysis process. This stage involved the researcher continually reflecting upon whether the resulting thematic map comprehensively and authentically represented participant’s accounts, and adjusted the analysis as necessary. After a period of going back and forth between the analysis and the data, a final thematic map was produced.

5.3.5.5 Theme definition and labelling
The final stage of data analysis involved identifying appropriate labels and definitions for each theme, and subtheme, within the analysis. The scope of each theme was established, as well as their relationship to the overall analysis. Working titles were replaced with carefully considered labels, hoped to concisely represent the core meaning of each theme and subtheme.

5.3.6 Quality Checks
Several authors provide evaluative criteria for qualitative research, and such criteria were carefully considered in the conduct of this study. Of particular consideration is the perspective that the researchers themselves bring to the research, and this issue features in Yardley's (2000) discussion of transparency in qualitative research. Whilst many believe that it is not possible, or desirable, to remove the researcher’s perspective from the qualitative research process, transparency through reflexivity allows the researcher to reflect upon how their own beliefs and assumptions may have influenced the research. Awareness of this influence is an important element of the research process, and may aid the researcher in ensuring that analysis is appropriately grounded in the
data. In line with such recommendations the researcher made reflective notes throughout the process of study design, data collection and data analysis.

5.3.7 Ethical considerations
Several ethical issues were considered in the design of this study, and a number of measures were taken in order to address potential ethical issues and avoid risk wherever possible. A favourable ethical opinion for this study was granted by the relevant NHS research ethics committee (see Appendix E) and University ethics committee (see Appendix F).

Informed consent was gained from every participant before participation, including informing every participant of the subject areas that the study will cover before they consent to take part. Participants were asked for their consent to have their interview audio-recorded, and all audio files produce were stored on a password-protected computer before transcription. After being transcribed verbatim, audio files were deleted and the transcripts produced were stored securely. Unless withdrawn from the study, participant’s data will be stored securely in accordance with University Ethical Procedures for at least 10 years. Each participant was assigned a pseudonym to ensure confidentiality in transcripts and in any subsequent publications. Participants were reassured that their data would remain confidential, and that the research was operating separately from the clinic where they received treatment. They were informed of all the precautions being taken regarding data protection, and that pseudonyms would be used in all data analysis and any subsequent publications.

Participants were reminded that they may withdraw from the study before commencing the interview, at any stage during the study or after participation. The researcher was vigilant to participant’s wellbeing throughout interviews, and if a participant appeared distressed at any time then the researcher reminded them that they didn’t have to answer any questions that they didn’t want to and that they could withdraw at any point. In addition, the researcher reminded participants of their right to not answer or withdraw before discussion of any sensitive areas, and every participant was given verbal and written debriefing information after participation. This debrief information included a detailed explanation of the research and its aims, contact details of the researcher and their supervisor, as well as contact details for various support
organisations should the participant want to talk further about anything brought up in the course of the research.

If at any point during participation in the study participants disclosed experience of poor clinical practice, or a complaint about their medical treatment, the researcher would advise them on their options to take this complaint further. This may have included details of how to contact their local Patient Advice and Liaison Service (PALS) or information about The Whiteley Clinic complaints procedure. The availability of such information was also stated on all information sheets, so that participants may also have requested this information at any time without disclosing a specific complaint or event.

5.4 Results
Eleven participants (n=11) were interviewed, all of whom had undergone Superficial Venous Surgery for the treatment of leg ulcers between 12 months and 6 years prior to interview. This surgery included Endovenous laser ablation and/or Foam sclerotherapy. Mean interview duration was 45 minutes, with all interviews lasting between 34 and 71 minutes. One participant requested that his spouse participate in a dyadic-interview due to hearing difficulties, and it was agreed that this would be appropriate. Participants were evenly split in gender (6 females; 5 males), aged 48-87 years old (mean=71), and mean leg ulcer duration was 91 months (range 3-480). One participant considered their leg ulcer to be ‘unhealed’, three participants considered their leg ulcer to be ‘healed, and expect to return’, and seven participants considered their leg ulcer to be ‘healed, and don’t expect to return’ (see Table 14). Ten participants were interviewed via telephone, and one via face-to-face interview.
Table 14. Participant’s demographic and medical information

<table>
<thead>
<tr>
<th>Pseudonym</th>
<th>Gender</th>
<th>Age (years)</th>
<th>Leg ulcer duration (months)</th>
<th>Approx. time since surgery (at time of interview)</th>
<th>Patient perception of ulcer status</th>
</tr>
</thead>
<tbody>
<tr>
<td>John</td>
<td>Male</td>
<td>48</td>
<td>48</td>
<td>2-3 years</td>
<td>Healed, don’t expect to return</td>
</tr>
<tr>
<td>Diana</td>
<td>Female</td>
<td>69</td>
<td>96</td>
<td>5+ years</td>
<td>Healed, don’t expect to return</td>
</tr>
<tr>
<td>Harry</td>
<td>Male</td>
<td>70</td>
<td>3</td>
<td>3-4 years</td>
<td>Healed, expect to return</td>
</tr>
<tr>
<td>Margaret</td>
<td>Female</td>
<td>60</td>
<td>480</td>
<td>2-3 years</td>
<td>Healed, expect to return</td>
</tr>
<tr>
<td>David</td>
<td>Male</td>
<td>84</td>
<td>36</td>
<td>3-4 years</td>
<td>Unhealed</td>
</tr>
<tr>
<td>Viv (Spouse)</td>
<td>Female</td>
<td>82</td>
<td>/</td>
<td>/</td>
<td>Healed, expect to return</td>
</tr>
<tr>
<td>William</td>
<td>Male</td>
<td>82</td>
<td>72</td>
<td>1-2 years</td>
<td>Healed, expect to return</td>
</tr>
<tr>
<td>Gloria</td>
<td>Female</td>
<td>77</td>
<td>11</td>
<td>1-2 years</td>
<td>Healed, don’t expect to return</td>
</tr>
<tr>
<td>Linda</td>
<td>Female</td>
<td>67</td>
<td>36</td>
<td>1-2 years</td>
<td>Healed, don’t expect to return</td>
</tr>
<tr>
<td>Edward</td>
<td>Male</td>
<td>81</td>
<td>96</td>
<td>3-4 years</td>
<td>Healed, don’t expect to return</td>
</tr>
<tr>
<td>Carol</td>
<td>Female</td>
<td>57</td>
<td>8</td>
<td>1-2 years</td>
<td>Healed, don’t expect to return</td>
</tr>
<tr>
<td>Lynn</td>
<td>Female</td>
<td>87</td>
<td>120</td>
<td>1-2 years</td>
<td>Healed, don’t expect to return</td>
</tr>
</tbody>
</table>

Three primary themes were identified: ‘Living in Flux’, ‘Perceptions of Chronicity’ and ‘Expectations’. These encapsulate participant’s experiences of surgery, with particular reference to the timeline of treatment and a mismatch between participant’s expectations of treatment and the reality. Each of the three primary themes has subthemes. These themes and subthemes will now be described and illustrated with exemplar quotes, before being considered within the overarching context of metaphor and agency.
Theme 1: Living in Flux

Participants described the ambiguity surrounding their leg ulcers prior to surgery, and the impact this had on their lives. Patient’s quality of life was negatively impacted by their leg ulcers, and this impact was worsened by the changing nature of leg ulceration. The changeability of symptoms and the recurrence of ulcers felt unpredictable, and this led to a higher psychological toll on participants. Many participants described a tipping point where normal functioning was interrupted to an extent that they were motivated to seek alternative treatment; and whilst many participants received practical support and care from those around them, they did not identify these people with the label of ‘carer’. This state of ‘flux’ that patients lived with was expressed in three subthemes: ‘uncertainty’, ‘tipping point’ and ‘relationships’.

Uncertainty

Participants discussed the anxiety that accompanies leg ulceration in terms of a constant consciousness of the ulcer, and in many cases this anxiety was due to uncertainty about the long-term prognosis of the condition prior to surgery. The physical impact of leg ulcers appeared to be closely linked to this psychological impact, and participants discussed how the psychological impact of leg ulcers was worsened by their changing nature and recurrence, making the impact unpredictable and harder to deal with:

“It's got worse and then it gets better again, it goes up and down ... You think 'Oh my god, it's gone!', and it hasn't gone, it's still ticking away there and waiting to come back again.” – William

Due to this uncertainty, participant’s experienced continued anxiety regarding leg ulcers, even in ulcer-free time, suggesting a more enduring impact than has previously been explored in the literature.

Tipping point

Participants also described the psychological impact of ulceration, prior to surgery, in terms of severe depression, with some participants describing feeling ‘almost feeling suicidal’ (Linda). As the impact of leg ulcers worsened, many participants described a
‘tipping point’, when the severity of this impact motivated them to seek alternative treatment options. For Lynn this tipping point came at Christmas:

“I’d spent the whole of the Christmas in bed ... I was hiding away, it wasn’t really doing me any good, it was just the only place I wanted to be where I couldn’t... nobody bothered me, I didn’t have to bother to talk or be cheerful” – Lynn

It was at this point, ‘in desperation’, that Lynn and her family sought alternative treatment for her leg ulcers.

**Relationships**

Relationships with the individuals around participants were felt to be influenced by the extra support that some participants required due to their condition. Some participants reflected on a reluctance to ask others for help, either because they felt independent enough that help was unnecessary, or because they considered themselves to have a personality that made asking for help difficult. In contrast, others readily accepted help from those around them. Describing how valuable this support was during surgical treatment and suggesting that this support often negated the need for paid help:

“Thanks to the fact that I have a very attentive wife who looks after me, I don’t have any outside help” - Edward

Importantly, whilst these individuals cared about participants or provided them with help doing day-to-day tasks, participants felt the label of ‘carer’ was not appropriate:

“He cares, but he wouldn’t call himself a carer” - Edward

This is potentially due to the reciprocal nature of this care or its consideration as an extension of existing roles and relationships:

“I feel that we love each other and that’s what we do for each other. If it was the other way round I’d do the same, you know, we look after each other” - David

**Theme 2: Perceptions of chronicity**

Throughout their narratives, participant’s often described the extent to which they felt their condition had a chronic or acute trajectory. Participants’ perceptions appeared to
change and develop as they journeyed through diagnosis, treatment and outcomes. Prior to treatment, participants appeared to expect an acute diagnosis. This did not match up with the chronic timeline that clinicians presented, leading them to reject this characterisation and the accompanying treatment plan. A more acute approach was sought and found in surgical management; however, participant’s feelings after surgery appeared to fall into three varied groups, characterised by feelings of empowerment. In order to demonstrate this journey, participant’s perceptions of chronicity can be viewed in three subthemes: Rejection of chronic characterisation, Acute approach and Looking forward.

**Rejection of chronic characterisation**

Upon diagnosis some participants had prior knowledge of leg ulcers, often from experiences with family or friends. All, however, initially expected that the problem was acute and treatment would be straightforward:

“Well when it first happened I was totally ignorant of it and I thought, well, you know, some cream or something will just send it away” – Edward

“you notice that you've got a sore on your leg which won't heal, erm, so you go and see the quack about it, but you are completely unaware of the eventual consequences and quite how long the process might take to get rid of the thing.” - Harry

When participants were presented with a treatment plan that appeared to be based on a ‘chronic’ characterisation of their condition, they described rejection of this characterisation and the idea of a ‘passive’ treatment plan to manage the condition:

“Because everytime I said to them ‘well what do the hospital do for you’, and they said ‘well you have this doppler scan’ … so I said, well okay, when they’ve done that, what happens then? ‘Oh well that’s when they tell you to use certain pressure stockings’, and I thought, well that’s not really clearing what’s wrong with me up!” – Gloria

Some participants initially proceeded with a conservative treatment plan, often until they observed that a period of time had gone by with little progress or improvement in their symptoms:

“It went on for weeks and weeks and weeks and it didn’t get better... I was then getting really concerned” - Carol
“they couldn’t give me a time limit...they were quite happy just for me to go down there, take the dressings off, re-dress it, go back another day and have the same thing done....It was getting me quite frustrated.” - Gloria

This resonates with the ‘tipping point’ subtheme discussed earlier and may suggest a point at which participants realised there was a mismatch between their more ‘acute’ characterisation of the condition and the ‘chronic’ characterisation that the treatment suggested, leading participants to seek alternative treatment methods.

For other participants the rejection of their condition as ‘chronic’ was more immediate, for example, John recalls this realisation as occurring in an early consultation:

“I suppose I was looking for a plan that they could give me to say ‘right you’ve got this now, this is what we’re going to do and this is when you’re going to get better, and this is when you don’t need to worry about it anymore, but they didn’t say that. They said ‘here’s a prognosis, you’re going to have to learn to live with it’... I just thought ‘well there’s got to be a better way, there’s got to be more to this than what I’m hearing’”

– John

For John, his beliefs that the leg ulcers were an acute condition led to an immediate rejection of the proposed treatment plan, and instead he sought an alternative treatment approach that matched his own illness beliefs.

**Acute approach to treatment**

The ‘acute’ characterisation of their condition, described above, left many participants frustrated with conservative treatment and led them to seek a treatment approach that also characterised their condition as ‘acute’. Participants appeared to seek a treatment method that would provide a ‘cure’ and many trialled various different treatments before exploring surgical treatment. Participants often discussed prior use of various advanced wound dressings or Manuka honey, and sought the advice of many different healthcare professionals:

“I’ve seen every –ologist throughout the world on this leg” - William
When these treatments were unsuccessful many participants experienced feeling ‘desperate’ and John describes this search for alternative treatment as wanting his ‘feelings of optimism validated’

Participant’s ‘acute’ perceptions of their condition appeared to have been legitimised by the clinicians they met during surgical treatment:

“They would not accept there was nothing you could do, and would not accept that there wasn’t any long-term outcome that would reinstate the quality of life that you had before, or as near to it as you could get” - John

Participant’s positive evaluations of these clinician’s attitudes appear to be the result of a harmony between the between the patient’s illness beliefs and the approach offered by surgical treatment:

“I knew they were experts, and they knew what they were talking about, and I just felt so comfortable and so lucky that I’d found them. It gave you hope that you were going to be cured and you were going to get better.” - Margaret

**Looking forward**

Participant’s expectations for the future post-surgery appeared to lay in three distinct groups. These groups differ with regards to their expectations regarding the future for their condition and their confidence in the efficacy of surgical treatment. No clear patterns were observed between these three groups in terms of demographics of treatment history.

The first of these groups appears to have maintained an acute characterisation of their leg ulcer post-surgery, stating with some certainty that surgical treatment had been successful and they did not expect the condition to return.

“In my mind, as far as I’m concerned, it’s not a problem anymore” - Carol

For this group, surgery appears to have validated their belief that their condition was acute, and they were not contemplating the possibility of recurrence.

A second group of participants had all experienced a recurrence in their condition after venous surgery, and were resolute in their feelings that the treatment they received was not effective. The long-term effects of these feelings can be seen in
William’s account, as he appears to have moved towards a more ‘chronic’ characterisation of his leg ulcers:

“I don’t think I will ever get rid of it, having had it for so long now, I think I’ll have it forever” – William

As a whole this group appeared to have been disempowered by the return of the condition after treatment and this influenced their beliefs regarding the chronicity of their condition. Although for one participant these negative feelings were clearly specific to Superficial Venous Surgery and he described very positive feelings regarding different surgery he has since received for his leg ulcer.

In great contrast to this second group, a third group of participants depict mixed beliefs regarding the likelihood of recurrence, but remained positive about the surgical treatment they had received. This group all describe feelings of empowerment to receive further surgical treatment if their leg ulcers were to return:

“I do expect it to go wrong eventually...but if they do, I’ll just go back to the clinic again...we’re not wealthy people... but it’s something I’d pay again without even thinking about it, because I don’t want to go backwards” – Diana

These feelings are further reflected in Lynn’s beliefs regarding the depression she suffered as a result of the leg ulcers:

“I don’t need to go down into the depths again, as soon as I feel like there’s something that’s not quite right... there’s always [the clinic]” – Lynn

Whilst these participants do not rule out the possibility of the leg ulcers returning, they appear to maintain an acute characterisation of their condition through their belief that they could be easily treated through further venous surgery if necessary.

**Theme 3: Expectations**

Participants often described a mismatch between their expectations and their experiences. They described perceived differences between their own identity and the identity of someone with leg ulcers, as well as vast differences between their expectations of treatment and their experiences; suggesting that a difficulty reconciling these differences may have driven their approach to treatment. These differences
between expectations and experience were particularly evident across two dimensions: *Identity* and *Treatment*.

### Identity

Participants discussed the discrepancy they felt between their perceptions of self and their condition, suggesting that their identity did not fit with that of someone who has leg ulcers:

“When you've had a life where you've had virtually no sickness at all and this hits you at a late age, you think, oh my god what's happening now, and you do get a bit annoyed” - William

“This sort of thing is always something that is going to happen to somebody else” - Harry, line 86

Upon diagnosis, this discrepancy between John’s identity and his illness appeared to have caused difficulties, as he recalls thinking upon diagnosis:

“I don’t get ulcers, that’s what old people get, you must be wrong” - John

It also appears from participant’s accounts that leg ulcers may have altered how individuals perceived their identity:

“Pain makes you a very different person” - Lynn

“It makes you feel very old, because as I say, everybody thinks it's an old persons problem.” – Margaret

Differences between participant’s identity and their illness appeared to be particularly salient around the issue of age. Participants believed they were too young to be limited by their illness, and suggest that this discrepancy may have driven their approach to treatment:

“Some people might be able to put up with it, I don’t know, but I wasn’t. I mean, I’m only 77 years of age and I still wanted a life, so this is one of the reasons I kept onto them, saying ‘what more can I do?’” - Gloria

However, whilst participants appear to use their age to justify gaining a better quality of life through surgical treatment, this was not necessarily the case in terms of cosmetic
results from treatment. When discussing the option to have further surgical treatment to treat the cosmetic elements of their leg ulceration, participants often dismissed this as unnecessary due to their age:

“I think at my time of life I’m not going to worry too much” - Gloria

*Treatment*

Differences between participant’s expectations from treatment and the reality of their experiences were apparent throughout the data. Such discrepancies can be seen reflected in the earlier theme ‘Perceptions of Chronicity’, as participant’s own illness timeline often did not match that of the proposed treatment:

“I could see myself another year or eighteen months still doing that sort of thing, and I just couldn’t face that” - Gloria

In addition, participants suggested that the approach of conservative treatment methods did not match their expectations:

“That’s like going back 150 years, that’s what they said then, it’s not what they’re supposed to say now” - William

And beliefs regarding the underlying cause of the leg ulcers were an important factor in some participant’s decision to have surgical treatment:

“the ulcers do clear up [with conservative treatment], but because they haven’t had any procedures to take away what’s wrong where the ulcer is, it can come back again, and I thought, well having healed up once I wouldn’t want that to come back” – Gloria

The distance between participant’s expectations of treatment and their experiences were most strongly conveyed through their criticisms of national treatment provision, with several participants citing this issue as one of the motivating factors for their participation in research. Some participants reported a micro-level problem with treatment provision:

“I just felt like I was a nuisance” – Margaret

Whilst the majority of participants also discussed issues with treatment on a national or macro-level, believing leg ulcer treatment is marginalised or not appropriately
prioritised by national treatment providers. Many participants had also considered the comparative cost of treatment and their frustration at not being able to access it via the National Health Service:

“And I just think that not enough attention is paid to the problem, or the solving of it, and I suspect that they don’t want to do it on National Health because it’s quite an expensive process. But in the long-term it would probably save money and I get very very angry when you see all these huge obese people and the cost of that to the country and the National Health, and yet they don’t want to, nobody looks into the ulcers”

– Linda

5.5 Discussion

This study aimed to explore patients’ experiences of Superficial Venous Surgery for the treatment of leg ulcers. Three themes were identified from participant’s narratives, these were: Living in Flux, Perceptions of Chronicity, and Expectations.

Participant’s illness narratives about their time prior to surgery were characterised by a state of ‘flux’. They discussed the impact of leg ulcers on their quality of life, supporting existing literature on the topic (Briggs & Flemming, 2007) and extending this impact to ulcer-free time; suggesting a more enduring impact than has previously been explored in the literature. Participants suggest that the changeable nature of their symptoms and the recurrent nature of the condition led to an uncertainty around their condition and an increased impact on their quality of life. Such impact often climaxed in a ‘tipping point’, leading them to seek alternative treatment and reduce these feelings of uncertainty. This finds reflection in research exploring sense making in chronic conditions and indicates that conditions which show substantial variability may be more difficult to adjust to (Heijmans et al., 2004; Moss-Morris, 2013).

Such a state of uncertainty and state of flux also has implications for the notion of care and carers, and in particular results from the present study indicate that those who provide informal care for participants do not necessarily identify with the label of ‘caregiver’ (O’Connor, 2007; Ugalde et al., 2012). Whilst the terms ‘caregiver’ or ‘carer’ are often used by researchers and organisations involved in the provision of resources for this group, research exploring the positioning of informal caregivers in other conditions suggests that the label ‘caregiver’ is often only adopted as a result of
contact with external bodies that make use of this term. It is suggested that caregivers would otherwise view their support as an extension of their relationship with the individual, and this study found substantial evidence to support these assertions.

Participants also considered their condition in terms of chronicity and in particular rejected leg ulcers as a chronic condition, describing frustration with a lack of progress when undergoing conservative treatment and a search for a more ‘acute’ approach to treatment. Whilst the term ‘chronic’ implies a condition that they may live with for the rest of their lives, participants were seeking a treatment approach that would effectively ‘cure’ them of the condition; an important characterisation that in turn influenced the treatment approach that patients adopted. This ‘acute’ approach was validated by clinician’s descriptions of surgical treatment as treating the underlying cause of the leg ulcers in order to reduce the probability of recurrence, and after surgery these beliefs in the ‘chronic versus acute’ nature of leg ulcers differed between individuals. Many participants maintained the belief that leg ulcers were an ‘acute’ condition, either believing that their condition had been effectively ‘cured’ by surgery or expecting that it could be effectively treated again in the future should it recur; whilst other participants, who had experienced recurrence of the leg ulcers since surgery, described this as evidence that their ulcer is now a ‘chronic condition’.

Previous research has suggested that the psychological impact of leg ulcers may be influenced by whether health professionals encourage patients to consider leg ulcers as a ‘chronic’ or ‘acute’ condition. Briggs and Flemming (2007) suggest that a ‘chronic care route’ could lead to adaptation to the illness and feelings of control, whilst belief in an ‘acute’ or ‘specialist healing route’ could lead to feelings of hopelessness and guilt. This reflects recommendations in the wider psychological literature that different treatment approaches should be adopted by clinicians dependent on whether a condition is considered chronic or acute. The current findings, however, suggest that patients’ own perceptions of chronicity also play an important role in the treatment approach that they adopt and the psychological impact of treatment outcomes. Whilst leg ulcers are often referred to in the literature as a chronic condition (eg. Douglas, 2001; Green & Jester, 2009; Hopman, Vandenkerkhof, Carley, Kuhnke, & Harrison, 2014; SIGN, 2010), the present findings suggest that such a dichotomy between chronic and acute conditions may be a simplification of the illness experience and the experiences of leg ulcer patients are more in line with the notion of a ‘cyclical’ timeline (Moss-Morris et...
al., 2002). Such results have implications for the decision-making process and how patients own beliefs are taken into account when making treatment decisions.

The final theme in this research relates to inconsistencies between participant’s expectations of treatment and the reality that they faced. Participants criticised both the national approach to leg ulcer treatment and their own experiences, and describe differences between their own identity and that of a person with leg ulcers. In this way leg ulcers can be seen as a disruption to personal biography, reflecting the work of medical sociologists, such as Bury (1982). Participant’s descriptions of a mismatch between their expectation and experiences reflect Bury’s description of illness as upsetting the relationship between ‘internal and external reality’ (Bury, 1982), a disruption that may be greater when the mismatch between internal and external realities is greater and which may be most strongly seen amongst those individuals who developed leg ulcers at a relatively young age. As a result of this disruption, participants in this study were motivated to seek an alternative treatment pathway in order to reconcile these differences and align their expectations with reality. This may represent an important mechanism in the treatment journey of leg ulcer patients, as whilst bandaging treatment was viewed as a low-status and repetitive intervention, the offer of surgical treatment was considered a sophisticated high-status intervention. This could be said to create a renewed faith in medicine, which involves a sense of investment and offers a chance for empowerment to pursue further treatment. This in turn generates a sense of agency and hope, which is in stark contrast to participant’s beliefs prior to surgery.

Previous research indicates both that healing from surgical treatment may represent more ‘active participation’ (Criddle, 1993) and that interventions which require greater investment have a greater impact on patient outcomes (Heinrich et al., 2014; Totman, 1976). If this ‘active participation’ is influential in leg ulcer patients’ beliefs about their illness after treatment, then this highlights how the experience of the treatment pathway itself may impact patients beyond physical outcomes. One could also ask whether surgical management is the only means by which patients could gain a feeling of ‘active participation’ in their treatment, whether ‘conservative/traditional’ treatment for leg ulcers ever elicits a similar response, and which elements are important in this process. Investigation of such mechanisms requires further research,
and may be viewed in terms of notions of mastery and sense making across a number of theoretical domains (Bandura, 1997; Taylor, 1983; Wallston et al., 1978).

When examined as a whole, the themes identified in this research represent a distinct element of the surgical treatment process for these patients. Through surgical management, patients feel able to reduce the uncertainty associated with this condition and gain control. They are able to make active choices regarding their treatment and many feel empowered to act again if the condition were to recur. As such, whilst participants had been seeking a ‘cure’ for their condition, the possibility that their leg ulcers may recur did not detract from their sense of agency in the same way as it had previously. In this sense, the experience of surgical management offers a qualitatively different psychological experience to traditional treatment approaches for leg ulcers – and through investment offers patients a sense of hope and agency that goes beyond physical outcomes.

5.5.1 Limitations
A potential limitation to this study is the motivation of participants to take part, as many participants related this motivation to negative feelings regarding national treatment provision for leg ulcers. This may indicate a sample of particularly motivated individuals who may also be more motivated to adopt an active approach to treatment and an acute characterisation of their condition than the general leg ulcer patient population. In order to counteract this limitation, future research should be conducted regarding the experiences of those individuals who have not undergone Superficial Venous surgery in the treatment of their leg ulcers and who are not recruited from a private medical clinic. Whilst it could be suggested that the sample of the current study might represent a wealthier demographic, due to their recruitment from private healthcare, observations during the study and through further research with this group would suggest that patients at this clinic represent a diverse section of society. This is thought to be due to the limited availability of equivalent treatment on the NHS, therefore many patients who would not normally choose to have treatment with a private provider may choose to explore this avenue for their leg ulcer treatment.

5.5.2 Clinical implications
This study’s findings suggest that patients ‘perceptions of chronicity’ with regards to their condition can play an important role in their illness beliefs and their approach to
treatment. It also emphasises the importance of a participants expectations for treatment versus their experiences. Both of these elements could be used to enhance the patient experience and reduce the likelihood of dissatisfaction with treatment. Many participants suggested feeling marginalized or experiencing a lack of support from healthcare providers, and this information could be used to provide a more holistic treatment experience to service users and improve the relationship between patients and clinicians. The findings emphasise the importance of psychological involvement throughout the treatment journey, as a means to explore a patients expectations for treatment and to ensure that these are taken into account when designing a treatment plan.

The findings also question whether leg ulcers are considered a chronic or acute condition, or whether they are more in line with a ‘cyclical timeline’ of illness. The way in which the medical profession considers leg ulcers may influence patient’s behaviour and the extent to which they feel their beliefs match those who are treating them. Healthcare professionals should carefully consider the language they use when discussing an individual’s condition, particularly around illness trajectory and future outlook. Further research is required to explore this issue and formulate specific recommendations. This research could have important implications for how clinicians discuss leg ulcers with patients and the way in which treatment options are presented.

5.5.3 Future recommendations
The next study in this thesis will explore the experiences of patients who have undergone non-surgical treatment for their condition, in order to explore their experiences of treatment and the factors that are important in their treatment pathway. The findings of this study can be seen in Chapter 6. Future research could also further examine the issue of leg ulceration as a chronic or acute illness. Quantitative measures could be used to explore the beliefs of a larger population, and these views could be explored in health professionals and relatives, as well as patients. This research should examine such perceptions over time, as it is possible that perceptions of chronicity change over time and with treatment experiences. Such research would provide a useful insight into the perceptions of the leg ulcer population regarding their illness and how this compares to the views held by health professionals. This could be used to shape the manner in which individuals with leg ulcers are approached and treatment is explained,
as well as further contributing to our understanding of the psychological journey through treatment.

5.5.4 Conclusions
This was a qualitative semi-structured interview study, which aimed to explore patient experiences of Superficial Venous Surgery for the treatment of leg ulceration. Three primary themes were identified: living in flux, perceptions of chronicity and expectations. This analysis contributes to our understanding of patients’ treatment experience in its in-depth exploration of patients’ beliefs surrounding their condition and the associated treatment. This study stresses the importance of time, in terms of participant identity, participant’s perception of their condition and their expectations of treatment. Important suggestions are made regarding how patient beliefs may interacts with those of their clinicians, via the treatment approach being offered. In addition, the findings are discussed within the context of agency and illness as a metaphor. The clinical implications of these findings regard the possibility of increasing patient satisfaction and in the importance of specific language on the interactions between doctors and patients. These findings will be extended in the next study, in order to consider how patients’ experiences of non-surgical treatment might further our understanding, but further research could also explore these concepts quantitatively with patients, their families and health professionals.
Chapter Six

Study 4: Patient experiences of conservative treatment for leg ulceration: a qualitative study

6.1 Overview
The results from the previous chapter illustrate the importance of empowerment and agency in the treatment process, as evident in the experiences of those who have undergone surgical management of their leg ulcers. Whilst these factors were found to have an important influence on the cognitions and wellbeing of those who had undergone surgery, it is not known whether these same factors are salient in other treatment modalities and the in-depth experiences of participants undoing non-surgical treatment for leg ulcers remains unexplored. The present study aims to investigate patient experiences of non-surgical treatment for leg ulcers, in an effort to understand the experience as a whole, and establish factors linked with patient wellbeing.

6.2 Introduction
Leg ulcers are most commonly treated in the community using a variety of dressings, advanced dressings and compression bandaging. Whilst there is much existing research regarding individual’s experiences of having leg ulcers and their impact on daily life, there is little research to specifically examine experiences of treatment. In the last chapter, it was concluded that empowerment and agency played an important part in the surgical treatment process. No other research, however, has examined patient experience of treatment for leg ulcers and thus little is known about experiences of other treatment modalities. Whilst some quantitative research comparing treatment outcomes have included ‘quality of life’ measures, few studies have examined such outcomes in greater depth. Similarly, little qualitative literature has explored this subject, focusing instead on the experience of the illness and in the course of this research incidentally capturing elements of the treatment experience. For example, a synthesis of qualitative research by Briggs & Flemming (2007) aimed to investigate patients’ experiences of living with a leg ulcer, identifying the theme ‘Describing the leg ulcer journey’. This theme describes treatment as taking either a ‘chronic care route’ or a ‘specialist treatment route’, and the ‘patient-professional relationships’ as being important to patients’ experiences. Equally, Chase, Melloni, & Savage (1997) discussed
the physical limitations that accompany treatment, the point at which participants sought help and the issues that are caused by having leg ulcers and their associated treatment in warm weather. Neither study, however, explicitly aimed to explore patients experiences of leg ulcer treatment, nor does any research to date appear to have conducted an in depth investigation of this experience.

In contrast, ‘experiences of treatment’ have been extensively researched in many other conditions, particularly via the use of qualitative research methods. To give just a few examples, in recent years studies have been conducted with individuals receiving therapeutic treatment for anorexia nervosa (Rance, Moller, & Clarke, 2015; Smith et al., 2016), walking as treatment for intermittent claudication (Galea Holmes et al., 2015), acceptance based pain management programme for chronic pain (Mathias et al., 2014), home haemodialysis for renal failure (Cases et al., 2011), complimentary medicine for a variety of conditions (Cartwright & Torr, 2005), and awake craniotomy for brain tumours (Howie et al., 2015). Such studies contribute to our understanding, but also add to practice, due to the relevant and practical recommendations they generate for future treatment. Many studies reveal elements of treatment that patients find to be particularly influential in terms of their overall satisfaction, and such elements often have knock-on effects on patient outcomes. For example, research has demonstrated that greater levels of satisfaction with communication in the consultation is associated with adherence to treatment, understanding of information and later recall (Ong et al., 1995; Zolnierek & DiMattero, 2009). Therefore, the practical recommendations made by many studies of this kind are not just significant for satisfaction and psychological wellbeing, but may also influence patients’ physical outcomes from treatment.

6.1.1 Aims
The aim of the current study was to investigate experience of non-surgical treatment for leg ulcers. Such treatment typically includes various dressings, advanced dressings, topical medications and compression bandaging. Whilst in the previous chapter it was found that empowerment and agency were important elements of surgical treatment for leg ulcers, these elements were thought to be specific to the sophisticated high-status intervention that surgery represented for those patients who underwent it. The current study will investigate whether this is indeed the case, and whether there are other salient elements of non-surgical treatment that influence patients’ wellbeing and beliefs in a
similar manner. Qualitative methods were employed, as in the previous study, due to the exploratory nature of the study and in order to ground the findings in participants’ lived experiences.

6.3 Methods

6.3.1 Design
This was a qualitative semi-structured interview study analysed using Thematic Analysis (Braun & Clarke, 2006). Qualitative methods were chosen due to the exploratory nature of the study, in order to collect rich in-depth accounts of participant’s experiences. Participants were invited to complete a telephone interview with the researcher, except in the case of hearing difficulties or similar circumstances, in which case a face-to-face interview was made available to participants. All details of the method, except recruitment, were a replication of those described in Chapter 5 (see section 5.3). Similar materials were used, providing participants with an information sheet (see Appendix M), asking participants to sign a consent form (see Appendix J) and providing them with written debrief information (see Appendix C). The interview protocol also differed slightly from that used in the Chapter 5, in order to focus on treatment in general, rather than surgical treatment specifically (see Appendix N).

6.3.2 Recruitment
Prospective participants were recruited from a previous quantitative research study (see Chapter 3), and had all indicated that they would be interested in taking part in future research on a similar topic. Participants were approached via email or post and were invited to take part in a telephone interview regarding their experiences of treatment for leg ulcers.

Participants were required to meet the following inclusion criteria:

- To be aged over 18.
- To have given informed consent.
- To have a good understanding of written and spoken English.
- To have previously had, or currently be receiving, treatment for leg ulcer(s).

6.4 Results
Twenty-one participants (n=21) were interviewed, all of whom were currently receiving, or had previously received, conservative treatment for leg ulcers. Participants
were aged between 49 and 87 years old (mean=65.15), and mean leg ulcer duration was 124 months (range 12-456). Thirteen of the participants were male, and eight were female. Nine participants considered their leg ulcer to be ‘unhealed’, six participants considered their leg ulcer to be ‘healing’, five participants considered their leg ulcer to be ‘healed, and expect to return’, and one participant considered their leg ulcer to be ‘healed, and don’t expect to return’ (see Table 15).

Table 15. Participant demographic information

<table>
<thead>
<tr>
<th>Pseudonym</th>
<th>Gender</th>
<th>Age (years)</th>
<th>Leg ulcer duration (months)</th>
<th>Leg ulcer recurrence</th>
<th>Current treatment</th>
<th>Perception of ulcer status</th>
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<tr>
<td>Kevin</td>
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<td>58</td>
<td>60</td>
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<td>Healed (expect recurrence)</td>
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<tr>
<td>Martin</td>
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<td>12</td>
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<td>James</td>
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<td>108</td>
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<td>Dressings</td>
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<td>Healed (expect recurrence)</td>
</tr>
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<td>120</td>
<td>20</td>
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</tr>
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<td>/</td>
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<td>0</td>
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</tbody>
</table>
Twenty participants were interviewed via telephone. One participant took part in a face-to-face interview due to hearing difficulties. Mean interview duration was 47 minutes, with all interviews lasting between 28 and 69 minutes.

Two primary themes were identified: ‘Failure’ and ‘Powerlessness’. Transcending these was the theme of ‘Relationships’. These will now be described and illustrated with exemplar quotes.

**Theme 1 – Failure**

Throughout the course of the interview, participants described elements of their experience that they felt had failed. Participants discussed believing treatment was failing due to a non-tailored, non-specialist and ‘trial and error’ approach by clinicians. They also described dissatisfaction with the communication that had taken place surrounding treatment, suggesting that this had a significant impact on their treatment experience. As a result, this theme will be explored through two subthemes: ‘treatment’ and ‘communication’.

**Treatment**

Participants overwhelmingly described treatment as inconsistent across time and between practitioners. Many described seeing a collection of different professionals,
each with a different method of treatment and often openly critical of the other’s approach. This led participants to feel their treatment was based on a ‘trial and error’ approach. Many mentioned feeling like ‘guinea pigs’:

“They would kind of... both of [the nurses] would groan at the others treatment of it so you never got any constant treatment, as I said, I felt like a bit of a guinea pig.”

– Susan

As a result, many lost confidence in treatment and practitioners. In addition, a lack of a clear knowledge-based treatment protocol led participants to doubt the qualifications and suitability of those treating them:

“There wasn’t a regime they all followed, it was sort of trial and error I thought. I got the impression they were sort of clutching at straws and not experienced.” – Michael

“I feel that in some instances the staff aren’t trained on what they’re being asked to do, they don’t know enough about the problem and they’re just grasping thin air” – Gary

Many suggested that specialist management would have been a more appropriate or effective pathway, which would have given them more confidence in treatment. Participants did not specify a treatment modality, but suggested that consultation with a specialist may have been more effective and given them more confidence in treatment. Instead, participant’s frustrations and lack of belief in practitioner’s abilities led many to self-manage elements of their treatment at home:

“I refuse to go back, because every nurse had their own theory and their own method of treatment... they just didn’t know what they were doing, that was my view on the matter” – Eric

“It never used to work anyway, so I just wanted it to be easy” – Martin

Participants described having little confidence in the results of treatment by practitioners, and therefore described self-management as being an easier way to get the same results.

Communication

Participants also described a paucity of good communication surrounding their treatment. Clinicians were at times described as ‘dismissive’ (Karen, line 430) or
‘condescending’ (James, line 252). In addition, some felt clinicians were rushed and that patients were not seen as individuals:

“The district nurse didn’t seem to care, I was just another tick in the box somewhere. She wouldn’t, she was not prepared, well none of them were prepared to put any extra effort into it. All they were going to do was maintain it, you need a bandage on your leg, stick a bandage on your leg, we’re not going to tell you how to get rid of it because we don’t know and we don’t care” – Eric

Eric’s account can be seen to reflect poor communication of the nurse’s knowledge, of the reasons for her treatment approach and of her own empathy. A similar situation is reflected in participant’s perceptions of how practitioners communicate with each other. As described above, many discussed clinicians complaining about other’s treatment approach, reinforcing a lack of patient confidence in their treatment and those delivering it. This is also evident in clinician’s attention to written communication from other professionals, as Karen describes:

“It’s written right on the front of your notes what I can and what I can’t have, what I’m allergic to, etc. And they still say when they see it, oh well put some Atrauman on that and I go ‘no you won’t, I’m allergic to it’, ‘oh erm…’, I say ‘look at the front of the notes … it gets to the point where I feel sometimes I do have to really take charge”

– Karen

Participants ‘trial and error’ perception of treatment may also be a manifest of this poor communication between clinicians, or it could be symptomatic of poor explanation between clinician and patient. The failures in both treatment and communication described by participants are inextricably linked, as it is not clear to what extent participants would have been more satisfied with treatment had they perceived communication to be better.

**Theme 2 – Powerlessness**

Participants described a sense of ‘powerlessness’ associated with treatment. On a regular basis many felt that they weren’t listened to by those treating them, but they also felt an overall lack of control due to the recurrence of the ulcers and the failure of treatment to achieve healing. As a result, participants appeared ‘resigned’ to their condition; a state quite distinct from the more traditionally discussed ‘acceptance’ of a
chronic condition. This theme is discussed further through the ‘patient voice’ and ‘resignation’ subthemes.

**Patient voice**

A recurring theme throughout participant’s narratives was a feeling of not being listened to by the professionals treating them. Participants described having developed their own knowledge base and their own beliefs about their condition, due to the length of time that many had experienced leg ulcers, but felt that they could not express these beliefs:

“I do not have any say in the matter, that’s one thing that annoys me most of all. It’s quite nice being able to say something to someone like you, because I feel that I don’t really have a say, I feel like I shouldn’t … I feel like I shouldn’t have an opinion about anything ... The fact that I’ve had it long enough to know what upsets it and what doesn’t, but I don’t feel I’ve got the authority to say so” – Shirley

When participants did express their opinions regarding treatment they described these being ‘overridden’ (Shirley, line 157) or not taken into account by those treating them:

“My ideas certainly weren’t taken into consideration by anybody, from the GP all the way up. I don’t think anybody seemed to be interested in what was going on” – Gary

Similarly, participants described a reticence to act on their own opinions between treatments, due to potential ramifications for future treatment. For example, Marjorie discussed the difficulties with wishing to take off a dressing due to pain:

“I think possibly if I do take a dressing off then one does get a, for really for genuine pain, then you get a reputation, well ‘why bother to see her? She always takes it off, so might as well not come’” – Marjorie

Such descriptions were frequent throughout the interview process, and appeared to be an significant element of the treatment experience for many participants. A feeling of powerless was evident throughout the treatment pathway, with one patient describing being ‘careful about what I say’ (Shirley, line 307) for fear of this negatively influencing her treatment. Many patients would only feel able to intervene if the impact of not doing so would be detrimental to their health, as can be seen from Karen’s allergy example in the previous theme.
Resignation

Feelings of resignation by participants were evident in discussions of treatment and in their expectations for the future. In terms of treatment, these feelings were associated with a failure to effectively heal the leg ulcers or prevent recurrence, and participants indicated a loss of hope in the efficacy of future treatment:

“I must say after the first few [treatments], two or three, I thought ‘no this isn’t going to work’. Yeah I was very negative, because I thought ‘oh it’s just going to be another one of these things that they’re going to try that isn’t going to work’” – Michelle

The frustration that participants were feeling is evident from their accounts. This appears to stem from the relentlessness of treatment, the differences between their own experiences and what clinicians are telling them, and therefore a lack of belief in the treatment that they are being prescribed:

“It felt like a never-ending circle. No-one really has an answer and everyone keeps telling me the same thing, just use compression and they don’t come back – well obviously that so-called treatment, if you like, is flawed. It’s a flawed system, it doesn’t work, you do everything you’re told, but they still come back” – James

Despite these feelings, many participants were still adhering to treatment, potentially due to a lack of alternative options. However, it’s suggested that these feelings may be influencing how they communicate with healthcare professionals:

“Is there anything to be gained from saying anything to anybody, because like I say, nobody can do anything to help” – James

Quotes such as James’ above also indicate a more general resignation to the condition, and many participants discussed coming to this feeling after an extended period of ineffective treatment:

“Every time I went to see the consultant ... I was hoping he’d have some sort of answer for when it was going to end, and eventually I figured out ‘this isn’t going to end’.” – Jack

In contrast to positively framed discussions of ‘acceptance’ in the chronic conditions literature, for many participants it was evident that these feelings were not about
accepting the limitations of their condition, but about a lack of hope, a fear that their condition may worsen and ‘coming to terms’ with the future:

“It’s in the back of my mind they’re always going to come back. I’ll have them for life and I’ve also come to terms that one day they’ll probably take the lower half of my leg off. Because it’s not getting better, it’s not getting worse but … I think you’ve really got to come to terms with things like that” – Jack

Whilst ‘acceptance’ may imply a positive or helpful state of thinking about a condition in order to live with it, the feelings of these participants possessed a more melancholy tone.

Participants therefore described their experiences in terms of failure, with a focus on treatment and communication, and a sense of powerlessness characterised by a feeling of having no voice and of resignation. Transcending these themes was the central role of relationships, which could both enhance and undermine their experiences.

**Theme 3 (Transcending) – Relationships**

Transcending both of these two themes is the overarching theme ‘Relationships’. The importance of patient-clinician relationships were described in terms of participant’s experiences of treatment, their beliefs about their condition and their expectations for the future. The importance of these relationships is particularly striking throughout the communication element of the first theme, ‘Failure’, and in discussions of patient voice within ‘Powerlessness’. Quotes demonstrating these themes are characterised by language such as ‘dismissive’ or ‘condescending’, and descriptions of clinicians who ‘didn’t seem to care’. Participants were perceptive to clinician’s attitudes throughout treatment and also described feelings of not being afforded adequate respect or empathy:

“You’re sometimes treated as if you don’t have any intelligence or you don’t know, kind of, what’s going on.” – Susan

“I’m not looking for sympathy, I don’t mean that, I just feel that, it just makes me feel sometimes that… I think they feel I’m a wimp, you know” – Shirley

Examples like these emphasise not only the lasting impact that these experiences may have on patients, but also the importance of non-verbal communication for how patients
feel about treatment. Participants discussed the consultation process and not feeling clinicians had adequate time to focus on each patient:

“You always feel sometimes when you do see consultants and whatever, that their time is valuable, of course it is, I’m not the only patient they’re going to see on that day, but you do feel as though they’re a bit *interviewee makes rushing noises*, trying to get all the questions out in the space of two minutes and then they’re off to see the next patient” – Karen

Tellingly the patient does not describe the time that they had with the clinician as not being long enough, but rather the impression that was given based on the consultant’s mannerisms.

From the descriptions above, and examples throughout the two primary themes, it appears that a poor patient-clinician relationship can be detrimental to confidence in treatment and have a significant impact on patient experiences. On the other hand, participants also discussed how positive relationships with clinicians can have powerful redemptive qualities, even when outcomes remain the same:

“Obviously the one-to one interaction between me and a nurse was really helpful, because I could talk to them and they’d listen... I did look forward to seeing them because they were nice people. I’m not saying they cheered me up and made me feel absolutely fantastic about the ulcer, but I felt, I just felt a little bit more confident”

– Jack

When a good relationship existed between patient and clinician, positive interactions were described as possible even when clinicians were very busy; demonstrating the importance of good communication:

“Usually the staff are really very pushed, but they are really kind, everybody is very kind and sympathetic” – Marjorie

Not only did participants discuss the impact that such positive relationships had on their treatment experience, but they also related this to better physical and psychological outcomes:

“If you believe in the practitioner you’re much more likely to have a quicker recovery than being pushed from pillar to post” – Paul
Whilst participants discussed the detrimental nature of poor communication and a poor patient-clinician relationship, these positive evaluations and their respective impact also demonstrate the redeeming qualities that good relationships can have for the treatment experience.

6.5 Discussion
This study aimed to explore patients’ experiences of conservative treatment for leg ulcers. Two primary themes were identified relating to ‘Failure’ and ‘Powerlessness’. Transcending these themes was the key role of ‘relationships’.

The ‘Failure’ theme encapsulates participants’ feelings that treatment had failed in its effectiveness to heal their leg ulcers, and in the communication involved in its delivery. Many had lost confidence in those delivering treatment, as a result of the amount of time that they had been undergoing treatment and the lack of progress observed. They described a ‘trial and error’ approach by the clinicians who treated them, as various treatment methods were trialled in quick succession with little explanation of the rationale behind their use. Participants suggested that treatment from a specialist team would have given them more confidence, seemingly because of the expertise that would accompany this treatment. This appears to be closely linked to communication, a subtheme within ‘failure’, as it is unclear whether the perceived ‘trial and error’ approach and lack of expertise that patients describe may actually be due to a lack of effective communication between clinician and patient. The majority of patients described experiencing poor communication at some point during treatment; describing encounters with condescending or inattentive clinicians and the negative impact that this had on their confidence in treatment.

The relationship between satisfaction with communication and overall satisfaction with treatment is well documented (Ley, 1990; Ong et al., 1995), with further repercussions for later recall of key information and patient adherence (Moore et al., 2004; Zolnierek & DiMattero, 2009). Similar patterns are observed in the present study, as patients report low levels of satisfaction related to their treatment and the poor communication they have experienced from healthcare professionals. Such dissatisfaction led many patients to shun the treatment they were receiving and self-manage their condition at home. Participant’s negative assertions regarding leg ulcer treatment echo recent findings by Guest, Gerrish, Ayoub, Vowden, & Vowden (2015),
who suggest there is a lack of continuity of care and specialist involvement in leg ulcer treatment. Guest et al. suggest that such experiences may impact on patient healing and imply issues with ecological validity in controlled trials, as patients’ experiences in clinical studies may be substantially different from the real-world treatment environment. Such research demonstrates the importance of these elements to patients’ physical outcomes, in addition to their contribution to patient satisfaction.

The second theme in this study, ‘powerlessness’, captures the lack of control that participants felt regarding their treatment. Participants felt unable to express opinions about their treatment, displaying frustration at not feeling listened to or consulted about decisions. After lengthy periods of illness, patients perceived themselves as relative experts in their condition and their treatment, but did not feel that this expertise was recognised by those treating them. This further reinforces the importance of communication and the overarching theme of ‘relationships’. Participants also demonstrated feelings of resignation, negatively framing their expectations for treatment and their future health, and this echoes earlier findings by Chase et al (1997). In their research into experiences of living with leg ulcers, Chase et al. (1997) also identified a feeling of ‘resignation’ amongst participants, although they relate this more to a lack of understanding of the causes of leg ulcers and how treatment may help. This was not found to be the case in the present study, as many participants understood the aetiology of their illness, with many demonstrating a good understanding of venous disease and its implications. The present findings might suggest a more widespread feeling of ‘resignation’ related not only to patient understanding, but also the treatment process itself.

Such feelings of ‘resignation’ sit in contrast to the more commonly discussed concept of ‘acceptance’, in the chronic illness literature. Whilst acceptance is thought of as a desirable end point for patients coming to terms with their illness and moving forward with their lives (Telford et al., 2006), the feelings of ‘resignation’ observed in this study were encapsulated in more despairing and melancholy tones. Such descriptions find parallels with the construct of ‘resigning acceptance’ described by Nakamura & Orth (2005). Nakamura & Orth (2005) suggest that whilst acceptance has been demonstrated to have a positive impact on coping, adaptation and pain tolerance in some conditions (Hayes et al., 1999), in certain circumstances ideas of acceptance may be maladaptive and harmful. They therefore recommend two separate constructs of
acceptance: ‘active acceptance’ and ‘resigning acceptance’. Whilst both constructs involve abandonment of effort to control or influence the situation, they differ in terms of an individual’s psychological reaction. ‘Active acceptance’ is an adaptive reaction associated with positive psychological outcomes and characterised by dealing with new situations in a constructive manner. Whereas ‘resigning acceptance’ is characterised by negative expectations about the future and a loss of hope. This latter construct is associated with passivity, disappointment and negative psychological outcomes. Whilst it is not clear from our results that participants have become passive in other areas of life, they appear to experience negative emotions such as frustration and hopelessness and thus the subtheme of ‘resignation’ could be seen to indicate a tendency for ‘resigning acceptance’ within this group.

It should be noted that several deviant cases did not demonstrate the same feelings of ‘resignation’ and possible ‘resigning acceptance’ at the time of interview, and it is suggested that these were cases where treatment had been more successful or where the participant described higher levels of satisfaction with treatment. Even in these cases, however, participants often described past experiences where they had not been so satisfied with treatment and as a result were more ‘resigned’ regarding their treatment trajectory. This perhaps emphasises again the importance of the whole treatment experience for participant outcomes and how patients’ illness trajectories may be influenced by their experiences. ‘Resigning acceptance’ is clearly a distinct experience from more traditional definitions of ‘acceptance’ and clinicians involved with leg ulcer treatment should be aware of the possible negative psychological outcomes that could accompany this state.

An overarching theme from the patients’ experience of treatment was ‘Relationships’. Participants described their relationships with clinicians as an important factor in their evaluation of treatment, and described experience of many different relationships through the course of treatment. A poor relationship with clinicians was characterised by a lack of clear treatment approach, failure to acknowledge the patients’ opinions and poor communication. In contrast, good relationships were characterised by empathy, approachability, the seeking of patient opinions and good communication skills. When a good clinician-patient relationship was established participants described the confidence that this gave them and the positive impact this had on their treatment experience. These polar experiences and
their implications demonstrate the redemptive quality that a good clinician-patient relationship can have on an otherwise negative illness experience.

This central role of ‘relationships’ reflects the extensive literature regarding the doctor-patient relationship. As previously discussed, satisfaction with communication in a consultation is closely linked to overall satisfaction, recall of information, and adherence (Ley, 1990; Ong et al., 1995; Zolnierek & DiMattero, 2009), and further research has suggested that a good relationship between individuals and the healthcare professionals involved in their care can lead to a greater sense of wellbeing, security and more confidence to self-manage their condition (Fox & Chesla, 2008). Fox and Chesla (2008) identified the value of mutual respect, shared decision making, empathy, good communication and personableness for good relationships. They also describe the difficulties experienced when a relationship is characterised by one party having more perceived control, and the difficulties establishing a good relationship when the health care professional is not perceived to be managing the condition competently; echoing the themes of ‘powerlessness’ and ‘failure’ found in the current study. This emphasis on relationships’ is also reflected in the leg ulcer literature more specifically, as a recent study examining the illness experiences of individuals with leg ulcers suggests that these experiences and patients illness-related beliefs may be influenced by relationships with healthcare professionals (Cipolletta & Amicucci, 2015). Another study, conducted by Briggs & Flemming (2007) synthesised the qualitative literature available at that time, and found that patients experience of living with a leg ulcer was influenced by the patient-professional relationship. The authors suggest that nurses may have therapeutic value and provide strategies for living with a chronic condition, but that individuals also reported a lack of empathy, trust and understanding in these relationships. Echoing these findings, participants in the current study discussed a range of relationships related to their treatment. Those relationships that were described positively appeared to give participants more confidence in their treatment and a greater sense of overall satisfaction with care, not necessarily connected to physical outcomes.

Existing research in the area of doctor-patient relationships can be seen to come to fruition in the concept of Patient Centred Care. Whilst definitions of person-centred care vary, it is generally understood to be a relationship-centred approach that is “respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions” (p.6) (Institute of Medicine,
The approach aims to improve clinical practice by considering the patients' personal characteristics and beliefs, as well as their physical condition, and actively involving them in their care (Epstein, Fiscella, Lesser, & Stange, 2010). Patient-centred care is not just influential in patient satisfaction and wellbeing, but has also been related to physical health outcomes (Kaplan, Greenfield, & Ware, 1989), and equivalent concepts can be seen across a wide range of disciplines. For example, in the educational psychology literature the concept of ‘learner-centred education’ was born out of writings by Carl Rogers and emphasises the role of genuineness, empathy, care, and student voice in order to achieve optimal learning. Learner-centred education is believed to be a vital component for thriving cognitively and emotionally in an educational environment (Cornelius-White, 2007) and sees many similarities with patient-centred care. In psychotherapy, the ‘therapeutic alliance’ may also be seen to hold similar values, and has been consistently identified as a significant factor in client outcomes (Horvath & Symonds, 1991; Krupnick et al., 1996). Whilst specialist treatment techniques evolve over time and are crucial for the field, the therapeutic alliance remains a significant and enduring element of good psychotherapeutic practice (Lambert & Barley, 2001). Applications such as these demonstrate the pervasiveness of genuine care and connections across a range of domains as elements that can drive wellbeing and achievement. Adding to this literature, the findings of this study suggest that much of patients’ experience with leg ulcer treatment is characterised by the presence, or lack of, a patient-centred approach. Participants discussed how elements such as relationships played a key role in their treatment experience, regardless of physical health outcomes, and this finds resonance in an often discussed element of medical and veterinary teaching. In such contexts, it is taught that many patients will assume the individual treating them is skilled in the physical elements of their care, and thus much value is placed on the more holistic elements of the consultation, such as communication and trust (Huntington & Kuhn, 2003). Whilst many of the participants in this study were clearly disappointed with poor physical outcomes, those who described positive experiences with healthcare professionals discussed the redemptive qualities that this carried.

6.5.1 Strengths and limitations
As with many volunteer samples, the motivation of participants in this study could be seen as a limitation. Many participants were keen to report poor treatment experiences,
and it could be suggested that these individuals possess stronger views than the wider sample population. However, when discussing their treatment history, many participants also reported positive experiences with certain clinicians or treatment regimes. This may suggest that by asking participants to explore their history of treatment, as well as recent experiences, a variety of opinions were gathered. It was apparent through data collection that many participants had a long history of leg ulcer treatment and had tried a multitude of treatments. This may have led to a more heterogeneous sample than studies exploring patients’ experiences of treatment in other chronic conditions.

‘Characteristics of good qualitative research’ were consulted throughout design, data collection, analysis and write-up of this study (Yardley, 2000), and based on guidelines by Guest, Bunce and Johnson (2006) it is believed that data saturation was achieved. These factors are hoped to increase the validity of the findings and are considered strengths of the study. In addition, many participants suggested that taking part in this research may have had therapeutic value. Participants described frustration with not being able to express their opinions regarding treatment to clinicians, and the release that they felt from being able to take part in this research. Whilst it is not the intention of the research method to provide therapeutic intervention, this benefit to participants may also be seen as a strength of the research.

6.5.2 Clinical implications

It is suggested that whilst good physical outcomes are the ultimate aim in leg ulcer treatment, many other elements of treatment are also considered important to the patient. Whilst complete healing of the ulcer is not always possible, there are other principal elements of the experience that could be influenced for the better, including: doctor-patient relationships, communication and patient voice. These principles encapsulate Patient Centred Care, an approach that is already being implemented in many areas of medicine and which features in the National Institute for Health and Care Excellence (NICE) recommendations for many chronic illnesses. Importantly, a large body of research exists examining patient centred care and demonstrating its influence on patient outcomes, with practical recommendations for implementation. It should be noted that some reports of good practice were evident in participant’s accounts for this study, but it is the pervasiveness of this approach across healthcare professionals and throughout national leg ulcer management that appears to be lacking. Particular
attention should be given to elements such as patient voice, shared-decision making and good communication.

Many practical recommendations for implementing patient-centred care have been formulated and tested for use in healthcare settings. For example, Ekman et al. (2011) suggest a series of routines that can be established by healthcare professionals to ‘initiate, integrate and safeguard’ patient-centred care in everyday practice. Aside from the challenges associated with incorporating any new approach into a busy working environment, the challenge for leg ulcer treatment may be in the disparate manner that treatment is organised around the UK. As treatment is often delivered in the community by non-specialist clinicians, including district nurses and general practitioners, there is not a clear route of disseminating clinical recommendations throughout leg ulcer care. Whilst some specialist leg ulcer clinics exist in the UK, it is unclear how many individuals have access to these services and therefore any changes to care delivery would need to be applied to both primary care (e.g. GP surgeries and district nurses) and secondary care (e.g. specialist clinics and tissue viability nurses). This has implications for the current study, regarding patient-centred care recommendations, but also for many other clinical guidelines.

6.5.3 Future recommendations

Many of the findings from this study are related to doctor-patient relationships and elements of this relationship, such as communication. An interesting direction for future research might be to explore the clinician’s point of view. Qualitative exploration of the clinician’s experience, the reasoning behind some of the treatment decisions that patients describe and their evaluation of the doctor-patient relationship might provide some interesting reflections on the current research and help to develop clinical recommendations to improve patient outcomes in leg ulcer treatment. An example such research in another chronic condition is demonstrated by Nelson, Barker, Griffiths, Cordingley, & Chew-Graham (2013), who conducted a similar study regarding in-depth experiences of psoriasis treatment. In order to investigate both patient and clinicians perspectives of psoriasis, Nelson et al. conducted semi-structured interviews with members of both groups and analysed these using Framework Analysis. Such methods allowed the authors to compare and contrast the feelings of patients and clinicians, finding areas of agreement and disagreement that could be taken forward to form highly-relevant practical guidelines for future treatment of the condition. Research of
this nature may also help to aid practical recommendations for how any resulting guidelines could be disseminated amongst clinicians who treat leg ulcers, as this appears to be one of the major challenges to clinical application.

6.5.4 Conclusions
This qualitative semi-structured interview study aimed to investigate patient experiences of non-surgical treatment for leg ulcers. Two primary themes and one overarching theme were identified: Failure, Powerlessness and Relationships. Feelings of dissatisfaction were found to stem from poor treatment progress, and the resulting frustration and hopelessness led many to a state of ‘resignation’. These feelings are discussed in contrast to traditional descriptions of ‘acceptance’ in chronic illness. Relationships were found to be an overwhelmingly influential factor in participant’s overall treatment experience, with particular reference to communication and patient voice. On the basis of these findings, clinical recommendations were made regarding patient-centred care and the challenges of encouraging such an approach in leg ulcer management were discussed. It is suggested that future research examine the clinician’s point of view in leg ulcer treatment, and specific methods of investigation are suggested. Overall, this study stressed the importance of good relationships in patient treatment, as they hold the power to be both highly damaging and greatly redemptive for patient evaluations of their treatment experience.
Chapter Seven

General Discussion

7.1 Overview
Whilst a significant body of research has been dedicated to exploring the experiences of those living with chronic leg ulceration and the physical treatment outcomes, little previous research had explored the impact of treatment on patient quality of life and no previous research had explored patients’ qualitative experiences of this treatment. Furthermore, little previous research in this area had addressed these issues from a psychological perspective, leading to a focus on biological or physical outcomes. Accordingly, this thesis aimed to address the gap in the existing literature, regarding the impact of chronic leg ulceration on quality of life, the psychological impact of treatment, and patient experiences of treatment. In particular, it aimed to draw upon the models and principles of health psychology theory to explore predictors of health related quality of life in individuals with leg ulcers, to investigate the psychological impact of surgical management for leg ulceration, and to explore the experiences of individuals undergoing treatment for chronic leg ulceration. These aims were achieved through a systematic review of the literature and four empirical studies. This final chapter will briefly present the findings of each of these chapters. It will then highlight key themes across the thesis, before considering the limitations and implications of the thesis as a whole.

7.2 Summary of findings
Chapter two used a systematic review of the literature to establish the comparative impact of conservative and surgical treatment on patient quality of life. It was found that all studies observed an improvement in patient quality of life to some extent, regardless of treatment type, and those individuals with greater ulcer healing appeared to report significantly larger improvements in quality of life. Bandaging type was not found to influence quality of life outcomes, however, surgical treatment was suggested to lead to better quality of life outcomes than compression bandaging alone. This review allowed synthesis of existing research and highlighted issues with the quality of data reporting in this research area. It was suggested that, whilst there appeared to be
differences in quality of life outcomes between surgical and conservative treatment, the reasons for these differences were not clear and further research was recommended to explore the processes underlying such differences.

Chapter three utilised a cross sectional quantitative design to investigate predictors of quality of life in leg ulceration, and the mediating role of psychosocial factors. Involving a sample of individuals with current or previous leg ulceration, the findings of this study supported a relationship between clinical ulcer severity and multiple elements of patient quality of life. Negative mood was found to mediate the relationship between clinical severity and quality of life, whilst social support was found to have an indirect effect on general quality of life through relationship quality. These findings support previous research investigating the importance of relationship quality in caregiving, highlight the role for psychological intervention in leg ulcer care, and stress the importance of including psychosocial variables in future investigation.

Chapter four explored the impact of superficial venous surgery on clinical, psychosocial and quality of life variables, in a quantitative cohort study with a small sample of individuals undergoing treatment at a private medical clinic. All participants were found to report improvements in clinical ulcer severity at six months post-surgery, and statistically significant improvements were observed in emotional aspects of disease-specific quality of life. Correlations were observed between perceived clinical improvements and participant quality of life, however, these relationships were not statistically significant and the small sample size in this study limited the conclusions that could be drawn. This study demonstrated the potential psychological impact of surgical management, highlighted the challenges of recruitment in this population, and suggested various avenues of future qualitative and quantitative investigation regarding patient beliefs.

Chapter five employed a qualitative design with in-depth interviews to explore patients’ experiences of surgical management for leg ulcers, specifically superficial venous surgery. The analysis identified three primary themes: Living in flux, Perceptions of chronicity, and Expectations. Participants reported the frustration and anxiety of living with recurrent ulcers before surgery, and described the mismatch between their perception of ulcers as an acute condition and traditional conservative treatment approaches. In contrast, surgical management validated these perceptions and
was more aligned with their expectations from treatment. Whilst some participants maintained an expectation that their ulcers may return, they also discussed feelings of empowerment after treatment. These findings stressed the importance of ‘hope’ and ‘agency’ in the treatment process, and were discussed in the context of surgery as a ‘high status intervention’. Implications for patient satisfaction and doctor-patient communication were considered, as well as the applicability of these themes to non-surgical management.

Chapter six applied a similarly qualitative methodology to chapter five, extending this investigation to explore the experiences of patients undergoing non-surgical management for leg ulcers. Analysis identified two primary themes and one overarching theme: *Failure, Powerlessness and Relationships*. Frustration with the treatment progress and a perceived failure by those treating them was found to lead many participants to a feeling of ‘resignation’. These feelings were often closely linked to the level of control that patients felt over their treatment and their illness, with many participants expressing concern over the lack of ‘patient voice’ involved in treatment. Transcending these themes, the relationships between patients and clinicians were found to be highly influential for the patient experience; holding the power to be both highly damaging and greatly redemptive. With this study focusing on the experiences of patients in particular, future research is recommended to include the experiences of clinicians and delve deeper into the complexities of these doctor-patient relationships.

### 7.3 Key themes across the thesis

Although the systematic review and four empirical studies in this thesis employed different methods and highlighted different components of the patient experience, there are clear commonalities across the studies, suggesting a consistency in how people experience their condition. This will now be explored in terms of three key themes, which can be seen to cut across both the qualitative and quantitative findings (see Figure 14). These are ‘notions of chronicity’, ‘impact of relationships’ and ‘hope and agency’. Transcending these themes is the proposal that leg ulcers are a holistic and systemic problem, which should be viewed as part of a complex mind-body interaction. With regards to treatment, it is suggested that it is not just the treatment itself, but how the treatment is delivered and the context in which it is delivered that influences patient wellbeing. This has wider reaching implications for treatment and research.
7.3.1 Notions of chronicity

The first of these key themes, ‘Notions of chronicity’, appeared across several chapters in the thesis. Leg ulcers are widely considered a chronic illness in the medical literature due to the presence of an underlying chronic aetiology. In contrast, the findings of this thesis suggest that patients’ beliefs regarding the timeline of their illness are wide ranging and play an important role in their beliefs regarding their illness and their experiences of treatment. For example, in Chapter Five chronicity was found to be a key theme in participants’ accounts of surgical treatment and in Chapter Six participant’s frustration with non-surgical treatment was suggested to be closely linked to their beliefs regarding the timeline of their condition. Many participants described initially holding an ‘acute’ perception of their condition, and felt increasing frustration with either a lack of healing or their clinicians more chronic-categorisation of their ulcers. Upon meeting with a surgeon, participants in Chapter Five described validation of their ‘acute’ timeline and a renewed faith in their treatment pathway. In contrast, after a period of unsuccessful treatment, either via conservative or surgical means, some participants appeared to come to a ‘resigned acceptance’ and a more chronic illness timeline. In both studies, participant’s perception of their leg ulcer as an acute or chronic illness shaped their reactions to treatment and the clinicians treating them. These studies highlight the role of patients’ beliefs about the chronicity of their ulcer, how these beliefs changed over time and how they interacted with the beliefs of clinicians.
These ‘notions of chronicity’ echo the ‘timeline’ component in Leventhal’s common sense model (Leventhal et al., 1980), and support previous literature suggesting a link between these ‘timeline’ beliefs and treatment beliefs in with leg ulcers (Chase et al., 1997). In contrast to recommendations made by Chase et al (1997), the findings of this thesis do not necessarily support the assertion that all patients should be encouraged to consider their ulcer as a chronic illness in order to encourage adaptation. This assertion is also made by Flaherty (2005), with both authors suggesting that framing an illness as chronic allows the patient to develop the appropriate coping mechanisms and accept the uncertainty that accompanies leg ulceration. Rather, the recent developments made in surgical treatment for leg ulcers and the results presented in this thesis suggest that the issue is more complex, complicated further by debate amongst the medical profession regarding the relative benefits of surgical versus conservative management. It is suggested on the basis of the studies presented in this thesis that the key issue in adaptation to leg ulcers may actually be a mismatch between the patients’ expectations of treatment and the outcome. Rather than recommending patients are encouraged to consider their condition as either ‘acute’ or ‘chronic’, the findings of this thesis suggest that open communication between doctor and patient regarding expectations, and an awareness of these beliefs, may be a more powerful tool to improve patient wellbeing. Indeed the nature of adaptation to leg ulcers as a chronic illness is itself controversial due to the ongoing debate which exists around the efficacy of various treatment modalities, the variability in treatment available around the UK and the belief by some that superficial venous surgery may offer a ‘cure’ for venous leg ulcers. The Common Sense model of illness suggests that “accurate illness perceptions form the cognitive basis for the persons adaptive coping responses” (p.942, Bonsaksen et al., 2015); however, given the variability that exists surrounding the treatment of leg ulceration and the timeline related beliefs expressed by professionals, the existence of a universally agreed ‘accurate illness perception’ in this condition appears unlikely. Including patients in this conversation and informing them regarding this debate in the literature may allow them to form a more flexible timeline which is not accompanied by the same frustration rising from mismatching beliefs and outcomes.

7.3.2 Impact of relationships
The ‘impact of relationships’ also cuts across the different studies in this thesis and was found to be highly pertinent to the experience of those undergoing treatment. In Chapter
three, it was found that the relationship between social support and quality of life was mediated by patient-carer relationship-quality, suggesting that the quality of relationship between patient and carer plays an important role in the value of social support. Chapters five and six highlighted clinician-patient relationships and communication as an integral part of the patient experience, with the ability to influence patients’ beliefs regarding their treatment and overall patient satisfaction. In particular, the relationship between patient and clinician was observed to influence whether the patient felt ‘listened to’ and involved in their treatment, with many participants suggesting that the relationship they had with nurses or doctors had been redemptive in an otherwise frustrating treatment experience. On the other hand, participants also spoke of overwhelmingly negative experiences, and the damage that this had on their confidence in treatment and the expertise of those treating them. Exploring this issue more broadly, negative mood was found in Chapter three to be a mediating factor between clinical severity and disease-specific quality of life. It could be suggested that a good relationships between the patient and those around them is likely to be one factor involved in levels of negative mood, although this suggestion is speculative.

Taken as a whole, these results demonstrate the powerful impact of relationships on the patient experience of leg ulceration and treatment. They echo existing literature linking carer-patient relationships and carer adaptation, and extend this to support an effect on patient wellbeing (Hui et al., 2011; Quinn et al., 2009; Spruytte et al., 2002). These findings support literature suggesting patient satisfaction is closely linked to elements of treatment such as the doctor-patient relationship (Ley, 1990; Ong et al., 1995), and suggest that communication is a crucial element in this relationship. In leg ulceration in particular, the uncertainty surrounding treatment and the lack of a defined treatment pathway across the UK appears to give a larger role to local services and individual clinicians. As a result, the clinician-patient relationship and the confidence that the patient has in those treating them appears to be of primary importance. Many participants in chapter six discussed a ‘trial and error’ approach adopted by their clinicians when undergoing non-surgical treatment, and the lack of confidence that this invoked, whilst those with a positive clinician-patient relationship described this relationship in terms of a creative approach to treatment or personalised care, trialling many different methods in order to find the optimal approach for that individual. Thus, the relationship between clinicians and patients appears to be highly
influential in the patient’s framing of their treatment and the rationale behind it, with a knock-on effect on their overall satisfaction. With relationship-quality mediating the link between social support and quality of life, the relationship between participants and their families, or informal caregivers, may also be said to influence the patient’s framing of their condition. Whilst further research is required to explore this link, findings such as this have clear application to psychological intervention.

7.3.3 Hope and agency
The third key theme found across this thesis is ‘hope and agency’. This theme was particularly poignant in the findings of Chapter Five, with many participants describing surgical management as giving them a sense of empowerment not associated with conservative treatment approaches. Whilst bandaging had been perceived as old fashioned and ineffective, surgery represented a ‘high-status intervention’ that gave patients renewed sense of control and faith in treatment. It is also echoed in Chapter Four, with participants reporting significant improvements in emotional elements of disease-specific quality of life in the six months post-surgery, more so than social, domestic or cosmetic elements. These same participants did not report significant increases in general health-related quality of life, perhaps indicating a particular improvement in emotional wellbeing and supporting the existence of a specific psychological benefit to surgery. In contrast, when investigating the experiences of non-surgical treatment in Chapter Six, patients did not describe the same feelings of hope and agency, rather compression bandaging and other conservative treatments were described in terms of frustration and a lack of progress.

With many professionals describing the advantages of surgical management in terms of reduced recurrence rates, these distinct psychological processes surrounding surgery are an interesting phenomenon and may reflect a literature suggesting surgical solutions offer an opportunity for patients to actively participate in treatment and evolve beyond the condition (Criddle, 1993). Previous research in this area has suggested that “the result of healing for ulcer patients is not the same as healing for a surgical patient” (p. 74; Chase et al., 1997), due to the remaining presence of the underlying condition causing the ulcer. With surgical management aiming to treat this underlying aetiology, however, the psychological impact of this treatment pathway is suggested to be more complicated. Findings in this thesis reveal that, even if ulcers are expected to return, patients describe a sense of control and renewed faith accompanying surgical treatment
that did not appear present in those undergoing non-surgical management. This sense of hope and agency elicited by surgical management is believed to be because patients view this as a ‘high status intervention’. Surgical management may be seen to adopt a radically different approach to treatment than previous methods and thus creates an opportunity for renewed hope.

It must be considered that this process was only explicitly observed in the private medical clinic where data was collected in Chapter Five, and this is discussed further in ‘methodological limitations’ below. There does, however, appear to be a distinct psychological process surrounding this ‘high status intervention’ and there may be elements of this experience that non-surgical management could also implement. For example, levels of satisfaction appeared to increase in non-surgical management when treatment was accompanied by a good patient-clinician relationship, and this effect could be harnessed with a greater focus on patient-centred care. Currently treatment for leg ulcers in the UK is locally managed and differs widely depending on the individual clinician delivering treatment, but it is possible that if conservative treatment were delivered as part of a cohesive treatment plan, with a focus on patient-centred care, evidence driven methods and a technological approach, then it is possible this could increase the perceived ‘status’ of the treatment and elicit a similar sense of hope and agency to that observed in this thesis connected with surgery.

7.3.4 Leg ulcers as a holistic problem
Transcending these three key themes and defining the thesis as a whole is the notion that leg ulcers and leg ulcer treatment illustrate a dynamic interplay between psychological and medical factors, and as such can be conceptualised as a systemic problem that requires a holistic approach to treatment. As discussed, until now there has been a focus in the leg ulcer literature on experiences of living with a leg ulcer, but little investigation into experiences of treatment. When treatment has been investigated, studies have explored the physical or biological outcomes of treatment, and there has been little research into patients’ psychological outcomes or experiences. This thesis stresses the value of psychological and quality of life outcomes in leg ulceration, and the role of these more holistic factors in the patient experience. Treatment does not occur in isolation, but interacts with patients’ beliefs and the context in which treatment is delivered. Treatment is guided by a patient’s beliefs, such as those regarding chronicity and expectations, and this echoes findings in other chronic conditions.
regarding adherence to treatment, satisfaction with treatment and the placebo effect. Treatment is framed by the context in which patients receive treatment, the way that information is communicated and the relationships with those around them, and this has a powerful impact on these beliefs.

In essence, it is not just the treatment itself which is important to patient outcomes, but also how the treatment is delivered and in what context. With leg ulcer’s characteristic fluctuations and recurrence rates associated with all treatment modalities, treatment for leg ulceration can be seen as a dynamic system of ongoing and bidirectional associations between beliefs, context and treatment. The psychological processes underlying treatment are believed to shape individuals illness beliefs going forward, and in turn shape experiences of any further treatment. For this reason, clinicians must not only consider the physical impact of treatment, but also the experience of treatment for patients. Psychological wellbeing and good quality of life should not be assumed to accompany good physical outcomes, but should be a primary and distinct goal of treatment that takes account of each patient’s individual beliefs and expectations.

7.4 Methodological limitations
As in all research, the studies presented in this thesis carry methodological limitations. Firstly, when designing the studies in this thesis it was intended that a carer population would be recruited into each study in order to allow analysis of the carer-patient relationship, the subjective impact of caregiving, and the influence of these factors on the wellbeing of both patients and carers. Unfortunately recruitment of carers into all studies was extremely low, despite collaboration with multiple carer-support agencies and encouragement for all participants to invite an informal caregiver to take part. This in itself is an interesting phenomenon, and was discussed in relation to previous literature in Chapters one and five. Researchers in this area have suggested that the term ‘carer’ is less often used by those who provide informal care, and more often applied by researchers or organisations external to the situation (O’Connor, 2007; Ugalde et al., 2012). For these reasons, it is suggested that those providing informal care to individuals with leg ulcers did not self-identify as ‘carers’, rather viewing their caregiving as an extension of their relationship with the individual. This was supported by the findings of Chapter five, with participants suggesting that they were motivated to maintain their independence as much as possible, and that those who provided them
with informal care would not be considered ‘carers’ by either party. Feedback from charities and organisations who provide support for ‘carers’ also suggested that they had little awareness of anyone they were in contact with who looked after someone with leg ulcers. Attempts were made to describe this group in different ways, advertising for individuals who ‘care about’ or ‘provide care for’ someone with leg ulcers, but the numbers recruited remained low and studies were adapted accordingly.

Recruitment issues were also encountered in Chapter four, and thus statistical analyses conducted on this data must be interpreted with caution. Whilst it was planned to recruit a substantially larger number of participants into this longitudinal study, unfortunately the nature of private medicine means the clinic is vulnerable to fluctuations in the market and this had a knock-on effect on recruitment. Also discussed in Chapters four and five are the potential methodological limitations of recruiting from a private medical clinic. It could be suggested, for example, that participants recruited from this source may occupy a different demographic to the general population. From researcher observations, however, it is argued that the unavailability of the equivalent treatment on the NHS leads to a more varied demographic accessing treatment from this clinic than would be typical of private healthcare. It could also be argued that the experiences of individuals receiving surgery in a private clinic may differ from those individuals receiving surgery from an NHS provider, particularly in terms of the context in which care is provided. Whilst superficial venous surgery is not currently widely available and offered to leg ulcer patients on the NHS, this is becomingly more common as evidence of its efficacy emerges and future research should certainly investigate the similarities and differences between the treatments provided in these two sectors. Whilst the experiences of those individuals undergoing non-surgical management in Chapter six are believed to be representative of the general population, the motivation of a volunteer sample must also be considered and there are a small number of specialist centres around the UK that are believed to provide a more cohesive treatment plan than described by participants in this study. It is important that future research also explores the experiences of treatment in ‘gold-standard’ services, in order to establish ‘best practice guidelines’ and apply these more widely.

7.5 Implications for theory
The studies from the thesis have implications for theory in terms of the dynamic nature of outcomes, the use of discrete constructs and the role of placebos.
7.5.1 Dynamic nature of outcomes
The four studies presented in this thesis are embedded in theory, using models such as Leventhal’s common sense model (Leventhal et al., 1980) and Lazarus and Folkman’s stress-coping model (Lazarus & Folkman, 1984) as a framework. It was hoped that the cohort study presented in Chapter Four would enable the testing of such theories in a clinical sample; however, this was unfortunately not possible due to a necessary reduction in questionnaire measures to reduce participant fatigue. Whilst this test of theory was not possible, the findings presented in this thesis are believed to have wider implications for the psychological models used to explore leg ulceration. Many patient beliefs identified as particularly pertinent to leg ulceration are present in Leventhal’s common sense model (1980) and this model provided a particularly relevant framework in which to interpret findings. This thesis offers support to the use of dynamic models of adaptation when exploring leg ulcers, due to the recurrent nature of the condition and the observed changes in individual’s beliefs regarding their condition over time. In her working-model of adaptation to chronic illness, Moss-Morris (2013) describes adaptation as a ‘process’ rather than an endpoint and this is echoed in the findings of this thesis.

7.5.2 Discrete versus enmeshed constructs
This thesis also highlights the enmeshed nature of some of the constructs involved in theories of chronic illness and our understanding of how people adapt to illness. Models of adaptation often depict constructs such as quality of life, coping, and sense-making as discrete constructs, but emerging from a mixed methods approach to chronic illness is the suggestion that each of these processes is embedded in the others. For example, when engaged in a qualitative discussion of patient experience, participants are likely to be drawing upon notions of sense-making, coping and quality of life simultaneously. Whilst theories of adaptation present these as discrete constructs, this research suggests that the separation of these factors may be artificial and not reflect the real-world experience of patients. This is not to say that theoretical models are not valid or useful, but that these real-world experiences should be considered at all stages of investigation.

7.5.3 Investment and the role of the placebo effect
One of the main findings in this thesis concerns the role of investment in patients’ beliefs surrounding treatment. As a more invasive and ‘high-status intervention’, surgical management is suggested to require more personal investment than
conservative treatment approaches alone, potentially eliciting levels of hope and agency not associated with other treatments. This echoes a substantial literature surrounding the placebo effect. For example, in his cognitive dissonance theory of placebos Totman (1976) suggested that placebos require significant investment of factors such as time, money and dedication to be effective. This in turn requires the individual to justify the investment as a rational decision and consider outcomes positively. The findings of this thesis support Totman’s theory, but also suggest some important complexities to this effect when applied to leg ulceration. For example, both conservative treatment and surgical treatment could be suggested to require considerable investment in terms of time and physical energy. Surgical management, however, also has an element of technological advancement and novelty. This, as well as the level of ‘contrast’ between the two treatments, could be said to increase patients’ expectations regarding outcomes. Although the findings of this study support many elements of Totman’s theories, they also emphasise the importance of these patient expectations - an element that Totman argues is not necessary in the placebo effect. Whilst it is certainly not suggested that outcomes from surgical intervention should be viewed purely as a placebo effect, this is a valuable component of treatment to consider and may be an influential factor in patients’ evaluations of leg ulcer treatment.

7.6 Implications for future research
Within each of the chapters presented in this thesis are recommendations for future research, suggesting ways in which the current thesis may be built upon and questions that have been generated from these findings. For example, it is suggested that future research may perform an in-depth investigation into the role of illness beliefs in adaptation to leg ulceration and how this may have influenced patient behaviour. It is also suggested future research conduct a qualitative exploration of clinician’s experiences of treatment and the doctor-patient relationship, as well as how these beliefs influence their own behaviour and perceptions of their patients’ behaviour.

Further research should also aim to overcome some of the methodological limitations identified in the current thesis. As discussed, a major limitation of the second quantitative study included in this thesis was the prohibitively small sample size. The findings of this study did, however, demonstrate the viability and value of a longitudinal study to explore the psychological impact of treatment. It is recommended that this design is extended, and a large-scale Randomised control trial (RCT) of the
psychological impact of treatment for leg ulceration is conducted. Such a study should include similar measures to those included in the present studies, including both a general and disease-specific quality of life measures, measures of psychological wellbeing and of subjective clinical severity. In addition, it is recommended that an RCT of this nature should include objective measures of clinical severity and a measure of illness beliefs and, as well as the potential for follow-up qualitative interviews to situate the findings within patients’ own narratives. In order to achieve a substantially larger sample size, it is recommended that this RCT is conducted across multiple NHS trusts and research sites across the UK.

Large-scale RCT studies in this area have been conducted in the past and are ongoing, for example the large-scale ESCHAR and EVRA trials (Davies & Heatley, 2016; Gohel et al., 2007), aiming to explore the clinical and cost effectiveness of surgical management. A larger focus is required, however, on the psychological impact of treatment and the experiences of patients. In addition, with significant variability in treatment accessibility and quality around the UK, it has been suggested that participants in both arms of such RCT’s may be receiving a higher quality of treatment than is commonly available in the community (Guest et al., 2015). Whilst studies of this nature are required in order to provide appropriate evidence to create best practice pathways and justify a higher quality of treatment across the country, it is also important to investigate current treatment practices and represent the experiences of individuals receiving treatment in the community.

7.7 Implications for practice

The findings of this thesis have many implications for practice, largely regarding the inclusion of psychological input in leg ulcer treatment, both on an individual and national basis. The empirical studies included in this thesis demonstrate various ways in which the input of a health psychologist would be invaluable to leg ulcer treatment, including: the assessment of patients beliefs regarding their condition and how these relate to a patient’s health-related behaviour, addressing patients beliefs and expectations regarding treatment and the impact that these have on psychological wellbeing, and advising on how communication between patients and health professionals might be improved. On an individual basis, the involvement of a health psychologist in centres providing treatment for leg ulcers could be invaluable, but this involvement should also be extended to committees and panels making decisions
regarding the care provision for this condition. The results of this thesis support the view that leg ulceration is a holistic problem, including a large psychological element, and thus the inclusion of psychologists in decision-making processes could be a valuable way in which to ensure treatment is also approached holistically.

Evident across all studies in this thesis is variability in the treatment available to participants around the country, and this is something that participants described as particularly frustrating. Not only does this cause a problem for research in this area, with issues surrounding generalisability and sampling, but this also suggests a substantial problem with clinical variability and poses substantial ethical questions regarding equal access to high-quality treatment. Thus, the findings of this thesis support the need for national service framework for the treatment of leg ulceration in order to provide the best possible care for all patients, based on evidence and guidelines. Such a framework was highlighted at a recent symposium (Bulbulia, 2016), with the aim to set national standards, establish implementation of these standards, and provide a coordinated measure of outcomes. It is believed that such a framework would allow the implementation of evidence based recommendations such as those presented in this thesis, as well as the expansion of positive results observed in local specialist centres (Barwell et al., 2001; Ghauri et al., 2000).

7.8 Conclusions
With much existing research focusing on the biological and physical elements of treatment, this thesis aimed to draw upon models and principles of health psychology theory in order to explore predictors of health related quality of life in individuals with leg ulcers, investigate the psychological impact of treatment on patients, and explore the experiences of individuals undergoing conservative and surgical treatment. After conducting a systematic review and four empirical research studies, three key themes appear to cut across the findings of this thesis. Participant’s beliefs and experiences of treatment are thought to be characterised by ‘notions of chronicity’, ‘impact of relationships’ and ‘hope and agency’. These three key themes are transcended by the conclusion that leg ulcers are a holistic problem that requires a holistic approach to treatment. This emphasis on patient experience and the psychological impact of treatment should be reflected in future research, and it is suggested that psychologists play a more integral part in treatment at a local and national level. The introduction of a national service framework is believed to be beneficial in order to improve equal access
to high-quality treatment across the country, as well as allowing implementation of evidence-based recommendations such as those presented in this thesis.
References


treating underlying venous pathology in patients with chronic venous ulcer. 

Markle, G. L., Attell, B. K., & Treiber, L. (2014). Dual, Yet Dueling Illnesses: Multiple 
Chronic Illness Experience at Midlife. Qualitative Health Research, 25(9), 1271–1282. 
doi:10.1177/1049732314559948

acceptance-based pain management programme: An interpretative 
doi:10.1080/08870446.2013.845667


of Venous Disease Using Duplex Ultrasound. In E. Mendoza, C. R. Lattimer, & N. 
Morrison (Eds.), Duplex Ultrasound of Superficial Leg Veins (pp. 105–118). New 
York, NY: Springer.

Michaels, J. A., Campbell, B., King, B., Palfreyman, S. J., Shackley, P., & Stevenson, 
M. (2009). Randomized controlled trial and cost-effectiveness analysis of silver-
donating antimicrobial dressings for venous leg ulcers (VULCAN trial). The 
00718880/frame.html

of the 3M Coban 2 Layer Compression System versus Profore to evaluate the 
product performance in patients with venous leg ulcers. International Wound 

Psychological factors in leg ulceration: a case-control study. The British Journal of 
Dermatology, 161(4), 750–6. doi:10.1111/j.1365-2133.2009.09211.x

Psychosocial Factors in Medical and Treatment Avoidance: The Role of the 


from http://cks.nice.org.uk/leg-ulcer-venous#!diagnosis


SIGN. (2010). *Management of chronic venous leg ulcers. (Clinical Guideline No. 120).*


Taylor, A. (2008). Leg Ulcers. In K. Ousey & C. McIntosh (Eds.), *Lower Extremity*


Van Damme, S., Crombez, G., Van Houdenhove, B., Mariman, A., & Michielsen, W.


Ware, J. E., Kosinski, M., & Keller, S. D. (1996). A 12-Item Short-Form Health Survey


Appendices
Appendices A – Study One Information Sheet

Participant Information Sheet

The impact of providing and receiving informal care for leg ulcers, and the caregiver-receiver relationship.

Introduction

You are being asked to take part in a research study, conducted by a PhD Psychology Student at the University of Surrey. This study will be submitted as part of the educational requirements for a PhD qualification.

Before you decide whether or not you would like to participate, you need to understand why the research is being done and what it will involve for you. Please take the time to read the following information carefully. Talk to others about the study if you wish.

What is the purpose of the study?

This study seeks to explore the impact of providing and receiving informal care for leg ulcers, and the caregiver-receiver relationship.

This research is being supported by ‘The Leg Ulcer Charity’ (Registered charity number: 1152113), who aim to empower patients, their families, and their carers to understand their condition and know what to ask in order to get the best possible treatment for them. It is hoped that this research will contribute to these aims, educate clinicians and professionals about the experiences of patients, and potentially lead to interventions to improve the lives of leg ulcer patients and their carers.

The data collected in this study will be used for the researcher’s PhD thesis and potentially in future academic publications. The results may be summarised and published on The Leg Ulcer Charity website, but all information will be anonymised and no participants or participant information will be identifiable. Please let the researcher know if you wish to be sent a summary of the study’s findings. This will be available by September 2016.
Why have I been invited to take part in the study?

You have been invited to take part in this study because of your status as a person who currently has, or used to have, leg ulcers.

As part of this study, approximately 400 participants are being recruited.

Do I have to take part?

No, you do not have to participate. Regardless of whether you decide to participate, your care or treatment will not be affected.

Your participation in this study is voluntary. You will not be given any form of compensation or paid any expenses in return for your participation.

You can withdraw at any time without giving a reason, including the withdrawal of your data after completing the study. You may choose not to complete any part of the task that you do not want to complete, and you may take a break at any time.

What will my involvement require?

You will be asked to fill in a number of questionnaire measures. These relate to your health and wellbeing, some elements of your personality, and your experiences receiving care. You will also be asked to provide some information regarding factors such as your gender, age, and some questions regarding the length of your illness.

Participation is anticipated to take approximately 30 minutes.

We will also ask whether there is somebody who supports you in an informal capacity (unpaid) who may also be willing to take part in the study. If so, we will ask for their contact details and may contact them regarding participation in the study. However, there is no obligation or pressure for them to participate and all responses will be kept completely confidential to the participant who provided them.

Unfortunately we cannot reimburse any expenses incurred from your travel or participation in this study.

What are the possible disadvantages or risks of taking part?

Whilst every effort is made to protect participants, some of the subject areas included in the research may be sensitive or distressing for some participants. If this is the case then you may withdraw at any point during the questionnaire, and you do not have to provide a reason for doing so. Details of confidential emotional support services will be
provided to all participants, and may be requested at any point.

**What are the possible benefits of taking part?**

No direct benefit to you is anticipated, although this study is hoped to improve the future treatment and care of leg ulcers.

**Will my taking part in the study be kept confidential?**

Yes. Names and personal details will be coded or anonymised in any publications produced as a result of this study; therefore you will not be identifiable from the data you provide.

However, should you disclose that you or someone else is at risk of harm then the researcher may need to report this to an appropriate authority. This would usually be discussed with you first.

If you disclose poor clinical practice or dissatisfaction with medical treatment, the researcher will discuss with you possible complaints procedures that you may wish to follow (such as those supported by Patient Advice and Liaison Services (PALS)). The researcher can also provide further information about this on request.

Data produced as a result of your participation will be stored securely for 10 years, in accordance with University Ethical Procedures. Data will also be stored in accordance with the Data Protection Act 1998.

**Who do I contact if I have any questions, complaints, or require further information?**

For further information about this study, to ask questions, or to make a complaint/raise a concern about any aspect of this study you may contact the primary researcher Philippa Tollow, on p.tollow@surrey.ac.uk or 01483 68 9444. You may also contact Professor Jane Ogden, as academic supervisor of this study, on j.ogden@surrey.ac.uk or 01483 68 6929. Or the Head of School, Peter Hegarty on p.hegarty@surrey.ac.uk or 01483 68 6898.

**Who is organising and funding the research?**

This research is being funded by ‘The Leg Ulcer Charity’.
Who has reviewed the project?

The study has been reviewed and received a favourable opinion from an NHS Research Ethics Committee (South Central – Berkshire B REC), and the University of Surrey Ethics Committee.

Thank you for taking the time to read this Information Sheet.
Appendices B – Consent Form (Studies One and Two)

Participant Consent Form

A study investigating the psychological impact of venous surgery on patients and their carers.³

Please initial the boxes corresponding to all statements to which you agree.

- I have read and understood the Information Sheet provided. I have been given a full explanation by the investigators of the nature, purpose, location and likely duration of the study, and of what I will be expected to do. I have been advised about any discomfort and possible ill-effects on my health and well-being which may result. I have been given the opportunity to ask questions on all aspects of the study and have understood the advice and information given as a result.

- I agree to comply with any instruction given to me during the study and to cooperate fully with the investigators. I shall inform them immediately if I suffer any deterioration of any kind in my health or well-being, or experience any unexpected or unusual symptoms.

- I consent to my personal data, as outlined in the accompanying information sheet, being used for this study and other research. 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 understand that I am free to withdraw from the study at any time without needing to justify my decision and without prejudice.

- I acknowledge that my participation in the study is completely voluntary, and that I will not receive any compensation or payment for my participation.

- I understand that in the event of my suffering a significant and enduring injury (including illness or disease) as a direct result of my participation in the study, compensation will be paid to me by the University, subject to certain provisos and limitations. The amount of compensation will be appropriate to the nature, severity and persistence of the injury and will, in general terms, be consistent with the amount of damages commonly awarded for similar injury by an English court in cases where the liability has been admitted.

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³ Study Two title - title adapted for Study One
• I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from The Whiteley Clinic, 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 confirm that I have read and understood the above and freely consent to participating in this study. I have been given adequate time to consider my participation and agree to comply with the instructions and restrictions of the study.

Name of volunteer (BLOCK CAPITALS) ...................................................

Signed ........................................... Date ...........................................

Name of researcher taking consent ...................................................

Signed ................................................... Date ...........................................
Appendices C – Debrief Sheet (All studies)

Debrief Sheet

Thank you for your participation in this study.

The aim of the study is to investigate the psychological impact of venous surgery on patients and their carers.¹

Leg ulcers affect approximately 500,000 people in the UK, and they are often a limiting and painful condition. Previous research has demonstrated how having a leg ulcer can negatively impact a patient’s quality of life, and spouses, children, family and friends often invest time and resources in taking care of those with leg ulcers. Whilst some research has been conducted in relation to other illnesses, it is not clear from the existing research how the person with leg ulcers may experience being cared for or how this caregiving may impact on the carer. Equally, there appears to be little or no research into the caregiver-receiver relationship in leg ulcer patients, how this relationship may change due to the caregiving role, and whether or not this relationship changes through treatment and upon healing.

This research aims to try and answer some of the above gaps in the research. It is part of a larger research project, which aims to:

- investigate the impact of caring for a leg ulcer patient, on informal caregivers and those that they are caring for,
- examine how surgical management of leg ulcers psychologically impacts the caregiver and the patient,
- explore the relationship between patients with leg ulcers and their informal caregivers,
- and investigate how this relationship changes through healing and treatment.

This research is being supported by ‘The Leg Ulcer Charity’ (Registered charity number: 1152113), who aim to empower patients, their families, and their carers to understand their condition and know what to ask in order to get the best possible treatment for them. It is hoped that this research will contribute to these aims, educate

¹Principle aim adapted for each respective study
clinicians and professionals about the experiences of patients, and potentially lead to interventions to improve the lives of leg ulcer patients and their carers.

If you feel any distress as a result of this study or wish to talk further about any of the issues discussed, there are several sources of emotional support available to you. The Samaritans are an organisation offering a confidential emotional support service. They may be contacted by phone, email, or visited in person.

_The Samaritans - 08457 90 90 90 (24 hours, 365 days a year), jo@samaritans.org. To find your local branch: http://www.samaritans.org/branches_

For more information about leg ulcers and your own care, please contact your GP. Alternatively, the following websites may provide more information:

_http://www.patient.co.uk/health/venous-leg-ulcers-leaflet_
_http://www.legulcercharity.org/index.html_

For more information about caring and carers support groups:

The Carers trusts (recently formed from the merging of ‘Crossroads Care’ and ‘The Princess Royal Trust for Carers’) offer useful information about caring, carers services, and respite care services. To find services local to you: phone 0844 800 4361, or visit http://www.carers.org/carers-services/find-your-local-service

Carers UK offer help & advice for carers, and also offer a local network. To find support near you: phone 020 7378 4999 or visit: http://www.carersuk.org/support/our-local-branches

If you have any further questions, or wish to withdraw your data from the study, please feel free to ask the researcher. If you wish to contact the researcher after completion of the study, you can do so by phone (01483 68 4444) or email: p.tollow@surrey.ac.uk. Alternatively, you may contact Professor Jane Ogden, who is supervising this study, on 01483 68 6929 or j.ogden@surrey.ac.uk.
Appendices D – Patient Questionnaire Measures (Studies One and Two)

Demographic and ulcer status questionnaire

1. Are you…? (Please select the appropriate answer)
   Male ☐ Female ☐

2. How old are you?
   …….. years

3. Some people feel they know what caused their leg ulcer, what do you believe is the cause of your leg ulcer(s)?
   (please select all that apply)

<table>
<thead>
<tr>
<th>Diet</th>
<th>Smoking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not enough exercise</td>
<td></td>
</tr>
<tr>
<td>Body weight</td>
<td></td>
</tr>
<tr>
<td>Accident/Trauma</td>
<td></td>
</tr>
<tr>
<td>Standing too much</td>
<td></td>
</tr>
<tr>
<td>Sitting too much</td>
<td></td>
</tr>
<tr>
<td>Hereditary</td>
<td></td>
</tr>
<tr>
<td>Venous disease</td>
<td>Arterial disease</td>
</tr>
<tr>
<td>Diabetes</td>
<td></td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>Other (please specify:)</td>
</tr>
</tbody>
</table>

I don’t know

4. Have you been told the cause of your leg ulcer?
   Yes ☐ No (skip to question 4) ☐

3a. If yes, please select the cause from the list:

<table>
<thead>
<tr>
<th>Venous disease</th>
<th>Arterial disease</th>
<th>Diabetes</th>
<th>Rheumatoid arthritis</th>
<th>Other (please specify:)</th>
</tr>
</thead>
</table>

5. How long have you had the leg ulcer/s? (eg. 24 months)  
(If your ulcer has healed and then come back, please specify the time since you had your first ulcer)

........ months

6. Have your leg ulcer(s) ever completely healed and returned (reoccurred)? If so, approximately how many times?

................... times

7. Has your leg ulcer(s) ever improved significantly and worsened again? If so, approximately how many times?

................... times

8. How would you describe your leg ulcer/s?

<table>
<thead>
<tr>
<th>Unhealed</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Healing (unhealed and improving)</td>
<td></td>
</tr>
<tr>
<td>Healed, but I expect the leg ulcer/s to return</td>
<td></td>
</tr>
<tr>
<td>Healed and I don’t expect the leg ulcer/s to return</td>
<td></td>
</tr>
</tbody>
</table>

9. Would you say that your current overall health is: (please select one)

| Very good                     |                  |
| Good                          |                  |
| Okay                          |                  |
| Poor                          |                  |
| Very poor                     |                  |
10. Some of the questions in this questionnaire will ask about a person that cares for you – this might be a friend, relative or neighbour. They might help you around the house or the garden, help with your shopping or provide you with emotional support. Importantly they should not be paid to help you with any of these things.

When answering questions about a ‘carer’ later in the questionnaire, please keep this person in mind.

If you can identify someone who fits this description, what kind of support do you believe they provide? (please select all that apply)

<table>
<thead>
<tr>
<th>Practical support (eg. housework, gardening, shopping, transport)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Personal support (eg. help with bandages, getting dressed, washing)</td>
<td></td>
</tr>
<tr>
<td>Emotional support</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
<tr>
<td>Please specify</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>No person like this</td>
<td></td>
</tr>
</tbody>
</table>
11. What medical treatment are you currently receiving for your leg ulcers (if any)?
(please select all that apply):

<table>
<thead>
<tr>
<th>Treatment</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No treatment</td>
<td></td>
</tr>
<tr>
<td>Compression bandages</td>
<td></td>
</tr>
<tr>
<td>Surgical treatment</td>
<td></td>
</tr>
<tr>
<td>Other (please specify:)</td>
<td></td>
</tr>
</tbody>
</table>

Please only answer questions 10a, 10b, and 10c if you answered ‘surgical treatment’ to question 10. Otherwise, please move to the next page.

a. If you have received surgical treatment for the ulcers, how long ago was this?

<table>
<thead>
<tr>
<th>Duration</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 3 months ago</td>
<td></td>
</tr>
<tr>
<td>3-6 months ago</td>
<td></td>
</tr>
<tr>
<td>6-12 months ago</td>
<td></td>
</tr>
<tr>
<td>More than 12 months ago</td>
<td></td>
</tr>
<tr>
<td>Not applicable</td>
<td></td>
</tr>
</tbody>
</table>

b. Was this surgery completed at The Whiteley Clinic?

<table>
<thead>
<tr>
<th>Answer</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Not applicable</td>
<td></td>
</tr>
</tbody>
</table>

c. Do you know what surgical procedures you have had/are having?

<table>
<thead>
<tr>
<th>Procedure</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Vein stripping</td>
<td></td>
</tr>
<tr>
<td>Endovenous Laser Treatment (EVLT)</td>
<td></td>
</tr>
<tr>
<td>Radiofrequency (RFA) or VNUS closure</td>
<td></td>
</tr>
<tr>
<td>Perforator Closure</td>
<td></td>
</tr>
<tr>
<td>Foam sclerotherapy</td>
<td></td>
</tr>
<tr>
<td>Other (please specify:)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Additional Information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>It hasn’t been decided yet</td>
<td></td>
</tr>
<tr>
<td>Don’t know</td>
<td></td>
</tr>
</tbody>
</table>
The Charing Cross Venous Ulcer Questionnaire

1. I have pain from my ulcer

<table>
<thead>
<tr>
<th>None of the time</th>
<th>A little of the time</th>
<th>Some of the time</th>
<th>A good bit of the time</th>
<th>All of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Having an ulcer on my leg stops me doing the following:

<table>
<thead>
<tr>
<th>None of the time</th>
<th>A little of the time</th>
<th>Some of the time</th>
<th>A good bit of the time</th>
<th>All of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

   a. Meeting friends and relatives
   b. Going on holiday
   c. Enjoying my hobbies
   d. Using public transport

3. How TRUE or FALSE are each of the following statements for you, when considering your leg ulcer?

<table>
<thead>
<tr>
<th>Definitely true</th>
<th>Mostly true</th>
<th>Don’t know</th>
<th>Mostly false</th>
<th>Definitely false</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

   a. My ulcer has slowed me down in general
   b. My ulcer has put a strain on my personal relationships
   c. The discharge from my ulcer is a problem
   d. I spend a lot of time thinking about my ulcer
   e. I am worried that my ulcer will never heal
   f. I am fed up with the amount of time it takes to treat my ulcer
4. I am unhappy about the appearance of my leg because of the ulcer and/or dressings:

<table>
<thead>
<tr>
<th></th>
<th>No, definitely not</th>
<th>Occasionally</th>
<th>Often</th>
<th>All of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5. My leg ulcer prevents me from the following household duties:

<table>
<thead>
<tr>
<th>Household Duties</th>
<th>None of the time</th>
<th>A little of the time</th>
<th>Some of the time</th>
<th>A good bit of the time</th>
<th>All of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Cooking</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Cleaning</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Shopping</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. Gardening</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6. I feel depressed because of my leg ulcer:

<table>
<thead>
<tr>
<th></th>
<th>Never</th>
<th>Occasionally</th>
<th>Often</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

7. Please state how much of a problem to you the following factors are regarding the dressings for your leg: (If not applicable, please leave blank)

<table>
<thead>
<tr>
<th>Factors</th>
<th>A huge problem</th>
<th>A big problem</th>
<th>A moderate problem</th>
<th>A little problem</th>
<th>No problem</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. The bulkiness of them</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. The appearance of them</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. They influence the clothes I wear</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8. I have difficulty with walking because of my leg ulcer:

<table>
<thead>
<tr>
<th></th>
<th>Never</th>
<th>Occasionally</th>
<th>Often</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The Positive and Negative Affect Scale

This scale consists of a number of words that describe different feelings and emotions. Please read each item and then mark the appropriate answer next to that word.

Indicate to what extent you have felt this way during the past few weeks.

<table>
<thead>
<tr>
<th></th>
<th>Very slightly or not at all</th>
<th>A little</th>
<th>Moderately</th>
<th>Quite a bit</th>
<th>Extremely</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interested</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Distressed</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Excited</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Upset</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Strong</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Guilty</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Scared</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Hostile</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Enthusiastic</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Proud</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Irritable</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Alert</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Ashamed</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Inspired</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Nervous</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Determined</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Attentive</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Jittery</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Active</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Afraid</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
MOS Social Support Survey

People sometimes look to others for companionship, assistance, or other types of support. How often is each of the following kinds of support available to you if you need it?

**Please circle one number on each line.**

<table>
<thead>
<tr>
<th></th>
<th>None of the time</th>
<th>A little of the time</th>
<th>Some of the time</th>
<th>Most of the time</th>
<th>All of the time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Someone to help you if you were confined to bed.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Someone to take you to the doctor if you needed it.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Someone to prepare your meals if you were unable to do it yourself.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Someone to help with daily chores if you were sick.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Someone you can count on to listen when you need to talk.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Someone to confide in or talk to about yourself or your problems.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Someone to share your most private worries and fears with.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Someone who understands your problems.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Someone to have a good time with.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Someone to get together with for relaxation.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Someone to do something enjoyable with.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
**The Scale for the Quality of the Current Relationship**

For the following questions, please think about somebody who provides care for you. This might be a family member, friend or neighbour, who is not paid to help you but helps with, for example, things around the house or similar.

Please think about your relationship with this person and answer the following questions about this relationship, by selecting the appropriate box. (Please select only one box for each question)

1. **This person and I often spend time together in an enjoyable way.**

<table>
<thead>
<tr>
<th>Totally disagree</th>
<th>Disagree</th>
<th>Not Sure</th>
<th>Agree</th>
<th>Totally agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. **This person and I often disagree.**

<table>
<thead>
<tr>
<th>Totally disagree</th>
<th>Disagree</th>
<th>Not Sure</th>
<th>Agree</th>
<th>Totally agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. **There is a big distance in the relationship between this person and myself.**

<table>
<thead>
<tr>
<th>Totally disagree</th>
<th>Disagree</th>
<th>Not Sure</th>
<th>Agree</th>
<th>Totally agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. **This person and I accept each other as we are.**

<table>
<thead>
<tr>
<th>Totally disagree</th>
<th>Disagree</th>
<th>Not Sure</th>
<th>Agree</th>
<th>Totally agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5. **If there are problems, this person and I can usually resolve these easily.**

<table>
<thead>
<tr>
<th>Totally disagree</th>
<th>Disagree</th>
<th>Not Sure</th>
<th>Agree</th>
<th>Totally agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6. **I get along well with this person.**

<table>
<thead>
<tr>
<th>Totally disagree</th>
<th>Disagree</th>
<th>Not Sure</th>
<th>Agree</th>
<th>Totally agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
7. This person and I are caring towards each other.

<table>
<thead>
<tr>
<th>Totally disagree</th>
<th>Disagree</th>
<th>Not Sure</th>
<th>Agree</th>
<th>Totally agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

8. This person often annoys me.

<table>
<thead>
<tr>
<th>Totally disagree</th>
<th>Disagree</th>
<th>Not Sure</th>
<th>Agree</th>
<th>Totally agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

9. I feel good if I am with this person.

<table>
<thead>
<tr>
<th>Totally disagree</th>
<th>Disagree</th>
<th>Not Sure</th>
<th>Agree</th>
<th>Totally agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

10. This person and I often try to impose our opinions on each other.

<table>
<thead>
<tr>
<th>Totally disagree</th>
<th>Disagree</th>
<th>Not Sure</th>
<th>Agree</th>
<th>Totally agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

11. I blame this person for the cause of my problems.

<table>
<thead>
<tr>
<th>Totally disagree</th>
<th>Disagree</th>
<th>Not Sure</th>
<th>Agree</th>
<th>Totally agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

12. This person and I appreciate each other as people.

<table>
<thead>
<tr>
<th>Totally disagree</th>
<th>Disagree</th>
<th>Not Sure</th>
<th>Agree</th>
<th>Totally agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
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</tbody>
</table>

13. This person does not appreciate enough what I do for him/her.

<table>
<thead>
<tr>
<th>Totally disagree</th>
<th>Disagree</th>
<th>Not Sure</th>
<th>Agree</th>
<th>Totally agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

14. I am always glad to see him/her if I have not seen him/her for some time.

<table>
<thead>
<tr>
<th>Totally disagree</th>
<th>Disagree</th>
<th>Not Sure</th>
<th>Agree</th>
<th>Totally agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Perceived caregiving impact

The following questions ask about your relationship with a caregiver, and the impact that you believe caring for you has on their daily life. This might be a friend or family member that cares for you on an ongoing basis; perhaps doing your shopping, or providing you with personal care.

Please read the questions and select the answers you feel are most appropriate on the two scales. If this is not applicable, please select ‘not applicable’

1. What impact do you believe that caring for you has on the daily life of your caregiver?

<table>
<thead>
<tr>
<th>No impact</th>
<th>Significant Impact</th>
<th>(If ‘no impact’, please go straight to question 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

☐ Not applicable

2. If we were to ask your caregiver the same question (ie. what impact does caring for you have on their daily life), what do you predict their answer would be?

<table>
<thead>
<tr>
<th>No impact</th>
<th>Significant impact</th>
<th>(If ‘no impact’, please go straight to the next page)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

☐ Not applicable
Do you think that someone who cares for you might also be willing to take part in this study?

We are also recruiting individuals who provide unpaid care for people with leg ulcers. This care may involve help around the house, emotional, personal or medical care; such as that often provided by a family member, friend or neighbour.

If this person does decide to take part, you will need to provide them with your unique participant number, so that we can link your data in analysis. This will not affect your data. Your data will remain completely confidential.

If you know someone else who would like to take part and you think they would prefer to take part in the study online, please give them the following website address:

http://surveys.fahs.surrey.ac.uk/Leg_Ulcer_Study1/

Alternatively, if you think they would prefer to take part in the study via paper questionnaires or on the telephone with a researcher, then please provide their contact details below then we will contact them about taking part in the study.

There is no obligation or pressure for them to take part, and both of your responses will be kept completely confidential.

Name: ………………………………………………………………………

Contact details (such as phone number, email address, or postal address):

……………………………………………………………………

……………………………………………………………………

……………………………………………………………………
Would you like to take part in future research studies on this topic?

If you would consider taking part in future research regarding this topic, please provide your preferred contact details below:

Contact details (phone number, email address, or postal address:

..............................................................................................................
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Appendices E – NHS Research Ethics Committee Approval Letter

Health Research Authority

NRES Committee South Central - Berkshire B
Bristol REC Centre
Whitefriars
Level 3, Block B
Lewins Mead
Bristol
BS1 2NT
Telephone: 0117 342 1331

21 March 2014

Miss Philippa Tollow
Department of Psychology
University of Surrey
Guildford
GU2 7XH

Dear Miss Tollow

Study title: The psychological impact of chronic leg ulceration on caregiver-recipient relationships and the influence of surgical management.

REC reference: 14/SC/0127
IRAS project ID: 148979

Thank you for your letter of 19 March 2014, responding to the Committee’s request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Manager Miss Gemma Oakes, nrescommittee.southcentral-oxforda-berkshireb.secoast-surrey@nhs.net.

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, subject to the conditions specified below.

Ethical review of research sites

NHS 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" below).

Non-NHS sites

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

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](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 within 5 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

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 contest the need for registration they should contact Catherine Bloxwell (catherine.bloxwell@nhs.net), the HRA does not, however, expect exceptions to be made.

Guidance on where to register is provided within IRAS.

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).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:
<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advertisement</td>
<td>Phase 1 Advertisement Materials v.1</td>
<td>19 February 2014</td>
</tr>
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<td>Covering Letter</td>
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<td>21 February 2014</td>
</tr>
<tr>
<td>Evidence of insurance or indemnity</td>
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<td>15 July 2013</td>
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<td>Interview Schedules/Topic Guides</td>
<td>Phase 2 Written Account Task - Patient v.1</td>
<td>19 February 2014</td>
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<td>Interview Schedules/Topic Guides</td>
<td>Phase 2 Written Account Task Carer v.1</td>
<td>19 February 2014</td>
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<td>Interview Schedules/Topic Guides</td>
<td>Phase 4 Interview Schedule - Patient v.1</td>
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<td>Interview Schedules/Topic Guides</td>
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<td>19 February 2014</td>
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<tr>
<td>Investigator CV</td>
<td>(Academic Supervisor 1) Jane Ogden</td>
<td></td>
</tr>
<tr>
<td>Investigator CV</td>
<td>(Academic Supervisor 2) Mark Whiteley</td>
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<tr>
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<td>19 February 2014</td>
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<td>Letter of invitation to participant</td>
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<td>Letter of invitation to participant</td>
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<td>Letter of invitation to participant</td>
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<td>Other: Phase 4 Debrief Sheet</td>
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<td>18 March 2014</td>
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<td>Participant Consent Form: Phase 2 Consent Form</td>
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<tr>
<td>Participant Information Sheet: Phase 1 Information Sheet - Carer</td>
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<td>Questionnaire: Family Strain Questionnaire Short Form</td>
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<td>Questionnaire: Satisfaction with Life Scale</td>
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<td>Questionnaire: (Validated) Positive and Negative Affect Scale</td>
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<td>Questionnaire: (Validated) Charing Cross Venous Ulcer Questionnaire</td>
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<td>Questionnaire: (Validated) Nottingham Health Profile</td>
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<td>Response to Request for Further Information</td>
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**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 NRES 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 website.

Further information is available at National Research Ethics Service website > After Review

14/SC/0127 Please quote this number on all correspondence

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/

With the Committee’s best wishes for the success of this project.

Yours sincerely

Chair

pp Dr John Sheridan

Email: nrescommittee.southcentral-berkshireb@nhs.net

Enclosures: “After ethical review – guidance for researchers” [SL-AR2]

Copy to: Professor Jane Ogden, j.ogden@surrey.ac.uk
30 May 2014

Miss Philippa Tollow
Department of Psychology
University of Surrey
Guildford
GU2 7XH

Dear Miss Tollow

Study title: The psychological impact of chronic leg ulceration on caregiver-recipient relationships and the influence of surgical management.

REC reference: 14/SC/0127
Amendment number: Substantial Amendment 1
Amendment date: 19 May 2014
IRAS project ID: 148979

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

The Committee approved the following changes:

The Nottingham Health Profile (NHP) will no longer be used to measure subjective health status. This will be replaced by a single item measure, asked of carers and patients.

Approved documents

The documents reviewed and approved at the meeting were:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
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<tr>
<td>Notice of Substantial Amendment (non-CTIMP) [Substantial Amendment 1]</td>
<td>Substantial Amendment 1</td>
<td>19 May 2014</td>
</tr>
</tbody>
</table>
Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

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.

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/

14/SC/0127: Please quote this number on all correspondence

Yours sincerely

Pp Dr John Sheridan
Chair

E-mail: nrescommittee.southcentral-berkshireb@nhs.net

Enclosures: List of names and professions of members who took part in the review

Copy to:
Professor Jane Ogden, University of Surrey
j.ogden@surrey.ac.uk
Appendices F – University Research Ethics Committee Approval Letter

Miss Philippa Tollow
School of Psychology
FAHS

08 April 2014

Dear Miss Tollow

The psychological impact of chronic leg ulceration on caregiver-recipient relationships and the influence of surgical management EC/2014/45/FAHS Fast-Track

On behalf of the Ethics Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the submitted protocol and supporting documentation.

Date of confirmation of ethical opinion: 8 April 2014.

The list of documents reviewed and approved by the Committee under its Fast Track procedure is as follows:-

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<th>Document</th>
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<th>Date</th>
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<tr>
<td>Email and List of documents- Philippa Tollow; annotated and scanned.</td>
<td></td>
<td>27 Mar 14</td>
</tr>
<tr>
<td>Protocol Cover Sheet</td>
<td></td>
<td>27 Mar 14</td>
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<td>Research Summary</td>
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<tr>
<td>Prof Mark Whiteley's (Co-Supervisor) CV</td>
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<td>27 Mar 14</td>
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<tr>
<td>Philippa Tollow's (Principal Investigator) CV</td>
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<tr>
<td>Phase 2 Written Account Task Carer</td>
<td>1</td>
<td>19 Feb 14</td>
</tr>
<tr>
<td>Document</td>
<td>Version</td>
<td>Date</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Phase 4 Interview Schedule Patient</td>
<td>1</td>
<td>19 Feb 14</td>
</tr>
<tr>
<td>Phase 4 Interview Schedule Carer</td>
<td>1</td>
<td>19 Feb 14</td>
</tr>
<tr>
<td>Coping Self-Efficacy Scale</td>
<td>1</td>
<td>19 Feb 14</td>
</tr>
<tr>
<td>MOS Social Support Survey</td>
<td>1</td>
<td>19 Feb 14</td>
</tr>
<tr>
<td>Rosenberg Self-Esteem Scale</td>
<td>1</td>
<td>19 Feb 14</td>
</tr>
<tr>
<td>Family Strain Questionnaire-Short Form</td>
<td>1</td>
<td>19 Feb 14</td>
</tr>
<tr>
<td>Satisfaction with Life Scale</td>
<td>1</td>
<td>19 Feb 14</td>
</tr>
<tr>
<td>The Positive and Negative Affect Scale</td>
<td>1</td>
<td>19 Feb 14</td>
</tr>
<tr>
<td>The Charing Cross Venous Ulcer Questionnaire</td>
<td>1</td>
<td>19 Feb 14</td>
</tr>
<tr>
<td>Questionnaire: Nottingham Health Profile</td>
<td>1</td>
<td>19 Feb 14</td>
</tr>
<tr>
<td>Phase 1 Demographics Patient</td>
<td>1</td>
<td>19 Feb 14</td>
</tr>
<tr>
<td>Phase 1 Demographics Carer</td>
<td>1</td>
<td>19 Feb 14</td>
</tr>
<tr>
<td>Phase 2 Demographics Patient</td>
<td>1</td>
<td>19 Feb 14</td>
</tr>
<tr>
<td>Phase 2 Demographics Carer</td>
<td>1</td>
<td>19 Feb 14</td>
</tr>
<tr>
<td>Phase 3 Demographics Patient</td>
<td>1</td>
<td>19 Feb 14</td>
</tr>
<tr>
<td>Phase 3 Demographics Carer</td>
<td>1</td>
<td>19 Feb 14</td>
</tr>
<tr>
<td>Phase 4 Demographics Patient</td>
<td>1</td>
<td>19 Feb 14</td>
</tr>
<tr>
<td>Phase 4 Demographics Carer</td>
<td>1</td>
<td>19 Feb 14</td>
</tr>
<tr>
<td>Perceived Caregiving Impact Patient</td>
<td>1</td>
<td>19 Feb 14</td>
</tr>
<tr>
<td>Perceived Caregiving Impact Carer</td>
<td>1</td>
<td>19 Feb 14</td>
</tr>
<tr>
<td>Phase 1 Debrief Sheet</td>
<td>1</td>
<td>19 Feb 14</td>
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<tr>
<td>Phase 2 Debrief Sheet</td>
<td>1</td>
<td>19 Feb 14</td>
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<tr>
<td>Phase 3 Debrief Sheet</td>
<td>1</td>
<td>19 Feb 14</td>
</tr>
<tr>
<td>Phase 4 Debrief Sheet</td>
<td>1</td>
<td>19 Feb 14</td>
</tr>
<tr>
<td>Risk Assessment</td>
<td></td>
<td>27 Mar 14</td>
</tr>
<tr>
<td>Public Liability Insurance Certificate</td>
<td>1</td>
<td>15 Jul 13</td>
</tr>
<tr>
<td>The Whiteley Clinic Indemnity Document</td>
<td></td>
<td>27 Mar 14</td>
</tr>
<tr>
<td>Mr Mark Whiteley Indemnity Document</td>
<td></td>
<td>27 Mar 14</td>
</tr>
<tr>
<td>Protocol Submission Proforma: Insurance, Trial Number 1,</td>
<td></td>
<td>27 Mar 14</td>
</tr>
<tr>
<td>Trial Number 2, Trial Number 3 and Trial Number 4</td>
<td></td>
<td>27 Mar 14</td>
</tr>
<tr>
<td>Signed letter from NRES Committee South Central-Berkshire B confirming</td>
<td></td>
<td>21 Mar 14</td>
</tr>
<tr>
<td>favourable ethical opinion REC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>reference: 14/SC/0127 IRAS project ID: 148979</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This opinion is given on the understanding that you will comply with the University's Ethical Principles and Procedures for Teaching and Research.

The Committee should be notified of any amendments to the protocol, any adverse reactions suffered by research participants, and if the study is terminated earlier than expected with reasons. Please be advised that the Ethics Committee is able to audit research to ensure that researchers are abiding by the University requirements and guidelines.

You are asked to note that a further submission to the Ethics Committee will be required in the event that the study is not completed within five years of the above date.

On-going favourable ethical opinion from the NHS is subject to supplying Annual Progress Reports and a Declaration of the End of Study to the NHS REC which gave the favourable ethical opinion. A copy should be sent to the University Ethics Committee also. The forms are available to download here [http://www.nres.nhs.uk/applications/after-ethical-review](http://www.nres.nhs.uk/applications/after-ethical-review).

Yours sincerely

Mrs Gill Fairbairn
Interim Research Liaison Manager, Research & Enterprise Support
Appendices G – Information Sheet (Study Two)

Participant Information Sheet

A study investigating the psychological impact of venous surgery on patients and their carers

Introduction

You are being asked to take part in a research study, conducted by a PhD Psychology Student at the University of Surrey. This study will be submitted as part of the educational requirements for a PhD qualification.

Before you decide whether or not you would like to participate, you need to understand why the research is being done and what it will involve for you. Please take the time to read the following information carefully. Talk to others about the study if you wish.

What is the purpose of the study?

This study seeks to investigate the psychological impact of venous surgery on patients and their carers, and how this changes over time.

This research is being supported by ‘The Leg Ulcer Charity’ (Registered charity number: 1152113), who aim to empower patients, their families, and their carers to understand their condition and know what to ask in order to get the best possible treatment for them. It is hoped that this research will contribute to these aims, educate clinicians and professionals about the experiences of patients, and potentially lead to interventions to improve the lives of leg ulcer patients and their carers.

The data collected in this study will be used for the researcher’s PhD thesis and potentially in future academic publications. The results may be summarised and published on The Leg Ulcer Charity website, but all information will be anonymised and no participants or participant information will be identifiable. Please let the researcher know if you wish to be sent a summary of the study’s findings. This will be available by September 2016.

Why have I been invited to take part in the study?

You have been invited to take part in this study as someone who is having a leg ulcer assessment at The Whiteley Clinic. We are looking to explore the long-term wellbeing of everyone who participates in this assessment, whether you go on to have venous surgery or not.
As part of this study, approximately 60 participants are being recruited.

**Do I have to take part?**

No, you do not have to participate. Regardless of whether you decide to participate, your care or treatment will not be affected.

Your participation in this study is voluntary. You will not be given any form of compensation or paid any expenses in return for your participation.

You can withdraw at any time without giving a reason, including the withdrawal of your data after completing the study. You may choose not to complete any part of the task that you do not want to complete, and you may take a break at any time.

**What will my involvement require?**

You will be asked to fill in a number of questionnaire measures. These relate to your health and wellbeing, some elements of your personality, and your experiences receiving or giving care. You will also be asked to provide some information regarding factors such as your gender, age, and some questions regarding the length of your illness.

These questionnaires are anticipated to take 30-45 minutes to complete.

The questionnaire measures will be repeated at five time points over the next 9 months. At each time point, the researcher will contact you to ask whether you are willing to participate and to provide you with the appropriate questionnaires (either in paper form or via an online survey, dependent on your preference).

We will also ask whether there is somebody who takes care of you in an informal capacity (unpaid) who may also be willing to take part in the study. If so, we will ask for their contact details and may contact them regarding participation in the study. However, there is no obligation or pressure for them to participate and all responses will be kept completely confidential to the participant who provided them.

Unfortunately we cannot reimburse any expenses incurred from your travel or participation in this study.

**What are the possible disadvantages or risks of taking part?**

Whilst every effort is made to protect participants, some of the subject areas included in the research may be sensitive or distressing for some participants. If this is the case then you may withdraw at any point during the interview, and you do not have to provide a reason for doing so. Details of confidential emotional support services will be provided to all participants, and may be requested at any point.

**What are the possible benefits of taking part?**

No direct benefit to you is anticipated, although this study is hoped to improve the future treatment and care of leg ulcers.
Will my taking part in the study be kept confidential?

Yes. Names and personal details will be coded or anonymised in any publications produced as a result of this study; therefore you will not be identifiable from the data you provide.

However, should you disclose that you or someone else is at risk of harm then the researcher may need to report this to an appropriate authority. This would usually be discussed with you first. If you disclose poor clinical practice or dissatisfaction with medical treatment, the researcher will discuss with you possible complaints procedures that you may wish to follow. For NHS treatment this includes the Patient Advice and Liaison Services (PALS), and for treatment at The Whiteley Clinic there is a formal complains procedure. The researcher can also provide further information about this on request.

Data produced as a result of your participation will be stored securely for 10 years, in accordance with University Ethical Procedures. Data will also be stored in accordance with the Data Protection Act 1998.

Who do I contact if I have any questions, complaints, or require further information?

For further information about this study, to ask questions, or to make a complaint/raise a concern about any aspect of this study you may contact the primary researcher Philippa Tollow, on p.tollow@surrey.ac.uk or 01483 68 9444. You may also contact Professor Jane Ogden, as academic supervisor of this study, on j.ogden@surrey.ac.uk or 01483 68 6929. Or the Head of School, Peter Hegarty on p.hegarty@surrey.ac.uk or 01483 68 6898.

Who is organising and funding the research?

This research is being funded by ‘The Leg Ulcer Charity’.

Who has reviewed the project?

The study has been reviewed and received a favourable opinion from NHS Research Ethics Committee (South Central – Berkshire B REC), and the University of Surrey Ethics Committee.

Thank you for taking the time to read this Information Sheet.
**Appendices H – Carer Specific Questionnaires (Study Two)**

**Demographic questionnaire**

1. **Are you…?** (Please select the appropriate answer)
   - Male □  Female □

2. **How old are you?**
   
   ........ years

3. **What kind of support do you provide for the person with leg ulcers?** (please select all that apply)

<table>
<thead>
<tr>
<th>Practical support (eg. housework, gardening, shopping, transport)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Personal support (eg. help with bandages, getting dressed, washing)</td>
<td></td>
</tr>
<tr>
<td>Emotional support</td>
<td></td>
</tr>
<tr>
<td>Other (please specify……………………………………………………………</td>
<td></td>
</tr>
<tr>
<td>...............................................................................................................</td>
<td></td>
</tr>
<tr>
<td>None of the above</td>
<td></td>
</tr>
</tbody>
</table>

4. **What is your relationship to the individual you care for with a leg ulcer?**

   | Spouse |   |
   | Sibling |   |
   | Son/Daughter |   |
   | Mother/Father |   |
   | Other family member |   |
   | Friend |   |
   | Neighbour |   |
   | Other (please specify: ) |   |

5. **Do you live with the individual you care for?**

   | Yes |   |
   | No |   |

4a. **If no, who do they live with?**

   ............................................................................................................

232
6. **Some people feel they know what caused their leg ulcer, what do you believe is the cause of this person's leg ulcer(s)?**
   (please select all that apply)

<table>
<thead>
<tr>
<th>Diet</th>
<th>Smoking</th>
<th>Not enough exercise</th>
<th>Body weight</th>
<th>Accident/Trauma</th>
<th>Standing too much</th>
<th>Sitting too much</th>
<th>Hereditary</th>
<th>Venous disease</th>
<th>Arterial disease</th>
<th>Diabetes</th>
<th>Rheumatoid arthritis</th>
<th>Other (please specify:)</th>
<th>I don’t know</th>
</tr>
</thead>
</table>

7. **Do you know the cause of their leg ulcer/s?**
   Yes ☐  No (skip to question 4) ☐

   3a. **If yes, please select the cause from the list:**

<table>
<thead>
<tr>
<th>Venous disease</th>
<th>Arterial disease</th>
<th>Diabetes</th>
<th>Rheumatoid arthritis</th>
<th>Other (please specify:)</th>
</tr>
</thead>
</table>

8. **How long has the person you care for had the leg ulcer/s?**
   (eg. 24 months)
   (If their ulcers have healed and then come back, please specify the time since the first leg ulcer occurred)

   ……… months

9. **Do you know if their leg ulcer/s have ever completely healed and returned (reoccurred)? If so, how many times?**

   ………………………times
10. Do you know if their leg ulcer(s) has ever improved significantly and worsened again? If so, approximately how many times?

………………times

11. How would you describe their leg ulcer/s?

<table>
<thead>
<tr>
<th>Unhealed</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Healing (unhealed and improving)</td>
<td></td>
</tr>
<tr>
<td>Healed, but I expect the leg ulcer/s to return</td>
<td></td>
</tr>
<tr>
<td>Healed and I don’t expect the leg ulcer/s to return</td>
<td></td>
</tr>
</tbody>
</table>

12. How long have you been providing them with this care? (eg. 24 months)

……….months

13. Approximately how many hours per week do you think you spend providing them with this care, on average?

……………hours

14. Apart from this caregiving role, please select any other roles that you currently occupy:

<table>
<thead>
<tr>
<th>Paid work</th>
<th>Please tick all that apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children under 18 years</td>
<td></td>
</tr>
<tr>
<td>Providing care for someone else</td>
<td></td>
</tr>
<tr>
<td>Other (please specify:)</td>
<td></td>
</tr>
</tbody>
</table>

15. Would you say that your current overall health is: (please select one)

| Very good                          | |  
| Good                               | |  
| Okay                               | |  
| Poor                               | |  
| Very poor                          | |  

234
16. **What medical treatment is the person you care for currently receiving for their leg ulcers (if any)?** (please select all that apply):

<table>
<thead>
<tr>
<th>No treatment</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Compression bandages</td>
<td></td>
</tr>
<tr>
<td>Surgical treatment</td>
<td></td>
</tr>
<tr>
<td>Other (please specify:)</td>
<td></td>
</tr>
</tbody>
</table>

Please only answer questions 15a, 15b, and 15c if you answered ‘surgical treatment’ to question 15. Otherwise, please move to the next page.

a. **If the person you care for has received surgical treatment for the ulcers, how long ago was this?**

<table>
<thead>
<tr>
<th>Less than 3 months ago</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>3-6 months ago</td>
<td></td>
</tr>
<tr>
<td>6-12 months ago</td>
<td></td>
</tr>
<tr>
<td>More than 12 months ago</td>
<td></td>
</tr>
<tr>
<td>Not applicable</td>
<td></td>
</tr>
</tbody>
</table>

b. **Was this surgery completed at The Whiteley Clinic?**

<table>
<thead>
<tr>
<th>Yes</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Not applicable</td>
<td></td>
</tr>
</tbody>
</table>

c. **Do you know what surgical procedures the person you care for has had/is having?**

<table>
<thead>
<tr>
<th>Vein stripping</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Endovenous Laser Treatment (EVLT)</td>
<td></td>
</tr>
<tr>
<td>Radiofrequency (RFA) or VNUS closure</td>
<td></td>
</tr>
<tr>
<td>Perforator Closure</td>
<td></td>
</tr>
<tr>
<td>Foam sclerotherapy</td>
<td></td>
</tr>
<tr>
<td>Other (please specify:)</td>
<td></td>
</tr>
</tbody>
</table>

| It hasn’t been decided yet |  |
| Don’t know |  |
Caregiving Appraisal Scale

The following questions relate to your role as a caregiver.

Where there is a blank space (eg. ____), please imagine the name of the person that you provide informal care for.

<table>
<thead>
<tr>
<th>Agree a lot</th>
<th>Agree a little</th>
<th>Neither agree or disagree</th>
<th>Disagree a little</th>
<th>Disagree a lot</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

1. For each of the following statements, please mark the extent to which you agree:

<table>
<thead>
<tr>
<th>I can fit in most of the things I need to do in spite of the time taken by caring for _____.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taking care of ______ gives me a trapped feeling.</td>
</tr>
<tr>
<td>I get a sense of satisfaction from helping ______.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nearly always</th>
<th>Quite frequently</th>
<th>Sometimes</th>
<th>Rarely</th>
<th>Never</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

2. How often do you feel:

<table>
<thead>
<tr>
<th>Nearly always</th>
<th>Quite frequently</th>
<th>Sometimes</th>
<th>Rarely</th>
<th>Never</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

| a. …that helping ____ has made you feel closer to (him/her)? |
| b. …that you really enjoy being with ____? |
| c. …that taking responsibility for ____ gives your self-esteem a boost? |
| d. …that ____’s pleasure over some little thing gives you pleasure? |
| e. …that your health has suffered because of the care you must give ____? |
| f. …that because of the time you spend with ____ you don’t have time for yourself? |
### How often do you feel:

<table>
<thead>
<tr>
<th></th>
<th>Nearly always</th>
<th>Quite frequently</th>
<th>Sometimes</th>
<th>Rarely</th>
<th>Never</th>
</tr>
</thead>
<tbody>
<tr>
<td>g.</td>
<td>…that your social life has suffered because you are caring for ___?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>h.</td>
<td>…very tired as a result of caring for ____?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>i.</td>
<td>…that caring for ___ gives more meaning to your life?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>j.</td>
<td>…that you will be unable to care for ___ much longer?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>k.</td>
<td>…isolated and alone as a result of caring for ____?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>l.</td>
<td>…that you have lost control of your life because of caring for ___?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
Appendices I – Participant Information Sheet (Study Three)

Participant Information Sheet

The psychological impact of venous surgery on patients, their informal carers, and the caregiver-recipient relationship.

Introduction

You are being asked to take part in a research study, conducted by a PhD Psychology Student at the University of Surrey. This study will be submitted as part of the educational requirements for a PhD qualification.

Before you decide whether or not you would like to participate, you need to understand why the research is being done and what it will involve for you. Please take the time to read the following information carefully. Talk to others about the study if you wish.

What is the purpose of the study?

This study seeks to explore the psychological impact of venous surgery on patients, their informal carers, and the relationship between the caregiver and the care recipient.

This research is being supported by ‘The Leg Ulcer Charity’ (Registered charity number: 1152113), who aim to empower patients, their families, and their carers to understand their condition and know what to ask in order to get the best possible treatment for them. It is hoped that this research will contribute to these aims, educate clinicians and professionals about the experiences of patients, and potentially lead to interventions to improve the lives of leg ulcer patients and their carers.

The data collected in this study will be used for the researcher’s PhD thesis and potentially in future academic publications. The results may be summarised and published on The Leg Ulcer Charity website, but all information will be anonymised and no participants or participant information will be identifiable. Please let the researcher know if you wish to be sent a summary of the study’s findings. This will be available by September 2016.

Why have I been invited to take part in the study?

You have been invited to take part in the study, as somebody who has previously undergone venous surgery at The Whiteley Clinic. As part of this study, approximately 20 participants are being recruited.
Do I have to take part?

No, you do not have to participate. Regardless of whether you decide to participate, your care or treatment will not be affected.

Your participation in this study is voluntary. You will not be given any form of compensation or paid any expenses in return for your participation.

You can withdraw at any time without giving a reason, including the withdrawal of your data after completing the interview. You may choose not to answer any questions that you do not want to answer, and you may take a break at any time.

What will my involvement require?

You will be asked to participate in a telephone interview, at a pre-arranged time. The interview will be audio-recorded, and you will also be asked to provide some information regarding factors such as your gender, age, and some questions regarding the length of your illness or your caregiving role. The interview is expected to take approximately 60 minutes.

During this interview you will be asked questions regarding your experiences living with a leg ulcer, your feelings surrounding assessment and surgery, your experiences of being cared for by others, any changes in the patient-carer relationship over time, and your experiences of leg ulcer related issues since surgery.

We will also ask whether there is somebody who takes care of you in an informal capacity (unpaid) who may also be willing to take part in the study. If so, we will ask for their contact details and may contact them regarding participation in the study. However, there is no obligation or pressure for them to participate and all responses will be kept completely confidential to the participant who provided them.

What are the possible disadvantages or risks of taking part?

Whilst every effort is made to protect participants, some of the subject areas discussed during interview may be sensitive or distressing for some participants. If this is the case then you may withdraw at any point during the interview, and you do not have to provide a reason for doing so. Details of confidential emotional support services will be provided to all participants, and may be requested at any point. If you feel at all unwell during participation, then a first aider is available and will be called.

What are the possible benefits of taking part?

Whilst not the aim of the research, you may find that discussing your experiences and your relationships with others may be a positive experience and may help you put an order to your experiences.

There are no other anticipated direct benefits to you for participating, although this study is hoped to improve the future treatment and care of leg ulcers.
Will my taking part in the study be kept confidential?

Yes. Names and personal details will be coded or anonymised in any publications produced as a result of this study; therefore you will not be identifiable from the data you provide.

However, should you disclose that you or someone else is at risk of harm then the researcher may need to report this to an appropriate authority. This would usually be discussed with you first.

If you disclose poor clinical practice or dissatisfaction with medical treatment, the researcher will discuss with you possible complaints procedures that you may wish to follow. For NHS treatment this includes the Patient Advice and Liaison Services (PALS), and for treatment at The Whiteley Clinic there is a formal complaints procedure. The researcher can also provide further information about this on request.

The interview will be audio-recorded and the resulting audio-file will be transcribed into a written format. The original audio-recording will then be destroyed, and the transcript produced will be stored securely for 10 years, in accordance with University Ethical Procedures. Data will also be stored in accordance with the Data Protection Act 1998.

Who do I contact if I have any questions, complaints, or require further information?

For further information about this study, to ask questions, or to make a complaint about any aspect of this study you may contact the primary researcher Philippa Tollow, on p.tollow@surrey.ac.uk or 01483 68 9444. You may also contact Professor Jane Ogden, as academic supervisor of this study, on j.ogden@surrey.ac.uk or 01483 68 6929.

Who is organising and funding the research?

This research is being funded by ‘The Leg Ulcer Charity’.

Who has reviewed the project?

The study has been reviewed and received a favourable opinion from the NHS Research Ethics Committee (South Central – Berkshire B REC), and the University of Surrey Ethics Committee.

Thank you for taking the time to read this Information Sheet.
Appendices J – Participant Consent Form (Studies Three and Four)

Participant Consent Form

The psychological impact of venous surgery on patients, their informal carers, and the caregiver-recipient relationship.

Please initial the boxes corresponding to all statements to which you agree.

- I have read and understood the Information Sheet provided. I have been given a full explanation by the investigators of the nature, purpose, location and likely duration of the study, and of what I will be expected to do. I have been advised about any discomfort and possible ill-effects on my health and well-being which may result. I have been given the opportunity to ask questions on all aspects of the study and have understood the advice and information given as a result.

- I agree to comply with any instruction given to me during the study and to co-operate fully with the investigators. I shall inform them immediately if I suffer any deterioration of any kind in my health or well-being, or experience any unexpected or unusual symptoms.

- I consent to my personal data, as outlined in the accompanying information sheet, being used for this study and other research. 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 understand that I am free to withdraw from the study at any time without needing to justify my decision and without prejudice.

- I acknowledge that my participation in the study is completely voluntary, and that I will not receive any compensation or payment for my participation.

- I understand that in the event of my suffering a significant and enduring injury (including illness or disease) as a direct result of my participation in the study, compensation will be paid to me by the University, subject to certain provisions and limitations. The amount of compensation will be appropriate to the nature, severity and persistence of the injury and will, in general terms, be consistent with the amount of damages commonly awarded for similar injury by an English court in cases where the liability has been admitted.

- I understand that the research interview will be audio-recorded and then this recording will be transcribed into written format. I understand that the original audio-recording will then be destroyed, and the transcript produced from the interview will be stored securely in accordance with the Data Protection Act 1989.
I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from The Whiteley Clinic, 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 confirm that I have read and understood the above and freely consent to participating in this study. I have been given adequate time to consider my participation and agree to comply with the instructions and restrictions of the study.

Name of volunteer (BLOCK CAPITALS) ...................................................
Signed ........................................... Date ...........................................

Name of researcher taking consent ......................................................
Signed .............................................Date……………………………………..

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Appendices K – Demographic Questionnaire (Studies Three and Four)

1. **Are you…?** (Please select the appropriate answer)

   Male ☐          Female ☐

2. **How old are you?**

   …….. years

3. **Have you been told the cause of your leg ulcer?**

   Yes ☐         No (please skip to question 4) ☐

   3a. If yes, please select the cause from the list:

<table>
<thead>
<tr>
<th>Cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>Venous disease</td>
</tr>
<tr>
<td>Arterial disease</td>
</tr>
<tr>
<td>Diabetes</td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
</tr>
<tr>
<td>Other (please specify:)</td>
</tr>
</tbody>
</table>

4. **What medical treatment are you currently receiving for your leg ulcers (if any)?**
   (please select all that apply):

<table>
<thead>
<tr>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>No treatment</td>
</tr>
<tr>
<td>Compression bandages</td>
</tr>
<tr>
<td>Surgical treatment</td>
</tr>
<tr>
<td>Other (please specify:)</td>
</tr>
</tbody>
</table>

5. **How long have you had/did you have the leg ulcer/s? (eg. 24 months)**
   (If your ulcer healed and then came back, please specify the time since you had your first ulcer)

   …….. months …….. years

6. **How many times have your ulcers healed and then come back (recurred)?**

   ………………………


7. How would you characterise your leg ulcer/s?

<table>
<thead>
<tr>
<th>Characterisation</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Healed</td>
<td></td>
</tr>
<tr>
<td>Healing (unhealed and improving)</td>
<td></td>
</tr>
<tr>
<td>Healed, but I expect the leg ulcer/s to return</td>
<td></td>
</tr>
<tr>
<td>Healed and I don’t expect the leg ulcer/s to return</td>
<td></td>
</tr>
</tbody>
</table>
Questions in this protocol will act as a guide; however questions may be added or removed from the protocol, depending on the responses of the participant.

**General Prompts**

*What was that like?*

*When was that?*

*How did that make you feel?*

*You say ‘…………’, could you elaborate on that for me?*

*That must have been difficult, could you tell me a bit more about that?*

*Why do you think that was?*

*Could you explain that a bit more for me?*

*Could you tell me any more about that?*

*What was your experience of that like?*

1. I wonder if you could tell me a bit about your experience with leg ulcers when they first started?
   a. When did you first notice them?
   b. How did that affect your day-to-day life?
   c. Who diagnosed the leg ulcers? When?
   d. What treatment did you have at the beginning?
   e. How did the leg ulcers affect your… overall wellbeing?
      a. Emotionally?
      b. Physically?
      c. Psychologically?
      d. Socially?

2. (Do you/when do you think you started) considering yourself a ‘leg ulcer patient’?

3. How did you feel when going for assessment at The Whiteley Clinic?
   a. Who went with you?
   b. What were you expecting from this assessment?
   c. How did you make the decision to have surgery?
   d. And how did you feel about the decision to have surgery?
   e. What outcome were you expecting of the assessment?
   f. What outcome were you expecting of surgery?

4. Could you tell me a bit about your experience of surgery?
   a. And how did you feel after surgery?
5. What kind of support did you receive from other people when your leg ulcers first started?

[May have to Specify that ‘informal caregiving’ is meant and not formal/paid caregiver.]

a. Could you tell me a bit more about them?
b. What sort of things do/did they do for you?
c. Could you tell me a bit more about your relationship with them?
d. How did you feel about this support?

6. (If participant identifies a particular caregiver) - what feelings did you have when <name of carer> started caring for you in this way?

7. (Do they/when do you think they started) to consider themselves as a ‘carer’?

8. How do you think other people felt about caring for you during this time?

9. What kind of support did you receive from <the carer/these people> after surgery?

10. How did you feel about the relationship between you and the carer/these people during this process?

11. And how do you feel about this relationship now?

12. How do you see the future with regards to leg ulcers?

13. Is there anything else you wanted to add that we haven’t covered?
Appendices M – Participant Information Sheet (Study Four)

(Non-NHS) Participant Information Sheet

The psychological impact of treatment for leg ulcers on patients and their informal carers.

Introduction

You are being asked to take part in a research study, conducted by a PhD Psychology Student at the University of Surrey. This study will be submitted as part of the educational requirements for a PhD qualification.

Before you decide whether or not you would like to participate, you need to understand why the research is being done and what it will involve for you. Please take the time to read the following information carefully. Talk to others about the study if you wish.

What is the purpose of the study?

This study seeks to explore the psychological impact of treatment for leg ulcers on patients and their informal carers..

This research is being supported by ‘The Leg Ulcer Charity’ (Registered charity number: 1152113), who aim to empower patients, their families, and their carers to understand their condition and know what to ask in order to get the best possible treatment for them. It is hoped that this research will contribute to these aims, educate clinicians and professionals about the experiences of patients, and potentially lead to interventions to improve the lives of leg ulcer patients and their carers.

The data collected in this study will be used for the researcher’s PhD thesis and potentially in future academic publications. The results may be summarised and published on The Leg Ulcer Charity website, but all information will be anonymised and no participants or participant information will be identifiable. Please let the researcher know if you wish to be sent a summary of the study’s findings. This will be available by September 2016.

Why have I been invited to take part in the study?

You have been invited to take part in the study, as somebody with leg ulcers who has previously taken part in research on a similar topic.

As part of this study, approximately 20 participants are being recruited.
Do I have to take part?

No, you do not have to participate. Regardless of whether you decide to participate, your care or treatment will not be affected.

Your participation in this study is voluntary. You will not be given any form of compensation or paid any expenses in return for your participation.

You can withdraw at any time without giving a reason, including the withdrawal of your data after completing the interview. You may choose not to answer any questions that you do not want to answer, and you may take a break at any time.

What will my involvement require?

You will be asked to participate in a telephone interview, at a pre-arranged time. The interview will be audio-recorded, and you will also be asked to provide some information regarding factors such as your gender, age, and some questions regarding the length of your illness. The interview is expected to take approximately 60 minutes.

During this interview you will be asked questions regarding your experiences of living with a leg ulcer and your experiences of treatment.

We will also ask whether there is somebody who takes care of you in an informal capacity (unpaid) who may also be willing to take part in the study. If so, we will ask for their contact details and may contact them regarding participation in the study. However, there is no obligation or pressure for them to participate and all responses will be kept completely confidential to the participant who provided them.

What are the possible disadvantages or risks of taking part?

Whilst every effort is made to protect participants, some of the subject areas discussed during interview may be sensitive or distressing for some participants. If this is the case then you may withdraw at any point during the interview, and you do not have to provide a reason for doing so. Details of confidential emotional support services will be provided to all participants, and may be requested at any point. If you feel at all unwell during participation, then a first aider is available and will be called.

What are the possible benefits of taking part?

Whilst not the aim of the research, you may find that discussing your experiences and your relationships with others may be a positive experience and may help you put an order to your experiences.

There are no other anticipated direct benefits to you for participating, although this study is hoped to improve the future treatment and care of leg ulcers.
Will my taking part in the study be kept confidential?

Yes. Names and personal details will be coded or anonymised in any publications produced as a result of this study; therefore you will not be identifiable from the data you provide.

However, should you disclose that you or someone else is at risk of harm then the researcher may need to report this to an appropriate authority. This would usually be discussed with you first.

If you disclose poor clinical practice or dissatisfaction with medical treatment, the researcher will discuss with you possible complaints procedures that you may wish to follow. For NHS treatment this includes the Patient Advice and Liaison Services (PALS), and for treatment at The Whiteley Clinic there is a formal complaints procedure. The researcher can also provide further information about this on request.

The interview will be audio-recorded and the resulting audio-file will be transcribed into a written format. The original audio-recording will then be destroyed, and the transcript produced will be stored securely for at least 10 years, in accordance with University Ethical Procedures. Data will also be stored in accordance with the Data Protection Act 1998.

Who do I contact if I have any questions, complaints, or require further information?

For further information about this study, to ask questions, or to make a complaint about any aspect of this study you may contact the primary researcher Philippa Tollow, on p.tollow@surrey.ac.uk or 01483 68 9444. You may also contact Professor Jane Ogden, as academic supervisor of this study, on j.ogden@surrey.ac.uk or 01483 68 6929.

Who is organising and funding the research?

This research is being funded by ‘The Leg Ulcer Charity’.

Who has reviewed the project?

The study has been reviewed and received a favourable opinion from the NHS Research Ethics Committee (South Central – Berkshire B REC), and the University of Surrey Ethics Committee.

Thank you for taking the time to read this Information Sheet.
Appendices N – Study Four Interview Protocol

Questions in this protocol will act as a guide; however questions may be added or removed from the protocol, depending on the responses of the participant.

General Prompts
What was that like?
When was that?
How did that make you feel?
You say ‘………..’, could you elaborate on that for me?
That must have been difficult, could you tell me a bit more about that?
Why do you think that was?
Could you explain that a bit more for me?
Could you tell me any more about that?
What was your experience of that like?

1. I wonder if you could tell me a bit about your experience with leg ulcers when they first started?
   a. When did you first notice them?
   b. How did that affect your day-to-day life?
   c. Who diagnosed the leg ulcers? When?
   d. How did the leg ulcers affect your… overall wellbeing?
      a. Emotionally?
      b. Physically?
      c. Psychologically?
      d. Socially?

2. Could you tell me about the treatment you’ve had for your leg ulcers?
   a. What were you expecting from this treatment?
   b. Were these expectations met?
   c. What outcome were you expecting of this treatment?

3. Could you tell me a bit about your experience of treatment?
   a. And how did you feel about this treatment?
   b. Have those feelings changed at all over time?
   c. How do you feel about this now?
4. What kind of support did you receive from other people when your leg ulcers first started?

[May have to Specify that ‘informal caregiving’ is meant and not formal/paid caregiver.]

a. Could you tell me a bit more about them?
b. What sort of things do/did they do for you?
c. Could you tell me a bit more about your relationship with them?
d. How did you feel about this support?

5. (If participant identifies a particular caregiver) - what feelings did you have when <name of carer> started caring for you in this way?
   a. (Do they/when do you think they started) to consider themselves as a ‘carer’?
b. How do you think other people felt about caring for you during this time?
c. How did you feel about the relationship between you and the carer/these people during this process?

6. How do you see the future with regards to leg ulcers?

7. Is there anything else you wanted to add that we haven’t covered or anything you want to stress is particularly important to you?