Examining the effectiveness of the Babytalk Home Visiting Service on parent talk to children and child language development:

A randomised controlled trial.

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STATEMENT OF ORIGINALITY

This thesis and the work to which it refers are the results of my own efforts. Any ideas, data, images or text resulting from the work of others (whether published or unpublished) are fully identified as such within the work and attributed to their originator in the text and bibliography. This thesis has not been submitted in whole or in part for any other academic degree or professional qualification. I agree that the University has the right to submit my work to the plagiarism detection service TurnitinUK for originality checks. Whether or not drafts have been so assessed, the University reserves the right to require an electronic version of the final document (as submitted) for assessment as above.

Clare Smith
ABSTRACT

Background: Socially disadvantaged children are more likely than their advantaged peers to have delayed language development. Parent talk to children has been found to be related to child language abilities and to socioeconomic status. Based on an interactionist theory of language development, it is proposed that child language may be supported, in part, by encouraging parents to talk to their baby. Speech and language therapy services in the UK have developed a range of preventative services to this end but there is little evidence of effectiveness. In this study, a randomised controlled trial (RCT) was carried out to investigate efficacy of the Babytalk Home Visit (BTHV) on parent talk to children and on child expressive vocabulary.

Method: 69 parent/baby dyads were randomised to BTHV and control groups, videoed and parent talk transcribed in their homes at baseline, post intervention and when their child was aged 2 years. Baseline to post-intervention change in parent word types spoken and parent report of child expressive vocabulary at age 2 years were compared between groups.

Results: No significant difference was observed between groups for either outcome measure. Subgroup analysis indicated a possible temporary effect on parental talk for parents from low socioeconomic backgrounds. This effect was not sustained at the 2 year follow up, however, and no effect on child language outcomes at age 2 was observed. In line with previous studies, a highly significant relationship was found between parent talk and child language.

Discussion: These results highlight the need to understand the potential and mechanism for change in parent talk and the need for further research into the nature of the relationship between parent talk and child language. They also highlight the value of controlled studies to inform commissioning of speech and language therapy services using the MRC’s guidance for complex interventions.
STATEMENT OF FAVOURABLE ETHICAL OPINION AND FUNDING

This study was granted favourable ethical opinion by the Berkshire Research Ethics Committee (reference: 09/H0505/101) and by the University of Surrey Ethics Committee (reference EC/2009/102/FHMS). It was also registered with the Hampshire and Isle of Wight shared Research Management and Governance Service (reference: MWP/083/09).

The study and the PhD studentship were funded by a Wessex Deanery Education Grant and the National Institute of Health Research under a Clinical Doctoral Fellowship Trainee programme (reference: CAT CDRF09/38).
DECLARATION OF WORK

**Background work:**
I conceived the idea for the systematic review, conducted the literature searches and interpreted the results under the supervision and guidance of Professor Karen Bryan and Dr. Emma Williams.

**Feasibility study:**
I conceived the idea and plan for the feasibility pilot study. I defined the primary and secondary outcome measures and planned the feasibility research methods. I carried out the feasibility study with the support of the Elaine Davis, speech and language therapy assistant and interpreted the results with the support of my supervisors, Professor Karen Bryan and Dr. Emma Williams.

**Intervention:**
The intervention investigated in this trial was developed by Dr. Deborah Gibbard and I prior to the development of this trial. The service was evaluated using quasi-experimental methods, and this was published. A protocol of this service was also developed.

**Trial:**
I designed the randomised controlled trial under the guidance of my supervisors as stated above. This included the study design, selection of outcome measures, sample size calculation, design of recruitment and randomisation processes, trial methods, data collection, transcription and analysis and interpretation of the outcomes. I was supported by Solent NHS Trust speech and language therapy department for the delivery of the trial, for which I acted as primary investigator. I held overall responsibility for the randomisation, allocation to experimental groups and delivery of the intervention, which was carried out by Elaine Davis and Louise Wakefield, speech and language therapy assistants.
ACKNOWLEDGEMENTS

First, I would like to thank all the parents and babies who so generously invited me into their homes and allowed themselves to be filmed. It was a delight to work with these families, and I was touched by their enthusiasm for and support of the trial. Their involvement, time, and commitment have helped to increase our understanding about child language development and what we can or cannot do to support it.

Many thanks to my supervisors Emma Williams and Karen Bryan for their continued support and encouragement over the course of this work. I also thank them for continuing my supervision at times of professional and organisational change for them, personally. This thesis would not have been possible without them. I would also like to acknowledge Professor Chris Fife-Schaw and Dr. Wendy Knibb for their advice on trial design and statistical analysis.

Dr. Deborah Gibbard at Solent NHS Trust has remained a constant source of support within my clinical setting and has provided reassurance, encouragement and often practical help when the clinical environment was undergoing significant reorganisation. Her voice and backing of the trial enabled it to continue in the face of funding cuts and redundancies, and her commitment to evidence based practice inspired me to put one of our own services to the test. I would also like to acknowledge the support of Dr. Sarah Williams, head of research at Solent NHS Trust and Margaret Meikle, Head of Speech and Language Therapy services, Portsmouth City Teaching Primary Care Trust.

The quality of the trial would have been significantly reduced without the help and assistance of Elaine Davis and Louise Wakefield, speech and language therapy assistants. Their contribution to the randomisation, allocation and service delivery helped significantly to reduce bias in the trial,
and to increase the service fidelity. They remained supportive and positive about the trial in the face of redundancy and significant organisational change. They also continued to support the trial after they were redeployed as a result of funding withdrawal. Thanks also to Helen Markey, Speech and Language therapist who helped with establishing validity of the transcriptions.

I would like to thank Jill Fitzgerald and Edwina Brennan from the Portsmouth Children’s Centre Service for supporting the development and evaluation of the BabyTalk Home Visiting Service and for their initial support of the trial.

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LIST OF CONTENTS

Statement of Originality i
Abstract ii
Statement of favourable ethical opinion and funding iii
Declaration of work iv
Acknowledgements v
List of Contents vii
List of Figures xii
List of Tables xiii
Glossary of terms and abbreviations xiv

Chapter 1: Background Literature: A justification for primary prevention of
environmentally based language delay................................................................. 1

1. 1: How important is language? An argument for the human fundamental need for language .......... 3
   1. 1. 1: Phylogenetic origins of language.................................................................................3
   1. 1. 2: Increased demands for language use in the modern world .........................................4
   1. 1. 3: Global recognition of communication as a human right...............................................5
1. 2: Language delay: presentation, prevalence and prognosis ...................................................... 9
   1. 2. 1: Defining language delay .................................................................................................9
   1. 2. 2: Clinical presentation of primary language delay............................................................ 13
   1. 2. 3: Prevalence of primary language delay............................................................................. 14
   1. 2. 4: Prognosis - long term outcomes for children with primary language delay............... 19
1. 3: Causes of primary language delay ......................................................................................... 21
   1. 3. 1: Biological factors...........................................................................................................22
   1. 3. 2: Environmental factors – an overview.............................................................................24
   1. 3. 3: Macro-environmental factors ..........................................................................................24
1. 3. 4: Micro-environmental factors .......................................................................................... 30
1. 3. 5: Parental linguistic input .................................................................................................. 35
1. 3. 6: Environmental factors, concluding comments .................................................................. 41
1. 4: Theoretical models of language development ...................................................................... 42
   1. 4. 1: Justification for a theoretical perspective .................................................................... 42
   1. 4. 2: The nature – nurture debate ......................................................................................... 43
   1. 4. 3: The nativist approach .................................................................................................. 44
   1. 4. 4: Non-nativist approaches to language development ...................................................... 48
   1. 4. 5: Moving on from the debate .......................................................................................... 51
   1. 4. 6: The role of environmental input ..................................................................................... 53
   1. 4. 7: Summary ....................................................................................................................... 55
1. 5: Incorporating the empirical and theoretical accounts: Implications for this study .............. 56

Chapter 2: An evidence-based approach for speech and language therapy services

aimed at family focused prevention of environmentally based language delay .................. 58

2. 1: Positioning family focused preventative practice within the framework of evidence based practice ............................................................................................................. 58
   2. 1. 1: The current picture of preventative practice for environmentally based language delay 58
   2. 1. 2: Primary prevention within speech and language therapy and evidence based practice... 60
   2. 1. 3: A critical overview of the development of evidence-based practice within the speech and
           language therapy profession ................................................................................................. 61
   2. 1. 4: Adopting an evidence-based approach for this study .................................................. 69
   2. 2. 1: Background to Systematic Reviews: strengths and limitations .................................... 71
   2. 2. 2: The case for a systematic scoping study ....................................................................... 74
   2. 2. 3: Systematic Scoping Review: Identification of the review question ............................... 76
   2. 2. 5: Study selection ............................................................................................................... 81
   2. 2. 6: Extraction and charting of data ...................................................................................... 84
   2. 2. 7: Collating, summarising and reporting results ................................................................. 85
   2. 2. 8: Results of systematic scoping review ............................................................................ 85
   2. 2. 9: The nature of the service; how is it delivered? ................................................................ 88
Chapter 4: Examining the effectiveness of the BTHV through a matched pairs randomised controlled trial

Section 4.1: Methods

4.1.1: Establishment of research team

4.1.2: Participants and recruitment

4.1.3: Trial procedure

4.1.4: Data analysis

4.1.5: Post hoc analysis

4.2: Results

4.2.1 Recruitment

4.2.2: Data entry and verification

4.2.3: Distribution of data

4.2.4: Review of appropriate statistical test

4.2.5: Randomised controlled trial results for primary and secondary outcome measures

4.2.6: Post-hoc analysis

Chapter 5: Overall study discussion, conclusions and directions for future research

5.1: Limitations of the randomised controlled trial

5.1.1: Summary of results and study limitations

5.1.2: Recruitment and attrition of participants

5.1.3: Sample size

5.1.4: Sample characteristics

5.1.5: Fidelity of service delivered

5.1.6: Hawthorne or Observer effects

5.1.7: Blinding

5.2: Why was there no effect of the BTHV?

5.3: Revisiting the theory on language development

5.3.1: Review – the theoretical assumptions of the BTHV
5.4: The evidence base for speech and language therapy practice for primary language delay ........... 214

5.4.1: How this study contributes to the evidence base for primary prevention .......................... 214

5.4.2: The way forward for prevention of primary language delay.............................................. 216

5.4.3: Reflection on developing and evaluating complex interventions using the MRC (2000, 2008)................................................................................................................................. 217

Chapter 6: Conclusion and final study reflections ................................................................. 220

6.1: Conclusion: The contribution of this study to evidence based practice in prevention of primary language delay ......................................................................................................................... 220

6.2: Final and personal reflections ........................................................................................ 220

List of References 224

Appendices 253
List of Figures

Figure 1  Phases of evidence for complex interventions (Medical Research Council, 2000)  64
Figure 2  Phases of evidence for complex interventions (Medical Research Council, 2008)  67
Figure 3  Flow chart of systematic scoping review study selection process  87
Figure 4  The Babytalk Home Visiting Service model (Smith & Gibbard, submitted)  102
Figure 5  Within subject variance: measures of total utterances (feasibility pilot study)  145
Figure 6  Within subject variance: measures of word types (feasibility pilot study)  145
Figure 7  Within subject variance: measures of word tokens (feasibility pilot study)  146
Figure 8  Study t-shirt for infant participants  167
Figure 9  Study toy given to children at the end of the 2 year follow up visit  167
Figure 10  CONSORT flow diagram for RCT (Schulz, Altman, Moher, & Consort Group, 2010)  173
Figure 11  Distribution of frequencies: parental level of education  175
Figure 12  Distribution of frequencies: home ownership status  175
Figure 13  Distribution of frequencies: primary outcome measure (post intervention)  176
Figure 14  Distribution of frequencies: primary outcome measure (2 year follow up)  177
Figure 15  Distribution of frequencies: secondary outcome measure  177
Figure 16  Boxplot showing distribution of frequencies for number of word types at the post-intervention minus baseline stage  181
Figure 17  Boxplot showing distribution of frequencies for number of word types at the 2 year follow up minus baseline stage  181
Figure 18  Boxplot showing distribution of frequencies for MCDI words produced scores  182
# List of Tables

| Table 1 | The five quality features of parental linguistic input (Hart & Risley, 1995) | 39 |
| Table 2 | Aspects defined in the scoping review question (Arksey & O'Malley, 2005; Armstrong, Hall, Doyle, & Waters, 2011; Levac, Colquhoun, & O'Brien, 2010) | 78 |
| Table 3 | Search terms identified for systematic scoping review of peer reviewed databases | 80 |
| Table 4 | Review eligibility criteria for systematic scoping review | 83 |
| Table 5 | Number of services identified according to nature of service delivery | 88 |
| Table 6 | Number of evaluation procedures identified according to method | 91 |
| Table 7 | Additional transcriptions conventions for pilot study | 139 |
| Table 8 | Frequencies of measures of parent talk across participants | 143 |
| Table 9 | Activities carried out by participant dyad | 147 |
| Table 10 | Means and standard deviations for 15 minute segments (total and randomised sample) | 147 |
| Table 11 | Measures of parent talk for total 45 minute video sessions | 148 |
| Table 12 | Descriptive statistics showing variance of frequencies across experimental groups for parental level of education | 174 |
| Table 13 | Skewness and kurtosis z-scores by experimental group for outcome measures | 178 |
| Table 14 | Mean word tokens across a range of studies with adjusted mean for 15 minute time periods | 198 |
## Glossary and abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>ADHD</td>
<td>Attention Deficit Hyperactivity Disorder – a developmental disorder affecting attention and behaviour</td>
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<tr>
<td>ASHA</td>
<td>American Speech and Hearing Association</td>
</tr>
<tr>
<td>ATP2C2</td>
<td>A gene located on chromosome 16 associated with language development (Newbury et al., 2009)</td>
</tr>
<tr>
<td>Autism</td>
<td>A spectrum of developmental disorders affecting social interaction, language and communication and behavioural development</td>
</tr>
<tr>
<td>BTHV</td>
<td>The Babytalk Home Visiting Service</td>
</tr>
<tr>
<td>C4EO</td>
<td>Centre for Excellence in Outcomes</td>
</tr>
<tr>
<td>CASLPA</td>
<td>Canadian Association for Speech-Language Pathologists and Audiologists</td>
</tr>
<tr>
<td>CASP</td>
<td>Critical Appraisal Skills Programme</td>
</tr>
<tr>
<td>CDS</td>
<td>Child Directed Speech</td>
</tr>
<tr>
<td>Children’s Centre</td>
<td>A government funded UK based multi-agency Centre dedicated to supporting early child development</td>
</tr>
<tr>
<td>CMIP</td>
<td>A gene located on chromosome 16 associated with language development (Newbury et al., 2009)</td>
</tr>
<tr>
<td>CNTNAP2</td>
<td>A gene regulated with FOXP2 gene and associated with specific language impairment (Vernes et al., 2008)</td>
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<tr>
<td>The Cochrane Collaboration</td>
<td>An independent organisation dedicated to the dissemination of evidence through systematic reviews</td>
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<tr>
<td>CONSORT</td>
<td>Consolidated Standards of reporting Trials</td>
</tr>
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</table>
**constructivist theory**
Theoretical approaches that stem from an assumption that language is constructed as a result of use

**EBP**
Evidence-based practice

**empiricist theory**
Theoretical approaches that stem from an assumption that skills are learned, rather than innate

**FOXP2**
A gene located on chromosome 7 responsible for the development of speech and language (Pinel et al., 2012)

**FUTON**
Full text available on the internet – a source of publication bias

**The Hanen Centre**
A Canadian charity responsible for the development of a number of speech and language therapy initiatives

**HCPC**
The Health and Care Professions Council

**The HOME Inventory**
A standardised measure of the home environment (Bradley & Caldwell, 1984a)

**ICAN**
UK based national charity of children with speech, language and communication needs

**ICP**
International Communication Project

**interactionist theory**
Theoretical approaches that stem from an assumption that language develops as a result of social interaction

**IQ**
Intelligence Quotient

**Macro-environmental effects**
Factors in the environment that are associated with but may not directly influence language development

**MCDI**
MacArthur Bates Communicative Development Inventory

**Micro-environmental effects**
Factors in the environment that are associated with and may directly influence language development

**MRC**
Medical Research Council

**n**
Number
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>nativist theory</td>
<td>Theoretical approaches that stem from an assumption that skills are innate, rather than learned</td>
</tr>
<tr>
<td>NESS</td>
<td>National Evaluation of Sure Start</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Service</td>
</tr>
<tr>
<td>NIHR</td>
<td>National Institute of Health Research</td>
</tr>
<tr>
<td>NRES</td>
<td>National Research Ethics Service</td>
</tr>
<tr>
<td>NS</td>
<td>Not significant</td>
</tr>
<tr>
<td>OME</td>
<td>Otitis-media with effusion</td>
</tr>
<tr>
<td>PICOS</td>
<td>An acronym for defining systematic review questions, highlighting the specification of Participants, Intervention, Comparison, Outcomes and Study design</td>
</tr>
<tr>
<td>p</td>
<td>Level of significance</td>
</tr>
<tr>
<td>phylogenetic</td>
<td>The evolutionary development of a trait within a species</td>
</tr>
<tr>
<td>Primary language delay</td>
<td>Delayed onset of receptive or expressive language development that is not explained by a separate aetiology (Law, Boyle, Harris, Harkness, &amp; Nye, 2000a)</td>
</tr>
<tr>
<td>PND</td>
<td>Postnatal Depression</td>
</tr>
<tr>
<td>RCSLT</td>
<td>Royal College of Speech and Language Therapists</td>
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<tr>
<td>RCT</td>
<td>Randomised controlled trial</td>
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<tr>
<td>REC</td>
<td>Research Ethics Committee</td>
</tr>
<tr>
<td>recursion</td>
<td>The potential for infinite repetition of a rule or function</td>
</tr>
<tr>
<td>R&amp;D</td>
<td>Research and Development</td>
</tr>
<tr>
<td>SALT</td>
<td>Systematic Analysis of Language Transcripts</td>
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<tr>
<td>SES</td>
<td>Socio-economic status</td>
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<tr>
<td>SLCN</td>
<td>Speech, Language and Communication Needs</td>
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<tr>
<td>Acronym</td>
<td>Description</td>
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<tr>
<td>SLI</td>
<td>Specific Language Impairment – a persistent, long term difficulty with language development that is of unknown origin (Bishop, 2014b)</td>
</tr>
<tr>
<td>SLT</td>
<td>Speech and Language Therapist</td>
</tr>
<tr>
<td>SLTA</td>
<td>Speech and Language Therapy Assistant</td>
</tr>
<tr>
<td>SPSS</td>
<td>Statistical Package for the Social Sciences</td>
</tr>
<tr>
<td>SSLM - R</td>
<td>The Sure Start Language Measure – Revised (Sure Start, 2002): A parent report based measure of language development</td>
</tr>
<tr>
<td>Sure Start</td>
<td>A UK government programme aimed at eradicating child poverty</td>
</tr>
<tr>
<td>UG</td>
<td>Universal Grammar, a theory of innate linguistic knowledge (Chomsky, 1980)</td>
</tr>
<tr>
<td>UN</td>
<td>United Nations</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
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Chapter 1: Background Literature: A justification for primary prevention of environmentally based language delay.

In the first part of this thesis the issue of environmentally based language delay is discussed and an argument for primary prevention of this condition is presented. Before this argument can be made, however, it is necessary to consider language development and use within the context of human life. How important is communication through language? What is full linguistic competence and what is language delay? What are the outcomes for individuals if they do not develop full linguistic competence? How do children develop language and what causes language delays? Ultimately the question of whether it is possible to support language development through supporting the environment needs to be addressed. It is only through consideration of all of these factors that the feasibility, value and effectiveness of any primary prevention intervention may be examined and it is these questions that form the focus of Chapter 1 of this thesis.

A note on terminology.

This thesis is concerned with the challenge of facilitating early language development through an environmental speech and language therapy primary prevention initiative. For the purposes of clarification of terminology it should be noted at this stage that the term ‘development’ is adopted to describe the development to full linguistic competence of a mother tongue (i.e. a first language) in children. Other terminology may be found in the literature, for example ‘language acquisition’ or ‘language learning’. The term ‘language acquisition’ neatly positions the topic as being about the development of a child’s first language, but has been reported to have been coined by proponents of the nativist school (Sampson, 1997) to reflect the innate nature of language. The term ‘language learning’ could be equally blamed for reflecting the empiricist school of thought. Further, it could be used to apply to second or third language learning (for example within an education
establishment), and is therefore less specific. The term ‘language development’ positions language ‘acquisition’ or ‘learning’ as part of child development, as understood by health and educational professionals. The term ‘development’ is also used clinically, especially in the case of developmental delays, which is particularly pertinent to this thesis. As the objective of this study is to assess the effectiveness of an intervention designed to prevent ‘developmental language delay’ then the term ‘language development’ is the most appropriate term to use. In this thesis, however, this term is not used to reflect a theoretical viewpoint. Those arguments will be made independently.

Concerning terminology to describe difficulties developing language, three terms will be used in this thesis. First, as described by Law, Boyle, Harris, Harkness, and Nye (2000b) the term ‘primary language delay’ will be used to describe the early indication of language delay that is not secondary to another condition, such as Down’s syndrome, Autistic Spectrum Disorder or hearing loss. Second, where the environment is proposed as the major contributing factor to primary language delay, the term ‘environmentally based language delay’ will be used. Third and finally, the term ‘specific language impairment’ is used to describe more persistent long-term difficulties with language development in the absence of a known aetiology. A discussion of and justification for the use of these terms is given in Section 1.2.1: ‘Defining language delay’.
1. 1: How important is language? An argument for the human fundamental need for language.

1. 1. 1: Phylogenetic origins of language

Evolution of language in humans

As primates, human beings are biologically adapted for social life (Joffe, 1997; Tomasello, 2007). In his summary of social adaptation, Winston (2002) reported that the ability to function within groups has enabled humans to increase their capacity for passing on learned skills and knowledge, and for engaging in group activities including finding food and tool use, and that the primary skill that enables these functions is the ability to communicate. As part of this biological adaptation for social and cultural life, humans have a highly developed communication system, the most complex feature of which, by far, is language.

The question of how humans evolved to use language and whether language structure itself is a biologically evolved adaptation, or a learned cultural process emerging from other social adaptations continues to be debated (Bickerton, 1992; Pinker, 1994; Sampson, 1997; Tomasello, 2008) and will be discussed further in section 1. 4. At this stage, however, for the purposes of understanding to what degree language is important to our species it is only necessary to state that it is widely agreed that human language is in some degree related to and dependent on our biological and evolutionary makeup (Sampson, 1997). Human language enables us to request and offer help, inform and share intentions and experiences (Tomasello, 2008). Not only is the ability to communicate using language beneficial to humans for all these reasons, it is in fact expected between conspecifics, and humans who do not understand or cooperate according to the underlying purposes of human communication (including cooperation, altruism) are likely to find themselves ostracised from society (Tomasello, 2008).
Universality of language

Human language use is universal. Whilst across the world we all speak different languages, all normally developing humans acquire some form of spoken or signed language. Even individuals raised without a linguistic model (for example deaf children born to non-signing parents, or slaves removed from their own linguistic environment and therefore only using pidgin versions of a language) generate full linguistic competence within a single generation (Bickerton, 1992; Pinker, 1994). Whilst there are limitations in these early anthropological studies (Pinker, 1994; Sampson, 1997), it appears that for all cultures worldwide language use is a robust human skill and full linguistic competence develops quickly between individuals, even in adverse circumstances. Language use appears therefore to be a fundamental feature of what it means to be human.

1. 1. 2: Increased demands for language use in the modern world

Reduction of manual labour

It has been proposed that in the twenty-first century the ability to communicate has become an even more vital skill for participation in the developed world. Several authors have highlighted that as society has moved towards advances in technology, the demand for traditional manual labour has decreased, (Hart & Risley, 1995; Law, Reilley, & Snow, 2013; Ruben, 2000). As Law et al. (2013) stated; “the more sophisticated, the better educated and the more automated or digitalised the society becomes, the greater the shift from the blue collar manual employment towards white collar ‘communication’ focused jobs” (p. 488). Ruben (2000) carried out a survey of employment in the USA which found that labour that would be considered to be manual had reduced from 80% of the workforce in 1900 to 37% of the workforce in 2000. He also postulated that even the work that is considered to be blue collar manual labour in 2000 would require employees to have certain cognitive skills, for example in process management or logistics. These skills rely to a degree on language abilities.
The need for language in a digitalised society

It is also noteworthy that the increasing dependence on the Internet for participation in society places demands on an individual’s communication skills. Livingstone (2002) highlights three different kinds of interactions that take place on the internet; user to user interactions, that is, computer aided interactions such as email, text and chat environments, user to document, such as access to information through hyperlinks and user to system, such as takes place in gaming environments. The internet is now used for so many aspects of life; participation in social life for forming friendships and relationships (e.g. McKenna, Green, & Gleason, 2002), access to information for the purposes of health (e.g. Norman & Skinner, 2006), education (e.g. Wright, 2010), employment (e.g. Kuhn & Skuterud, 2000) and for leisure (e.g Sanchez-Navarro & Aranda, 2012). The ability to interact in these three ways using the internet is now considered to be a basic skill (Skills for Life Network, 2015). There is even some evidence of an attempt to measure social status in part according to level of social networking on the internet (Savage et al., 2013). It is proposed in this study that the ability to take full advantage of all aspects of a digitalised society is largely dependent on an individual’s communication and language skills, and that those with speech, language and communication needs are further disadvantaged.

1. 1. 3: Global recognition of communication as a human right

Given the importance of these highly developed communication skills through language in the evolution of humans and the universality of language use, it is not surprising, therefore, that the ability to communicate effectively (and arguably, thus, to use language) is considered globally to be vital to an individual’s health and wellbeing and is recognised internationally to be a basic human need.
Declaration of communication rights and human rights

Last year the International Communication Project published a universal declaration of communication rights (International Communication Project, 2014). This declaration was developed by its member organisations across the globe, that is, the speech and language therapy professional bodies of the UK, Canada, Ireland, USA, Australia and New Zealand. This declaration is not representative of the world as a whole as it represents only the interested profession of English speaking developed world. It also does not have the legal gravitas of the Universal declaration of Human Rights (United Nations, 1948) which was agreed by fifty member states and now forms the basis of human rights law. The communication rights declaration does, however, highlight that the ability to communicate affects significant aspects of life that are referenced in the United Nations Declaration of Human Rights (1948). For example, the declaration of communication rights states that barriers to communication affect an individual’s ability to relate to and interact with others (thus affecting their right to realise social and cultural rights and develop their personality, as outlined in Article 22), to learn (affecting their right to an education as stated in Article 26) and to access the justice system (affecting their right to equal protection before the law as stated in Article 7). Furthermore, the World Health Organisation (WHO) recognises the importance of communication as vital for health literacy. The WHO defines ‘communication and interpersonal skills’ as one of five areas of life skills globally relevant and necessary for health promotion and the protection of human rights across the world (World Health Organisation, 1999).

The rights of children

The importance of communication is also recognised internationally concerning the rights of children. The United Nations Convention on the rights of the Child (1989), signed by all member States (excluding the USA and Somalia) acknowledges the rights of children to be able to express their views (Article 12, p.5). Furthermore, Article 13 (p.5) states that “the child shall have the
right to the freedom of expression; this right shall include the freedom to seek, receive and impart information and ideas of all kinds... either orally, in writing or in print...”.

Recognition of communication as a human right in the UK.

The international recognition of the importance of communication is reflected in UK policy and law. Numerous reviews and white papers highlight the importance of communication to support child development and wellbeing. Just as in the case for the UN declaration of human rights, barriers to communication would also affect a child’s ability to achieve the five outcomes which are identified in the government green paper ‘Every Child Matters’ (2004) and underpinned in the Children Act 2004. These outcomes are ‘be healthy’, ‘stay safe’, ‘enjoy and achieve’, ‘make a positive contribution’ and ‘achieve economic wellbeing’. In the green paper the role of speech and language therapy as a priority in meeting a child’s educational and social outcomes is cited as an example of good practice (p. 19 Department for Education and Skills, 2004). The Children Act specifies the need for the Children’s Commissioner to ‘consult with’ and ‘communicate with’ children regarding the discharge of his/her function (Part 1, section 4, page 2, 2004). Furthermore, the Act also stipulates that the Children’s Commissioner take steps to accommodate the needs of children who do not have adequate means to make their views known (Part 1, section 4, page 2, 2004).

The Bercow Review

In 2008, mindful of the importance of communication for health and wellbeing the UK government carried out a review of services for children with speech, language and communication needs (SLCN) (Department for Children Schools and Families, 2008). The evidence gathering process of this review was comprehensive and included a range of enquiry methods. Whilst the methods of sampling were not reported, the consultation questionnaire received 2000 responses, which considerably exceeds the usual requirements for a 95% confidence interval in findings for the
population of the UK (Raosoft, 2014). Consultation groups were held with a variety of interested parties, including a range of people affected by SLCN and services and professionals employed to support children and young people with SLCN. Consultations were convened in a diverse selection of geographical locations, but did not include Wales, Scotland or Northern Ireland (so therefore may only be representative of views in England). The review also commissioned research from a range of UK academics with expertise in SLCN. It may be concluded, therefore, that the findings of this review are representative of interested parties concerned with SLCN, particularly in England. The review confirmed international opinion that communication is an essential life skill, stating, “the centrality of communication is not simply a personal statement of value. It is a formal, public and multilateral declaration...[and] is a fundamental human right.” (p. 16).

**Summary**

The use of language, therefore, is universal; it is the direct or indirect result of biological adaptations in humans to facilitate highly complex levels of cooperation necessary for advanced social life. Language competence has been proposed as even more essential for participation in a technologically advanced society. It is recognised internationally at a governmental and legal level to be a fundamental life skill, necessary for health, education as well as for emotional and economic wellbeing, and the protection of human rights. Indeed, it has of itself been described as a human right (Department for Children Schools and Families, 2008; International Communication Project, 2014). The centrality of language to human life was summed up succinctly by Tammet (2014): “there is almost nothing we can do to a human being worse than take away their language and their ability to communicate and... relate to other human beings through language... language is a side effect of a much larger goal” (that goal being participation in social life) (quote from video material spoken at 04:42 - 04:51 minutes).
Given the importance of language for all the factors cited above, it is necessary to consider what the outcomes may be for individuals who do not achieve full linguistic competence within the normally expected timeframe, what proportion of the population are affected and why they are affected. The focus of this chapter, therefore, is turned to children who present with primary language delay, as this is the first sign that all may not be well with an individual’s language development. Through considering the presentation, prevalence and prognosis of primary language delay the burden of this condition on individuals and society is more clearly understood and the question of whether there is a role for preventative services for primary language delay is addressed.

1. 2: Language delay: presentation, prevalence and prognosis

1. 2. 1: Defining language delay

Defining primary language delay is not easy. This is evident even within the speech and language therapy profession as the International Journal of Language and Communication Disorders recently dedicated an special edition of the journal to the issue of defining language difficulties in young children (Ebbels, 2014).

The first issue to be considered is that difficulties with learning and using language fall along a continuum into the normal range of development. Establishing a cut off point for purposes of diagnosis may be fairly arbitrary (Bishop, 2014b). Traditionally, children who score at the lower centiles of a standardised assessment of language are identified but this has been highlighted as a rather circular approach that bears no relevance to the functional implications of such a condition (Bishop, 2014b; Law et al., 2000b).
The second difficulty encountered concerns the multifactorial nature of primary language delay. Differences in the causes, underlying skills processes and presenting features of language delay result in a heterogeneous population (Bishop, 2014b).

Thirdly and finally, as a result of the nature of causes and presentation of developmental language delays there is a plethora of different and often overlapping terms used to describe children’s difficulties. These include (but are not limited to): primary speech and language delay (Law et al., 2000a), speech and language impairment (Snowling, Adams, Bishop, & Stothard, 2001), specific language impairment (Rice, Wexler, Marquis, & Hershberger, 2000), language disorder and specific language disorder (Lees & Urwin, 1997), and specific speech disorder (Stackhouse & Wells, 1997). A recent review using Google Scholar carried out by Bishop (2014b) yielded 132 different terms with 33 resulting in over 600 returns. Whereas, in other disciplines there are (albeit not universal) agreements on diagnostic terminology (American Psychiatric Association, 2013), there are currently no published guidelines on agreement in terminology for speech and language difficulties. Whilst attempts have recently been made to work towards a consensus (Bishop, 2014b; Ebbels, 2014; Reilly, Bishop, & Tomblin, 2014a; Reilly et al., 2014c), the historical interpretations of individual labels and the need for clarity in both clinical practice and research portends a long and difficult path to this end.

A terminological complication that is pertinent to this study is the distinction between primary language delay that is largely the result of biological factors and primary language delay that is the result of environmental factors. There have been attempts to identify the differences in and prognosis of these two types of language delay (Roy & Chiat, 2013). Various grammatical markers have been identified that are reported to indicate a biologically based language impairment (Bishop, 2008). Understanding the difference between these two causal factors and the consequences for presentation of impairment and prognosis might inform interpretation of the literature. Teasing
apart the differences between these two groups, however, is not a straightforward task as there is likely to be considerable overlap between the groups (Roy & Chiat, 2013). This is discussed more fully, below, in the discussion on the influence of socioeconomic status on language development (section 1.3.5).

Cognisant of this call for a consensus on terminology, the term that is used in this thesis is primary language delay. This was defined by Law (1998) as when the “speech and language skills of a child are delayed relative to other skills, usually in the absence of a clear aetiology.” (p. 17). This term has been adopted in other studies using the same definition (Blackwell, Harding, Babayiğit, & Roulstone, 2015; Vigil & Hodges, 2005). In her review paper on terminology Bishop (2014b) argued that distinguishing language abilities from other skills, usually non-verbal skills is no longer considered to be a defining factor as non-verbal ability has been demonstrated not to limit verbal ability, as had been previously proposed. Furthermore, she proposed that children presenting with language difficulties of unknown origin should not be diagnosed by exclusion from children with a known aetiology. This is because some children with a known aetiology may still present with language difficulties that are either not entirely explained by the primary condition, that are similar to children with a primary language impairment or who may benefit clinically from similar approaches.

In the same review Bishop (2014b) recommended the term specific language impairment (defining specific as idiopathic, of unknown origin) as this was the most commonly used term. Concerning children who present in the early years with language difficulties, however, this term has not been used in this thesis for a number of reasons.

First, past use of specific language impairment has been associated with older children for whom a disordered pattern has been identified. There are many children who present early in ontology
(usually the 3rd year of life) with delayed onset of language. The clinical picture is often unclear at this stage as there is very little expressive language and comprehension may be difficult to assess. The outcomes for children with specific language impairment may differ from other children with primary language impairment and this may be dependent on the underlying causal factors (which are often unknown).

Second, Bishop (2014b) distinguished this group from late talking toddlers who are predicted to catch up with their peers after a slow start with no significant difficulties later on. The trouble with this dissociation is that, whilst certain risk factors such as comprehension difficulties and family history have been identified, there is currently no clear cut way of distinguishing one group from another. Furthermore, as with the distinction between environmentally and biologically based language delays, it is probably not feasible to create two distinct groups, one with significant long term complications and one without, as risks to other outcomes in life are also likely to fall along a continuum. This is discussed in more detail in the section on prognosis in this chapter (section 1.2.3).

Whilst there is sympathy for the argument towards a common terminology, therefore, at an early stage in ontology, the use of primary language delay, which may encompass all children presenting with delayed onset of language is postulated as the more conservative approach. The term ‘specific language impairment’ as defined above has been used in this thesis when describing more persistent longer-term language difficulties. Furthermore, in order to factor out additional complications arising from other aetiologies in this study, the primary nature of the definition given by Law (1998) has been retained in this thesis. Concerning the discussion below, for the purposes of consistency, studies that have used other labels may be discussed using the term primary language delay, environmentally based language delay or specific language impairment. Where there may be implications concerning the interpretation of studies, this will be highlighted.
1.2.2: Clinical presentation of primary language delay

A child is considered to have a primary language delay when they present early in ontology, usually around age 2 years of age with delayed onset of receptive or expressive language development, or phonological development (see, for example Law, 2000; Law et al., 2000b). The clinical presentation of children with primary language delay is heterogeneous (Bishop, 1997, 2014b; Law et al., 2000b; Reilly et al., 2014a) and each child will have a unique pattern of ability. This is due to the multifactorial causality of primary language delay and reflects the dependence of language on a range of foundational skills. These include conceptualising referents, joint attention, intention reading, pattern forming or categorising skills, and lexical and linguistic contrast (Tomasello, 2005). Children also require skills specific to spoken language, which include segmenting speech (Tomasello, 2005), phonological short term memory (Bishop, 2008), articulation, phonology and praxis, voice fluency and prosody (Law, 2000). Even within these broadly defined skills, speech and language processing can be broken down further into ‘sub-skills’. These have been described in detail for several of the skills required for typical speech and language development, e.g. phonology (Stackhouse & Wells, 1997) and comprehension of language (Bishop, 1997). Thus, even two children presenting with difficulties in the same language skill may have differing underlying presentations of difficulty. Difficulties with one or more of any of these individual cognitive or motor processes may result in an initial presentation of primary language delay.

As described above, children presenting with primary language delay may present as having a delayed or disordered pattern of development in any of the domains of communication described above. There have been difficulties separating out late talkers from children who will go on to have specific language impairment. Certain factors have been identified as putting children at increased risk for specific language impairment, including difficulties with comprehension (Bishop, 2009a) heritability of language or literacy difficulties (Tomblin et al., 1997) and late talker status (Feldman
et al., 2005; Reilly et al., 2010; Weitzman & Greenberg, 2010). An additional consideration is the finding that children from low socioeconomic backgrounds are underrepresented in clinic populations (Roy, Chiat, & Dodd, 2014).

1.2.3: Prevalence of primary language delay.

Estimations of prevalence

Mindful of the multifactorial and terminological problems, it is possible to gain an estimate on the perceived prevalence of developmental speech and language difficulties from the literature. There appears to be agreement, for example that speech and language difficulties are common in early childhood (Hall & Elliman, 2006). For a mainstream population, government policy documents, reviews and guidance manuals often report prevalence at 7-10%. For example, in the Bercow Review of Services for Children and Young People (0-19) with Speech, Language and Communication Needs (Department for Children Schools and Families, 2008), the prevalence of 5 year olds with significant difficulties with speech and / or language in England was estimated to be approximately 7% and ICAN, the UK’s national charity of children with speech, language and communication needs cites 10% as a prevalence estimate (ICAN, 2014). However, the studies from which these figures were drawn are not always appropriately referenced, hence it is not possible to confidently rely on these prevalence estimates.

A systematic review of prevalence

Law et al (1998a) carried out a systematic review of prevalence studies for primary language delay in order to provide a more robust estimate. They highlighted the difficulties inherent in establishing agreement on prevalence related to nationality, diagnostic criteria and assessment criteria. These difficulties were evident in the wide range of prevalence figures reported, from 0.6% - 33.2%. The studies in their review represented populations from around the world, including English-speaking
populations in the UK (for example; Silva et al., 1983), the USA (e.g. Rescorla et al., 1993) and Australia (Kirkpatrick and Ward, 1984), as well as children from other language backgrounds, including Quebec French (Dudley and Delage, 1980) and Chinese (Wong et al., 1992). Other studies from around the world carried out since this review also report prevalence figures within this range, e.g. a prevalence of 16.33% in girls and 27.1% in boys was seen in preschool children from a sample of 4005 children in Bavaria, Germany (Caniato et al., 2010) and a 10.1% prevalence was seen in children aged between 6 and 10 years of age from a sample of 1043 children in Norway (Hollund-Møllerhaug, 2010).

The figures reported in the Law et al’s (1998b) systematic review are broken down by diagnosis (e.g. expressive or receptive language, and speech). The inclusion criteria for case identification were reported to lead to considerable variance in the reporting of prevalence. This relates to the question of when exactly a child is considered to have a difficulty. Variance was reported between studies in the cut off point for identification of cases (in the number of standard deviations below the mean). Furthermore, one highlighted study (Tomblin et al., 1997) required a low score for both receptive and expressive language measures, resulting in a lower prevalence figure than other studies (which only required a low score in one measure). Other factors affecting variance included the professional background of the researcher carrying out the assessments, the expectations of the population assessed, whether the assessment was an objective measure administered by a healthcare professional or a parent-based report.

The studies based in Bavaria (Caniato et al., 2010) and Norway (Hollund-Møllerhaug, 2010) also illustrate the range in prevalence figures reported, and these differences again may be due to the methods used. The Bavarian study used language scores from a more generic developmental tool, whereas the Norwegian study used a specific standardised language assessment, which is likely to
result in higher levels of specificity when calculating the number of cases, thus resulting in a lower prevalence figure.

Law et al. (1998) reported that the main methods of measurement used in their systematic review were standardised assessments. As discussed, above in section 1.2.1, they highlight the circular nature of this method of assessment in prevalence studies. To clarify this point they illustrate that the cut-off point, i.e. the point at which a judgment is made on the status of each case is based on an arbitrary line (usually 1 – 2 standard deviations below the mean) from a psychometrically assessed population study. This point is clearer if percentiles are considered. If one bases identification of a true ‘case’ on the grounds that a subject scores within, say, the bottom 10th centile, then by definition, 10% of a population will be true cases. Furthermore, they also highlight that the use of standardised assessments in prevalence studies does not allow the researcher to establish whether the prevalence of a condition diminishes with increased age, as the cut off is continually adjusted to the next age cohort in the standardised population.

Law et al. (2000b) argue that a cut off based on a standardised sample is rarely justified in the literature on clinical grounds. When considering why language difficulties are a problem (with reference to the usefulness of language for participation in society, discussed in section 1.1), a more appropriate question might be ‘at what point is a child unable to fully participate in their community, school and society at large?’ This point may reflect children who are functioning at the bottom 10th centile on an assessment, or it might just as feasibly be the 5th centile, or the 25th centile. Law et al. (1998) identified one study, which provides a cut off based on clinical judgement (Tomblin et al., 1997). It should be noted, however, that Law et al. (1998) based their conclusion on the studies that they included in the systematic review. As the inclusion criteria required a replicable measure, then it became more likely that studies using standardised assessments would be selected in their review.
Law et al. (1998) highlight that the argument for clinical judgement as the appropriate method for judging true cases is also circular. Case status is usually influenced by availability of local resources, and expected response to intervention services. Furthermore, Enderby and Pickstone (2005) note the apparent presence of any need is likely to be heavily influenced by the weight of importance that society places on the skills that the said need affects, and therefore even a clinical judgment based approach for language development is likely to be influenced by socially constructed values.

There is a dilemma, therefore, facing the epidemiologist studying language delay. The main method of establishing prevalence has been standardised assessment, which is of questionable value in establishing prevalence in non-mainstream culture (discussed further in section 1.3.5), and yet the populations apparently most at risk are those very populations (i.e. those from non-mainstream culture), as discussed below in this section. Law et al. (1998) argue that an alternative approach to prevalence studies is taken, where, rather than adopting the “circular” nature of standardised psychometric assessment; “prevalence should reflect the number of cases that the natural history would suggest are least likely to resolve spontaneously, and therefore most likely in need of intervention” (p14).

**Prevalence of primary language delay in areas of social disadvantage**

The prevalence of primary language delay has been found to increase in areas of social disadvantage. A number of studies based on socially deprived communities, for example, have reported high levels of delayed language development. Locke, Ginsborg, and Peers (2002) investigated the language abilities of a cohort of 3-year-old children in a nursery in Sheffield recognised as being in an area of deprivation by the proportion of free school meals available. Using the CELF – P UK they found that the mean standard score for the cohort was 84.3, considerably lower than the standardised average of 100. Receptive and expressive scores were
depressed and 55.6% of the cohort was found to have a moderate or severe delay. There was also a significant difference between children’s language abilities and nonverbal IQ, with greater levels of language disadvantage. A follow up study which included a wider cohort found prevalence to remain high at age 5, and whilst slightly decreased overall, the number of children with severe language delays had risen from 9% to 26% (Locke & Ginsborg, 2003). Another study by King et al. (2005) found 46% of at risk 3-year-old children scored at or less than 1 standard deviation below the mean on the Preschool Language Assessment 3, with 10% severely delayed. These studies indicate that in areas of social deprivation there is a much higher prevalence of language delay in young children.

The prevalence of primary language delay in an area of high social deprivation was also examined in primary school aged children (aged 5 – 12 years) by Law, McBean, and Rush (2011). Using the CELF IV they found high levels of primary language delay, with a mean standard score of 87 and 10% of children having severely delayed language development. Their findings were in accordance with those reported by Locke et al (2003; 2002) and they also found a discrepancy between language development and nonverbal abilities.

Socioeconomic status has been highlighted as a risk factor for language development in studies other than those that examine prevalence and a wider discussion on the effects of socioeconomic status on language development can be found below in section 1.3.5. There are also difficulties establishing a true picture of need in areas of socioeconomic status, in particular, distinguishing between whether the observations reflect a delay or a difference in language skills. The methods employed in these prevalence studies, particularly standardised assessment, may indicate an inaccurately higher prevalence level. This is also discussed in section 1.3.5. Evidence of a higher prevalence from these studies, however, indicates a potentially higher level of need according to socioeconomic status.
1. 2. 4: Prognosis - long term outcomes for children with primary language delay

The implications of specific language impairment in terms of long-term outcomes for individuals have been documented. Leitão and Fletcher (2004) found that children who entered school with expressive speech disorders continued to have more difficulties with reading and spelling than their typically developing peers at age 12–13. Snowling et al. (2001) reported in their study that children with a history of specific language impairment (whether resolved or persisting) achieved lower GCSE results, and were less likely to go on to study ‘A’ levels than their typically developing peers. In her summary of literature on outcomes for children with childhood speech and language difficulties, Clegg (2006) cites language difficulties, low socioeconomic status and low IQ as particular risk factors for poor outcomes later in life.

Educational outcomes are not the only factors affected by speech and language difficulties. Specific language impairment can lead to emotional and behavioural difficulties, (Stringer and Clegg, 2006, Qi and Kaiser, 2004). Furthermore there is some evidence to suggest a link between specific language impairment and anti-social behaviour and employment prospects (Clegg, 2006). In a study by Bryan et al. (2007) a much higher prevalence of communication and language difficulties was seen in a sample of young offenders than is seen in the general population.

It appears, therefore, that poor language outcomes are associated with a number of negative outcomes in later childhood and adulthood. Whilst the exact nature of the relationship between language and these outcomes is not fully understood and causality has not been established in these studies it is likely that difficulties with language and communication may pose a risk for later life outcomes.
Speech and language difficulties, as has been highlighted in section 1. 2. 1, are multifactorial in both their presentation and their causes. Teasing apart the differences in outcomes for different children in this population can be problematic (Roy & Chiat, 2013). Caution should be applied when making generalisations from studies of children with language difficulties, as there are likely to be subgroups of children within the total population for whom prognosis and long-term outcomes differ. Understanding the differing prognoses according to subgroups of children is crucial to the overall question of whether there is a justification for preventative methods for environmentally based language delay. Again, whilst attempts have been made to distinguish groups of children, there are unlikely to be clear groups with distinct features, and patterns of difficulty (and, indeed, prognosis) are likely to fall along a continuum. For example, Rescorla (2005) reported that in her studies and the research conducted by Snowling et al. (2001) there is evidence of some continuum of difficulty, with a continuum of long-term outcomes. The children with specific language impairment in the Snowling et al. (2001) study have the worst educational outcomes, with the children with resolved language impairment faring a little better. It is possible that these children may form part of the primary language delay group. The late talking toddlers in the Rescorla (2005) study do better still, but not as well as typically developing peers.

There is evidence, therefore, that speech and language difficulties, across the continuum of severity, have negative long-term implications for children, socially, emotionally and academically. Whilst the outcomes for children with specific language impairment appear to be worse, there is evidence that outcomes for other children, including those with primary language delay are poorer than outcomes for children who develop language within the normal range of development. Furthermore, several studies highlight the additional risks of the socioeconomic environment on language and overall outcomes for children (Clegg, 2006; Hart & Risley, 1995; Nelson, Welsh, Trup, & Greenberg, 2011; Roy & Chiat, 2013).
The multifactorial influences on language development are evident when examining the presentation, prevalence and prognosis of primary language delay. In order to understand to what degree a preventative initiative or, indeed, any therapeutic intervention might support language development it is necessary to critically examine what these factors are and the weight of influence they may have on language development. These factors are discussed below. As the aim of this study is to examine the effectiveness of a service designed to prevent environmentally based language delay, the factors are considered as ‘causes of delay’. It should be noted, however, that these factors might be conversely considered as factors that ‘influence language development’, the absence of which might result in primary language delay.

1.3: Causes of primary language delay

The causes of primary language delay are reported widely as being multifactorial (Bishop, 2008; Lees & Urwin, 1997; Roy & Chiat, 2013). Over the past thirty years a range of genetic, physiological and environmental factors have been attributed to developmental language difficulties. These were summarised by Lees and Urwin (1997) under three categorical headings: factors affecting language input, factors affecting language processing and factors affecting language output. A number of the factors highlighted by Lees and Urwin (1997) were attributed to other aetiologies (e.g. autism or general learning difficulties). Concerning primary language delay, however, the factors they cited included environmental factors, bilingualism and hearing loss. Some of these are now considered to be less important than previously thought. Examples of these factors are given below.

Bishop (2008) provides evidence from a range of studies to demonstrate that mild to moderate conductive hearing loss (often as a result of otitis media with effusion – OME) and early brain damage associated with perinatal complications do not present a significant risk for specific
language impairment. Concerning mild to moderate conductive hearing loss, the findings reported by Bishop (2008) are also supported by two systematic reviews that have yielded no evidence for the benefits of either screening for OME (Butler, van der Linden, MacMillan, & van der Wouden, 2003) or treatment with grommets (Browning, Rovers, Williamson, Lous, & Burton, 2010) for child language outcomes. Concerning early brain damage, the arguments against this risk through perinatal complications made by Bishop (2008) include the low prevalence of birth complications amongst the specific language impairment population, and the different pattern of difficulties seen when compared with adults and children with known brain damage. The third factor cited by Lees and Urwin (1997) was bilingualism. Whilst the effect of learning two languages has previously been considered to have a confounding effect on language development, there is now evidence that it is not a risk factor for primary language delay (Moore & Pérez-Méndez, 2006).

The current consensus in the literature is that primary language delay remains a condition with multifactorial causes (Bishop, 2014b; Hughes, 2005; Law, 2000; Rice, 1997; Tomblin, 2009). The main culprits concerning causality may be categorised into two groups: biological and environmental (Bishop, 2008). These are discussed below. It is beyond the scope of this chapter to provide a detailed critique of the biological factors as the main focus of this study is the influence of the environment on language development. An overview of the developments in this field, however, is provided in order to inform understanding of development and aid consideration of how the environment interacts with biological factors in language development.

1. 3. 1: Biological factors

*Genetic inheritance*

Language development has been found to be highly influenced by genetic inheritance in the early years (Dale et al., 1998; Hayiou-Thomas, 2008; Plomin & Dale, 2000; Van Hulle, Goldsmith, &
Lemery, 2004). For example, in a UK twin study involving over 700 participants Kovas et al. (2005) found moderate genetic effects for articulation, phonology, grammar, vocabulary and verbal memory. This heritability has been found in other studies for both expressive vocabulary and syntax (Plomin & Dale, 2000; Van Hulle et al., 2004), and for heritability within the normal range of development (Van Hulle et al., 2004), at the lower end of performance (Spinath, Price, Dale, & Plomin, 2004) and for children with severe impairments (Bishop, 2008). Specific genes have been isolated for language disorders affecting expressive speech and syntax. For example, rare mutations of the FOXP2 gene are associated with severe difficulties sequencing speech sounds (Graham & Fisher, 2013; Pinel et al., 2012), whilst more common mutations of CNTNAP2, ATP2C2 and CMIP with a smaller effect size are associated with language impairments (Graham & Fisher, 2013). The full genetic picture of language development, however, is still unknown and the likelihood is that language develops through an interaction of multiple genes each with a small effect size (Bishop, 2009a). This reflects the range of cognitive, social and motor skills underpinning language development and, in part, explains the considerable overlap with other aetiologies, including dyslexia (Bishop, 2008), autism (Bishop, 2014b) and ADHD (Mueller & Tomblin, 2012). Due to the multifactorial nature of the different genes involved, although the role of genetics has been highlighted as significant, a biological test for specific language impairment is not currently considered to be feasible (Bishop, 2014b).

**Cognitive neurological indications**

Several recent studies have highlighted differences in both brain structure (Badcock, Bishop, Hardiman, Barry, & Watkins, 2012; Herbert et al., 2005; Soriano-Mas et al., 2009) and function (Badcock et al., 2012; Dibbets, Bakker, & Jolles, 2006; Ellis Weismer, Plante, Jones, & Tomblin, 2005) in children with specific language impairment when compared to typically developing children. For example, grey matter in children with specific language impairment was increased in the inferior left frontal cortex and reduced in the right basal ganglia when compared to typical peers...
(Badcock et al., 2012). In this study functional differences with reduced activity in these areas and bilaterally in the superior temporal cortex were also reported. The degree to which these differences are genetically or environmentally influenced is still unknown. Understanding the neural pathways involved in learning new tasks in typically developing subjects (e.g. Simmonds, Leech, Iverson, & Wise, 2014) may inform this understanding. Information may also be gained from studies examining the brain development of babies at risk of certain conditions such as primary language delay. An example of a study of this kind is the research into the development of stuttering being carried out by the Australian Stuttering Research Centre (2015).

1.3.2: Environmental factors – an overview

Concerning language development, the term ‘environmental factors’ has been interpreted in different ways. Bishop (2008) highlighted that, for geneticists, the term ‘environmental’ is interpreted as “anything and everything that is not genetic…(including)….the quality of language spoken to the child, early brain damage and ear disease” (p. 70). This interpretation is evident in twin studies examining language development (Dale et al., 1998; Hayiou-Thomas, 2008). For many, however, the term ‘environmental’ may be interpreted more specifically as the socio-economic, emotional, behavioural and linguistic environment a child experiences during development (Ginsborg, 2006; Morisset, Barnard, Greenberg, Booth, & Stieker, 1990; Pickstone, Goldbart, Marshall, Rees, & Roulstone, 2009). These aspects form the focus of the next section.

1.3.3: Macro-environmental factors

A number of environmental risk factors have been highlighted in the literature. These may be considered as ‘macro-environmental’ in the sense that it is not the factor itself that is directly
associated with primary language delay but that child language development is influenced as a result of its effect on another aspect, either biological or environmental. The more specific environmental effects are referred to in this study as ‘micro-environmental’ and are discussed below. Awareness of macro-environmental factors highlighted in the literature may inform understanding of the micro-environmental features. Macro-environmental factors include certain aspects of parental health and wellbeing, including parental alcohol or substance abuse (Cone-Wesson, 2005; Dinehart, Kaiser, & Hughes, 2009; Dixon, Thal, Potrykus, Dickson, & Jacoby, 1997; Lewis et al., 2011; Michaud & Temple, 2013) postnatal depression (Brennan et al., 2000; Field, 2010; Foster-Cohen, Friesen, Champion, & Woodward, 2010; Grace, Evindar, & Stewart, 2003; Stein et al., 2008), poor social support (Coster, Gersten, Beeghly, & Chichetti, 1989), domestic violence (Chamberland, Lacharité, Clément, & Lessard, 2014; Udo, 2014) and high levels of stress (Morisset et al., 1990; Talge, Neal, & Glover, 2007).

The special case of socioeconomic status (SES)
The risk factors cited above may, but do not always, coexist with low socio-economic status (SES). SES is the macro-environmental effect that has arguably been most frequently reported in the literature as influencing child language development. SES has been reported to be a relative term that has been measured in different ways (Ginsborg, 2006; Roy et al., 2014). Different measures have included parental level of education (e.g. Qi, Kaiser, Milan, & Hancock, 2006), parental income (e.g. Qi & Kaiser, 2004), parental occupation (e.g. Roy et al., 2014) and a socioeconomic index based on a range of measures (e.g. Hart & Risley, 1995). In addition, some prevalence studies have focused on populations for whom a higher prevalence of social disadvantage compared to the wider population has been hypothesised, for example, schools with a high proportion of children on free school meals (Locke et al., 2002), young offenders institutions (Bryan, Freer, & Furlong, 2007) or adolescent mothers (McDonald Culp, Osofsky, & O'Brien, 1996).
The relative nature of SES and how it is measured in different studies results in some difficulties interpreting the data, as the degree to which the same phenomenon is being compared is unknown. This is discussed more fully in Ginsborg (2006) and will be referred to concerning the design of this study in Chapter 3. Regardless of these difficulties, relationships between low SES and language delays have been found in the literature. A number of longitudinal studies (Foster-Cohen et al., 2010; Hart & Risley, 1995; Locke & Ginsborg, 2003; McGregor, Oleson, Bahnsen, & Duff, 2013; Reilly et al., 2009; Reilly et al., 2010; Sylvestre et al., 2012) have found a significant relationship between low SES and poor language outcomes. As discussed in section 1.2.2, prevalence studies in populations postulated as being socially disadvantaged (Bryan, 2004; Pickstone, cited in Enderby & Pickstone, 2005; Locke et al., 2002; Pickstone, McLeod & McKinnon, 2007) have also found high prevalence rates of language difficulties.

There have been varied conclusions in the literature regarding language ability and SES. It has been argued that the findings may not necessarily report a deficit but may reflect a cultural difference (Ginsborg, 2006). The appearance of a delay may be the result of the methods used to assess the language skills of children. As highlighted by Roy and Chiat (2013) and Ginsborg (2006), the conclusions from many of the studies are based on standardised language assessments, the use of which may bias findings in favour of higher socioeconomic groups.

There is also a possibility that studies may score standard dialects more favourably, disadvantaging children from minority groups. This argument has been proposed for some time. For example, in the debate on the difference between socioeconomic groups, Berntstein (1996) proposed from his studies that children from lower SES groups used restricted codes when speaking, whereas higher SES groups used elaborated codes, which allowed more freedom of expression of ideas, resulting, perhaps, in more complex vocabulary and syntax. Pinker (1994) illustrated, however, the highly grammatical nature of Black English Vernacular in his discussion on the universality of grammar.
His illustration was based on studies by Labov, who explored differences between white and black vernacular in the USA (1969, 1979). He found that there were differences in the language spoken between children in urban black ghetto culture, and language from children when speaking with adults. The language that children addressed to each other was much richer and more varied than that directed to adults. He concluded, therefore, that language either heard by teachers or researchers was not representative of the children’s full repertoire.

It is also noteworthy that not all studies have found a relationship between SES and language development. For example Black, Peppé, and Gibbon (2008) did not find a significant relationship between expressive vocabulary measured using a standardised assessment and SES as measured by the Edinburgh deprivation scale. The distribution of scores for participants on the socioeconomic scale may explain why a relationship was not seen. Roy and Chiat (2013) highlight, for example, that the relationship between SES and language development is not linear and individuals at the very lowest end of the socioeconomic scale are significantly more disadvantaged than those in the middle range. Another source of studies suggesting no relationship between language development and SES are twin studies examining the role of genes and the environment. Several of these found minimal influence of environmental factors (Bishop, 2008; Dale et al., 1998). This is discussed more fully under the heading ‘micro-environmental factors, parental linguistic input’, below.

These studies highlight the need to use a range of methods in order to understand more fully the relationship between socioeconomic status and language development. Two methods of language assessment have been reported in the literature that have aimed to overcome the limitations associated with standardised assessments. Hart and Risley (1992, 1995) analysed transcripts of parent-child interactions within the family home over 2 and a half years. This data may be considered to be more reliable and valid for the following reasons; first, the analysis was carried out on naturally occurring spontaneous utterances in the home so has ecological validity. Second, a
large amount of data was gathered (just under 1800 minutes of data per subject, with 42 families in the study). Finally, Hart and Risley (1995) compared measures of all the word types and tokens spoken by the parent and child. This eliminated the risk of standard dialect prejudice in the data analysis. Their study still found significant differences in quantity and quality of the language spoken to children and by children according to SES in the early years. They also found that these features of language correlated strongly with child language outcomes at age 3 years and then later with results of standardised language assessments at age 9-10 years (Walker, Greenwood, Hart, & Carta, 1994). The value of these findings is in their freedom from the methodological limitations described above, through the analysis of naturalistic language occurring in the home environment.

The second approach that attempted to overcome the limitations of standardised assessments was reported by Roy et al. (2014). They postulated that scores on standardised language assessment may be influenced by the amount and richness of language a child had been exposed to (this is discussed in more detail in the section below), whereas core language skills, such as non-word repetition, sentence repetition and production of speech sounds did not depend as much on previous language exposure. They argued, therefore, that tests of core language would provide an indicator of whether the children from lower SES backgrounds did present with deficits in their language skills, or whether the differences seen in previous studies were a manifestation of the standardised testing approach. After testing children aged 3 1/2 to 5 years of age from lower and higher SES groups, they found that core language skills were related to SES, with children from the low SES group achieving significantly lower scores than those from the higher SES group. The degree to which these skills do actually depend on previous language exposure, however, remains unknown.

The older children, who had experienced around two years in nursery or at school showed improved core language skills compared to the younger children. This finding was confirmed in a follow up study reported in the same paper, which found that the younger children also demonstrated improved core language skills by the time they were 5 years old. They postulated that the development of these core skills may, therefore, depend on experiencing a critical amount of
language. This argument is also supported by other studies, which have found a relationship between language processing skills and the amount of language to which a child has been exposed (Hurtado, Marchman, & Fernald, 2008; Weisleder & Fernald, 2013). These reports, in conjunction with the correlational and prevalence studies cited above, demonstrate that, whilst there remains a debate on this issue, the influence of SES cannot be ignored as a macro-environmental factor influencing language development.

The effect of technology

In addition to the major macro-environmental factors cited above, the number of additional factors that have been blamed for contributing to language development extends to factors associated with modern life. Modern appliances and technology are more likely to be factors reported in the mainstream press. For example, television viewing (Henry, 2003) and forward facing buggies (Paton, 2014) have been reported in British newspapers over the past 15 years for contributing to the perceived decline in children’s language skills. These claims are often sensationalist and without underpinning evidence. For example, in response to an article blaming forward facing buggies on the decline in young children’s language skills, Smith (2014) analysed the basis of the claims made. The newspaper’s argument was found to be flawed at number of levels. First, there was no evidence in the literature of an overall decline in language skills over time; second, there was no evidence that current parents are talking less to their children than they used to and third; there was no evidence that forward facing buggies are causing parents to talk to their children less overall than they would normally or that children’s language development has been adversely affected. In cases where there may be conclusions drawn from empirical studies they are often based on correlational or regression analyses, and causality has not been established (Certain & Kahn, 2002). Whilst the question of the potential effect of modern technologies on language development is relevant to modern life, the focus of this chapter is not on these culprits, but rather
on the core issues that modern technologies are often blamed for. These are the micro-environmental factors, and are discussed below.

1. 3. 4: Micro-environmental factors

An overview

The micro-environmental factors influencing language development explored in this chapter are specifically concerned with the parenting environment that a child is exposed to. Several factors have been explored in the literature, including attachment security, parenting style, the educational quality of the home environment, specific parenting activities such as shared book reading and singing nursery rhymes and parental linguistic input. These are discussed below.

Attachment security

The level of attachment between parents and children has been reported to be related to child language development. For example, Murray and Yingling (2000) found a positive correlation between increased scores for attachment security and for receptive and expressive language abilities. This finding is supported by other studies, which also found positive associations between attachment security and language outcomes (Costantini, Cassibba, Coppola, & Castoro, 2012; Meins, 1998; Robinson & Acevedo, 2001).

As with other studies cited above, relationships and not causality have been demonstrated. Furthermore, the degree of association or relative predictive value of attachment security has differed in some studies. Whilst a significant relationship was found in the studies cited above, Lemche, Joraschky, and Klann-Delius (2013) found a much weaker association for attachment when compared to other measures such as parental verbal input, although this may be a result of the very specific linguistic features examined in this study. Morisset et al. (1990) found that attachment
security may be a protective feature for the cognitive and language development of children at high psychosocial risk, but only in the more extreme cases.

The mechanism through which secure attachment might support language development has recently been explored. One explanation proposed is that parents may be more responsive to children within the context of a secure attachment, and this has been shown to have a causal relationship with language development (Landry, 2014). Responsiveness as a feature of parenting style is discussed in more detail below. Another explanation proposed by Meins (2012) is that secure attachment supports a child’s development of theory of mind, a cognitive skill which underpins language development.

**Parenting style**

The extent to which a parent uses a directive or responsive parenting style is reported to be related to child language development. For example, Murray and Hornbaker (1997) reported that a directive parenting style was negatively correlated to child receptive (but not expressive) language development. Hebert, Swank, Smith, and Landry (2004) found a negative association between a directive style and language and play development in children up to 56 months. Conversely, a number of studies have demonstrated a positive association between parental responsiveness and language outcomes (Girolametto et al., 2002; Tamis-LeMonda, Bornstein, Baumwell, & Damast, 1996).

These studies have been criticised for only exploring the relationship between parenting style and child behaviour in a unidirectional sense, that is, examining how parenting effects child outcomes. Lloyd and Masur (2014) demonstrated that infant behaviour may have an influence on parental use of responsive or directive behaviours. Regardless of the direction of influence, however, parental responsiveness is a factor that has evidence of causality through experimental studies (Girolametto,
As these are intervention studies based on a population of language-delayed children, they do not conclusively demonstrate that parental responsiveness is a prerequisite for language development. However, in an experimental setting Tomasello and Farrar (1986) found that normally developing 17-month-old children learned new words more easily when their focus of attention was labelled, rather than an item not in their immediate focus. These findings, therefore, demonstrate that language development may be facilitated by a responsive parenting style.

The home environment

A relationship between the home environment and child language development has also been reported in the literature (Adkins, 2013; Bradley & Caldwell, 1984b; Dale, Greenberg, & Crnic, 1987; Duhan & Punia, 1998; Murray & Yingling, 2000; Thompson, Fulker, DeFries, & Plomin, 1986). Specifically, the quality of the home environment has been found to be positively associated with expressive language skills (e.g. Adkins, 2013; Murray & Yingling, 2000), although a positive association has been observed in all language measures in other studies (e.g. Siegel, 1982). A significant relationship with the quality of the home environment was not always reported, however (e.g. Mello, 1997). Pinto, Pessanha, and Aguiar (2013) found that, whilst a positive association with language outcomes was seen in the early years, the effect of the quality of a child’s educational environment was equally important. Positive associations with the home environment reduced substantially in later years for children who attended a low quality educational environment.

When interpreting the literature concerning the home environment it is important to consider a number of factors. First, it is necessary to determine what exactly is meant by the term ‘home environment’. Interpretations may differ according to the methods of measurement used in different studies. For example, Jones (1972) used a 70 minute interview to assess the quality of the
home environment. She highlighted features of parent to child interaction, academic and vocational aspiration and occupational status as the factors assessed. Many studies have adopted the HOME inventory (Bradley & Caldwell, 1984a), a validated and standardised measure with specific subscales assessing different aspects of the home environment. The studies adopting this measure have reported positive associations, and have also identified specific aspects of the home environment found to have the strongest associations. The provision of adequate learning and play materials, for example, was found to have a stronger association (Bradley & Caldwell, 1984b; Duhan & Punia, 1998), as were opportunities for variety in daily stimulation (Duhan & Punia, 1998).

**Specific parenting activities – nursery rhymes**

Singing nursery rhymes has been associated with increased language outcomes. For example, in a large scale study of the language skills of children aged 25 months Roulestone, Loader, Northstone, Beveridge, and the ALSPAC team (2002) found that children’s language skills were positively correlated with the amount of nursery rhymes that their parents sung to them. Bryant, Bradley, Maclean, and Crossland (1989) also found a strong relationship between reading, spelling ability and nursery-rhyme knowledge (in particular between nursery-rhyme knowledge and phonological sensitivity). These studies may indicate that learning nursery rhymes enhances linguistic ability, however, again, the studies only showed relationships between these features, and no causality assumptions were made.

In an experimental study Kouri and Winn (2006) presented language delayed and generally delayed children with non-words in a sung or spoken context over 2 sessions. They found no effect of the sung context in a non-word naming and comprehension task, although they did find a significant increase in unsolicited non-word target productions in the second session for those children who had been exposed to the sung environment. They concluded that only particular aspects of quick
incidental word learning were enhanced by sung exposure. However, as the children observed were language delayed, and may have required more than 2 sessions to benefit from the exposures there could have been a more significant difference if an increased dose of intervention was given over a longer period. In natural childcare settings, such as the home or a childcare environment, children are exposed to nursery rhymes repeatedly over a long period of time.

In an experimental study of second language acquisition Allen-Tamai (2000) found that Japanese children who had been exposed to nursery-rhyme instruction had significantly greater English phonological awareness than those who had not. Although this is a study into second language acquisition, it reflects the relationship found by Bryant et al. (1989) discussed above. Whilst further research is required, it is possible that the highly structured phonological and suprasegmental features of nursery rhymes support the development of language, in particular, of phonological skills.

Specific parenting activities - Book Sharing

Sharing books with young children has also been positively associated with language development, and with later academic achievement at school (Kalia, 2007; Laakso, Poikkeus, & Lyytinen, 1999; Murray & Egan, 2014; Scarborough, Dobrich, & Hager, 1991). The importance of book sharing for child language and literacy development is widely accepted as a given (High & Klass, 2014; Lennox, 2013; National Literacy Trust, 2014). Following a review of the literature, however, the magnitude of the association when compared to other variables, such as parental level of education was called in to question by Scarborough and Dobrich (1994). They reported that the effect sizes seen in the studies they reviewed to be variable and surprisingly modest. The variability in the effect size may be a result of differences in certain features of book reading practice. Dunning (1994) reported that the interaction between parent and child is likely to be a significant factor in the effectiveness of book reading. The way that parents read with their children has been reported in
other more recent studies as a significant factor concerning future outcomes, with shared or dialogic book reading (e.g. Vally, Murray, Tomlinson, & Cooper, 2014) and higher levels of lexical diversity (e.g. Liu, 2014) having optimal outcomes for language development. The type of reading material has also been examined. Leech and Rowe (Liu, 2014) found that reading chapter books was less effective than picture books for children with early stages of language development. Positive effects of e-books for vocabulary development have been reported (Butler, Brown, & Woods, 2014) but the interactive nature of e-books was reported by Parish-Morris, Mahajan, Hirsh-Pasek, Golinkoff, and Collins (2013) as interrupting the flow of the narrative when compared to paper picture books, with smaller effect sizes on comprehension than paper books.

The experimental studies reported confirm the positive associations reported above and indicate that shared dialogic book reading supports language development in young children (Butler et al., 2014; Korat, Levin, Atishkin, & Turgeman, 2014). Positive outcomes have also been reported concerning large scale book promotion interventions, such as BookStart (Moore & Wade, 2003) and Reach out and Read (Zuckerman, 2009). Given that many societies in the world do not have high literacy levels, however, book reading cannot be considered to be a prerequisite for language development and the size of effect remains unknown.

1.3.5: Parental linguistic input

Quantity of input

There is a considerable amount of evidence for the relationship between the quantity of parental linguistic input and child expressive language development. Correlational and regression studies indicate that an increase in the quantity of parental linguistic input to children is positively associated with child expressive language outcomes (Hart & Risley, 1992, 1995; Hoff & Naigles, 2002; Hoff-Ginsberg, 1991; Weisleder & Fernald, 2013; Zimmerman et al., 2009a). This
relationship has been found across languages (Hoff & Tian, 2005; Weisleder & Fernald, 2013) and for bilingual children (Pearson, Fernandez, Lewedeg, & Oller, 1997). It has also been found to be associated with socioeconomic status, such that parents from lower socioeconomic backgrounds tend to speak less to their children than parents from higher socioeconomic backgrounds (Hart & Risley, 1995; Hoff & Tian, 2005; Hoff-Ginsberg, 1991). When socioeconomic status is accounted for, however, the association between parental linguistic input and child language outcomes remains (Hart & Risley, 1995; Rowe, 2012). Furthermore, there is evidence specifically highlighting the relationship between direct parent to child interactions. Weisleder and Fernald (2013) found a relationship between the language spoken directly to children by their parents and the child’s language development, but not between language simply overheard by children and child language development. Zimmerman et al. (2009a) also found that adult to child conversation was a partial mediator in the relationship between overall levels of parental talk and child language development.

This relationship has been questioned in a number of studies, which found no difference between the parental language environment of normally developing and language delayed children. A systematic review of studies examining the difference in parent to child interaction between parents of language delayed children and typically developing children by Blackwell et al. (2015) reported outcomes of nine case control studies deemed of moderate or high quality. Through a narrative synthesis of outcomes they concluded that there was not a significant difference between the parental linguistic environment of typically developing children and language delayed children. This report was confirmed in another study by Vigil and Hodges (2005) which also found no significant difference between the number of utterances spoken to normally developing and language delayed children.
A number of methodological issues arise when attempting to interpret these studies in this way. First, these studies all report a case control design. The age range of children varied across studies, as did the identification of case status and control group status (e.g. in some studies the control group was age matched, whilst in others it was language matched). This is likely to have resulted in a heterogeneous population, therefore causing difficulties with comparisons. Second, as reported by Blackwell et al. (2015) the degree of exposure to previous speech and language therapy services had not been reported in the studies. Exposure to speech and language therapy services may have affected the parent to child interaction in families. Third, the sample sizes in all studies were small. Given the considerable variance in parent talk reported in the general population (Hart & Risley, 1995; Hoff & Naigles, 2002), these studies were unlikely to have had adequate power to identify a significant difference in any but the largest of effect sizes. Whilst the Vigil and Hodges (2005) study did not identify a significant difference, the mean, minimum and maximum values for total words spoken was higher for the normally developing group than the language delayed group, thus supporting the case for a relationship between parental talk and child language development. Fourth and finally, all studies were based on a sample of middle class families. Given the association of parental linguistic input with socioeconomic status, when compared to the correlational and regression studies cited above, these case control comparisons have lower ecological validity. The weight of evidence from the correlational studies, therefore, indicates that a relationship exists.

The question of how parental linguistic input is related to child language outcomes has been raised in the literature. The findings are based on correlational and regression analyses and so, as with aspects highlighted above, causality cannot be assumed. Arguments against a causal relationship have been proposed by Bishop (2014a, 2014b). Her contention is based on a number of twin studies, which demonstrated much lower effects of environmental factors compared with genetic inheritance for language development (Dale et al., 1998; Kovas et al., 2005). Bishop (2014a,
2014b) proposed that a third casual factor, such as shared genetic inheritance influenced both parental linguistic input and child language outcomes. Whilst the role of genetic inheritance cannot be ignored, a number of different studies provide evidence against a pure inheritance based hypothesis. For example, there is evidence of the role of the environment in some aspects of language development from other twin studies (e.g. Hayiou-Thomas, 2008; Van Hulle et al., 2004). In addition, a study into the language development of Romanian orphans raised in foster homes or institutional care demonstrated significantly higher language abilities for the children raised in foster care (Windsor, 2007). As all were orphans a genetic bias for one group was unlikely, suggesting that it was the environment that influenced the language outcomes of the children. Whilst this study was not specifically concerned with adult linguistic input to children, it adds to the weight of evidence for environmental effects on language development. It is likely that genetic inheritance does play a part in both parental linguistic input and the child’s capacity to learn language. This does not eliminate, however, the role of linguistic input as an element of the language learning mechanism in child language development. Indeed, Bishop (2014b) states that language enrichment may be a beneficial aspect of therapy for children with specific language impairment, thus reinforcing the role of the environment in language development.

The mechanisms through which linguistic input supports child language development have been examined in the literature. Merz et al. (2015) found that inferential language input was more highly associated with language development for children with stronger initial language skills than for children with weaker skills, whereas parental responsiveness was highly associated for all children. This indicates that different aspects of parent to child interaction may be important at different stages of development. As discussed above, Weisleder and Fernald (2013) found that parental linguistic input was associated not only with child language outcomes but also child language processing skills. Children who heard more language had faster language processing skills than children who heard less language. The role of language input in facilitating the development of
language processing skills is also demonstrated in the study of school aged children by Roy et al. (2014) who found that socially disadvantaged children who had experienced more years in school (and therefore, they postulated, had experienced more linguistic input) had better core language skills than younger children. It should be noted, however, that whilst these studies may indicate the role of language input as part of the learning mechanism in developing language processing skills, the possibility that genetic inheritance or maturation are responsible cannot be ruled out and further research is required to address these questions.

**Quality features of parental linguistic input**

The studies cited above illustrate a clear relationship between the quantity of parental linguistic input and child language development. The quality features of the parental linguistic environment and how these relate to child language development have also been explored. Hart and Risley (1995) found that the amount and richness of certain quality features correlated with language outcomes at age 3 and age 9-10 years (Hart & Risley, 1995; Walker et al., 1994). They postulated, therefore, that it was these features that facilitated language development. The features they described were language diversity, feedback tone, symbolic emphasis, guidance style and responsiveness. These features are found in Table 1, and are described below with reference to other studies also supporting their value for language development:

Table 1: The five quality features of parental linguistic input described by Hart and Risley (1995)

<table>
<thead>
<tr>
<th>Language Feature</th>
<th>Described by research team as:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Language Diversity</td>
<td>“They just talked”</td>
</tr>
<tr>
<td>Feedback Tone</td>
<td>“They tried to be nice”</td>
</tr>
<tr>
<td>Symbolic emphasis</td>
<td>“They told children about things”</td>
</tr>
<tr>
<td>Guidance Style</td>
<td>“They gave children choices”</td>
</tr>
<tr>
<td>Responsiveness</td>
<td>“They listened”</td>
</tr>
</tbody>
</table>
Language diversity and symbolic emphasis refer to the range and variety of parental talk to children. Specifically, language diversity is concerned with the range and variety of vocabulary and syntactic items used, and symbolic emphasis refers to the labelling of items and description of daily events. Hart and Risley (1995) reported that language diversity was positively associated with the overall quantity of linguistic input, such that parents who spoke more to their children also demonstrated greater diversity in their talk. Their analysis showed that language diversity also correlated strongly with language outcomes at age 3 and age 9-10 (Hart & Risley, 1995; Walker et al., 1994). The relationship between language diversity and child language outcomes is supported in the literature by a number of other studies (Hoff & Naigles, 2002; Liu, 2014; Rowe, 2012). Symbolic emphasis may also be considered to be related to parental responsiveness. Parents who are both responsive and who use diverse language with their children are likely to label items and talk about events.

Feedback tone referred to the proportion of positive affect in parent talk contrasted with negative affect. Hart and Risley (1995) found that a greater proportion of positive affect was related to higher language outcomes. They also reported that the proportion of positive affect in parent talk was related to socioeconomic status, with parents from higher socioeconomic backgrounds using a greater proportion of positive language. These findings are supported in the literature. For example, McDonald Culp et al. (1996) reported that when compared to older mothers, adolescent mothers used fewer words expressing positive affect when talking to their infants who were also found to have reduced language skills.

Guidance style refers to parenting style that parents employ, particularly when guiding children to a specific activity. Hart and Risley (1995) found that the use of directive statements was negatively correlated with language development; a greater use of directive statements was associated with lower child language outcomes. The alternative guidance style, that is, the use of auxiliary fronted
yes/no questions to request compliance from children, for example ‘can you get down from the table?’ was found to be positively associated with language outcomes. There are two possible interpretations of this finding. First, guidance style may be related to the quality feature ‘responsiveness’, as the use of directive statements is reported to be an indicator of a directive parenting style (Murray & Hornbaker, 1997). The evidence supporting a responsive parenting style is discussed above as a separate micro-environmental factor. It is relevant to parental linguistic input, however, because responsiveness is in part evident in the language a parent uses. A second interpretation of Hart and Risley’s (1995) findings concerning guidance style is a data driven approach. The use of auxiliary fronted questions instead of directive statements results in an increase in the overall quantity of language spoken by parents. Hoff and Naigles (2002) found in their study of parental linguistic input that the quantity of language is more strongly correlated with language outcomes than social interaction features such as following a child’s lead, a common strategy employed in therapy to facilitate parental responsiveness. Given the considerable evidence supporting both responsiveness and quantity of language input, both interpretations are likely to contribute to an understanding of how guidance style facilitates language development.

1.3.6: Environmental factors, concluding comments

A number of macro and micro environmental factors have been highlighted in this chapter as being related to language development in children. Whilst evidence has been presented for each factor separately, these factors have been found to interact in a number of studies. For example, interactions have been reported between socioeconomic status, parental education and the quality of the home environment (Magnuson, Sexton, Davis-Kean, & Huston, 2009), the home environment and the school environment (Pinto et al., 2013), book sharing and parental mood (Katz, 2010) and reading and socioeconomic status (Morag, Dixon, Masterton, & Quinlan, 1998). Furthermore, both macro and micro environmental factors have been found to mediate for other factors concerning
language development (Hart & Risley, 1995; Raviv, Kessenich, & Morrison, 2004; Robokos, 2007).

As stated by Bishop (2014b) language development is very likely to be the result of a number of causal factors each with a small effect size. Whilst Bishop’s (2014b) proposal alluded to the influence of the environment, this was considered minimal and her focus was on the interaction of the different genes involved in language development. Cognisant of the influence of heritability, this thesis proposes that the argument for multiple influences of small effect sizes extends beyond the genetic influences. It is likely that the environmental factors highlighted above also influence language development in small measures. An understanding of current theoretical debate on language development may inform this argument further and is discussed below.

1.4: Theoretical models of language development

1.4.1: Justification for a theoretical perspective

Theoretical models of language acquisition inform understanding of how children develop to full linguistic competence. A sound theoretical model incorporates a wide body of empirical evidence, which can provide support for or against proposals seeking to explain the underlying mechanisms involved in language development. Valian (2014) states that “[theoretical] models … have to specify (i) the content of the initial state, or the child’s innate endowment; (ii) the content of the final state, or the adult’s syntactic knowledge; (iii) the mechanism that gets the learner from the initial to the final state; and (iv) the role of input in that process” (p. 78). Concerning services that aim to support child language development through supporting (or manipulating) the caregiver environment understanding the role of the input in language development is particularly pertinent. Does the quantity of linguistic input matter? Is the way in which the input is received important
(linguistically, socially)? How does linguistic input influence child language? This section of the thesis provides a critical overview of the main theoretical debate before addressing the question of the role of linguistic input more specifically.

1.4.2: The nature – nurture debate

The language acquisition debate has for many years focussed around a nature – nurture, or nativist / empiricist divide (Bickerton, 1992; Chomsky, 1959; Jackendoff, 1994; Pinker, 1994; Sampson, 1997; Tomasello, 2006) and this dichotomy is still highlighted in introductory textbooks on language development (McLaughlin, 2006; Owens, 2012). Bishop (2009b) argues in her review of the contemporary theoretical debate on language acquisition that “the polarisation between the Grammar Gene (that is, nativist) and Big Brain (that is, empiricist) account is rather a caricature of the current state of debate.” p 189. There is still, however, disagreement around what aspects of language development are innate, and the different viewpoints do appear to stem from these original philosophical stances, as will be illustrated below.

Both theoretical positions have moved away from pure nativist / empiricist viewpoints. In her overview of theories of language acquisition Hoff (2001) argued that whilst the nativist proposal can be defined in terms of its acceptance of innate linguistic abilities, there are few current theories that could really be considered to be empiricist in its purest sense (that is, suggesting that all development is based on experience as in the ‘humans as a blank slate’ analogy). She proposed that alternative approaches to the nativist account might be termed ‘interactionist’ or ‘constructivist’. The role of both nature and nurture in child language development is now accepted by most. The question that remains and continues to be the focus of this debate is whether the innate structures are specific to language development (domain specific) or whether they are used for other functions, that is, domain general (Bishop, 2009b; Hoff, 2001). Given that the historical
underpinnings do appear to continue to resonate throughout the current debate, the critical theoretical overview provided in this thesis is structured around this dichotomy. Cognisant of the development, however, the term ‘empiricist’ is not used and theoretical viewpoints are grouped as ‘nativist’ and ‘non-nativist’ approaches.

1.4.3: The nativist approach

The original nativist argument

The nativist approach to language was first postulated by Noam Chomsky (Chomsky, 1959), who illustrated the inadequacies of language learning using the strict behaviourist theory proposed by Skinner (1959). Chomksy’s theory of language development gained popular appeal in the 1960s and 1970s, and following a relative lull in activity in the 1980s the nativist cause was reignited in the 1990s by, amongst others, Bickerton (1992), Jackendoff (1994) and Pinker (1994, 1999). It is noteworthy that Chomsky’s initial theory formed the basis of all subsequent nativist arguments (Sampson, 1997).

The original arguments proposed by Chomsky were based on the concept of innate linguistic knowledge. He proposed that humans possess an innate formal language known as universal grammar (UG), which describes all possible adult linguistic structures across languages (Chomsky, 1968, 1980). UG provided a template upon which the meaningful components sit. As children are exposed to their native tongue, certain parameters within the UG would be set (Chomsky, 1968, 1980). This parameter switch-setting feature allowed for the differences in syntactic structure across languages. Whereas UG (that is, knowledge of syntax and morphology) is innate, the meaningful components are learned by general cognitive methods. These components include the words, idioms and irregular grammatical structures within a child’s native language. The challenge for children is to learn these components and to link the two strands together. This is known as a
dual process approach, or a ‘words and rules’ approach (Pinker, 1999). The idea that grammar or syntax is developed in a different way to other aspects of language is supported by others from the nativist school of thought (Chomsky & Lasnik, 1993).

**Arguments in favour of the original nativist approach.**

Arguments for innate knowledge were made with reference to the speed of acquisition in childhood, age-dependence (the idea that there is a critical window beyond which acquisition of full competence is not possible), the similarities of other non-linguistic abilities such as number acquisition, the fact that grammar in a given community does not differ between individuals (referred to as ‘convergence amongst grammars’) and the universal and species specific nature of language use (Pinker, 1994). Additional arguments made in support of innate grammar have included observations that child language acquisition appears to take a leap from simple one word or learned phrase utterances to full grammatical complexity with no apparent intermediary stage (e.g. Valian, 2014), the development of pidgin to creole languages and the development of sign languages in the absence of parental input, both of which have been reported to occur over a couple of generations (Bickerton, 1992), and the example of the ‘KE’ family who present with an inherited language disorder affecting grammatical production (reported in Pinker, 1994). The strongest argument made by Chomsky (1968), however, and developed by subsequent nativists (Bickerton, 1992; Jackendoff, 1994; Pinker, 1994) is the concept referred to as ‘poverty of the stimulus’ (Pinker, 1994). It is contended that children would be unable to learn grammar based solely on what they heard, as the linguistic input they are exposed to by their parents is inadequate and degenerate, and therefore not substantial enough on which to base any experiential learning methods.
Arguments against the original nativist approach

Arguments against the original nativist proposals were made on the grounds that they were based on a number of factors that are not empirically based (Bishop, 2009b; Sampson, 1997). For example, Sampson (1997) highlighted that the argument of ‘speed of acquisition’ is not objective. He noted that it is not beneficial to the argument to comment that children learn language remarkably quickly, as there is no means by which to compare the rate of learning. The ‘poverty of the stimulus’ argument was also criticised as being proposed without underpinning empirical evidence (Sampson, 1997). Furthermore, evidence now exists that suggests that parental linguistic input is not only plentiful (e.g. Hart & Risley, 1995; Hoff & Naigles, 2002) but also syntactically accurate (Snow, 1994). For example, a study by Newport, Gleitman, and Gleitman (1977) found that speech addressed to children by their mothers was “unswervingly well formed” with less than 1% of utterances being inaccurate.

Another argument made by the nativists, which has been undermined by empirical research, was the apparent observation that children take a leap in language development from rudimentary single word utterances to complex sentences. There is a now a considerable body of evidence, which undermines this claim (Bates & Carnevale, 1993; Braine, 1963; Brown, 1973; Crystal, 1976; Girolametto & Weitzman, 2006). Also, the ‘parameter setting’ hypothesis proposed by the nativist school, whereby innate grammatical parameters in the brain are triggered through language exposure, does not make sense to many developmental psychologists (Bishop, 2009b). For example, Sampson (1997) notes that the concept of innate knowledge (in a Cartesian sense) is at odds with empiricist or Darwinian thinking, which accounts for much of our current view of evolution. Bishop (2009b) also states that understanding of the neural processes involved in learning goes against any predefined knowledge.
Elements of the nativist argument have also been criticised on account of their inability to explain linguistic phenomena. For example, cross-linguistic researchers postulate that some non-European languages have to be forced into the structure of Universal Grammar (Croft, 2001; Foley & van Valin, 1984). Also, Tomasello (1995) highlighted that universal grammar does not account for the ‘continuity’ problem, that is, that young children display rudimentary item-based grammars early in ontogeny that are different to adult grammar. This item-based grammar, he postulated, as well as the development towards full adult language structure is not adequately explained by the nativist account of language development. Tomasello’s argument has been challenged by the generativist Valian (2005), who stated that such ‘formulae’ are actually evident in some aspects of syntax, so their presence in child language is not incompatible with a UG. The argument by Valian (2014), however, does not explain why children would use item based grammars in the ‘wrong’ place if they had an innate grammar with the correct forms pre-wired.

*Development of the nativist argument*

In more recent years there has been a move away from the concept of innate knowledge within the nativist school towards an idea of domain specific skills. This move has been reported by the most vocal and well known of the nativist proponents, including Noam Chomsky and Steven Pinker (Fitch, Hauser, & Chomsky, 2005; Hauser, Chomsky, & Fitch, 2002; Hauser et al., 2014; Pinker, 2003). For example, in his development of an ‘adaptionist’ approach, Pinker (2003) proposed the evolution of a number of complex language specific cognitive functions (rather than innate knowledge), which are found in humans as a result of natural selection. Also, Chomsky’s more recent reports do not specify an innate grammar but, rather, specialised innate learning mechanisms for language, including the faculty for language – narrow sense, which enables computation of language structure in humans through the brain’s capacity for recursive thinking (Fitch et al., 2005; Hauser et al., 2002). It is worth noting, however, that some of the features present in the original
nativist approach remain in the new proposals, particularly that of a dual words and rules process (Pinker, 2003).

1.4.4: Non-nativist approaches to language development

Developing from an empiricist to constructivist approach

As stated above in section 1.4.2, with the exception of Sampson (1997), non-nativist approaches addressing the question of language development are no longer empiricist in its purest sense and were more appropriately categorised as being ‘interactionist’ or ‘constructivist’ by Hoff (2001). It is now argued that a purely empiricist model of learning language within an historical and cultural environment (such as that proposed by Sampson, 1997) does not sufficiently account for the development of underlying cognitive abilities required for language development and social life and that it cannot account for the way that infants have been observed learning within a social framework, nor for the levels of socio-cognitive skills, for example, shared understanding required for language (Elman, Bates, Johnson, & Karmiloff-Smith, 1996; Tomasello, 2005).

The non-nativist approach adopted is ‘interactionist’ in that it is the interaction between the organism and its environment that brings about language, and ‘constructivist’ in that it is based on the view that children construct language using a number of domain-general cognitive processes (Bates, 1994; Hoff, 2001; Tomasello, 2005). The term ‘emergentist’ has also been used in some cases to describe the emergence of a phenotype (in this case, language) as a result of an interaction between the organism and its environment (Elman et al., 1996; Hoff, 2001), although this term has been criticised for being too vague in explaining how the phenotype might emerge (Elman et al., 1996). As well as accounting for the organism and its environment, the historical and cultural dimensions which go to construct the complexity of grammar are acknowledged in non-nativist approaches (Sampson, 1997; Tomasello, 2005). According to the constructivist approach, a child
born into a given community learns its specific linguistic features, in part, through exposure to that language. As highlighted by Owens (2012) “Linguistic input is crucial to this process” (p. 43).

*Specification of the cognitive skills required for language development*

Developments in cognitive psychology have enabled a greater understanding of the potential underlying processes that may be responsible for language development. For example, Tomasello (2005) proposed that three groups of cognitive processes are present in young children and are necessary for constructing a language, as discussed below.

The first group consists of the prerequisite skills for language development. These include segmenting speech and conceptualising referents (Tomasello, 2005). Support for this proposal can be found elsewhere in the literature (Bishop, North, & Donlan, 1996; Stokes & Klee, 2009). For example, the role of auditory discrimination and phonological short-term memory have been highlighted recently as significantly predictive components in the development of language (Bishop et al., 1996). The development of the conceptual system has also been found to develop alongside language development in children learning Korean by Choi (1997). The second group of cognitive processes described by Tomasello (2005) are the social foundational processes necessary for language development. These include intention reading and cultural learning (Tomasello & Farrar, 1986; Tomasello & Todd, 1983). According to Tomasello (2008) the cognitive process that evolved in humans and enabled them to extend communication to the iconic level required for language is recursive mindreading. This process facilitates the foundational processes of joint attention forming, intention reading and role reversal imitation (Tomasello, 2008). Humans are only able to communicate using an abstract system such as language as a result of a recursive shared understanding of the referent (Tomasello, 2005, 2008). The third group includes facilitative processes enabling the contrasting of lexical targets and the ability to use linguistic context to support learning. For a full description of these processes, see Tomasello (2005).
Another example of a non-nativist account of language development is the ‘connectionist’ or ‘neuroconstructivist’ model (Elman et al., 1996). The model was developed in recognition of the role of cognitive neuroscience in understanding language development. Elman et al (1996) postulated that there is no need to impose language functions on the brain as it is through connections between the different processes that language emerges. Language rules are calculated through analysis of statistical regularities in the input. Thus, the phenotype of language is a result of a number of combining factors rather than one language specific genotype.

*Arguments against constructivist approaches*

The robustness of a non-nativist approach depends on the degree to which it explains the cognitive functions involved in language development. As highlighted above in section 1.4.3, Skinner’s (1957) original account of language learning through a behaviourist mechanism was criticised by Chomsky (1959) on its inability to account for how something as complex as language develops. Criticisms have been made of other, more recent non-nativist accounts on similar grounds. For example, Foster (1990) highlighted the inadequacies of Slobin’s language acquisition device (Slobin, 1981) to account for language development, and more recently Pinker (2003) criticised the ‘general cognitive’ approach, including that made by Tomasello (1995), on the same grounds. Pinker (2003) reported that general cognitive approaches were “difficult to evaluate, because no one has spelled out a mechanistic theory of ‘general intelligence’ or ‘cultural learning’ that is capable of acquiring human language.” (p. 21).

Whilst accounts such as that proposed by Tomasello (2005, 2008) and Elman et al. (1996) specify the learning mechanisms involved in more detail than previous non-nativist accounts, they still do not adequately explain certain key factors involved in the evolution of language in humans. For example, neither account explains how the highly complex vocal repertoire now used in human language evolved, the processes involved in, or the physiological adaptation for, spoken verbal
production present in humans, including the low position of the larynx that has been highlighted by Hauser et al. (2002). Furthermore, whilst the constructivist accounts are implicitly much more dependent on linguistic input, as postulated by Owens (2012) above, they still do not adequately explain how linguistic input influences child language development (Snow, 1994).

1.4.5: Moving on from the debate

Calls for a more constructive dialogue

Whilst the effects of the nativist/non-nativist divide are still evident in current accounts of language development, there appears to be a convergence of opinion and the differences between the two camps have reduced. Theorists on both sides now agree on a number of factors: that language is complex and likely to involve a number of interacting processes, (Elman et al., 1996; Hauser et al., 2002) and that these processes are likely to be a result of a biological adaptation in human evolution (Pinker, 2003; Tomasello, 2008). Kates (1980) proposed that some of the difficulties in the debate have been a result of the range of disciplines involved in the study of child language development, with linguists adopting a more formal algebraic approach to describing language and psychologists approaching the topic from an empirical perspective. As the range of disciplines interested in this topic has grown over the years, any confusion caused will have increased further; an issue that has been highlighted again more recently (Bishop, 2009b; Hauser et al., 2002).

There have been suggestions that a more constructive dialogue, rather than polarised debate might aid greater understanding of the underlying mechanisms involved in language development (Bishop, 2009b). As stated by Hauser et al (2002) “linguists and biologists, along with researchers in the relevant branches of psychology and anthropology, can move beyond unproductive theoretical debate to a more collaborative, empirically focused and comparative research program aimed at uncovering both shared (homologous or analogous) and unique components of the faculty
of language” (p. 1579). Rather than focusing on the domain specificity or otherwise of underlying skills, more recent studies have sought to account for the processes involved in constructing a language in more detail.

**Evidence for statistical and rule based learning**

Several studies have recently highlighted the role of statistical learning in language development. According to this proposal children learn language based on statistical regularities of linguistic patterns that they hear in linguistic input. Empirical evidence for this approach has been found in studies exploring infants abilities to segment words from fluent speech (Saffran, Aslin, & Newport, 1996) word learning (Lany & Saffran, 2011), phonological learning (Maye, Werker, & Gerken, 2002) and early learning of syntax (Saffran, 2003). These studies shed light on how children might construct linguistic structures. Another study using infant perception found that infants were able to construct algebraic rules from phonologically manipulated speech input (Marcus, Vijayan, Bandi-Rao, & Vishton, 1999). Infant perception has also been found to be related to language acquisition later on in childhood in a longitudinal study (Tsao, Liu, & Kuhl, 2004), supporting proposals that statistical learning forms part of the language learning mechanism. Statistical learning alone is unable to account fully for language development, however, as artificial intelligence simulations using statistical learning alone have thus far failed to construct a language (Kuhl, 2004).

**The role of social interaction in constraining statistical learning**

A number of studies have explored the relationship between statistical learning and social interaction in child language development. Kuhl (2004) proposed that infants are ‘primed’ to attend to and learn features of the speech stream when they are engaged in social exchanges with an adult. This proposal was supported by a number of studies, which demonstrate that infant perception was facilitated by social exchanges or infant directed speech (Kuhl, 2004; Kuhl, Tsao, Liu, Zhang, & Boer, 2001; Liu, Kuhl, & Tsao, 2003). This evidence is also in accordance with findings from
Weisleder and Fernald (2013), cited above in section 1.3.5, that language processing skills in young children are related to the linguistic input they receive.

1.4.6: The role of environmental input

Questions around quality and quantity of input

The statistical learning accounts described above begin to shed some light on the role of the linguistic and interactive environment in language development. Much about the role of linguistic input is still unknown, however. It is widely acknowledged, for example, that a degree of linguistic input is necessary for linguistic competence. Examples of language deprivation reported in the literature, for example the case of Genie (Rymer, 1993) or studies into the development of children raised in Romanian orphanages (Graham et al., 2014) show that children raised with severely limited interactions fail to develop full language abilities. The question that remains, however, is how much language does a child need to be exposed to in order to develop full linguistic competence? Snow (1994) postulated that there is a significant amount of buffering, citing the apparent normal and robust language levels acquired by children from a vast range of social and linguistic environments. The relationship between the developing child and the environment, however, is not straightforward, as Snow (1994) highlighted:

“one could argue that the skills associated with connected discourse and with pragmatic appropriateness are somewhat less evenly distributed in the population, but clearly there is a central set of language skills, the acquisition of which is very likely to be successful … buffering implies either that only a relatively small amount of social support of the right sort might be necessary or alternatively that any of several different environmental events might be sufficient for some bit of learning to occur.” (p. 11)
The fact that children appear to develop apparently normal language levels despite wide variance in the linguistic and social input they receive might lead to an assumption that the quantity or quality of input is not particularly important, as has been suggested by some (Bishop, 2014b; Foster, 1990; Pinker, 1994). However, Snow (1994) highlights several factors which should be considered. First, as stated above, when the basic or ‘central’ skills of lexical, phonological, morphological and syntactical skills are developed there is likely to be considerable variance in the population concerning the higher language level skills, such as connected discourse and pragmatic skills highlighted by Snow (1994), above. In addition, vocabulary size is known to vary across the population and to be associated with parental linguistic input (Hoff & Naigles, 2002; Weisleder & Fernald, 2013), and there is also some evidence of variance in the population according to syntactic skills (Moyle, Weismer, Evans, & Lindstrom, 2007; Spencer, Clegg, & Stackhouse, 2012). There is disagreement on the level of variability of syntactic ability. As highlighted by Vasilyeva, Waterfall, and Huttenlocher (2008), differences in the literature are likely to be a result of a number of factors. These include different methodological approaches, sample size, sample characteristics, aspects of syntax examined in studies and assessment used. Their study sampled a socially diverse range of participants, examined both simple and complex syntax and used transcription of videoed real time language use. They found that development of simple syntax did not differ according to SES but that use of complex structures varied considerably according to SES. This finding supports the comment made by Snow (1994) that basic grammatical rules appear to be independent of all but the most deprived environments. It also, however, may explain why discrepancies are seen across the socioeconomic continuum concerning language abilities.

Evidence from cross-linguistic studies has also demonstrated that children’s acquisition of word categories and syntactic forms is dependent on the frequency of those forms in their input. For example, Choi (1997) found that Korean learning children acquired verbs more quickly than English speaking children, and that this was directly related to the frequency of verb use in the
parental linguistic environment. Mothers’ child directed talk was more action focused in Korean families and more nominally focused in English speaking children. Furthermore, Choi (1997) found that Korean children’s conceptual awareness of actions also developed more quickly, suggesting a bidirectional relationship between experience and learning of concepts and the language associated with those concepts. The effect of frequency in linguistic input with order of acquisition has been reported in a number of other cross-linguistic studies (Kauschke, Lee, & Pae, 2007; Koptjevskaja-Tamm, 2008).

*How does input influence language development?*

The studies highlighted in the above section and in section 1.3, above, indicate that the quantity and frequency of vocabulary and grammatical forms in child directed speech influences order of development and speed of acquisition of language. The question that remains is this; does the quality and quantity of language input and social interaction support the acquisition of language forms and categories only, or are language processing skills themselves facilitated through input? Evidence from Hurtado et al. (2008) suggests that the input does indeed strengthen language processing skills, enabling children to learn new words from the environment more easily. Furthermore, Moyle et al. (2007) found that children with typical vocabulary development used lexical knowledge as a bootstrapping strategy to support syntactic knowledge more than children with delayed vocabulary development, suggesting facilitative links between the different aspects of language.

**1.4. 7: Summary**

The role of the input in the environment was previously considered to be fairly insignificant for the original nativist approach and was considered to be much more relevant for non-nativists. Whilst
the nativist argument has developed over recent years, and the role of input therefore considered to be more influential, the modular nature of the nativist approach, in particular the duality of word and syntax acquisition has implications for the importance of input. The development of syntax for children with lower expressive vocabularies as a result of reduced input would be unaffected according to the words and rules approach. If, however, as Tomasello (2005) suggests, language is constructed and further abstractions formed based on prior knowledge and language use, then the quality and quantity of input is relevant for all modalities of language. Evidence from the statistical learning studies (Kuhl et al., 2001) as well as from studies demonstrating links between language modalities (Moyle et al., 2007) and also between language and conceptual development (Choi, 1997) support the one language learning process postulated by Tomasello (2005). It is suggested that, whilst considerable buffering within the language learning system allows the majority of normally developing children to acquire core conversational grammar, that the quality and quantity of linguistic input does influence the range and variability of language a child develops. Furthermore, another factor considered by Snow (1994) is that children who do present with additional difficulties, for example, hearing loss, visual impairments or with specific language impairment may not benefit from as much buffering as normally developing children, and would therefore be much more reliant on the quantity and quality of linguistic input to support their language development.

1.5: Incorporating the empirical and theoretical accounts: Implications for this study

Having considered language development from a range of perspectives, its importance for functioning in society, the presentation, prevalence and prognosis of primary language delay, causal influences on language development and theoretical approaches to how language develops in humans, the following assumptions are made. First, language is essential for participation in human
society. Second, primary language delay presents in different ways and is not easy to clinically define. Some children, particularly those with comprehension difficulties and from low socioeconomic backgrounds may not be identified. Primary language delay, does, however, affect a significant proportion of the population. Whilst there may be different outcomes for different subgroups of children, the picture is, largely, that poor language skills are associated with negative outcomes later in life across a number of domains. Also, whilst the evidence of heritability is strong, there is also evidence of the role of the environment in supporting language acquisition, particularly the social and linguistic parenting environment, such that a greater amount of language spoken to children by parents is associated with a greater level of language development. This interaction between biological and environmental aspects of language development is comprehensively accounted for by the usage based linguistics approach proposed by Tomasello (2005). Further support for the role of the environment is found concerning the development of language processing skills (Hurtado et al., 2008; Weisleder & Fernald, 2013) and in studies examining statistical learning (Kuhl, 2004).

What implications does this interpretation have for the present study? As the research in this study is concerned with the effectiveness of a primary prevention service for environmentally based language delay, recognition of the role of the environment in language development is key. The case for supporting child language development through facilitating optimal parental linguistic environment is made. If a primary prevention service facilitated change in the parental linguistic environment, and this in turn facilitated child language development, then the theoretical argument for the role of the environment in supporting language development as a causal element would be supported. This study examines the effectiveness of such a service and therefore contributes to the question of the effect of the environment on child language development.
Chapter 2: An evidence-based approach for speech and language therapy services aimed at family focused prevention of environmentally based language delay.

In this Chapter the focus is turned to speech and language therapy services targeted at supporting the parenting environment to prevent environmentally based language delay. This practice is considered within the framework of evidence-based practice (section 2.1) and a systematic scoping review is reported in section 2.2, which highlights the range and scope of family focused primary prevention within the speech and language therapy profession (particularly in the UK). Finally, the intervention that is the subject of the randomised controlled trial reported in this thesis, the Babytalk Home Visiting Service (BTHV) is described in section 2.3 with reference to previous evaluations and the Medical Research Council’s guidance on the development and evaluation of complex interventions (Medical Research Council, 2000, 2008).

2.1: Positioning family focused preventative practice within the framework of evidence based practice

2.1.1: The current picture of preventative practice for environmentally based language delay

In the UK the remit of supporting language development in young children has historically fallen within the domain of public health services (Law, 2006). Indeed, it is still largely recognised as being a multi-agency and disciplinary responsibility (Department for Children Schools and Families, 2008; Department of Health, 2009; Ferguson & Spence, 2012; Law, 2006; Pickstone et al., 2009). Child language outcomes are reported in a number of studies describing generic child
development and welfare programmes, as they are a key indicator of social mobility (Landry et al., 2012; Love et al., 2005; Olds et al., 2004). Over the past 15 years the public health remit has been extended to include speech and language therapists. This was largely a result of the Sure Start government initiative to address the negative effects of child poverty in the UK (Glass, 1999). The Sure Start unit set targets for children, which were later encapsulated into five key outcomes that every child in the UK should be entitled to achieve. These were the outcomes highlighted in Chapter 1 (section 1.1) namely; to be healthy, stay safe, enjoy and achieve, make a positive contribution and achieve economic wellbeing (Department for Education and Skills, 2004). Key performance indicators agreed by the Sure Start Unit for these outcomes included targets for language development (Law & Harris, 2001). Given that speech and language therapists were able to provide highly skilled services in this respect, local Sure Start programmes funded posts for therapists, with a clear aim of providing preventative services (Fuller, 2010; Law & Harris, 2001; Sawyer, Pickstone, & Hall, 2007).

Since this date a number of speech and language therapy initiatives have been developed aimed at addressing the early identification and support of children at risk of environmentally based language delay. Attempts have been made to develop an effective screening instrument for language delay but these have so far lacked adequate sensitivity and specificity (Law et al., 1998; Maas, 2000; Nelson, Nygren, Walker, & Panoscha, 2006). Initiatives aimed at primary prevention of language delay have also been described in the literature (Dockrell, Stuart, & King, 2006; Farmer & Griffiths, 2006; Hobbs, 2006). These initiatives are largely aimed at supporting children within a nursery setting, either directly or through education and empowerment of the professionals employed by the setting. It has been reported, however, that speech and language therapists have also offered primary prevention services to parents in these newly funded roles (Fuller, 2010; Sawyer et al., 2007). In a survey to Sure Start programmes, Fuller (2010) identified a range of new services offered to parents and to families with children aged under 12 months, including talks to parent
groups, baby signing groups, individual advice, information packs and published programmes such as The Hanen Centre’s ‘You Make the Difference’ programme (Manolson, 1995).

Speech and Language therapist involvement in UK based prevention services as part of a health promotion remit was thus established and the role of speech and language therapists to this end has been recognised in more recent reports (Department for Children Schools and Families, 2008; Department of Health, 2009; Law et al., 2013). Health Promotion is now positioned within the Royal College of Speech and Language Therapists’ model of service delivery (2006). This acceptance of prevention practice is also reflected around the world by other national professional bodies (e.g. American Speech-Language-Hearing Association, 1988; Canadian Association of Speech-Language Pathologists and Audiologists, 2014). Ferguson and Spence (2012) reported that speech and language therapists are now reported to consider health promotion as an integral part of their role. They also noted, however, that the speech and language therapists interviewed had limited knowledge of health promotion as a concept or of what is effective practice within this domain. Whilst their research was based on a qualitative study in Scotland, so the generalisability of their findings is limited, this raises the issue of if and how health promotion is currently embedded within routine speech and language therapy practice. The reports above (Fuller, 2010; Sawyer et al., 2007) suggest, at the very least, that prevention practice is no longer considered to be a public health only concern.

2.1.2: Primary prevention within speech and language therapy and evidence based practice

When a new form of practice is adopted into the speech and language therapy profession, this practice is subjected to the profession’s clinical standards. Such is the case for primary prevention, health promotion or public health based speech and language therapy services. A significant
requirement of service delivery in speech and language therapy is the need to embed practice within a sound evidence base. The concept of evidence-based practice (EBP) is not unique to the health professions and has also been adopted within other professions such as education and social policy development (Bernstein-Ratner, 2006; Medical Research Council, 2008). EBP has, however, had a dominant voice within the healthcare professions and the expectation that speech and language therapists seek to provide care that is evidence based is now considered to be a fundamental professional standard (American Speech-Language-Hearing Association, 2005; Health and Care Professions Council, 2013; Royal College of Speech and Language Therapists, 2006). In order to develop health promotion services within an evidence-based framework, however, it is first necessary to understand what is meant by EBP, the current debate around the value of EBP and to have an understanding of how a robust and meaningful evidence base might be established.

2.1.3: A critical overview of the development of evidence-based practice within the speech and language therapy profession

Development of EBP within speech and language therapy services

Whilst the philosophical underpinnings of EBP are claimed to extend back to the mid nineteenth century (Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996) the terminology used today emerged in the medical profession in the early 1990s (Rycroft-Malone et al., 2004; Sackett et al., 1996). Sackett et al. (1996) defined EBP as: “the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.” (p. 1). The principle of providing EBP spread from the medical profession to other healthcare providers, and was incorporated into speech and language therapy practice from the late 1990s and the turn of the millennium (e.g. Glogowska, 2000; Law et al., 1998). The wider adaptation was facilitated by the publication of a framework for developing and evaluating complex interventions (Campbell et al., 2000; Medical Research Council, 2000). This framework gave a series of 5 phases (1 preclinical
phase, followed by 4 clinical phases) as shown below in Figure 1. At the preclinical phase, the relevant theory pertaining to the intervention is explored, in order to make realistic predictions about what is likely to be effective in the intervention. The first clinical phase involves identifying the necessary components of an intervention, how these components relate to each other, and developing a model of the service. The second clinical phase is concerned with exploratory evaluations and trials, in order to define how the intervention might work in different settings, estimated effect sizes, and to identify variables and appropriate outcome measures for a main trial. The third clinical phase is identified by the MRC (2000) as the definitive randomised-controlled-trial stage and the fourth stage as the long term implementation stage where the replication and real world dissemination of the intervention is evaluated.

Concerns about the dominance of EBP

Since the emergence of EBP its value to professions allied to medicine has been debated in the literature. The debate has largely focussed around the opinion that the evidence-based agenda, stemming from the medical profession, was underpinned by a medical model of intervention, with too strong a focus on the research element of evidence (Bernstein-Ratner, 2006; McCurtin & Roddam, 2012; Rycroft-Malone et al., 2004). Rycroft-Malone et al. (2004) proposed that evidence was formed not only from research findings, but also from clinical experience, patient values and experiences, and the local environmental context. They postulated that the perceived value of evidence was too heavily weighted on information from research to the detriment of the other sources of evidence. They also highlighted that research evidence is not as ‘watertight’ as is often claimed, and even narrowly focussed questions may have been addressed in different ways by different researchers with different outcomes. They concluded that: “whilst research evidence is important to delivering evidence based care, it is less certain and less value free than is sometimes acknowledged” (p. 84).
Concerns about the reliability of research evidence were developed further by Bernstein-Ratner (2006) in an analysis of the application of EBP within the speech and language therapy profession. She highlighted that research evidence may be subject to bias. The bias towards positive findings was reported to be pertinent, arising from a number of sources, including positive publication bias and investigator allegiance to a particular intervention. The bias for publication of positive outcomes has been raised by a number of researchers (e.g. Lof, 2011; McCurtin & Roddam, 2012; Pring, 2004), including those within the medical profession who are proponents of EBP (e.g. Chalmers & Glasziou, 2009). Other sources of bias were also reported, including the FUTON bias. FUTON stands for ‘full text on the net’ and reflects the proposal by Bernstein-Ratner (2006) that research outcomes are more likely to be read by clinicians if the full text is available on the internet. If the full body of evidence concerning an intervention is not appraised due to differences in availability of reports (such as may be the case if FUTON reports are more readily accessed) then this may result in a potential bias towards the more available studies.

Other criticisms of the EBP agenda were concerned with its dominance in the healthcare professions, and how it is interpreted by different professionals and policy makers (Bernstein-Ratner, 2006; McCurtin & Roddam, 2012). Interventions that have empirical support may be privileged above others, which may be equally effective but which do not have such support by policy makers, despite clinicians’ opinions to the contrary. Bernstein-Ratner cites the case of eye-movement desensitisation and reprogramming therapy, a psychological intervention that has demonstrated empirical evidence of effectiveness but which has sparked debate amongst psychologists over whether it really is the new therapy that is effective or some other variable (see Bernstein-Ratner, 2006 for a summary of the debate). Concerns were particularly focussed on the findings that in some disciplines practice that was not supported by empirical studies might be withdrawn from service delivery by policy makers. Given that so many allied health profession services have not been subjected to a randomised controlled trial, and indeed may never be able to
be, as randomisation would be considered unethical given that they have been routine practice for some time (McCurtin & Roddam, 2012), this potential withdrawal of services on the justification of EBP is a concern to the profession. As Bernstein-Ratner (2006) argues: “no evidence that something works YET is not the same as evidence that it does not work.” (p. 262).

Figure 1: Model of Phases of development of evidence for complex interventions (MRC, 2000)

The role of the therapist and the therapeutic relationship in the effectiveness of care were also highlighted as key factors in the efficacy of an intervention that is not measured by most empirical research (McCurtin & Roddam, 2012; Rycroft-Malone et al., 2004). Bernstein-Ratner (2006) highlights several factors relevant to complex interventions, including the individual nature of therapy, the fact that interventions may not work for all clients presenting with the same symptoms and the need to fit the right treatment to the client. Concerns that policy makers only endorse
blanket protocolised research based interventions are valid, as they undermine the role of the therapist in tailoring the service to the individual.

*Concerns about not having an EBP approach in speech and language therapy services*

The dangers of not valuing the research source of evidence, however, and relying too strongly on therapist opinion and experience have been raised by Lof (2011), who highlights that interventions that are not empirically based may be published and sold to clinicians, who may adopt them and share them with their colleagues. In this way an untested intervention becomes part of the folklore of the profession and, if widely adopted, it then becomes very difficult ethically to subject that intervention to a randomised trial design. Lof (2011) cautions the profession against adopting ‘quackery’ by carrying out ‘science-based’ clinical practice and maintaining a sceptical mind. Whilst this debate has highlighted that no evidence of effectiveness does not equal evidence of non-effectiveness, there is a call in the literature for more research (and reporting of research) to establish for clinicians which practices do and (equally important) do not work (Bernstein-Ratner, 2006; Lof, 2011).

*EBP redefined*

The debate highlighted above has led to attempts to redefine evidence-based practice. Based on the definition quoted above from Sackett et al. (1996), Dollaghan (2007) redefined EBP as “the conscientious, explicit and judicious integration of (1) the best available external evidence from systematic research, (2) best available evidence internal to clinical practice and (3) best available evidence concerning the preferences of a fully informed patient” (p 2).

The recognition of the experience of the therapist and the views of the patient are thus acknowledged as being valid sources of information contributing to EBP. Furthermore, following a consultation workshop in 2006, the Medical Research Council (2008) published a revision of their guidance on the development of complex interventions (MRC, 2000). The revised guidelines were
based on the 2000 paper with some amendments and additions. First, it was recognised that whilst there are phases in the development of evidence, the process is not always linear. The original phases shown above in Figure 1 were retained and incorporated into a new model, which is shown, below, in Figure 2. Additional aspects identified as important to the process of developing evidence for services included process evaluation and assessment of cost effectiveness and so these were also added to the model. Furthermore, the MRC (2008) guidance acknowledged that, whilst randomisation was the preferred method of minimising bias in a definitive study, this was not always possible. Alternatives to the randomised controlled trial were recommended to deal with different presenting scenarios, such as evaluation of existing services (where the formation of a control group is not possible). The later guidance also highlighted that reporting is not stated as a separate phase, as it was considered by the advisory panel to be an important component at every phase of the model.

**Alternative EBP models**

The MRC models described above are not the only frameworks for development of research evidence. Within the speech and language therapy profession Pring (2004) cited a model developed by Robey and Schultz (1998). This was proposed initially for the development of evidence in aphasia therapy, and adopted by Pring (2004) for wider speech and language therapy use. The model has five distinct phases following a linear progression. Phase 1 is concerned with identifying a potentially effective therapeutic intervention (through case studies, clinical observation and small group experiments). At Phase 2, the research seeks to define how the therapy works and which clients are suitable. Phase 3 involves an efficacy study, a controlled experimental design aimed at establishing if the intervention works in optimal conditions. At Phase 4 the effectiveness of the intervention in real clinical settings is investigated. Finally Phase 5 involves examination of other features described by Robey and Schultz (1998) as appraising “the worth of a treatment” (p. 798).
These may include cost-effectiveness studies, studies of quality of life or customer satisfaction surveys.

Figure 2: Model of Phases of development of evidence for complex interventions (Medical Research Council, 2008)

This model has some features that overlap with the MRC’s (2000, 2008) models. For example, Phase 2 may be likened to the modelling phase in the MRC’s models, and Phases 3 and 4 to the definitive trial and wider dissemination/long-term follow up phases. This model is limited, however, for a number of reasons. First, neither Robey and Schultz (1998) nor Pring (2004) acknowledge the need for a theoretical grounding of the intervention. It is not clear how the ideas for interventions emerge in the Robey and Schultz (1998) model, apart from reports of ‘clinical observation’. There is, therefore, a risk of a trial and error approach at the early stages of development. Furthermore, Breakwell and Rose (2006) highlight that all predictions in research are based upon some implicit theory at the very least. They argue the case for articulating these theories, as through doing so researchers are able to analyse any weaknesses in them.
The second limitation in the Robey and Schultz (1998) model concerns the positioning of cost-effectiveness studies, quality of life assessment and parental satisfaction surveys at the end of this linear process at stage 5. This is problematic for a number of reasons. To start, carrying out cost effectiveness studies at the end of the development of evidence process may increase the risk of significant resources being wasted in the development of interventions that are not cost effective. In contrast, the revised MRC (2008) guidance recommends cost effectiveness analysis at early stages in the development of complex interventions, in order to establish the economic feasibility of a service. In addition, by positioning “appraisal of the worth of the treatment” at phase 5 the Robey and Schultz (1998) devalue the role of patient related factors such as quality of life and satisfaction (and thus potentially causing further waste by developing evidence of a service that is not agreeable to the patient). Chalmers and Glasziou (2009) highlight the importance of patient involvement at all stages of research, but particularly at the beginning, as they report that a source of avoidable waste in clinical research stems from asking the wrong research questions. Patient involvement at the beginning of the research process is therefore necessary to establish what issues in a disease process are priorities for them. Finally, as discussed above and acknowledged by the MRC (2008), a linear process is often not appropriate for development of evidence of interventions.

*Justification for use of the MRC (2000, 2008) model.*

Cognisant of the limitations in the development and interpretation of evidence-based practice the need for objective evaluation of services through EBP is highlighted. The MRC’s (2000, 2008) guidance on the development and evaluation of complex intervention is, therefore, proposed as a useful tool in the development of speech and language therapy services. It should be noted, however, that it does not adequately inform all the elements given in the definition cited by Dollaghan (2007) above. Specific guidance on appraisal of evidence relating to clinical practice (element 2 of Dollaghan’s model) and patient experience (element 3 of the model), including critical appraisal checklists can be found in Dollaghan (2007). The guidance provided by the MRC
(2000, 2008) does, however, provide a useful framework for researchers who wish to contribute to element 1 of Dollaghan’s (2007) model, that is ‘the best available evidence from systematic research’. In the case of family focused primary prevention services in speech and language therapy, the theoretical and empirical underpinnings justifying primary prevention are acknowledged in the MRC (2000, 2008) framework. This allows these underpinnings, particularly concerning the role of the parental linguistic environment in supporting language development and the mechanisms involved, to be tested and revisited through the later stages of service development and evaluation.

2.1.4: Adopting an evidence-based approach for this study

As Pring (2004) highlighted, it has been difficult for clinicians to draw conclusions about effective practice from research evidence because many previous studies in speech and language therapy were weak, methodologically. Further, he stated that attempts at systematic reviews or meta synthesis have been problematic due to the diverse nature of studies. This may be due to the methodology of systematic reviews at the turn of the millennium, which focussed largely on meta analysis of randomised controlled trials (Marshall, Goldbart, & Phillips, 2007). This is discussed further in section 2.2.1, but for the purposes of this section it is worth noting that there are now a range of systematic reviews for different purposes, with different methods. This range enables the researcher to make sense of different types of data and therefore address a wider range of questions. Mindful of the limitations raised in the debate stated above and cognisant of where the speech and language therapy profession is now with regards to research evidence, the position taken in this thesis is based upon the MRC (2000, 2008) guidance on development of complex interventions. This is a position of pragmatic optimism. EBP, for all the limitations stated above, remains the most robust way to offer effective service to clients. As a profession, it is necessary to recognise that current evidence of effectiveness cannot be sourced from appraisal of randomised controlled
trials alone. It is important to recognise the expertise of clinicians, and to consult with service users. It is also important to ground practice in theory, and to attempt to develop a body of research evidence supporting practice. Where it is possible, it is argued that the profession benefits from robust research evidence. The MRC (2000, 2008) guidance provide a comprehensive framework for this research evidence. The argument made in this thesis is that, in combination with robust clinical expertise (supported by research active clinical practice and training in EBP) and meaningful patient involvement at all stages of research and clinical practice, the value of the research aspect of EBP is strengthened by the MRC (2000, 2008) guidelines.

Concerning the development of an evidence base for a particular type of service, it is necessary to understand what practice has taken place previously, and what evidence of effectiveness currently exists. The next stage in the development of an evidence base for family focused prevention services for environmentally based language delay, therefore, was to review the literature on parent targeted prevention practice within the speech and language therapy profession. In accordance with the MRC (2000, 2008) guidelines a systematic scoping review was therefore carried out.

2. 2: Scoping the field and critical appraisal of current evidence: A systematic scoping review of family-focused primary prevention of environmentally based language delay within the speech and language therapy profession.

The focus of the overall study reported in this thesis was the investigation of the effectiveness of the BTHV. This is a family focused primary prevention intervention for environmentally based language delay. The BTHV is described in full in this chapter (section 2. 3). For the purposes of this section, however, the MRC (2008) guidance proposes that existing evidence on interventions be collated, ideally through a systematic review of the literature. In this section a systematic scoping review is reported for family focused primary prevention initiatives for environmentally based
language delay. First, the justification for and limitations of systematic reviews for the development of evidence-based practice in this clinical area are presented. A case is then made for a systematic scoping review of the literature and research questions are proposed. The review is then reported based on guidance from a range of sources from The Cochrane Collaboration (Armstrong et al., 2011; Higgins & Green, 2011; Naumann, 2007). Finally the issues arising from this review are discussed, with conclusions and recommendations for future research.

2. 2. 1: Background to Systematic Reviews: strengths and limitations

Strengths of systematic reviews

Systematic reviews are recognised within the health professions as a valuable resource for both clinicians and commissioners. The Cochrane Collaboration was established following a call for a systematic method of reporting research findings from randomised controlled trials (Chalmers, Dickersin, & Chalmers, 1992). Marshall, Goldbart, Pickstone, and Roulstone (2011) highlight that there are also an increasing number of organisations through which authors may register systematic reviews, and gain guidance on systematic review methodology.

Through a systematic review, a large volume of reports is identified, critically appraised and summarised so that a clear and concise account of evidence in practice can be reported (Mulrow, 1994). The remit of research findings now summarised, synthesised and disseminated through systematic reviews has extended and guidance exists for carrying out systematic reviews for non randomised studies, patient reported outcomes, public health research and qualitative research (Higgins & Green, 2011). Systematic reviews have also been employed in the speech and language therapy profession for a variety of purposes, for example, evaluation of therapy treatment effects (Pickstone et al., 2009), to establish reliability of screening tools (Law et al., 1998; Nelson et al.,
2006), to establish estimates of the prevalence and natural history of speech and language difficulties (Law et al., 2000b) and to examine methods used to measure quality of life for children with speech and language difficulties (Gomersall et al., 2015). As cited in Chapter 1 (section 1.3) of this thesis, systematic review methodology has also been employed to examine characteristics of parental linguistic input to children (Blackwell et al., 2015). The number of systematic reviews carried out in the speech and language therapy domain continues to grow. For example, whereas in 2011 Marhsall et al. reported that there were 15 speech and language therapy focussed systematic reviews identified in the Cochrane Library, an updated search of the Cochrane Library carried out on 27th February 2015 identified 45 speech and language therapy reviews (28 registered on the Cochrane Database of Systematic Reviews and 17 from the database of abstracts of reviews of effects).

Limitations of systematic reviews

Limitations of systematic reviews for the speech and language profession have been reported in the literature (e.g. Marshall et al., 2011; Pring, 2004). For example, Pring (2004) highlighted that the research base for speech and language therapy interventions was not extensive enough, that there was a lack of high quality randomised controlled trials and that systematic review methodology was inappropriate to answer questions relevant to speech and language therapy. Marshall et al. (2011) addressed some of these issues by highlighting the development in systematic review methodology. They stated, however, that the criticisms proposed by Pring (2004) remain valid to a degree. For example, the lack of robust research in many clinical areas is still a problem for systematic reviewers. Marshall et al. (2011) highlight another limitation of systematic reviews, which is that speech and language therapy evaluation studies often report a small heterogeneous clinical population. The critique of the systematic review carried out by Blackwell et al. (2015) highlighted in Chapter 1 (section 1.3) is a case in point. Conclusions drawn from the narrative synthesis in this review were based on a small heterogeneous population and the validity and generalisability of
these conclusions was therefore limited. Marshall et al. (2011) also reported that diversity across language, culture, terminology, service structure and provision all result in difficulties with synthesis of data and comparison of studies in systematic reviews.

A result of many of the limitations highlighted above is that much reported information about current practice that may be of interest to the reader is lost in the critical appraisal stage, as papers are excluded from the data synthesis stage due to poor quality methodology. Marshall et al. (2011) highlighted that systematic reviews are beneficial because they “assist with the management of large bodies of information” (p.263). If, however, as Pring (2004) has highlighted, the literature mainly consists of studies using different methods, or limited in methodological rigor a traditional systematic review may not yield adequate information to address the question asked. As the aim of many systematic reviews is to report on the depth and quality of evidence for a particular topic, the question defined requires a narrow focus. Quality of evidence is critically appraised using methods such as the checklists provided by the Critical Appraisal Skills Programme (2014). The purpose of these systematic reviews is to give the reader confidence in the quality of evidence provided so reports that are not considered robust in their methods and evaluation procedures are not included in the synthesis or meta analysis. Whilst it is important to assess and inform on the quality of evidence reported, an unfortunate consequence of this process is that any other information on the nature of the service given in reports that have poor evaluation procedures is lost, or as stated by Arksey and O'Malley (2005) “hidden from publication” (p.27). Although a systematic review may identify many studies, if the vast majority are disregarded as a result of the critical appraisal process, then the conclusions drawn will only be based on the few studies that remain. The systematic review process thus becomes an ‘all or nothing’ procedure, with either high quality evidence or no evidence. The shades in between these extremes, however, may shed light on potential directions in research.
2.2.2: The case for a systematic scoping study

**Background to scoping studies**

In the case of emerging clinical practice, such as speech and language therapy primary prevention practice for environmentally based language delay, there is justification for a systematic scoping of innovation. Scoping review methodology has been developed by a number of researchers over the past 10 years (Arksey & O'Malley, 2005; Daudt, Mossel, & Scott, 2013; Levac et al., 2010). This methodology arose as a result of recognition that, in the case of emergent practice with a lack of robust studies, there is a need for a literature review with greater breadth of focus than the traditional systematic review. Scoping reviews have been recommended by the Cochrane Public Health Group (Armstrong et al., 2011), who stated that “such reviews may be published as a research outcome in their own right and are appealing since they produce a broad map of the evidence that, if sufficiently transparent and widely available via publication, can be used by many and for applications beyond the authors originally intended purpose.” (p. 147). The reliability and clarity of the systematic review process was a feature highlighted by Arksey and O'Malley (2005) as being valuable to other types of review. In order to incorporate this transparent and systematic approach into scoping methodology they proposed a five stage methodological approach for scoping studies that has now been incorporated into the Cochrane Public Health review body guidance (Armstrong et al., 2011). This comprises: 1, identifying the research question, 2, identifying relevant studies, 3, study selection, 4, charting the data and 5, collating and summarising the results. An optional consultation stage was also proposed (stage 6). This original approach did not involve any critical appraisal of the literature, as Arksey and O'Malley (2005) noted this would not be feasible with larger amounts of data. Levac et al. (2010) proposed, however, that some critical appraisal was necessary as without this appraisal of quality of studies, it would be impossible to identify gaps in the research.
**Alternative scoping methods**

A scoping study is not the only way to scope innovative practice. Scoping of preventative practice for environmentally based language delay has already been attempted using a number of methods. For example, an online survey into early years universal and universal plus practice in speech and language therapy was carried out by Fuller (2010). This survey highlighted that such practice with families of children under 3 years was being carried out by speech and language therapists within the UK and provided an initial picture of this developing field of practice. As a survey does not rely on other publications it is able to report findings earlier than any literature reviews. This information is therefore likely to be highly relevant to practitioners. The comprehensiveness of surveys, however, may be limited for a number of reasons. Respondents may only be able to provide information as an answer to predetermined questions. Furthermore response rates and response bias may limit the validity of findings.

Another example of scoping practice may be a qualitative study into practice. Such a study into prevention practice for environmentally based language delay was carried out by Sawyer and Picksone (2007). They conducted a qualitative study using semi-structured interviews to explore the role played by speech and language therapists in fifteen Sure Start Centres. They found that SLTs were engaging in a wider range of practice than in a clinical context, and reported evidence of primary prevention practice with families and involvement at an early stage in a child’s life (even during pregnancy). This study was able to highlight examples of innovative practice in primary prevention, and was not limited by a predetermined checklist. The limitations in sampling for a qualitative study, however, do not enable a comprehensive picture of scope of practice to emerge.

It is argued that, for this study, a review of the current literature that is systematic in its approach, has the breadth of the scoping study but with a critical appraisal element would yield a comprehensive account of what is taking place at the client/clinician interface. This innovative
practice may be reported in articles that would be rejected from many systematic reviews, including the grey literature. Data from these reports concerning the type of intervention offered and the advice given is valuable to the profession for a number of reasons. First, it informs on current innovative practice. Second, this data may provide evidence at levels 1 and 2 of the MRC’s (2000) model of evidence as it informs current professional consensus on what is considered to be effective and outlines how current evaluation is taking place. Without a foundation of knowledge of current practice, researchers have little information from which to build evidence to the definitive trial stage. Third, evidence of current practice may also inform on clinician consensus concerning what is effective, a valuable component of evidence based practice as highlighted by Dollaghan (2007).

A systematic scoping review for family-focussed primary prevention of environmentally based language delay

A systematic scoping review was, therefore, carried out using the guidelines originally proposed by Arksey and O’Malley (2005) and updated by the Cochrane Public Health Group (Armstrong et al., 2011). The five stages of the review are reported below as follows: first, identifying the question, second, identifying relevant studies, third, study selection, fourth, charting the data and fifth, collating, summarising and reporting the results. Due to limited staffing and time resources, the optional sixth stage of consultation was not included for this review.

2. 2. 3: Systematic Scoping Review: Identification of the review question

The review question was defined as follows:

What is the current scope of practice and evidence-base for family targeted primary prevention practice within the speech and language therapy profession for primary language delay in children aged 0-3?
This question was defined using the first stage of Arksey and O’Malley’s (2005) methodology for a scoping review. Specifically, Armstrong et al. (2011) identified that a scoping review question should identify three aspects, namely, the concept to be scoped, the target population and the health outcomes of interest. These are defined in Table 2, below. It is noted that the aspects recommended by Armstrong et al. (2011) are similar to the PICOS objectives (Higgins & Green, 2011) recommended for defining systematic review questions but they allow for greater breadth of scope within the question. For example, the concept defined in this question is similar to the intervention component of the PICOS acronym in that it defines the type of service in question. Unlike the PICOS process, however, a specific intervention type is not defined, allowing for a range of processes to be examined. Like PICOS’s participants component, the population is clearly defined using the Armstrong et al. (2011) aspects. The health outcomes are similar to the outcomes component of the PICOS acronym but, again, allow for a range of evaluation outcomes to be examined. Appropriate use of the PICOS acronym would require specification of specific outcomes. Whilst a particular language outcome has not been defined, the review question defined identification of studies using child language outcomes in order to allow for critical appraisal of studies based on these outcomes. Specifically, the degree to which the literature demonstrated evidence of prevention of language delay in young children (through child language outcomes) was of interest. As this is a prevention service, the comparison in a PICOS definition would be no intervention, rendering this element of PICOS redundant. Also, the study designs component of the PICOS acronym was not relevant as all designs are examined in a scoping review.
Table 2: Aspects defined in the scoping review question (Arksey & O'Malley, 2005; Armstrong et al., 2011; Levac et al., 2010)

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Defined as</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Concept</td>
<td>Family targeted primary prevention services within the speech and language profession</td>
</tr>
<tr>
<td>2 Target population</td>
<td>Children aged 0 - 3 years</td>
</tr>
<tr>
<td>3 Health outcomes</td>
<td>Prevention of primary language delay</td>
</tr>
</tbody>
</table>

2.2.4: Identification of relevant studies

Armstrong et al. (2011) recommended that when identifying relevant studies, review authors should consider the following: where to search for studies, which search terms to use, other potential sources of studies, the time span to include and language of studies. Studies were identified for this review using these guidelines as follows:

*Where – identification of peer reviewed literature.*

Nine databases in total were used to identify relevant studies from the peer-reviewed literature. An initial search was carried out using the Cochrane Library to identify if any previous systematic reviews had taken place (from the Cochrane Database of Systematic Reviews and the Database of Abstracts of Reviews of Effects). A search was also carried out on the Cochrane Central Register of Controlled trials. A search of the wider literature was then carried out using the following databases: Child development and adolescent studies, CINAHL, PsychInfo, Medline and the Psychology and Behavioural Sciences Collection.
Identification of search terms.

Naumann (2007) recommended a number of stages in the development of a search strategy for Cochrane reviews. These included identifying appropriate text and keyword search terms, carrying out test searches and customising the syntax of the search terms to the specific databases. Naumann (2007) also recommended identification of search terms based on the defined PICOS targets for the review in question. Naumann’s (2007) recommended checklist was completed for this study and can be found in the appendices (Appendix 1). As this was a scoping study, rather than using the PICOS acronym the search terms were based on the aspects highlighted above in table 2. These search terms are shown below in Table 3.

Other sources

In addition to the peer reviewed literature search stated above, the review was extended to the grey literature within the UK as follows:

1: A search of local evaluation reports and synthesis reports on the National Evaluation of Sure Start website (NESS)
2: A search of interventions described on the What Works website (Communication Trust)
3: A search of interventions listed on the Centre for Excellence in Outcomes website
4: A hand search of the RCSLT Bulletin

A call for information was also placed on the RCSLT website discussion forum, and in the RCSLT Bulletin.
Table 3: Search terms identified for systematic scoping review of peer-reviewed databases.

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Keyword</th>
<th>Text word</th>
</tr>
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<tbody>
<tr>
<td><strong>Concept</strong></td>
<td>Language promotion</td>
<td>Promot*</td>
</tr>
<tr>
<td></td>
<td>Health promotion</td>
<td>Prevent*</td>
</tr>
<tr>
<td></td>
<td>Prevention</td>
<td></td>
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<tr>
<td><strong>Target population</strong></td>
<td>Early childhood development</td>
<td>Child*</td>
</tr>
<tr>
<td></td>
<td>Infant development</td>
<td>Toddler*</td>
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<td></td>
<td></td>
<td>Infant*</td>
</tr>
<tr>
<td><strong>Health outcomes</strong></td>
<td>Language delay</td>
<td>Language dev*</td>
</tr>
<tr>
<td></td>
<td>Language disorder</td>
<td>Language delay*</td>
</tr>
<tr>
<td></td>
<td>Language development</td>
<td>Language disorder*</td>
</tr>
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</table>

*Time span*

The search was limited to articles published between 1995 and 2015. These dates were selected for the following reasons. First, the grey literature was UK based. It was postulated that the majority of primary prevention practice within the UK speech and language therapy profession would have been developed after this date, as a result of funding opportunities and government policy drivers as stated above. The peer-reviewed literature was also limited to this timespan for a number of reasons. First, the aim of the review was to capture and report on current and recent practice. Second, changes in guidance on evidence based practice that have occurred over the past fifteen years render historical articles less valuable to the review.

*Language.*

Reports were limited to the English language (or articles for which a translation was available) as translation services were not available to the author.
2.2.5: Study selection.

Eligibility criteria

A prior establishment of eligibility criteria distinguishes a systematic review from a narrative review (Higgins & Green, 2011). Arksey and O’Malley (2005), however, suggest that a scoping review is iterative, as practice not anticipated may emerge from the literature that is valuable to the scoping study. In the case of this study, it is argued that the iterative nature of a review results in limited transparency and replicability, a feature that is valued in systematic reviews. Furthermore, it is proposed that careful establishment of eligibility criteria ensures that a range of practice is captured that is confined to the research question. Finally, as it was not feasible to establish a research team (discussed below in this section), establishment of eligibility criteria was considered necessary to minimise potential bias. Eligibility criteria were therefore established for this study using the aspects described in Table 2 above. These are summarised below in Table 4, and discussed below:

Concept:

The focus of this review was services developed with a primary focus on the family or home environment. This focus was defined because the influence on the home environment is established in the literature (as discussed in Chapter 1, section 1.3). It is recognised, however, that there are many speech and language therapy services with Early Years settings as a primary focus, and that a separate, similar review is indicated to support development of an evidence base for these services. Services were excluded from the review if the participants were identified following a screening procedure as screening for language development has been reported to be an unreliable method of identifying risk (Law et al., 1998; Maas, 2000).
Interventions were only included if they reported involvement of a speech and language therapist. The case has been made for speech and language therapy involvement in public health services (Law et al., 2013). These services have been developed against a backdrop of established universal / universal plus practice without speech and language therapist involvement (e.g. Anderson et al., 2003; Olds, 2006). Whilst these projects often measure language development as an outcome of their effectiveness, the focus of the intervention is often more broadly defined as child development, and encompasses a range of outcomes. The focus of this review was specifically for language services to support language development.

**Target population:**

The focus of the review was interventions for children aged 0-3 years. The first 3 years of life has been highlighted as highly influential for language development. Furthermore, as many children above the age of 3 years attend an Early Years setting on a regular basis, the primary focus of many universal/universal plus services for older preschool children is often the Early Years setting itself (e.g. Dockrell, Stuart, & King, 2010).

Children with no prior diagnosis of developmental disorders were the focus of this review as the general population is the focus for universal development. Whilst some preventative practice for populations with a specific diagnosis may be considered to be universal plus, the focus for universal plus practice in this review was based on environmental risk factors (for example, socially deprived communities, children of young parents, or children of parents with disabilities).

**Health outcomes:**

As stated above, all reported outcomes and study designs were included for scoping analysis. Studies that had used child language outcomes as an evaluation method, however, were identified
for further critical analysis, in order to inform on current evidence supporting preventative services for environmentally based language delay

Table 4: Review eligibility criteria for systematic scoping review

<table>
<thead>
<tr>
<th>Included in review</th>
<th>Excluded from review</th>
</tr>
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<tbody>
<tr>
<td><strong>Concept</strong></td>
<td></td>
</tr>
<tr>
<td>Primary focus - Home environment</td>
<td>Primary focus - Early Years setting</td>
</tr>
<tr>
<td>Universal - i.e. pre-referral</td>
<td>Targeted - following a language screen</td>
</tr>
<tr>
<td>Targeted - at risk populations stated above</td>
<td>Specialist services - i.e. post SLT referral</td>
</tr>
<tr>
<td>SLT involvement specified</td>
<td>SLT involvement not specified</td>
</tr>
<tr>
<td><strong>Target population</strong></td>
<td></td>
</tr>
<tr>
<td>Children aged 0 - 3</td>
<td>Children above age 3 years</td>
</tr>
<tr>
<td>No diagnosis of developmental disorder</td>
<td></td>
</tr>
<tr>
<td>‘At risk” populations (environmental, socioeconomic factors)</td>
<td></td>
</tr>
<tr>
<td><strong>Health outcomes – for scoping</strong></td>
<td></td>
</tr>
<tr>
<td>All evaluation methods reported</td>
<td>None</td>
</tr>
</tbody>
</table>

In addition to these criteria, articles identified on the NESS website were removed for the following reasons:

1: The report was in draft format

2: The report did not give an author or date of publication

3: The report was a duplicate

4: A more up to date report of the programme described was available
Study selection procedure

Studies were selected for inclusion in the review by the author. Ideally, a review team is identified for systematic reviews and scoping studies. Bias is minimised through cross-referencing by two or more reviewers and differences resolved through discussion (Armstrong et al., 2011; Higgins & Green, 2011). Due to resources it was not possible to establish a review team for this study. As discussed above, prior eligibility criteria were established in order to maximise transparency. Titles of all articles were screened for relevance to the review question and eligibility criteria. After articles were extracted based on the title screen, where available, abstracts were then screened according to the same criteria. The full text of the remaining studies / reports were then assessed for inclusion in the review, again, according to the eligibility criteria.

2.2.6: Extraction and charting of data

The objective of the review was to provide information on the scope of universal and universal plus practice in this area. Of particular interest were aspects of service delivery considered to be key components of a complex intervention. These included the nature of service delivery; that is, how and where the service was delivered and the information that was given in the service. Given that a prevention service is, by nature, relevant to a universal population, the extent to which reach of the service was reported was also of interest. To facilitate the summarising and reporting of the data, data was therefore extracted from the selected studies and charted according to the following questions: what is the nature of the service delivery (how is the service delivered), what information is given (what are the components of the service) and what is the reach of the intervention (what population does the intervention serve, and what attempts are made to increase reach)?

A benefit of a scoping study is to provide a numerical analysis (or frequency analysis) of reported practice (Arksey & O'Malley, 2005). As the data was charted, themes concerning nature of service
delivery, information given and evaluation methods were added as columns to enable frequency of theme to be established. The completed chart can be found in the appendices (Appendix 2).

2.2.7: Collating, summarising and reporting results

As recommended by Arksey and O'Malley (2005) data was collated and summarised through numerical analysis and narrative synthesis involving extraction of themes around service delivery, information given and evaluation methods. In order to inform on the quality of evidence for this field of practice studies identified as using child language outcomes were also critically appraised using the CASP checklists (Critical Appraisal Skills Programme, 2014).

2.2.8: Results of systematic scoping review

A flowchart outlining the study selection process is shown below (Figure 3). A total of 1612 reports were found in the review, 1496 from the peer reviewed literature and 102 from the grey literature. A further 14 reports were found from other sources, including conference records (8) and through personal communication (6). When duplicates were removed the total number was reduced to 1233 reports. After reviewing the titles and abstracts 72 reports were included for full text analysis. Fourteen of these studies were excluded at this stage as they did not meet the eligibility criteria. The remaining 58 articles were charted for data extraction and analysis.

Three studies were sourced from the peer reviewed literature (Conway & Gooden, 2012; Oetting, Pruitt, & Farho, 2010; Smith & Gibbard, 2011), with many of the studies rejected due to their being based on a population of children identified as language delayed as a result of screening or formal language assessment or due to not reporting speech and language therapist involvement. Just over
half of the studies identified (29) were sourced from the National Evaluation of Sure Start website. This suggests that a substantial amount of practice has taken place within the context of Sure Start local programmes within the UK. No purely family focussed primary prevention services for environmentally based language delay were identified on the Communication Trust’s “What works” website, although 6 were identified from the “Centre for Excellence in Outcomes” (C4EO) website”. The “What works” website is specific to speech and language therapy interventions, whereas the C4EO website provides information on a range of children’s services. Fourteen reports were selected from the Royal College of Speech and Language therapists’ monthly magazine, the Bulletin. A further five studies were identified from conference reports and one study was communicated personally as a result of the call for information. A number of reports highlighted more than one service, resulting in a greater number of services identified than reports.
Figure 3: Flow chart of study selection process

 Studies identified:
 Databases = 1496
 Grey literature = 102
 Other sources = 14
 Total reports = 1612

 Total number of studies after duplicates removed = 1233

 Total number of studies after Title screen extraction = 127

 Full text articles screened for eligibility criteria = 72

 Number of studies included in data charting, summarizing and reporting process = 58

 Number of duplicates
 Peer reviewed literature = 373
 Grey literature = 6
 Total duplicates = 378

 Studies extracted following Title screen = 1106

 Studies extracted following abstract screen (did not meet eligibility criteria) = 55

 Studies extracted following full text eligibility criteria screen = 14
2.2.9: The nature of the service; how is it delivered?

Numerical analysis of service delivery resulted in a range of services being identified in the literature. The nature of service delivery, that is, how the service was delivered largely fell into one of 7 themes. These were public awareness raising, drop in clinics, group based services, home visits, community based training courses, the production of free gifts and information leaflets and one-off events. Table 5, below highlights the number of services identified according to nature of service delivery. For more detail please see Appendix 2:

Table 5: Number of services identified according to nature of service delivery

<table>
<thead>
<tr>
<th>Drop in visiting</th>
<th>Group</th>
<th>Home visiting</th>
<th>Parent / community training</th>
<th>Leaflets or other resources</th>
<th>Public-Awareness raising</th>
<th>One off</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/105 (11%)</td>
<td>37/105 (35%)</td>
<td>5/105 (5%)</td>
<td>25/105 (24%)</td>
<td>18/105 (17%)</td>
<td>6/105 (6%)</td>
<td>2/105 (2%)</td>
</tr>
</tbody>
</table>

*Public awareness raising*

Six reports were identified describing major community-wide public awareness raising campaigns.

Some of these campaigns made use of local media and advertising to publicise their message, such as bus-side and roadside posters (Abba & Hughes, 2006; Jones, 2007). Other services described a city wide strategic approach to public awareness raising. For example, Stoke Speaks Out (2012) involved a wide range of stakeholders to ensure that the whole community spreads the same communication friendly messages to parents and children.
Drop – in clinics

Twelve reports were identified describing speech and language therapy drop-in clinics where families were able to directly access speech and language therapy advice without the need for a referral.

Group-based service, and input at other groups/services

The most popular method of service delivery was group-based delivery, with 26 reports describing some form of specific speech and language group-based intervention. Groups were for parents and children. Some groups targeted specific groups, e.g. Featherstone and Manby (2004) provided a group service specifically for refugee families, and Potter and Barner (2004) provided different groups for families with children of different ages (toddler groups and baby groups). Furthermore, some groups were offered as a set number of weeks (e.g. Cahill, 2006), others as an on-going service (e.g. Rogers, 2003), and others as a one off event (e.g. Sure Start Myton and St. Andrews, 2004).

There were 11 additional reports of speech and language therapy involvement within other existing groups. The nature of this input varied from a member of the speech and language therapy team being present in other groups, in order to be able to answer questions that parents may have (e.g. Rooke, 2005), to the full delivery of a speech and language group within another group on a regular basis (e.g. Tyrrell, 2005).

Home Visits

Five reports were identified where a preventative service was delivered as a home visit. Some services accompanied health visitors during routine visits (e.g. Rydin-Orwin & Cottle, 2003).
Community-based training courses

Community-based training programmes were another popular preventative approach. Twenty-five reports were identified where training to parents and community members was provided.

Distribution of leaflets and other promotional material

Eighteen reports were identified where promotional materials were distributed to parents and community workers. These varied, with leaflets being particularly popular, and CDs and DVDs also being distributed. Some were produced by the service (e.g. Rooke, 2005), other services report using externally sourced material, for example, the Royal College of Speech and Language Therapists (2007) report the use of the Talking Tips posters produced by the National Literacy Trust’s Talk to Your Baby campaign.

One-off projects and events

Two reports were identified where a one-off project or event was provided to promote speech and language development. Featherstone and Manby (2004) describe a party for young children where parenting advice, including advice on speech and language, was given. Murtagh and Roberts (2010) reported on a video production project with teenage mothers on communication with babies.

2.2.10: What information was given?

Thirteen articles made some mention of the information given to parents and families. Of these, the amount of detail given ranged considerably. For example, some reports only highlighted the aims of their intervention, such as ‘aims to promote or encourage language development’ (Cummings, Pickard, & Hare, 2005; Denholm, 2004; Wadsworth, Taylor, & Watson, 2004), or to give parents ‘realistic expectations of their child’s language development’ (Royal College of Speech and Language Therapists, 2005). In contrast, a detailed account of the aims of the service and
information given was reported by Smith and Gibbard (2011) and Conway and Gooden (2012). The most detailed reports of information given were found in the peer reviewed publications (Conway & Gooden, 2012; Smith & Gibbard, 2011) and the services identified on the C4EO website (Barking and Dagenham play and communication service, 2012; Hillingdon Smalltalk Service, 2012; Stoke Speaks Out, 2012). Other articles specified aspects of information given. These included language skills that were being encouraged, for example; listening, turn taking, and eye contact (Cummings et al., 2005; Wadsworth et al., 2004). Several reports highlighted the promotion of singing within the service (Cahill, 2006; Cummings et al., 2005; Rogers, 2003; Sure Start Shiremoor and Killingworth, 2004).

There was some report of specific interaction advice given in groups. This included advice for parents on letting the child lead in play based activities, commenting on the child’s focus of interest and giving children choices to encourage communication (Cahill, 2006).

2. 2. 11: What evaluation was carried out and what are the results?

Of all the services identified, twenty-nine reported an evaluation method. Some studies reported more than one method. Table 6, below gives a numerical analysis of the evaluation methods used in the reports identified.

Table 6: Number of evaluation procedures identified according to method

<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>Rating</th>
<th>Qualitative</th>
<th>Other</th>
<th>Child language measure</th>
<th>Measure of Parent strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>18</td>
<td>1</td>
<td>10</td>
<td>2</td>
<td>6</td>
<td>3</td>
</tr>
</tbody>
</table>
The most popular method of service evaluation reported was a parental evaluation questionnaire, with eighteen of the evaluation reports stated above using this approach to gain feedback from parents on their service (e.g. Barking and Dagenham play and communication service, 2012; Conway & Gooden, 2012; Smith & Gibbard, 2011). The use of parental questionnaires was identified in services reported in the peer reviewed and grey literature. Very little information, however, was given on the parental questionnaire, and only Smith and Gibbard (2011) provided a copy of the evaluation questionnaire in their report.

The reported results of these evaluations included parental satisfaction with the service (Cummings et al., 2005; Krijnen-Kemp, 2005; Wadsworth et al., 2004). Wadsworth et al. (2004) reported that parents felt they were able to listen more to their child and have more conversations as a result of the service they received. They also reported that parents felt they had increased knowledge of language development, interaction and play. Wadsworth et al. (2004) also noted that project staff reported positive changes in children. Featherstone and Manby (2004) highlighted increased parental awareness of positive parenting strategies as a result of their service, including having a special time every day to play and talk, turning off the television, singing, looking at books and taking children to the library.

Ten studies reported the use of qualitative methods to evaluate their services, such as focus groups and parental interviews (Piggot-Smith, 2004; Sharples et al., 2005; The Evaluation Team, 2004). In addition, Lees (2002) used parent diaries as a method of evaluation and Murtagh and Roberts (2010) employed qualitative evaluation methods through the filmmaking project they carried out with young parents. Whilst the reports specified how they generated the data in their studies (e.g. interviews or focus groups), however, there was no report of the methods of analysis or steps taken to ensure credibility and transferability of the data.
Other methods of evaluation were also identified in the review. One service evaluated their interventions through SLT rating methods alone (Cordis Bright Ltd., 2003) and two services used other methods. Conway and Gooden (2012) reported using ‘observation’ as an evaluation method, although what was being observed and how this was evaluated was not reported.

**Critical appraisal of evaluations using child language outcomes.**

Six of the studies identified used some measure of child language or interaction outcomes to evaluate their service. Measures used included monitoring the referral rate to speech and language therapy (Thornton & Searle, 2008), child interaction scores from an observational checklist (Baxter & Cahill, 2008), parent report based vocabulary inventories (Smith & Gibbard, 2011), parent report based child language profiles (Barking and Dagenham play and communication service, 2012), screening tools (Wiseman, 2007), foundation stage profile scores (Barking and Dagenham play and communication service, 2012) and standardised language assessments (Stoke Speaks Out, 2012). The reports varied according to the level of information given on the evaluation method, and the amount of control in the study.

None of these studies used a randomised design. Three studies reported a cohort study design (Barking and Dagenham play and communication service, 2012; Smith & Gibbard, 2011; Stoke Speaks Out, 2012). These studies fulfilled the criteria for critical appraisal using the CASP checklist for Cohort studies (Critical Appraisal Skills Programme, 2014), according to which none were judged to be of a high quality due to the low level of control. Whilst all the reports addressed a clearly focussed issue, the Stoke Speaks out project (2012) was the only study which adequately defined the recruitment process to ensure that the cohort was representative of the population defined and that everyone who should have been included was included. This report, however, did not report the steps taken to minimise bias or account for confounding variables (for example, changes in education practice, or effects of other services). Furthermore, there was inadequate
information on the outcome measures gained and no statistical analysis of outcomes beyond frequency was reported. There was, therefore, no estimate of effect size of the intervention.

2. 2. 12: Evaluation of reach of service.

One service reported the use of a poll to evaluate the reach of the service (Abba & Hughes, 2006). They found that 40% of those questioned were aware of the campaign.

The only other measure of reach was contact monitoring, with fifteen of the evaluation reports reporting contact outcome details of activity monitoring. Although this gave some indication of how widely the service was being used, no other studies reported any proportion of the population that was being reached, or gave any measure of the effectiveness of the service in meeting hard to reach families.

2. 2. 13: Conclusions from systematic scoping review

This systematic scoping review has highlighted that a range of family focussed primary prevention practice for environmentally based language delay is being, or has recently been delivered within the speech and language therapy profession. The scoping method has enabled a comprehensive account of the nature of service delivery offered, with a range of delivery methods. Reports on the information given were more limited, with more information given in the reports that were peer reviewed. Evaluation methods have been identified, again, with a range of methods employed. The quality of evaluations reported, however, was low and there were no studies reported with adequate levels of control to minimise bias in the outcomes.
The review highlighted that group based delivery is the most popular form of service delivery. The reasons for this form of delivery and the effectiveness of groups in comparison to other delivery methods have not been reported in the literature, however. The reasons therapists choose certain delivery methods, as well as parental perceptions of different methods are areas for potential future research and may inform future service modelling. Equally, concerning evaluation methods, parental questionnaires constitute the most popular form of evaluation employed in the reports identified. As questionnaires may inform evidence-based practice (as a measure of the views of the client), it is argued that a critical appraisal tool to assess the quality of outcomes reported using this method needs to be developed. This tool might assess the appropriateness of questionnaires as a method to address the evaluation question, the sampling procedure, management of bias, question style and validity. It is suggested that a more robust approach to carrying out and critically appraising parental questionnaires might ensure that the results gained from this popular approach to evaluation are captured for future development and research.

The critical appraisal that was carried out in the scoping review highlighted that there is a lack of quality evaluation studies in this field of practice. In addition to the peer-reviewed literature, reports identified on the Centre for Excellence in Outcomes website were also critically appraised (as reports on this website are peer reviewed for quality). It is noted that reports cited as ‘validated’, the highest status on the C4EO website, were judged to be of low quality using the CASP checklists. Whilst it is useful to have resources such as the C4EO for interventions, particularly in areas where there is a low evidence base, it is suggested that databases such as the C4EO website have a level for high quality studies such as would pass the CASP quality appraisal process.

This systematic scoping review is the first time such a method has been used within the field of speech and language therapy. It is argued that this approach has enabled a broad scope of practice
to be captured and summarised in a way that the original systematic review methods do not (due to the critical appraisal process as stated above in section 2.1.1). It is therefore suggested that this is a valuable methodological approach for summarising the early stages of practice development, or for scoping practice in areas where, either there is a lack of robust evidence, or where there is a high level of heterogeneity in practice or evaluation. The systematic scoping method is recommended as a first step, therefore, in summarising the literature for speech and language therapy interventions.

This review was carried out to establish the appropriateness of further research into the effectiveness of the BTHV. Specifically, the review aimed to provide a comprehensive account of practice in this field of practice, to establish the evidence base, if any, for similar services, and to explore whether other services were more appropriate for further research. The review has highlighted that there was no evidence of effectiveness of other similar services. Furthermore, no other services have been reported in a manner that would enable replication. The lack of controlled studies of high quality in this review highlighted that research into effectiveness of family focused primary prevention services is needed. The development of the BTHV and continued evaluation, in line with the MRC (2000, 2008) guidance is, therefore, justified.

2.3: Development and modeling of Babytalk Home Visiting Service and early evaluations

Following the summary of scope of practice provided above in Section 2.2, the focus of this study is now turned to the assessment of effectiveness of the Babytalk Home Visiting Service. In this section the BTHV is presented, and its development prior to this study is described and appraised with reference to its theoretical underpinnings, service modelling and evaluations. The development of the BTHV is positioned within the MRC (2000, 2008) framework of development
of complex interventions described in section 2.1. Justification is given for research to investigate further the effectiveness of the BTHV and next steps are proposed.

2.3.1: Theoretical Underpinnings of the BTHV

The theoretical underpinnings of the BTHV are based on a usage-based approach for language development described in Chapter 1, section 1.4. The argument that environmental factors, in particular, aspects of the parental linguistic environment are key components for language development is supported by the usage-based approach (Tomasello, 2005). As discussed in Chapter 1, section 1.4, in an account of this approach given by Tomasello (2005) it is postulated that the biological adaptations in humans for cultural life combined with exposure to language, which has been constructed socially and historically, results in the development of vocabulary and grammar in ontology. The effect of the quality and quantity of linguistic input is further accounted for by the concept of the intergenerational transmission of linguistic knowledge postulated by Hart and Risley (1995) and by the evidence of statistical learning in infants proposed by, for example, Kuhl (2004).

These effects of parental linguistic input specifically provided the theoretical underpinnings for the BTHV, with particular emphasis on the 5 quality features of parental linguistic input reported by Hart and Risley (1995). They concluded that the most significant influencing factor of parent talk for child language acquisition was the overall amount of language spoken to children and that increased quantity of talk was also positively associated with all of the other quality features of language. Increasing the degree to which parents spoke directly with their children was therefore the primary aim of the BTHV. This aim has been highlighted in other key campaigns outside of the speech and language therapy profession, such as the Talk To Your Baby Campaign developed by the National Literacy Trust (2014) and the Thirty Million Words project in the USA (Suskind et al., in press).
Hart and Risley (1995) also found that, whilst the 5 quality features were found to happen more frequently in parents with a high SES background, all parents were observed using all the features some of the time. The focus of the BTHV was, therefore, to reinforce parenting strategies that parents would already be familiar with, rather than teaching new skills. This approach has been used in other speech and language therapy approaches (Kelman & Nicholas, 2008) and in interventions delivered by other professionals (Webster-Stratton & Reid, 2007). It was postulated that if parents could be encouraged to increase the quantity of the positive features of their linguistic input, this might, in turn, facilitate their child’s language development.

The aims of the BTHV were also underpinned by empirical evidence on the beneficial parenting activities found to support expressive language development discussed in Part 1 section 1.3, specifically encouraging book reading and singing nursery rhymes.

2.3.2: Development of the BTHV

The BTHV was developed in Portsmouth City in 2003. It formed one service within a portfolio of Universal and Universal Plus speech and language therapy services developed for a local Sure Start Programme in response to local and national drivers associated with the development of Sure Start in the UK.

*Background to development of the BTHV - stakeholder and parental consultation.*

Prior to service development local stakeholders; including the Children’s Centre leadership team, Children’s Centre parent forum, the Health Visiting team, the local library service, local hostels, and private and voluntary sector agencies associated with the Sure Start programme were consulted to establish local perceived need and to avoid duplication of services. The consultation process included local meetings, attendance at forums and one to one consultations, and was focused around
stakeholders’ perception of local need, perceived barriers to the current speech and language therapy service, and expectations of the Sure Start speech and language therapy service. The consultation highlighted that other professionals were concerned that local parents lacked awareness of the normal pattern of language development. This was particularly apparent from comments made by the Health Visitors in the area, who reported that parents often did not consider their children to be delayed when the health visitors had observed the children falling significantly behind recognised developmental milestones. This resulted in an under-referral of children to speech and language therapy services at the appropriate time and a resistance to access speech and language therapy services. Difficulties with language development were not then addressed until a child started nursery at age 3 years. In addition, concerns were raised by Children’s Centres and private and voluntary sector staff that parents were often not observed directly engaging with their children during the group sessions they ran, or during home visits. Parents within the parent forum highlighted that they often felt they were unable to borrow books from the library (either because they had been blacklisted themselves in the past, or for fear of their children damaging the books). This parental concern was confirmed by the city children’s librarian, who raised concerns that families in the area were not accessing library services. Parents within the parent forum also noted that they felt some parents lacked the confidence to speak with their children in public, and that they would like more support with activities such as singing nursery rhymes, as they wanted to sing with their children but often did not know the words or actions to songs.

Following this consultation period, and in line with the theoretical and empirical underpinnings stated above, the Babytalk Home Visiting Service was developed.

_Aims of the service:_

The overall aim of the BTHV was to facilitate optimal child language development through:
• Increasing caregivers’ awareness of language development, in particular, developmental milestones, and to highlight the multimodal nature of communication.

• Illustrating to primary caregivers the reasons why it is important to encourage language development in children.

• Illustrating ways in which language development can be facilitated through parental linguistic input, based on the 5 quality features of linguistic input proposed by Hart and Risley (1995).

• Encouraging parenting activities reported to facilitate child language acquisition.

• Supporting families in accessing the speech and language therapy service when appropriate.

**Modelling of the service:**

The components of the BTHV service were identified and are shown in Figure 4 below. It should be noted that the terminology has been brought in line with the current literature on services supporting child development, for example, the term ‘universal plus’ was not used when the service was initially developed. Previously, the term used for the universal delivery within a targeted area was ‘targeted’ support. Since the publication of the Healthy Child Programme (Department of Health, 2009), however, the term ‘universal plus’ has become the established term in the UK for services that are universally delivered to a targeted population known to be at risk. This term has been used in the current model to avoid confusion in the use of multiple terms.

**Service delivery**

Method of service delivery: As discussed above, this service takes an environmental approach. Pickstone et al. (2009) highlight that speech and language therapy interventions may be divided into two types; those that take a child focused approach and those that take an environmental approach. In accordance with the theoretical underpinnings of the BTHV described above, the focus of the intervention was on supporting the child’s linguistic environment. Specifically, it was the parental
linguistic environment that was the focus of the BTHV with the aim of supporting child language
development and preventing environmentally based language delay.

**Dosage:**

As a universal service, the BTHV was developed as a one-off information giving service. This is an
unusual approach for a therapy service and might be considered an insufficient dose for behaviour
change. As the advice served to reinforce strategies that all parents are reported to already use
(rather than teaching new skills), however, with the aim of increasing the frequency of the strategies
in parental linguistic input to their child, a one-off visit was considered to be feasible. The BTHV
also acted as a signpost to other services where advice given could be further reinforced. It was
postulated that the BTHV would provide a focus on language development for parents, which could
then be supported by messages given by other professionals through their services.

**Delivery method:**

A home visit was identified as a service delivery method that would maximise the reach of the
service and, in particular, be accessible to families who may not ordinarily attend a group based
service. Engagement with health and parenting support services is reported to be a challenge in
areas of low SES (Maggi et al., 2010, Justice, 2010). It was proposed that by bringing the service to
the family home parents would be able to engage with the service in a familiar environment with
minimal disruption to their routine. The one to one nature of the home visit facilitated an
individually tailored conversation to develop around the information, and the child’s own toys
could be used to model any strategies suggested.

**Clientele:**

Target clientele: The service was targeted to families of babies aged 6-18 months (but was available
to families from 0-18 months). This age range was identified as a period where families were
receiving reduced input from other services (such as maternity services, Health Visiting, or nursery based services), and where other infant related issues such as sleep management and breast feeding (commonly a focus of concern in the first 6 months) were less likely to be competing priorities.

Figure 4: A model outlining the components of the Babytalk Home Visiting Service (Smith & Gibbard, submitted)

Additionally, it was predicted that a baby’s responses to any increased attempts to communicate on the part of the parent may be more obvious to parents after 6 months of age, and would therefore provide a positive reinforcement.

Reach and access:

Reach, and particularly reach of vulnerable populations, is an important aspect of public health services, and needs to be planned as a component of a public health intervention (Ashford,
Gwatkin, & Yazbeck, 2006; Lord, Southcott, & Sharp, 2011). The systematic scoping review reported above in section 2.2 highlighted that the majority of services identified did not report their plans to maximise the reach of their services, nor did they make attempts to evaluate the reach of the services. The BTHV was designed to be a universal service. This approach was taken for two reasons; first, it would be impossible to identify which children are at risk of low parental language exposure and second, the universal approach was adopted to avoid stigmatisation and any sense of blame being passed on to parents. Universal services are still recognised to be a key element of services targeted to meet the needs of vulnerable families (Lord et al., 2011). Initially the service was universally available (and publicised within the Children’s Centre) but accessed through request or referral process. Early into the development of the service, however, families were directly contacted from the Children’s Centre database and Health Visitor birth records, to ensure that a wider range of families accessed the service.

**Staffing:**

The service was delivered by a fully trained Speech and Language therapy assistant (SLTA) in accordance with a developed training development programme. A report of the training process and knowledge and skills profile for the SLTA is given in the Smith and Gibbard (2011) paper, (found in Appendix 3).

**Information given:**

Information given at the BTHV was framed in a conversation around the following themes:

Normal language development from birth to two years, covering eye contact, nonverbal communication, turn-taking, cooing and babbling, comprehension of language and expressive language.
Benefits of caregivers encouraging language development, including increased vocabulary, increased attention and listening skills, narrative development and educational and social benefits.

Information on facilitative interaction, including following the child’s lead, copying babbling, special time, talking through every day routines and child directed speech. This information was based on the 5 quality features of parental linguistic input highlighted by Hart and Risley (1995). In addition, parenting activities that encourage language development, including sharing books, singing nursery rhymes, with examples of age-appropriate toys and books were also promoted.

Additional Resources:

A number of resources were given to families at the BTHV to reinforce information given in the service. Families were given a CD of nursery rhymes, books and information leaflets. They were also given information about local parent and baby groups.

Finally, parents were advised how to contact the speech and language therapy department if they were concerned about their child.

2. 3. 3: Delivery and evaluation of the BTHV

As a result of changes in the political and economic climate, delivery of the Babytalk Service was carried out in 2 distinct ways between 2003 and 2013. Between 2003 and 2008 the service was delivered solely by the speech and language therapy service within 2 specified Sure Start Centres. Later the service was extended to the whole of Portsmouth through a multi-agency collaboration. The model described above incorporates the development of the extended service following the staffing and supervision changes (Smith & Gibbard, submitted). These two methods of service delivery created opportunities for evaluation of components of this model. Two reports of BTHV
service evaluation were reported by Smith and Gibbard (2011; and submitted). These evaluations are summarised and appraised below:

**Study 1: Initial evaluations of the BTHV (Smith and Gibbard 2011)**

The first report by Smith and Gibbard (2011) described two separate evaluations of the BTHV, which were carried out between 2003 and 2008. First a parental evaluation questionnaire was given to all parents following receipt of the BTHV. The questionnaire assessed parental satisfaction with the service, parent perceptions of knowledge gained on language development and perception of knowledge about supporting language development at home. In addition, the open question ‘what will you do differently as a result of this visit?’ explored parents' predictions of behaviour change in response to the information given in the service. In this evaluation study 349 responses were received from a total of 351 visits. The majority (91.1%) of respondents rated themselves as very satisfied with the service and 94.6% reported perceived increased knowledge about language development. Most respondents (72.5%) reported that they would do something differently as a result of the service. Responses to the open question ‘what will you do differently’ included ‘talk more to my baby’, ‘look at books’, ‘play more’ and ‘sing nursery rhymes’. A more detailed summary of the results can be found in Smith and Gibbard (2011), which is included in the appendices (Appendix 3).

A questionnaire was an appropriate method to evaluate parent perceptions of the value of the service. The original questionnaire is included in the paper, and there are a range of question types suitable to the questions asked. As the questionnaires were given to all clients sampling bias was minimised. The total number of responses was reported. Based on a population of 800 children (local data) the number of responses was sufficient for 98% confidence in the findings, based on a 5% margin of error and a 50% response distribution (Raosoft, 2014). Whilst it was not piloted,
which would have validated the findings further, it has provided information that contributes to further development.

**Comparative evaluation of parent ideas to support language and child language outcomes:**

Parents of children aged 2 years registered with the Sure Start programme were contacted as part of the National Evaluation of Sure Start project. These parents were invited to provide a report of their child’s language development using the Sure Start Language Measure - Revised (SSLM-R, Harris, Law, & Roy, 2005). In order to evaluate the effectiveness of the BTHV, additional questions were asked, including ‘have you received a BTHV’ and additional questions exploring what ideas parents had about facilitating language development. For full details of the methods of this evaluation, please refer to Smith and Gibbard (2011).

Parents who reported that they had received a BTHV were found to give a greater number of appropriate ideas on how to facilitate language than parents who reported that they had not received a BTHV. When controlling for other covariates this increase was found to be statistically significant, $F(1,127) = 8.00, p = 0.005$. They also reported their children as having a higher expressive vocabulary measure on the SSLM - R than parents who did not. Again, when accounting for confounding covariates this difference was statistically significant, $F(1,128) = 4.859, p = 0.029$.

The results of the comparative study provided indicative evidence that the BTHV was effective in increasing parental knowledge about supporting language development in the home, and facilitating child expressive language development. There were, however, a number of methodological limitations to these evaluations, which reduced the value of these findings. First, as this was a quasi-experimental study there was no established control group. Families who did not receive the BTHV therefore may have differed from those who had received it in some other variable not
accounted for in the evaluation. Second, as the authors were not blind to participants’ group status, the risk of bias was increased. Finally, whilst the SSLM-R has been tested for validity and reliability, the additional questions parents were asked had not been piloted and there was no inter-rater reliability testing reported. These factors reduce the reliability of the outcomes. Finally, as the allocation of groups was dependent on parent report of whether they had received the BTHV or not, the control group may have included families who had received the BTHV but had not remembered (thus introducing another element of bias into the findings).

Study 2: Evaluation of Multi-agency collaboration (Smith & Gibbard, submitted)

In response to the National Driver to increase the number of Children’s Centres across the UK (Moss, 2004) the SLT service was commissioned to extend the provision of the BTHV service from one local programme with a population of 800 0-5 year old children to a city wide service serving a population of 10,619 0-5 year olds (local data). This service extension was achieved through a multi-agency collaboration. Staff based in a local Special Needs nursery and Children’s Centre were identified to deliver the extended service. Staff identified had existing Early Years Knowledge and Skills and some specialist speech and language therapy experience from a local Children’s Centre. The BTHV model and protocol of service were developed to enable trans-agency delivery of the service. Full details of this service modelling was reported in Smith and Gibbard (submitted), which can be found in the appendices (Appendix 4).

The extent to which the service was successfully extended (reach), and the staffing and supervision components of the newly developed model were evaluated in this report.

Extension of service:

Service availability was assessed through monitoring the availability of promotional material and referral information for the BTHV within Children’s Centres to parents as well as promotion of the
service to multiagency professionals (assessed through quarterly service level agreement reports). Population data was used to estimate the increase in service availability and for one financial quarter actual service delivery was monitored using contact monitoring data. Availability of the service was successfully extended across the population of Portsmouth City by 965% and actual contacts were increased by 396% from a staffing increase of 288%.

As discussed above in this chapter, evaluation of reach of a service is valuable in public health services, and the results indicate that the service was successfully promoted and availability increased. Furthermore, there is evidence of an increase in actual service delivery. The extent to which families across Portsmouth were aware of the availability of this service, however, was not reported. A measure of public awareness of the BTHV would inform the success or otherwise of these attempts. The poll investigating public awareness of a campaign reported by Abba and Hughes (2006) and cited above in section 2.2 is an example of a more appropriate method of establishing public awareness of a health promotion message.

**Evaluation of quality of extended service:**

The development of knowledge and skills was monitored through assessment of completed competencies profiles, monthly supervision notes, rating records of service delivery in shadowed visits and evidence gained in individual portfolios. In addition, the questionnaire developed in the previous evaluation (Smith and Gibbard, 2011) was given to parents receiving the extended service and responses were compared with the outcomes reported by Smith and Gibbard (2011) for the original service. The Children’s Centre workers demonstrated evidence of achieving the essential competencies for the BTHV within a comparable timeframe to internally employed staff and were able to demonstrate satisfactory performance on shadowed visits. Parental satisfaction responses were also comparable to the responses received for the original service. For example, for the extended service, 76.5% of respondents answered ‘yes’ to the question ‘will you do anything
differently as a result of this visit, compared to 72.5% of respondents reported in the initial evaluation by Smith and Gibbard (2011). Furthermore, in the extended service, 69.3% gave concrete responses to the open question ‘what will you do differently?’ of which, 86.2% of responses (and 59.7% of total responses) were classified as beneficial. In comparison, 217 (62.1%) of respondents in the initial evaluation reported by Smith and Gibbard (2011) gave responses, of which 84.8% (52.7%) were classified as beneficial.

These evaluation results provided indicative evidence that original service quality was maintained through the multi-agency service extension. Process evaluation took place through the shadowing of staff, and through on-going supervision. Smith and Gibbard (submitted) proposed that on-going supervision may be a valuable component in multi-agency service delivery, as their study highlighted evidence that information given in the training course needed to be reinforced in the monthly meetings. The comparison of parental questionnaires also gave an indication that parental satisfaction levels were similar in the extended service to the original service, again, indicating that the service delivered by the trained and supervised Children’s Centre workers was similar in quality to that provided by the Speech and Language therapy assistants. This second evaluation study also reinforced the validity of the parent views of the service highlighted in the initial evaluations reported by Smith and Gibbard (2011). Limitations of the study, however, included the fact that it did not address the question of whether the service is effective in supporting child language development. Furthermore, as with the initial evaluation study, whilst parental perceptions of behaviour change were investigated through the questionnaire, actual evidence of behaviour change was not examined.

2.3.4: Positioning the BTHV within the MRC (2000, 2008) framework

In order to attempt to develop and evaluate the BTHV further within the Medical Research Council (2000, 2008) framework, it is necessary to position the previous development and evaluation studies
discussed above within the model. Whilst the 2008 guidance acknowledges that the process is not linear, it is proposed that the development of a new service needs to start with the theoretical and modelling stages. For this purpose, the original 2000 model with 5 distinct phases is referred to, mindful of the fact that information from later stages can lead to reworking of earlier stages, with reference to the 2008 guidance where necessary.

Pre-clinical phase - Theory

The Medical Research Council (2000) guidance for this phase states that researchers should “explore relevant theory to ensure best choice of intervention and hypothesis” (p. 3). Furthermore, the (2008) guidance recommends that the theory is used systematically to develop the intervention, that examination of existing evidence should take place, ideally through a systematic review and that stakeholders are consulted and involved. The systematic scoping review reported in section 2.2, above, has informed the development of the BTHV by positioning it within the context of the current status of speech and language therapy services for primary prevention of language delay. Findings from this systematic scoping review have confirmed the following: first, that information given in the BTHV is in accordance with information given at other primary prevention services, indicating some level of professional consensus and; second, that further development and evaluation of the BTHV is justified on the grounds that there is very little evidence of effectiveness of any services in family focused primary prevention, indicating that future research is needed.

The BTHV is reported by Smith and Gibbard (2011) to be based on sound theoretical underpinnings, which are evident in the advice given to parents in the service that work within the model. In particular, the 5 quality features of parental linguistic input reported by Hart and Risley (1995) have been used to predict potential outcomes for the BTHV. A range of stakeholders, including service users, were consulted prior to service development and the outcomes of this consultation informed the service development. It is therefore proposed that the BTHV fulfils the requirements for service development at this phase of the MRC (2000, 2008) model.
Phase 1 - Modelling

At this phase the following is recommended by the Medical Research Council (2000) framework: “Identify the components of the intervention and the underlying mechanisms by which they will influence outcomes” (p. 3). The development and evaluation work by Smith and Gibbard (2011, and submitted) has resulted in a model of the service with identified components and a protocol enabling replication of the service. The ways in which the components of the BTHV model relate to each other and are dependent on each other have been predicted, and quality processes have been established to ensure those components are not compromised in a changing environment (Smith & Gibbard, submitted). This reflects the acknowledgement in the Medical Research Council (2008) guidance that environments vary and that complex interventions may not be able to be delivered the same way in different settings.

The Medical Research Council (2000) guidance also states that at this phase the intervention may be evaluated through qualitative testing through “focus groups, preliminary surveys, case studies, or small observational studies” (p. 4). The evaluations reported by Smith and Gibbard (2011, submitted) give preliminary indications that the service may be effective and that it is valued by service users.

Phase 2 - Exploratory Trial

The purpose of this phase is to prepare the ground for a definitive trial (phase 3). At this phase, factors such as primary and secondary outcome measures, predicted effect size, variability, predicted necessary sample size recruitment and retention issues are investigated (2000, 2008). The work carried out by Smith and Gibbard (2011, and submitted) has informed this stage to a degree. The initial evaluations indicated that effects of the BTHV were in accordance with predicted outcomes. A significant number of parents questioned in both studies reported that they would talk more to their child as a result of receiving the intervention. Furthermore, in the initial evaluation
(Smith & Gibbard, 2011), parents were found to report that their children had a larger expressive vocabulary if they also reported having received the BTHV (in comparison to parents who reported that they had not received the service). In addition, some element of effect size was indicated in the (2011) study: children whose parents had received the BTHV’s expressive vocabularies (as measured on the SSLM -R) were around 21% greater than children whose parents had not. These findings have informed the definitive trial stage, and prepared the ground for further feasibility piloting (described in Chapter 3 of this thesis).

It is clear from this analysis, therefore, that prior to the present study the BTHV had been developed and evidence gained at the developmental and modelling stages of the MRC’s framework (2000, 2008). Some information had also been gained at the phase 2 level to support the design of a definitive trial at phase 3 of the 2000 model. Significantly, findings of the initial evaluations (in conjunction with predictions from the theoretical stage) indicated that the main effects of the service were on parental talk to children and on child language outcomes. Further work, however, was needed at phase 2 to inform questions of effect size (particularly for parent talk), variability and sample size, and recruitment and retention. Investigation of these factors through a pilot feasibility study prior to the definitive trial was, therefore, justified.
Chapter 3: Design of a randomised controlled trial for the BTHV and a feasibility pilot study

In this chapter the development and delivery of the randomised controlled trial of the BTHV is described. The current state of evidence for the BTHV with reference to the MRC’s framework for development of complex interventions (Medical Research Council, 2000, 2008) was highlighted in section 2.3 in the previous chapter. It was proposed that the next stage of evaluation for the BTHV would be a definitive trial of the service. The study design and planning is, therefore, described below in section 3.1. Certain questions concerning feasibility, reliability and validity and sample size were addressed in a feasibility pilot study, which is described in section 3.2. The main study is then described in Chapter 4 and the results of the study are discussed in Chapter 5.

3.1: Study design, planning, practical and ethical issues.

In this section the methodological design and structure of the present study is described and justified with reference to the background literature, previous evaluation of the BTHV and guidelines for clinical research described in the previous chapters. Consideration of the practical and ethical issues surrounding clinical research and steps taken for the registration and implementation of this study, including involvement of parents and stakeholders, is described. Finally the proposed outline of the main study design is summarised to inform the feasibility pilot testing.
3.1.1: Aim of the study

The aim of the present study was to investigate whether the BTHV effects lasting benefits in child language development through effecting change in parent talk to their children. This aim was based on the original aims set for the service (outlined in Chapter 2, section 2.3.2). These were to support child language acquisition through advice and support to parents. The third aim of the BTHV specifically focussed on advising parents how they can support child language development through their own talk to their children, and drew on the five quality features of language highlighted by Hart and Risley (1995). Furthermore, Smith and Gibbard (2011, submitted) found that the most frequently cited change that parents reported following the BTHV was that they would talk more to their children. As the literature discussed above in Chapter 1 illustrates that increased parent talk is associated with increased child language development (e.g. Hart & Risley, 1995; Hoff & Naigles, 2002), it was postulated that the effect of the BTHV on parent talk to their children would be the main mechanism by which child language development could be facilitated.

3.1.2: Methodological design

The methodological design of a study is shaped by the original research questions (Breakwell & Rose, 2006). Methodological approaches used in the evaluation of services are classified as either quantitative or qualitative (Breakwell & Rose, 2006). Questions concerned with how an intervention process works, or how participants make sense of or interpret the experience of an intervention may be approached with qualitative research methods (Breakwell & Rose, 2006; Willig, 2001). These questions are valuable to clinicians (Law, 2004) and are increasingly considered to be an important source of evidence within the EBP framework (e.g. Bernstein-Ratner, 2006). Qualitative approaches are also now recognised as part of the evidence building process...
within the MRC’s framework for development and evaluation of complex interventions (Medical Research Council, 2008). Quantitative approaches, by contrast, are employed to address questions concerning differences, changes over time, and matters that are measured in terms of magnitude (Breakwell & Rose, 2006). Many, but arguably not all, questions concerning the effectiveness or otherwise of an intervention are comparative by nature (Rycroft-Malone et al., 2004; Willig, 2001). Within the MRC framework of evaluation of complex interventions a comparative question of effectiveness is still recognised as being the appropriate methodological approach for establishing effectiveness of an intervention (Medical Research Council, 2008), and, rightly or wrongly, remains the method of choice for establishing evidence of effectiveness of an intervention amongst researchers and policymakers (Bernstein-Ratner, 2006; Law, 2004; Schulz et al., 2010).

3. 1. 3: Research Questions

The research questions for this study were derived from the overall aim, based on the theoretical underpinnings and previous evaluation outcomes described above and were as follows:

1. Do parents who receive the BTHV talk more to their babies than parents who do not?
2. Do children who receive the BTHV develop more language than children who do not?

Both of these research questions are concerned with a comparison of two states. In essence, the questions explore whether there is a difference between families who receive the BTHV and families who do not. Through comparing these two states, the potential value of delivering the BTHV as a primary prevention service is examined. As these are questions concerned with difference and comparison, this study was designed according to a quantitative methodological approach. Furthermore, the two questions are concerned with differences in magnitude that may be measured over time (parent talk and child language). Finally, a quantitative research design using appropriate statistical analysis enables the results of the study to be generalised to the wider
population (Field, 2005), a factor that is valuable to the establishment of evidence for universal services.

3. 1. 4: Choice of study design

Within a quantitative paradigm a range of study designs are available to measure change. Study designs are based on comparison between groups; namely between-subjects designs, for example comparing subjects who receive an intervention with subjects who do not and within-subjects designs which may use before and after intervention methods (Davis & Bremner, 2006). A range of more complex study designs are now available which examine these states in ways that do not compromise ethical considerations such as manipulating the withdrawal or withholding of treatments. These include cluster-based trials, step wedge designs and crossover designs (MRC, 2008, Lof, 2011).

For the purposes of this study, a within subjects design was not appropriate to address the research questions stated above. A within subjects research design may not account for individual variability, and it would be difficult to mask the purpose of the investigation from the participants. (The purpose would need to be masked from the participants, as the first research question is related to participant behaviour - i.e. parent talk. If parents were aware of this, it is likely that they would change their talk behaviour). It would also not be possible to measure comparatively the long-term effects of the service on child language outcomes if a within subjects design or a crossover design were used. As the BTHV was not routinely offered to all families as part of the core NHS service, it was possible to have a control group, and therefore a simple between subjects design was selected.
3.1.5: Minimising bias in the experimental design

The value of a quantitative research design lies in the extent to which one may have confidence in its findings. Having a positivist epistemological viewpoint, a quantitative study assumes an objective and unbiased outcome. The debate on evidence-based practice discussed in Chapter 2, section 2.1 has highlighted that findings from quantitative methods are not always as reliable as they may seem (Bernstein-Ratner, 2006; McCurtin & Roddam, 2012). Mindful of this dilemma it was necessary to consider the steps to be taken within a quantitative approach to minimise bias and enable greater confidence in the reliability of the findings.

Randomisation

Issues of bias discussed above may be addressed in part through randomisation. The MRC (2000) framework was criticised initially for its focus on the randomised-controlled-trial as the only appropriate method for a definitive trial (MRC, 2008). The revised guidance (MRC, 2008) acknowledges that other methodological approaches may be more appropriate for certain studies, but continues to maintain that, wherever possible, randomisation is a preferable option as it is an effective method with which to minimise bias in comparative studies. Parent talk and child language development are reported to be influenced by a number of variables, including (but not limited to) parental level of education (Hart & Risley, 1995; Smith & Gibbard, 2011), SES (Locke et al., 2002), post natal depression (Murray & Yingling, 2000) and sex of child (Aznar & Tenenbaum, 2014). Further detail on these environmental influences was given in Chapter 1 of this thesis (section 1.3). The process of randomisation aims to equally distribute the effects of these variables across experimental groups, to ensure that any effects observed are a result of manipulation of the independent variable.
Parental education, in particular, is one reported measure of socioeconomic status (Ginsborg, 2006; Roy et al., 2014) and has been repeatedly found to be positively associated with both parental talk to children (Hart & Risley, 1995; Smith & Gibbard, 2011) and child language development (e.g. Hershberger, 1996; Smith & Gibbard, 2011; Terrisse, Roberts, Palacio-Quintin, & MacDonald, 1998; Tomblin et al., 1997). In order for randomisation to effectively minimise bias for covariates such as parental education, which are known to be highly influential, a much larger sample size would be required. Concerning known covariates such as parental education, it has been proposed that a matched pairs randomisation approach may increase the sensitivity of a study, particularly if the effects are small (Davis & Bremner, 2006). A matched pairs randomised between subjects design in the form of a randomised controlled trial was therefore selected to ensure even distribution of parental education across experimental groups.

**Blinding**

Blinding of the researcher and the participant to the experimental condition a participant has been allocated to (double blinding) has also been developed as a means of reducing bias in quantitative studies (Breakwell & Rose, 2006). It is now recognised as a necessary component of any randomised-controlled-trial examining the effectiveness of interventions within the health service (Moher et al., 2010). Studies that have not reported blinding as part of the research design are not considered by the health professions to be reliable as the effects of lack of blinding on increasing bias has now been well documented (e.g. Noseworthy et al., 1994; Wood et al., 2008). Whilst it was not possible to design a full double blind trial, as participants receiving the service would be aware that they had done so, the study design included the maximum level of blinding possible (this is described in detail in Chapter 4, below).
3. 1. 6: Selection of outcome measures

The primary and secondary outcome measures selected for the study were based on the research questions and rationale outlined earlier in this section, and are discussed below.

Primary outcome measure – parent talk to children

To address Question 1; “Do parents who receive the BTHV talk more to their babies than parents who do not?” a measure of parent talk to children, obtained through transcription and analysis of videoed interactions was selected. A range of measures of parent to child interactions have been used previously to examine the effect of various speech and language therapy interventions, for example, levels of joint attention (Girolametto et al., 1994) and use of specific strategies, e.g. focussed stimulation (Girolametto, Weitzman, & Clements-Baartman, 1998). Measures of parent talk have also been reported, including rate of talk and length of utterance (Girolametto et al., 1996). Measures of parent talk to children from transcriptions have also been frequently reported in the literature in other quantitative research designs, such as those examining relationships that exist between aspects of parent talk and child language (Hart & Risley, 1995; Hoff & Naigles, 2002). The data in these studies was captured through transcripts of audio (Hart & Risley, 1995) and video (Hoff & Naigles, 2002) recordings and included measures of word tokens and word types. The number of recorded word tokens is a measure of the overall total number of words spoken in a transcript and word types is a measure of the total number of different words in a transcript. To illustrate, if a transcript contains the word ‘book’ uttered 3 times in a given sample, this word would constitute three word tokens and one word type. The mean length of utterance in morphemes is also commonly reported. Whilst word types and tokens have been used as measures in studies exploring associations between variables (Hart & Risley, 1995; Hoff & Naigles, 2002; Hoff-Ginsberg, 1991; Weisleder & Fernald, 2013), with the exception of mean length of utterance, these
direct measures of parent talk have not been reported as used in between-subjects comparative studies.

Measures of word tokens or word types were selected as the most appropriate outcome measure for this study for a number of reasons. First, these measures are specifically concerned with the quantity of parental linguistic input a child hears and addresses the first research question “do parents who receive the BTHV talk more to their child than parents who do not?” Mean length of utterance was also considered, however, it is argued that even when adhering to strict transcription guidelines, mean length of utterance may be affected by linguistic features observed in some individuals such as fillers and tag utterances.

**Secondary outcome measure: Child language outcomes at age 2 years**

A formal measure of expressive vocabulary was selected to provide an outcome measure of language development at age 2 years to address the second research question; “Do children who receive the BTHV develop more language than children who do not?” A range of measures are available for formal assessment of language development, including standardised clinician administered assessments, for example the Preschool Language Scales – 4 UK (Zimmerman, Pond, & Steiner, 2009b), or the New Reynell Developmental Language Scales - IV (Edwards, Letts, & Sinka, 2011). Tools such as these have been standardised on a large UK population, and have claimed reliability on these grounds. Unlike a measure of expressive vocabulary, they also assess all aspects of linguistic competence (including prelinguistic social and cognitive skills, phonological development and comprehension).

There are a number of reasons why formal standardised assessments, such as those illustrated above, were not selected for this study. The reliability of objective standardised assessment for children aged 2 years and under has been questioned by some (e.g. Fenson et al., 2007). This is
particularly relevant when administered in a strange environment by a person unknown to the child (Feldman et al., 2005). The normal range in linguistic ability at this age is also considerably wide and yet the standard scores allocated to children according to age are often organised into tables encompassing 6 months of development. The problem with this wide age range is evident when trying to increase the confidence intervals of a child’s score at these ages as the range of scores a child might actually achieve widens considerably.

Another issue that arises when using overall standardised language assessments in very young children concerns the lack of sensitivity these tools have to smaller differences in language competence between children. For example, size of expressive vocabulary, a feature of considerable interest concerning a 24 month old child, who is often at a pre-grammatical stage, is only addressed in 2 questions in the PLS – 4 UK (Zimmerman et al., 2009b). Furthermore, children’s varied expressive vocabulary sizes that are larger than 10 single words but who are not yet combining words (all other phonological and prelinguistic skills being equal) will receive a very similar score on the PLS – 4 UK (Zimmerman et al., 2009b). Given that 10 single words is a very low count for a 24 month old, and the literature highlights 50 or less single words as a clinically relevant marker at age 2 years (Reilly et al., 2009) it is argued that the comprehensive approach to language development employed in these assessments is not appropriate to detect smaller effect sizes in expressive language abilities in this age group.

A final consideration concerning choice of language assessment concerns feasibility. Administration of a formal objective assessment is time consuming, and therefore not feasible as a secondary outcome measure for the number of participants likely to be needed in this study, particularly when considering the time needed to collect and analyse data for the primary outcome measure.
An alternative method of capturing language development in very young children is to use a parental report measure. Parents are likely to spend the most amount of time with their young children and may, therefore, be considered to be a reliable source of information concerning their child’s expressive language abilities. Indeed, parental report of expressive vocabulary at 2 years of age has been found to be a reliable measure when compared with other, more objective, measures of child language abilities (Fenson et al., 2007). Furthermore, expressive vocabulary at age 2 years has been reported to be predictive of later cognitive and language competence (Feldman et al., 2005; Marchman & Fernald, 2008; Weitzman & Greenberg, 2010).

It should be noted that there is not complete agreement on the predictive status of expressive vocabulary skills at age 2 years. For example, Reilly, McKeen and Levickis (2014b) concluded from the findings of the Victoria longitudinal study of language development that expressive vocabulary was not a strong predictor of language impairment at age 4 years. Their conclusions were based on their findings that only 30% of late talking toddlers went on to have a language delay at age 4 years of age and, conversely, there were 6% of children in their study who had typical language at age 2 but went on to have language impairments at age 4 years. An alternative conclusion that may be drawn from these findings is that a substantial proportion (just under 50%) of later language impaired children were identified from within the late talking toddler population.

It is noteworthy that the Reilly et al. (2014b) analysis of the predictive value of expressive vocabulary was based on regression analysis of status based on categorical binary distinctions around a predetermined cut off point. Analysis of distribution of scores and correlational (linear regression) analysis may have revealed trends along a continuum. Their findings are not at odds with those reported by Marchman and Fernald (2008), who also stated that some typically talking toddlers go on to have language difficulties, and some late talking toddlers catch up with their normally developing peers, but they conclude that vocabulary size does predict later cognitive and
language abilities. It is possible that the conclusions drawn from the different studies reflect the underlying reasons for the research. Whereas Marchman and Fernald (2008) are seeking to report relationships between cognitive processing, language abilities and later cognitive skills at a broader level, the stated purpose of the Victoria longitudinal study (Reilly et al., 2014b; Reilly et al., 2010) was to identify clinically predictive markers based on a categorical case/non-case status. It could be concluded, therefore, that whilst expressive vocabulary does not provide a failsafe clinical prediction of the presence of language impairment, there is considerable reported evidence of a relationship between expressive vocabulary at age 2 years and later language and cognitive abilities.

A more practical justification for the use of an expressive vocabulary measure in the present study is that assessment of other aspects of language development at age 2 years which may be stronger predictors of later language ability, particularly comprehension, are problematic as they involve formal standardised assessments with all the issues stated above. Therefore, assessment of expressive vocabulary arguably remains one of the most viable tools for measuring the status of language development at age 2 years.

There are several parent report based tools available to measure expressive vocabulary levels at age 2 years (Fenson et al., 2007; Rescorla, 1993). Parent report based tools are quick to administer – increasing feasibility of use in a trial involving a higher number of participants. The validity of a vocabulary inventory is dependent on the dialect it has been standardised on, and therefore tools validated with a US sample are less valid for a UK population. The MacArthur Bates Communicative Development Inventory (MCDI) Toddler version has been adapted for British English, validated and norm referenced (Klee & Harrison, 2001; Klee, Marr, Robertson, & Harrison, 1999). It was this tool, therefore, that was selected to provide a measure of child expressive vocabulary development at age 2 years in this study.
3.1.7: Practical and ethical considerations

It was necessary to examine a number of practical considerations in order to assess the feasibility or otherwise of the main trial. Barrett (2006) highlights that issues such as participant availability, participant willingness to be recruited and their understanding of the research process or any instructions given as part of the research should be examined prior to a main study to prevent contamination of the trial. Information on the research process and appropriate tools was gained from the literature review. The remaining questions, and information on participant availability and involvement, were examined in a feasibility pilot study (described in detail in section 3.2). In addition, Barrett (2006) highlighted that financial factors such as equipment needed, consumables, travel and additional personnel required to complete the study should also be estimated prior to the main study. Finally, he states that a timetable of the study should be established to ensure the feasibility of its completion.

Participant availability, willingness and compliance

Participants required for the main study would be children aged 6-15 months at time of recruitment and their main carer as this is the age that the BTHV has been delivered in previous reports (Smith & Gibbard, 2011, submitted). These children would need to be available for two observations at the start of the study (a baseline measure followed by a post intervention/control measure) and to be followed up in the study around the time of their second birthday for the secondary outcome measure. A number of questions were raised concerning participant availability, willingness and compliance and are discussed below:

Were there sufficient numbers of participant dyads available for the study?

In order to address this question it was necessary to obtain an estimate of the sample size required for the main study. Factors such as variance of the primary outcome measure, effect size required
and statistical method used to analyse the data needed to be established in order to calculate a sample size. Following this, an estimation of the population and possible recruitment rates was required, as well as information on access to the population and likely gatekeepers (e.g. health visitors or Children’s Centres staff).

*Would participants be able to comply with the research process?*

It was necessary to examine the extent to which participants were willing and able to carry out the activities as instructed by the researcher and to keep successive appointments prior to the main study, in order to rectify any misunderstandings before the main study and to highlight steps which may enhance retention. The effect of the video recording environment on the child and parent, as well as the extent to which the participant felt that the recorded episode reflected their normal life, also required examination.

*Equipment, materials and consumables and other funding implications*

As this study formed part of a career development fellowship, the National Institute of Health Research Clinical Doctoral Research Fellowship, funding was available to meet research costs. It was necessary, however, to estimate these costs as part of the application process for the award. The following equipment was identified as necessary for the main study and was included in the application:

- Video camera and memory cards
- DVDs for video data storage
- Language Transcription Software for video recordings
- Transcription pedal
- Language Analysis Software for calculating word tokens and types (Systematic Analysis of Language Transcripts – SALT (Miller & Chapman, 1985))
- DVDs, T-shirts and toys as thank you gifts for participants
Ethical considerations

Barrett (2006) reported that the estimation of feasibility of any study needs to account for whether the study would be ethically acceptable to administer. Any research involving participants needs to prioritise the protection and welfare of its participants. Furthermore, research that involves participants in the National Health Service in the UK is subject to favourable ethical opinion from the National Research Ethics Service (NRES), a department of the National Patient Safety Agency. The role of NRES is twofold: “to protect the rights, safety, dignity and well-being of research participants” and “to facilitate and promote ethical research that is of potential benefit to participants, science and society” (p.1 National Research Ethics Service, 2011). The design of research carried out in the NHS must be justified, therefore, both on its recognition of the rights of participants and other potentially involved patients, but also on its potential value to NHS service users. The relevance of the research to the wider population is also of interest to potential funding bodies (Barrett, 2006), including the National Institute for Health Research (2015) who were the funding body for this study.

Research in England in the NHS is approved through submission to one of around 80 regional Research Ethics Committees (RECs) (National Research Ethics Service, 2011). For this study, an application was made to the Berkshire Research Ethics Committee. This was achieved through online submission of the application form, and attendance at the review meeting. Furthermore, all documentation pertaining to the study was written according to guidance from NRES (2011) and also submitted. In addition, favourable ethical opinion was required from the University of Surrey’s own ethics committee, and the study was registered with Hampshire and Isle of Wight Shared Research Management and Governance service. Letters from Berkshire REC giving favourable ethical opinion as well as documents approved by the Berkshire REC can be found in the appendices (Appendix 5).
The potential value of this study for NHS service users was justified as outlined in the literature review (Chapter 1) and background to evidence based practice for preventative practice in this clinical area discussed in Chapter 2, above. Concerning the safety and rights of participants, and the safety of the researchers, there were a number of ethical issues arising from the study design, which are discussed below:

**Informed consent**

The right for participants to be fully informed and to consent to participate is recognised as an underlying ethical principle (Barrett, 2006; National Research Ethics Service, 2011). A number of issues were raised concerning the extent to which participants would be fully informed, and consent gained. The first issue arising was concerning the extent to which participants would be fully informed. It would not be appropriate to inform participants that the study was about language development, or that parental talk to their child was the primary outcome measure. It is recognised that in psychological research, the topic of interest to the researcher may need to be masked from participants, as knowledge of this factor may influence the behaviour of the participants (Barrett, 2006). It was predicted that if parents knew that the researcher was interested in their talk, they might talk more or less to their child as a result of their awareness, therefore reducing the ecological validity of the primary outcome measure. Furthermore, if parents knew at the start of the study that the focus was on their child’s language development, this too may have influenced their attention to supporting language development throughout the course of the study. As this information needed to be withheld from families, opinion was sought from the Berkshire REC, and favourable opinion was gained on the basis of the following information being given, that the researcher was interested in the home environment and would be videoing both the child and the parent, and that the researcher was interested in child development, but that she was unable to specify exactly which aspect of child development until the end of the study when participants would be fully debriefed.
The second issue was concerned with ability to consent. The research involved very young children who were unable to consent to participation. In these instances it is acceptable for parents to consent to participation on their child’s behalf (Barrett, 2006; National Research Ethics Service, 2011). Consent was obtained in all cases on behalf of the child for their involvement from a carer with parental responsibility of the child. The parent was then required to sign additional consent for their own involvement, thus recognising the involvement of both parent and child in the research process. In addition, in accordance with guidance given by Barrett (2006), where a child showed avoidance or reluctance to participate in the video process, this was interpreted as lack of consent, and the material was not used.

Another ethical principle stated by the National Research Ethics Committee (2011) is that participants have a right to withdraw consent at any time without giving a reason. Withdrawal of consent half way through a study may be an indication that the participant no longer wishes any previous data gathered to be used (Barrett, 2006). As the study had a longitudinal element to it with two distinct outcome gathering stages (post intervention and again at 2 years of age) opinion was sought and favourable opinion obtained from Berkshire REC concerning the consent to use existing data if participants pulled out of the study after the first stage. Participants were advised that if they pulled out at a later stage in the research process, the data gathered up to the point of leaving would be used. Participant attrition was recorded in the participant flow according to the CONSORT guidance (Schulz et al., 2010) and is reported in Chapter 4, below.

Confidentiality, anonymity and invasion of privacy

The research involved visiting the participants’ homes, and carrying out video recordings in the home. This raised the ethical issue of invasion of privacy, confidentiality and anonymity. These are discussed below:
Invasion of privacy: In addition to consent being obtained in writing for video recording to take place within the home, the researcher planned to ask for verbal consent to video families at every visit. In addition, in the case of particularly intimate activities taking place in the home, such as dressing a child, changing a nappy or breastfeeding, procedures were agreed with parents in advance (e.g. in the case of nappy changing the researcher planned to agree with parents to avoid directly filming children being changed by diverting the camera focus to the parent).

Confidentiality and anonymity: Arrangements were planned for the secure storage of participant records and video data on NHS premises as a requirement of NRES (2011). This included locked file storage and encryption of electronic data. Consent was obtained from participants to inform their Health Visitor that they were participating in the study, but assurance was given that no further information would be shared with anyone outside of the research team. The exception to this was in the case of any safeguarding issues, which were to be explained fully to participants at the information giving stage. Consent was also obtained for the sharing of data with the research team at the University of Surrey and for any research audit purposes. Assurance was given that data would be anonymised prior to any reporting of results, and consent was gained to use data for this purpose. Additionally, the consent form included a section for written consent to be obtained for the use of video material in presentations and training. Participants would be assured that they did not have to consent to this point and could still be part of the study if they wished.

Risks and burdens to research participants and researchers

It was not anticipated that there would be a risk to the health, wellbeing or development of the participants as a result of participating in the study, as all advice given in the service would be in accordance with current theory and practice on supporting language development (Smith & Gibbard, 2011).
As the research involved young children and their parents, and took place in the family home, there was a risk that information relevant to safeguarding children may arise in some families. The researcher, as well as the professionals carrying out the interventions, had received training on Safeguarding Children, and would be obliged to share information that would otherwise be treated as confidential if they felt that the safety of a child was at risk. In such cases Safeguarding Procedures would be followed and the participants would be withdrawn from the study.

There was a risk to the safety of the researcher and the speech and language therapy assistants carrying out the intervention as the study involved a considerable degree of lone home visiting. In order to minimise this risk, the health visitors were advised by letter of each participant involved, so that any risks could be identified to the researcher. The Solent NHS Trust Lone working policy was also adopted as a working policy for this study. This included the use of a diary system advising team members of the worker’s whereabouts and estimated time of return, Trust mobile phones and a buddy system for checking safe return from visits at the end of a working day.

Issues arising concerning the ethical issues reported above are reported in the results section (Chapter 4, section 4.1).

3.1.8: Stakeholder and user involvement in research process

The involvement of the public, including service users is now recognised by commissioners and regulators of research as a key component in all aspects of the research process (Department of Health, 2013; National Institute for Health Research, 2015; National Research Ethics Service, 2011). The perspective of those who are likely to be affected by the research outcomes is recognised as important in ensuring that research is relevant to the public, thus reducing the potential for avoidable waste in research (Chalmers & Glasziou, 2009). It is also of value to the potential success of the research process. Involvement from the population that participants are
likely to be drawn from, in this case, of parents of young children can help to shape research in ways that may ensure its successful delivery.

Parents were consulted at various stages of the development and evaluation of the BTHV, described in Chapter 2 section 2.3, through the use of Children’s Centres parent forums, feedback questionnaires and parent representatives at service meetings. In order to inform the research design for this study parent views were gained through these channels, and also at parent and practitioner events. As a result of engaging parents in this way, parent perspectives were incorporated into the design and delivery of the study, including potential sources for recruitment, how to keep in contact with families throughout the research process, procedural issues around filming the children and parents and recognising family involvement.

3. 1. 9: Summary: Proposed design and structure of main study

Following consideration of all of the above factors, an outline of the main study design and structure was formulated. The development and evaluation of a complex intervention has been recognised as being a non-linear process (Medical Research Council, 2008), and this outline was necessary to highlight the questions to be addressed in the pilot study.

**Planned outline of Main Study**

Aim: To examine the effectiveness of the BTHV for supporting child language development on increasing parental talk to children, and child language outcomes.

**Hypothesis 1 (H1):** Parents in parent/child dyads who receive the BTHV will show greater measures of quality and quantity of their talk to their children than parents who do not receive the service.
Hypothesis 2 (H2): The children in dyads who receive the BTHV will show higher expressive vocabulary levels at age 2 years than the children who do not.

Study design: A matched-pairs randomised controlled trial with the following experimental groups:

Group A: Control group; to receive child and family services as normal.

Group B: Experimental group; to receive child and family services plus one home visit where the BTHV is given.

Outcome measures:

Primary outcome measure: Parent recorded word types or tokens from a videoed sample of ‘everyday life at home’ (to be informed by pilot study).

Secondary outcome measure: Child expressive vocabulary at age 2 years, measured using MCDI – words and sentences, British Adaptation (Klee & Harrison, 2001).

Recruitment: Participants to be recruited from the Portsmouth area and identified through Health Visitor birth records and Children’s Centres staff (feasibility to be informed by pilot study).

Selection criteria:

• Families where child spends at least 60% of waking hours with main carer at the start of the study

• Families where English Language is spoken routinely with the child

• Families where parent and child have no identified cognitive, language difficulty or sensori-neural deafness

Intervention: BTHV to be delivered in the family home by trained Speech and Language Therapy Assistants according to protocol described in Smith and Gibbard (2011; and submitted).
Methods of data collection and analysis: Language samples to be obtained by researcher through video recordings of everyday activities in the family home. Length of video and transcripts and activities included to be informed by pilot study. Data to be transcribed and analysed using SALT language analysis software (Miller & Chapman; 1985) calculating number of word tokens and types per transcript.

Mean differences of word types or tokens from baseline measures to post intervention measures and to measures at 2 years to be calculated using a repeated measures analysis of variance.

The planning and development of the main study described in this chapter highlighted factors which are already known as well as factors that required clarification before the study was implemented. Section 3. 2, below, describes the feasibility pilot study that took place to address these uncertainties and provide data to inform the definitive randomised controlled trial.


Following the design of the main study a number of questions concerning participant factors, choice of primary outcome measure and methods of research procedure and analysis remained. This section describes a feasibility pilot study that was carried out to address these questions in order to inform further the design of the main trial.

3. 2. 1: Justification for feasibility pilot study

The purpose of a feasibility pilot study is to assess “testing procedures for their acceptability, estimating the likely rates of recruitment and retention of subjects, and the calculation of appropriate sample sizes” (MRC, 2008 p. 10). This guidance states that the pilot study does not
have to be a small-scale version of the full trial, but that its purpose is to examine the feasibility of the parameters of the trial. In the case of this trial a number of essential parameters of the main trial required further investigation in a pilot study, as follows:

Recruitment and retention of participants

Engagement with families has been reported to be a challenge in areas of low socio-economic status (Maggi et al., 2010). Given that the aim of the BTHV was to facilitate child language development for those at risk, and that those at risk were postulated to be families in areas of social disadvantage, the extent to which recruitment would be possible in an area of social disadvantage needed to be established. Furthermore, it was necessary to investigate participants’ acceptance of video recording as a research method.

Time burden of video transcription for the primary outcome measure

It was necessary to establish the feasibility, in terms of the time taken, of using parent talk measures in a between subjects design. Language transcription is reported to be a time consuming process (e.g. Hart & Risley, 1995), however, given the reported variance of parent talk across the population (McDonald Culp et al., 1996; Hoff-Ginsberg, 1991; Hart & Risley, 1992; Hart & Risley, 1995; Hoff & Naigles, 2002), the need for a large sample size was predicted in order to ensure enough power in the statistical tests for the main study. A number of questions addressed in this pilot study informed the overall question of whether it was feasible to use a parent talk measure in this trial. These were, first; how much time does transcription and analysis per minute of video material take?, second; is a fifteen minute sample of parent talk as reliable as a 45 minute sample?, and third; what is the overall sample size required for adequate power in the statistical analysis? The sample size was determined by examining the variance in the proposed primary outcome measures. From these three factors an estimate of the overall time needed to capture and analyse the primary outcome measure was calculated.
Reliability of measures of parent talk

An outcome measure is considered to be reliable if it gives a stable measure of a phenomenon at different points in time. Conversely, a measure that gives vastly different results at different points in time is not considered to be reliable. The quantity of parental linguistic input to children is reported to vary not only across subjects, but also within subjects, particularly according to activity (Hoff-Ginsberg, 1991; Jones & Adamson, 1987). It is proposed, however, that each family would have differing patterns of activity in their daily routine (Hoff-Ginsberg, 1991). Hart and Risley (1995) measured parent talk within naturally occurring everyday situations, with no control over activities carried out by each family. A measure such as this is ecologically more valid, but has the potential to be affected by variation in parent talk according to different activities, thus reducing reliability.

For a between-subjects experimental design, a higher level of reliability of the primary outcome measure would increase the experimental validity of the findings. Higher control over activity, however, would reduce the ecological validity of the measure, as some parents may carry out the proposed activity less frequently than others. An aim of the pilot study, therefore, was to examine and compare the reliability of the two proposed primary outcome measures, that is, parent word tokens and parent word types. Reliability of these measures was assessed through comparison of variance across a number of separately recorded measures for the same participant, videoed during naturally occurring every day activities within the home. Variance was then compared across participants. A second aim was to identify features in the environment that were associated with greater variance in the data, in order to inform the design of the main trial. Of particular interest were activities carried out that are reported in the literature to be associated with changes in parental talk or with child language development, including book reading (Hoff-Ginsberg, 1991) and television viewing (Zimmerman et al., 2009a).
Validity of measures of parent talk

An outcome measure is considered to be valid if it truly measures what it claims to measure. A measure of parent talk appears to be valid as it a direct measure of the phenomenon observed (as opposed to a therapist’s rating of parent talk). How parent talk is captured and transcribed, however, may influence the validity of the measure. Validity is not to be confused with ecological validity, which is concerned with whether the measure taken in the study is reflective of everyday life, and is therefore more relevant to the question of reliability. The validity of the proposed primary outcome measures, parent word tokens and parent word types may be influenced by a number of factors. First, if a transcript contains a high percentage of unintelligible utterances, then the overall measure (which would not count these utterances) would be lower than the true amount spoken. A question addressed in this pilot study, therefore, was concerned with examining levels of intelligibility within the transcripts of video samples and how levels of intelligibility were affected by environmental factors, such as number of people present and environmental noise (for example, caused by television). Second, it was proposed that the validity of the measure would be influenced by the accuracy of transcription. A high level of agreement between independent transcribers (inter-transcriber reliability) would indicate a greater likelihood that the transcriber had correctly identified the participant’s speech, therefore indicating higher levels of validity.

3.2.2: Pilot study – Method

Participants and Recruitment

Six parent/child dyads were recruited for the feasibility pilot study according to the inclusion/exclusion criteria outlined above. The participants were recruited from a geographical location served by a 2nd wave Sure Start Centre in Portsmouth City, and therefore identified as being an area of low socioeconomic status. Participants were recruited from Baby Clinics operating in the Sure Start Centre, other parent and child groups and directly from the Sure Start registration
database by the speech and language project (as parents were contacted directly for other services). Prior to the start of the research process families were visited in their homes, and the study was described to them in detail, with the aid of an information sheet, which they were able to keep. The information sheet can be found in the appendices (Appendix 5). Participants were asked to sign a consent form and their rights concerning consent and confidentiality were also described.

All families were of white British ethnic origin. All families spoke English and were monolingual. All the main carers recruited were mothers. The number of years of full time education completed by the mothers ranged from 11 years (a basic high school education) to 17 years (college degree). One mother had a history of postnatal depression. One mother lived in a residential family centre for young mothers identified as needing additional parenting support, one in council accommodation and 4 were in their own homes (privately rented or owned).

Within the recruited dyads, 3 children were around 7 months of age and 3 were around 2 years of age. Two of the children were female, and four were male. Children were recruited at these age ranges to investigate any effect of child age on parent talk at both ends of the age range in the proposed main study.

Procedure

Each dyad was videotaped in their own home on 2 separate occasions. On each occasion, following the gaining of consent, and recording of basic demographic data, the dyad was videoed for 45 minutes.

For the video, parents were instructed to act and talk to their child as they would normally, to “carry on with life as normal” and to try to ignore the presence of the researcher. The researcher did not attempt to change the environment in any way (for example, the researcher did not ask the participants to turn off the television, to carry out any activity, or to ask other family members to
leave). For four out of the twelve video sessions recorded, additional family members were present in the room. The researcher did not talk to the parent at all during the video session, and avoided any communication with the child.

At the end of the video sessions the researcher asked the parent if the session was representative of what the parent would have done that day. The researcher then clarified any potentially confusing words heard during the session, for example, family names. The researcher also noted the following additional information, number and relationship of people present, status of television, and starting activity.

The video data was transcribed manually. Parent talk measures were then extracted from the transcripts using a language analysis software programme; the Systematic Analysis of Language Transcripts, or SALT (Miller & Chapman, 1985). SALT transcription conventions were followed with the additional conventions added shown below in Table 7.

When segmenting utterances, starter words, such as <right> or <look> were added to main utterances in the same way as tag utterances are added to the end in the SALT conventions. This was to ensure consistency of utterance segmentation and therefore increase intra and inter rater reliability of the transcripts. Yes and no were also added as starter words when the intonation pattern in the video data indicated one utterance.

Certain sounds are given word like status in the SALT transcription conventions. These include <hmm> as a question or affirmation and <hey>. Some sound effects not listed in the SALT conventions were used by all mothers, and carried meaningful elements. For example, all mothers began some utterances with a sharp intake of breath. This could be translated as a carrying similar
meaning to a starter word (e.g. <look>), and was thus given status in the transcription data. Other similar sounds are listed above in Table 7, below.

Certain play sounds, such as animal and transport noises, also carry iconic representation and are included in the MCDI- words and sentences word count (Klee & Harrison, 2001). These were, therefore, given status in the transcripts. To ensure that the word count was not over inflated, spelling conventions for these were listed as in Table 7.

Table 7: Additional transcription conventions for pilot study

<table>
<thead>
<tr>
<th>Utterance segmentation</th>
<th>Starter utterances to be included with main utterance, for example:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M Right, what have we got here</td>
</tr>
<tr>
<td></td>
<td>M Hey, don’t do that!</td>
</tr>
<tr>
<td></td>
<td>M Look, where does this go?</td>
</tr>
<tr>
<td></td>
<td>The following words are examples of starter utterances</td>
</tr>
<tr>
<td></td>
<td>Child’s name, see, look, uhoh, oy, yes and no</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Spelling conventions for sound effects</th>
<th>The following sound effects to be transcribed in the data</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>wow, hey, youhoo, oy, argh, ah, ow, oops, hhh (intake of breath)</td>
</tr>
<tr>
<td></td>
<td>neeeow, choo_choo, neenaw, broom_broom, raar, yeehah</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Spelling conventions</th>
<th>All number words except one to be linked together and given code, for example:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M one_two_three</td>
</tr>
<tr>
<td></td>
<td>M he’s got four</td>
</tr>
<tr>
<td></td>
<td>M a_b_c_d_e</td>
</tr>
<tr>
<td></td>
<td>but not</td>
</tr>
<tr>
<td></td>
<td>M that’/s a nice one isn’t it</td>
</tr>
</tbody>
</table>

All parents counted and some recited the alphabet during the video sessions. To ensure that the mean length of utterance was not overinflated by these recitals, the numbers or letters were linked together and given a code as shown above. The count codes were also used when numbers were
used on their own in a sentence. Whilst this represents a different use of the number, the code was applied to avoid inflation of the word type count. The only exception to this was the number one, which was given a different word status when it was not being used with numeric meaning, (for example, <that’s a pretty one, isn’t it>).

The data was then checked for transcription errors, and the word root tables and bound morpheme tables were examined for spelling errors and duplicate words, (for example <yeah> and <yes>).

Data analysis: Recruitment and retention of participants
Recruitment processes for the pilot study, potential difficulties with recruitment and drop out rate after recruitment were noted. Participants’ responses to the question of whether the videoed activities were reflective of everyday life, as well as how they felt about the interactions were noted and summarised.

Data analysis for questions concerning the primary outcome measure (time burden, reliability and validity)
The language measures extracted from the SALT package (Miller & Chapman, 1985) were entered and verified using SPSS version 18 (SPSS, 2009). Variance of frequencies for word types and word tokens were examined to inform questions of required sample size and reliability of measures. Percentage of intelligible utterances for each participant was examined to inform questions of validity of the measures. As this was an exploratory pilot study and the sample size was small, it was not appropriate to analyse the data using parametric tests. Variance was therefore investigated through observation of means and standard deviations and also through examination of variance around medians and interquartile ranges using boxplots.
**Time burden of video transcription for the primary outcome measure**

Question 1: How long does transcription of parent child talk take?

Time taken to transcribe data was recorded, and the minimum, maximum and average time taken calculated. Factors associated with increased transcription time were noted.

Question 2: Can 15 minutes of data yield a reliable measure (in comparison to a longer 45 minute sample?) To investigate reliability of a 15-minute sample as a measure of a particular participant, the 45-minute transcripts were divided into 15-minute samples and the total number of utterances, as well as the number of word types and tokens, were recalculated. Variance of mean scores for word types and word tokens for the 15-minute segments within participants was examined using box plots. One 15-minute segment was randomly selected from each 45-minute video and the means and standard deviations for these segments for these measures were compared with means and standard deviations for the whole sample. In addition, the effect of order of segment was analysed through comparison of raw scores.

**Reliability of primary outcome measure.**

Variance for word types and tokens was compared overall, and for the fifteen-minute segments compared above. In addition, outliers were identified and the transcript examined for each of them in order to identify features of the environment that differed to the remainder of the sample.

**Validity of primary outcome measure**

The percentage intelligibility was calculated for transcripts to give an indication of the validity of the primary outcome measure. Transcripts with lower levels of intelligibility were examined in order to identify potential reasons for reduced intelligibility.
To measure the inter-transcriber reliability of the transcripts, 5% of the total transcript for each participant was randomly selected and transcribed a second time by the researcher. Five per cent was also randomly selected and transcribed a second time by a separate speech and language therapist, trained in SALT transcription convention methods. Mean percentage levels of agreement across samples for each sample were calculated for total complete and intelligible utterances, word tokens and word types.

3.2.3: Pilot study - Results

Recruitment and retention of participants

Six participants were identified for the pilot study from within the Sure Start Centre. Participants responded to invitations from the Sure Start speech and language therapy team, and flyers posted in Sure Start Centre groups. Participants were enthusiastic and supportive of the research study, and all pilot study participants remained involved throughout the research process, and attended each session. Some participants reported feeling a little self-conscious being videoed, but no participants objected to video recording as a research method. When questioned, all participants reported that the time videoed was representative of ‘life as normal’ at home.

Time burden of video transcription for the primary outcome measure

Question 1: How long does transcription of parent child talk take?

The time taken to transcribe the video data ranged from 5 minutes per minute of video to 10 minutes per minute of video. Time taken to transcribe increased with additional people present, and television noise. The average time taken to transcribe 45 minutes of video, verify the data and produce SALT analysis tables was 7 hours.
Question 2: Can 15 minutes of data yield reliable measures (in comparison to a longer 45 minute sample)?

*Overall variance:*

The overall variance of frequencies of measures for the 45-minute video transcripts across participants is reported in Table 8 below. Whilst the samples were not large enough to establish whether these measures are normally distributed, an examination of box plots for each variable indicated that there were no outliers. These box plots may be found in the appendices (Appendix 6).

<table>
<thead>
<tr>
<th></th>
<th>Total Utterances</th>
<th>Word Tokens</th>
<th>Word Types</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N Valid Missing</strong></td>
<td>12</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Mean</strong></td>
<td>631.17</td>
<td>2129.58</td>
<td>315.83</td>
</tr>
<tr>
<td><strong>Standard Deviation</strong></td>
<td>193.553</td>
<td>848.609</td>
<td>81.597</td>
</tr>
<tr>
<td><strong>Coefficient of variation</strong></td>
<td>31%</td>
<td>40%</td>
<td>26%</td>
</tr>
</tbody>
</table>

*Within subject variance:*

Within subject variance for measures of total utterances, word types and tokens in 15-minute segments of the transcripts is shown below in Figures 5 (total utterances), 6 (word types) and 7 (word tokens). With the exception of outliers, within subject variance for measures of total utterances in 15-minute video segments was similar across all participants. Variance for Participant
Five was the greatest. Measures for this participant were significantly lower for the second video than for the first. Examination of the transcripts revealed that in the first video session the baby’s older sibling (aged 2 years) was also present. The mother addressed a large proportion of speech to the older child in this first session. (It should be noted that the same change in conditions applied to Participant Four between the first and second video sessions, but this did not result in increased variance in scores for this participant).

Outliers were observed for Participant 1 and Participant 3. Examination of the video transcripts for these outliers revealed the following:

Participant 1: The video segment associated with the low score outlier was the second segment of the second video session (covering the fifteenth to thirtieth minute of the video session). During this segment, the child was eating a snack at the dining table whilst his mother was seated on the sofa and watching the television. The snack time lasted for the duration of this segment, and with the exception of a few minutes of the segments immediately before and after this segment, this activity did not occur in any other video segments.

Participant 3: The video segment associated with the low score outlier for participant three was the first segment of the second video session (covering the first fifteen minutes of video session). The mother and child were sitting on the floor, and the child was playing with various toys. The toy play also continued for the whole of the second fifteen-minute segment.
Figure 5: Within subject variance for Measures of Total utterances in 15 minute video sections

Figure 6: Within subject variance for word types in 15 minute video sections:
Variance and activities carried out by each participant dyad:

Table 9 below, reports the different activities carried out by each participant dyad across the two video sessions. Variance on all measures was greater for participant dyads 1, 3 and 5. This appears to be associated with greater variety of activity carried out, and with a greater amount of time spent on different activities.
Table 9: Activities carried out by participant dyad

<table>
<thead>
<tr>
<th>Participant</th>
<th>Toy Play</th>
<th>Book reading</th>
<th>Meal</th>
<th>Childcare (e.g. nappy changing)</th>
<th>Household chores</th>
<th>Phone</th>
<th>Estimated time (minutes) spent on activities other than toy play</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>30</td>
</tr>
<tr>
<td>2</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>45</td>
</tr>
<tr>
<td>4</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>15</td>
</tr>
<tr>
<td>5</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>30-45</td>
</tr>
<tr>
<td>6</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>15-30</td>
</tr>
</tbody>
</table>

The means and standard deviations for the randomly selected 15 minute segments compared to the whole sample are given below in Table 10:

Table 10: Means and standard deviations for 15-minute segments (total and randomised sample)

<table>
<thead>
<tr>
<th></th>
<th>Total Utterances</th>
<th>Word Tokens</th>
<th>Word Types</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total</td>
<td>Random</td>
<td>Total</td>
</tr>
<tr>
<td>N Valid Missing</td>
<td>36</td>
<td>12</td>
<td>36</td>
</tr>
<tr>
<td>N</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Mean</td>
<td>210.39</td>
<td>219.42</td>
<td>709.86</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>69.69</td>
<td>65.65</td>
<td>289.54</td>
</tr>
</tbody>
</table>
Effect of order of video session: Measures of parent talk for each 45-minute video session are reported below in Table 11:

Table 11: Measures of parent talk for total 45-minute video sessions

<table>
<thead>
<tr>
<th>Participant</th>
<th>Total utterances</th>
<th>Word Tokens</th>
<th>Word Types</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Video 1</td>
<td>Video 2</td>
<td>Video 1</td>
</tr>
<tr>
<td>P1</td>
<td>593</td>
<td>442</td>
<td>1957</td>
</tr>
<tr>
<td>P2</td>
<td>830</td>
<td>783</td>
<td>2269</td>
</tr>
<tr>
<td>P3</td>
<td>822</td>
<td>594</td>
<td>3005</td>
</tr>
<tr>
<td>P4</td>
<td>797</td>
<td>848</td>
<td>3208</td>
</tr>
<tr>
<td>P5</td>
<td>509</td>
<td>230</td>
<td>1643</td>
</tr>
<tr>
<td>P6</td>
<td>649</td>
<td>477</td>
<td>2554</td>
</tr>
</tbody>
</table>

Observation of the means, and of boxplots of measures across video sessions for the 15 minute segments of video sessions indicated that for 5 out of 6 participants, results for each measure were lower for the second video than for the first video.

Reliability of primary outcome measure

Overall variance: Overall variance of word types and word tokens as shown above in Table 8 showed greater variance in the data for measures of word tokens (Coefficient of Variation = 40%) than for measures of word types (CV = 26%).

Outliers: On measures of word types one high score outlier was observed for Participant Four. The video segment associated with this outlier was the second segment of the second video session (covering the fifteenth to thirtieth minutes of the second video). The mother and child were seated on the floor looking at books together. For word tokens no outliers were observed, however the
variance was substantially larger for Participant 3 than for the other participants. Examination of the measures for Participant 3 revealed that the highest and lowest measures of word tokens were for the first fifteen minutes of each video session.

**Validity of primary outcome measure**

Intelligibility levels of transcripts: Intelligibility levels for each 45-minute transcript ranged from 85% to 96%. The lowest 25% of measures for intelligibility were in settings where there were 3 or more people present. The lowest intelligibility levels were for one participant where on both occasions there were 3 people present, the television was on and there was a high level of overlapping speech. The television status did not always result in low intelligibility levels, as one of the highest intelligibility measures was recorded in a setting where the television was on continuously.

Inter-rater reliability: Intra-rater agreement was 96% for complete and intelligible utterances, 98% for Word Types and 97.5% for word tokens. Inter-rater agreement was 92.5% for complete and intelligible utterances, 96.3% for Word Types and 95.5% for word tokens.

**3. 2. 4: Discussion**

The purpose of the feasibility pilot study was to trial recruitment procedures within the target population, test retention and participant acceptance of the research process and to examine the variance, reliability and validity of the measures parent word types and tokens in order to select one as the primary outcome measure.
Recruitment and retention

Regarding the questions of recruitment, there was an enthusiastic and supportive response to the research project in the local Sure Start Centre in Portsmouth with potential participants quickly coming forward to volunteer for the study. This may have been due to parents’ allegiance to the BTHV, which was developed in this location. Families appeared to be supportive of the research project, enjoyed the video process and reported liking the t-shirt and video at the end of the process. This indicated that there may be similar responses for the main study. The pilot also informed the question of retention as all participants stayed with the study through to its completion. This pilot was not able to fully examine issues of retention, however, as the research process in the pilot study was much shorter, being over in a few months.

Selection of primary outcome measure

In order to inform the main study design, it was necessary to identify from this pilot whether parent word tokens or word types would provide a more valid and reliable primary outcome measure for the randomised controlled trial. It is from this measure that the sample size is calculated. In the pilot study the number of word types was found to be a more stable (and therefore reliable) measure with less variance both within and across participants. Furthermore, it gives some indication of both the quantity and diversity of language and has been associated with child language outcomes (Hoff-Ginsberg, 1991; Hart & Risley, 1995; McDonald-Culp et al., 1996; Hoff & Naigles, 2002). Whilst variance was associated with the activities undertaken by participants, those who took part in activities known to be associated with higher measures of word types and tokens (discussed above) also achieved higher scores overall. For example, participants 4 and 6 both engaged in book reading and they also achieved the highest median scores for word types. Given that restricting the activities a family might undertake would substantially diminish the ecological validity of the recording, activities were not restricted in the main trial.
Validity of parent talk was found to be high, with high levels of intelligibility and inter-rater reliability. Intelligibility was affected by number of people present and in the presence of other sources of noise, including the television and noisy toys. Whilst the difference was not great, intra and inter-rater agreement for word types was higher than for word tokens, suggesting that the validity of word types is not as influenced by these factors than the measure of word tokens.

**Time burden for primary outcome measure**

Concerning the question of the time burden of a parent talk measure as the primary outcome measure, several aspects of the data were examined, namely, how many participants are required, how much video is needed for each sample, and how long does each transcription take? The variance of scores obtained for each participant was similar across participants, and analysis of 15-minute transcripts when compared to overall mean scores indicated sufficient reliability to render 15-minute samples a feasible sample size. As variance was affected by the number of people present in one case (that is, for participant five) it was possible that this might influence the reliability of the measure for other participants in the main trial. Whilst the variance for another family (participant four) was unaffected, the risk of multiple persons in the video recording affecting the reliability of the measure could not be ruled out. Variance also appeared to be affected by the order of the segment analysed, with the first 15 minutes of each video session showing more variance than later segments. It appears, therefore, that there may be an effect of the first 15 minutes of video recording, and that this effect does not appear to be evenly distributed across participants. It is possible that some participants feel more uncomfortable being videoed, and that it takes some time for their interactions to fall into a natural pattern, whereas for other participants the effect of researcher and video presence is not as great.
This phenomenon posed questions regarding the reliability of data captured in the first fifteen minutes in a between subjects design. The practice of not using the first section of a video recording is also reported in other studies (e.g. McDonald Culp et al., 1996).

The results of the pilot study indicated that an average of 7 hours transcription and analysis time is required for each 45-minute video sample. This time burden places constraints on the number of participants that can feasibly be recruited to the main study, and the number of samples that can be collected and analysed. In order to calculate a sample size for the main study, an estimate of a clinically relevant effect size was needed. There are no reports of effect sizes of parent talk in the literature for child language outcomes, with most studies being correlational or regression based, and therefore reporting overall shared variance along a continuum of variables (Hart & Risley, 1992; Hoff & Naigles, 2002; Vernon-Feagans et al., 2008). Given that the relationship between parent talk and child language outcomes falls along a continuum and that the case status for primary language impairment is not clear cut (as discussed in Chapter 1, section 1.2) it is difficult to establish exactly how much of an increase in parent talk would be clinically relevant. As the data captured in the pilot study illustrated a high level of variance in parental word types across participants, an increase of 0.5 of a standard deviation might be clinically relevant, as for the lowest scores this would result in a large proportional increase in word types. In light of this, it would be beneficial for the study to observe the presence or otherwise of a smaller effect, in order to establish if this has an influence on the child language outcomes that are also to be measured in the main study.

To inform the question of time burden, therefore, the variance of word types reported from the feasibility study was used in a power calculation using G*Power (Faul et al., 2007) to establish the required sample size for the RCT. Using a repeated measures analysis of variance, with a power level of 0.8 and an effect size of 0.5 standard deviations, 94 subjects would be required for a 2
armed randomised controlled trial (RCT). If an attrition rate of 30% were taken into consideration, this means that for a 2 armed study 141 participants would need to be recruited. Allowing for three 15-minute transcripts per participant (a baseline measure, post intervention measure and long term follow up measure) a total time burden of 658 hours was calculated for transcription and analysis of word types as the primary outcome measure, or 17.5 working weeks.

3.2.5: Conclusion and proposals for main study

The pilot study was able to provide further information to support the design of the main study. Specifically, the results of the pilot informed the choice of the primary outcome measure, video procedure and recruitment and retention of participants.

*Primary outcome measure:* The main finding from the pilot study concerned the reliability and validity of the two potential measures of parent talk examined: word tokens and word types. At this stage, measures of word tokens or types had not been reported in the literature as used in a between subjects experimental design, such as the randomised controlled trial in this study. Furthermore, there were no reports of reliability or validity of these measures for such use. The pilot study indicated that word types demonstrated less variance, higher reliability and higher validity than word tokens. The measure of parent word types, therefore, was selected as the primary outcome measure for the main trial. The pilot study was also able to address questions of variance, which has enabled a calculation of an appropriate sample size for the primary outcome measure.

*Recruitment and retention:* The positive response from parents in the Sure Start Centre to the pilot study and recruitment success in the pilot study indicated that recruitment for the main study was feasible. Furthermore, the feedback given by participants, particularly concerning acceptability of the video procedure, and the extent to which the video represented their ‘life as normal’ also
indicated that the research methods were feasible and were not likely to contribute to high levels of attrition. The recruitment process, therefore, was adopted for the main study within a wider geographical area.

*Video procedure:* As the pilot study indicated that fifteen minutes of video provided a reliable sample of parent talk, this was adopted as the video length for the main study. The pilot also demonstrated that the first segment of video demonstrated greater variance, so within the main trial, thirty minutes of video was to be taken and the last fifteen minutes of each video used for data analysis. Videos in the main trial were designed to be one to one parent to child daily interactions within the family home. The activities carried out by the parent and child were to be determined by the parent and were not restricted by the researcher. This was in order to maintain ecological validity.

The guidance on developing and evaluating complex interventions given by the Medical Research Council (Craig et al., 2008; Medical Research Council, 2000, 2008) highlights the need for adequate feasibility testing and piloting to ensure that the intervention can be delivered “as intended” (p. 4, Medical Research Council, 2008) but also that assumptions about effect sizes, variability, recruitment and retentions are underpinned with evidence. Previous protocol development and evaluation of the BTHV reported in Chapter 2, section 2.3 (Smith & Gibbard, 2011) have addressed the issue of delivery of the intervention. This pilot study enabled the assumptions on effect size, variability, recruitment and retention to be addressed, enabling the evaluation of the BTHV to be taken to the next stage.
Chapter 4: Examining the effectiveness of the BTHV through a matched pairs randomised controlled trial.

Section 4. 1: Methods

4. 1. 1: Establishment of research team

The research team consisted of the author – primary investigator and two speech and language therapy assistants who were responsible for randomising participants to experimental groups and for carrying out the intervention. Details of the research team, including CVs, employment status and an up to date criminal records bureau check were forwarded to and authorised by the local research development and governance service.

4. 1. 2: Participants and recruitment

Identification of potential participants

Babies aged between 6 and 15 months at time of recruitment and their main carer resident within the city of Portsmouth or registered with Portsmouth Children’s services and resident within the local area were identified as potential recruits to the RCT. In addition to age and residency inclusion and exclusion criteria were as follows:

Inclusion criteria:

- Child spends at least 60% of waking hours with main carer at the start of the study
- Families where English Language is spoken routinely with the child
• Families where parent and child have no identified cognitive or language difficulty or sensori-neural deafness

Exclusion criteria:
• Parent or child has known congenital diagnosis affecting learning or language
• Parent or child has known sensori-neural deafness
• A language other than English is spoken routinely with the child
• Child spends less than 60% of waking hours with main carer at start of study

Favourable ethical opinion was originally granted by Berkshire NHS research ethics committee to identify and recruit participants within the geographical location covered by the Portsmouth City speech and language therapy service. This area spanned Portsmouth City, East Hampshire and Fareham and Gosport. Potential participants were to be identified by Health Visitors and Sure Start Children’s Centres staff from Health Visitor birth records and Children Centres registration databases. In addition agreement was obtained from the participating Children’s Centres and the local Health Visitors’ services and approval granted from the research management and governance bodies of the two relevant NHS Trust provider organisations. Health Visitors and Children’s Centres were identified as gatekeepers to these databases and these services were to forward details of potential recruits to the research team.

A number of changes, however, took place between September 2011 and January 2012, which necessitated a review of the identification and recruitment process and, where appropriate, a request for a substantial amendment to the protocol to be approved by Berkshire REC. These changes are outlined as follows:
Withdrawal of approval for recruitment outside of Portsmouth City.

The Health Visitor service outside of Portsmouth City (that is, Fareham and Gosport and East Hampshire), which was hosted by a different NHS Trust to the Health Visitors within Portsmouth City and to the speech and language therapy service for the region, withdrew their approval for recruitment to take place to the RCT in January 2012. Reasons given for this were related to the recent restructuring of NHS provider services in the region. The Health Visiting service manager for this region reported that her line manager was uneasy about collaborative work with a competitor service at this time. This resulted in a reduction in the pool of potential participants, as recruitment was now limited to families either resident within Portsmouth City, or families who used Portsmouth City Children’s Centre Services.

Children’s Centre Service redesign

The Children’s Centres within Portsmouth City underwent a restructuring exercise between September 2011 and January 2012. Services originally delivered only within the most deprived parts of Portsmouth City were now extended to all Children’s Centres and were accessible to all residents of Portsmouth city. The Children’s Centres’ speech and language therapy team was also extended to accommodate this increase in service delivery. The Speech and Language therapy team and the Health Visiting Team moved from a shared office for three Children’s Centres in the most deprived part of Portsmouth to dedicated offices within their own professions, resulting in an end to co-located working. This presented a geographical barrier to information sharing between the health visitors and the speech and language therapy service.

Changes to record keeping

Management of medical records within the local NHS Trust in Portsmouth City was transferred from paper records to an electronic system. This was a phased process, with the Health Visiting
Records transferred in January 2012. It was therefore necessary to access birth records via the electronic database from this date.

The extension of the Children’s Centres speech and language therapy service, together with the migration of patient records to the electronic system resulted in a number of factors affecting the participant recruitment strategy. Whilst the Health Visiting Service continued to approve access to their clients for the RCT, they no longer wished to provide an active gatekeeping and referral role, due to the lack of co-located working and the extension of Children’s Centres services, which placed additional pressures on the Health Visiting team. Following approval from the NHS Trust’s information governance lead, the Health Visiting Team Leader approved the speech and language therapy service direct access to birth records and basic information on families within Portsmouth City for the purposes of offering Children’s Centres services. This provided an opportunity for the speech and language therapy service to contact families directly concerning the RCT.

Recruitment strategy

Following these changes it was necessary to review the agreed recruitment strategy. Changes to the recruitment process were made (as outlined below) and, in the case of initial contact, a substantial amendment to the protocol was submitted to and approved by Berkshire REC. This process took 6 months (with the substantial amendment request being made in January 2012 and approved in June 2012), resulting in significant delays to the recruitment procedure.

Following the revised protocol, potential participants were identified from Portsmouth City and advised about the RCT in a number of ways as follows:

1. Families that were eligible for Children’s Centres’ services were routinely contacted directly by the speech and language therapy service by telephone. During this routine call they were
advised about the RCT on the telephone as part of the telephone call and invited to participate. For those that expressed an interest in the trial, an information giving appointment was arranged with the researcher (details of which are discussed below).

2. Posters were put up in Children’s Centres advising families about the RCT, with a contact number for interested families.

3. The Children’s Centres’ Speech and Language therapy assistants advertised the RCT in their own and in other Children’s Centres groups. An information giving appointment with the researcher was offered to interested families.

4. Letters were sent to all other eligible families identified from the health visitor birth records with a response sheet and a postage paid envelope for interested families to return.

A number of risks were identified with this amended process. These are described below, together with appropriate measures that were taken to minimise these risks:

*Risks associated with potential recruit identification*

Unlike the previous paper records, the electronic database did not distinguish between live births and still born children, so birth lists included names of children who were deceased. Furthermore, these deceased children were only indicated as such via a small black diamond on their record. The following steps were taken to minimise the risk of attempting to recruit children who were deceased; first the speech and language therapy team were all trained on use of the electronic system, where identification of deceased patients was trained. Second, a flowchart was established to ensure that speech and language therapy assistants adhered to a prescribed procedure, where status of the birth was checked. Third, speech and language assistants were alerted to this risk in supervision sessions.
Risks associated with lone home visiting

Families known to the health visiting service as posing a risk to safety of staff for lone home visiting were previously communicated to the speech and language therapy team as part of the gatekeeping role provided. This was the case for the pilot study, for the first recruits to the main trial, and was an extension of the process adopted for the BTHV service delivery. Changes made to the identification and recruitment procedure described above resulted in increased risk of this information not being shared with the speech and language therapy service. Furthermore, as the Health Visiting service migrated to the electronic database, a period of parallel paper record keeping and electronic record keeping took place. Whilst an alert system existed on the electronic records that should indicate any known risks to lone home visiting, the Health Visiting Team Leader indicated that risks were not always initially recorded, rendering the electronic alert system unreliable. In order to minimise this risk, the speech and language therapy service emailed the Health Visitors every month with a list of families to be contacted, and the Health Visiting Service advised the speech and language therapy service by return of email of any families that posed a known risk to lone home visiting. No visits were made until a response had been received from the Health Visiting service.

The recruitment procedure

Once potential recruits to the RCT had been identified and contacted, families who expressed an interest in the service were offered an appointment with the primary investigator at their home. At this appointment the researcher gave the parent the approved information sheet (Appendix 5) and discussed the contents with the parent. Parents were given an opportunity to ask questions about the research project and these questions were answered. Families were advised at this appointment that they were not obliged to participate, and that even if they agreed at this appointment but changed their mind afterwards, they were able to withdraw at any time, and they did not have to give a reason. This procedure is in line with ethical guidelines given by NRES (National Research
Ethics Service, 2011). Families who expressed interest were asked to sign the agreed consent form (of which they were given a copy). The following demographic information was taken: parental level of education (indicated by number of years of full time education), home ownership status (categorised as ‘privately owned’, ‘privately rented’, ‘council/housing association’, ‘armed forces’ or ‘other’) and reported history of postnatal depression. Home ownership was recorded in this way as an additional measure of socioeconomic status. Home ownership was selected as this is a measure reported in studies exploring socioeconomic status (Cohen et al., 2013; Grow et al., 2010; Ivtzan & Goodhand, 2012) but is less sensitive to obtain than other measures of SES such as family income. In addition to the sex of child, this information was based on the covariates reported in the literature to influence the primary and secondary outcomes (as reported in Chapter 3, section 3.1.5) and were recorded to enable a matched pairs randomisation (described below in section 4.1.3) based on parental level of education and to facilitate post hoc analysis of the other covariates (described below in section 4.1.5). A mobile contact number and email address for the researcher was given to parents, as well as the main telephone number for the base clinic. At this point an appointment was made for the first research visit.

**Participant characteristics**

Ninety participant dyads were identified as potential recruits to the study from the Portsmouth area, of which, sixty-nine were deemed to fulfil the inclusion criteria and were recruited. The mean age at recruitment was eleven months. Sixty-seven dyads were mother – child dyad, two were father – child dyads. Thirty-eight of the children were male, thirty-one were female. Thirty-three parents had received an education equivalent to high school level, thirty-six were educated to college level or above. Forty-four families lived in homes that were privately owned, twenty-five in rented, council owned or other accommodation. Fourteen parents reported a history of postnatal depression.
Risk management during the recruitment process

During the recruitment process two incidents arose that were related to the issues highlighted in the ethical application form concerning the identification of safeguarding issues. In both cases, the policy highlighted in the ethics application form (that is, the Solent NHS policy on safeguarding) were fully adhered to and the incidents were documented.

4.1.3: Trial procedure

Randomisation and blinding procedure

Once recruited, participant dyads were matched into pairs according to number of years of education by the researcher. The details of each pair were then logged and forwarded to the speech and language assistants, who carried out the randomisation process and assigned participants to the experimental groups. Randomisation took place for each pair of dyads separately and was carried out by pulling participant numbers out of a hat.

The researcher was blinded to the randomisation and experimental procedure as follows. Participant pairs were recorded on an experimental status document by the speech and language therapy assistants and this was concealed in an envelope in the research filing system. During the intervention phase the participant records were held as a matched pair to prevent identification of experimental status. The experimental group status was not recorded in the participant files. The experimental status document remained concealed from the researcher until the end of the data capture and recording stage.

Participants were not aware of their experimental group status until after the first video recording (video procedures are described below in this section). At the intervention stage, it was no longer possible for participants to remain blind to their status. The researcher, however, advised
participants that she was blinded to their experimental status and asked them not to reveal this
throughout the study.

*Intervention to be assessed*

The BTHV was delivered by one of the two speech and language therapy assistants within the
research team. After randomising participants to the experimental groups, the speech and language
therapy assistants contacted participants in the experimental group and offered to visit their home at
a mutually convenient time. The BTHV was delivered according the protocol developed and
reported by Smith and Gibbard (2011, Smith and Gibbard; submitted). A nursery rhyme CD and
Bookstart pack was given at the visits to reinforce the information given.

*Assessment procedure*

The primary outcome measure assessed in this study (mean number of word types) was taken at
three intervals as discussed below:

Baseline measure. The first measure of parent word types was taken shortly after the recruitment
visit, prior to the experimental condition. This measure was taken to establish group means in order
to calculate the mean effect of the experimental condition on number of word types.

Post intervention measure. This measure was taken at one to three months post intervention/control
stage. The purpose of this measure was to calculate the difference in word types spoken when
compared to the baseline measure, in order to assess whether the BTHV had had a short term effect
on the number of word types spoken by parents to children in an everyday setting.
Follow up measure at child age 22-26 months. This measure was taken to calculate the difference in word types spoken when compared to the baseline measure, in order to assess whether there had been a sustained effect of the BTHV on parent word types spoken to the child.

Method of assessment – primary outcome measure

Samples of parent talk to their children were obtained at each of these stages through a video recording of everyday life in the participants’ home. For each language sample, thirty minutes of ‘everyday life’ was captured using a Cannon Legria FS200 hand held camcorder. The researcher carried out all data gathering for the primary outcome measure. Participants were visited in their homes at a mutually convenient time. In addition to the written consent gained at the beginning of the study, additional verbal consent was gained on the day. Participant identification number, video number, date and time of recording, child age and persons present was recorded on a video information sheet (Appendix 7) for each sample. One to one video interactions only were recorded. Any video that included additional persons was excluded from the analysis.

Prior to the video recording, the researcher advised the parent to carry on with ‘life as usual’ and not to do anything differently because of the recording. Examples of everyday activities such as household chores and meal or snack times were highlighted as possible activities. The researcher advised, however, that she was not expecting to see any particular activity but simply what the participant would have done if she were not there. The researcher requested that the participant did not do anything differently or talk to the child differently because she was there. Furthermore, the researcher did not ask the parent to switch off the TV or radio or to make any changes to the home environment during the recording. Whilst the TV status was associated in some cases with validity of the measure of parent word types in the pilot study (discussed in Chapter 3, section 3.2.3), it was proposed that manipulation of TV status would adversely affect the ecological validity of the study.
The researcher confirmed with the parent that she would follow the family around with the camera but that if the parent and child separated, the researcher would stay nearer to the child. This was to ensure that the video captured an experience of parental talk as similar as possible to that experienced by the child. The researcher also advised that she would not talk to the child or parent during the recording, and asked the parent not to talk to her. This was to ensure that the video captured only interactions between the parent and child. Parents were advised that they did not have to act as though the researcher and the camera were not there, and that if the child showed an interest in the camera, the parent could talk about the researcher or the camera to the child, just as she or he might talk about anything else. This advice was given cognisant of the impact of the researcher’s presence and the camera on the dyad’s home environment, and with an aim to minimise the risk of this impact on natural parent to child interactions. Finally the researcher advised the parent that, apart from cases where the child’s safety might be at risk, she would not intervene or tell the parent if she observed the child carrying out any activity which the parent may not like (such as taking apart an electronic device). This was to clarify to the parent that the researcher had no childcare role during the video recording.

Following this discussion the researcher then captured 30 minutes of continuous video recording of the parent and child at home. During this time, the researcher did not speak with the child or parent. The focus of the camera was on both parties, but remained with the child if the dyad separated. At the end of the video recording, the researcher asked the parent if she or he felt the activities were reflective of everyday life and whether there were any words that were spoken that may be difficult to recognise (such as family names).

A gift was given to the families at the end of each post intervention video session as a thank you for their time and commitment to the study. At the first post intervention visit the children were given a study T-Shirt with a caption that had been suggested by Portsmouth Children’s Centres parents.
“You’re never too young to learn”. A photograph of the T-shirt can be found below in Figure 8. At the end of the 2 year follow up visit the child was given a cardboard ‘Tube toy’, that is, a tube shaped construction toy that parents and children make together to form a vehicle (either a fire engine, a train or a tractor). The toy was classified in the UK as being suitable for children aged 2 years and above but the researcher cautioned the parents, nonetheless, against leaving the toy alone with the child due to small parts. A photograph of one of the toys is shown in Figure 9.

The video sample was then transferred to a .mov file format for analysis using the iMovie ‘09 software package (Apple, 2009). The video was stored on a study specific encrypted portable hard drive, and a backup copy was made on a DVD, which was stored with the participants’ file.

11. 3. 5: Transcription and analysis

Fifteen minutes of the video sample was transcribed, using the Inqscribe software package (Inquirium, 2011), a transcription foot pedal and noise cancelling headphones. Transcripts followed conventions specified in the SALT software handbook (Miller & Chapman, 1985), with the additional guidelines highlighted in Chapter 3, section 3.2. The last transcribeable fifteen minutes of each sample were used. Speech directly to other adults or to the researcher was not transcribed.

Each transcript was then checked and entered onto the SALT software package. Each transcript was given header information, including participant identifier number, target and other speaker labels, sex of child, location and collection number (first, second or third transcript for that family) and interaction context.
Figure 8: Study t-shirt

Figure 9: Toy given to children at the end of the 2 year follow up visit.
Once the transcripts were entered onto the SALT system and checked for errors, a list of word and bound morpheme types was checked for misspelt words, for uncoded bound morphemes and for duplication of words (e.g. thankyou and thank you in the same transcript). This procedure was taken to ensure that the number of calculated word types was not inflated by these errors. A standard measures report was obtained for each transcript, and the number of word types, tokens, type to token ratio and mean length of utterance in morphemes was recorded. Whilst the number of word types was the primary outcome measure, other measures were recorded for further analysis if indicated. An example of a standard measures report produced by the SALT software programme (Miller & Chapman, 1985) can be found in the appendices (Appendix 8).

In order to calculate the primary outcome measure, the number of word types measured at the baseline stage (that is, before the experimental intervention stage) was subtracted from the post intervention measures to gain a measure of change in the number of word types spoken for each participant at both post intervention stages. The outcomes were, therefore a; post-intervention minus baseline and b; two year follow up minus baseline. These measures were used as they take into account the baseline measure for each participant and therefore account for individual differences in quantity of speech.

Method of assessment - Secondary outcome measure: - vocabulary measures as recorded on the MCDI British Adaptation (Klee et al., 1999)

The secondary outcome measure was the mean number of words used by the child, measured at age 22 – 26 months as reported by parents using (with written permission from the first author) the word count section of MacArthur Communicative Development Inventory: Words and Sentences (British English Adaptation, Klee et al., 1999).
As described in Section 3.1 of this chapter, the MCDI is a parental report based assessment of child expressive vocabulary. Section A comprises the vocabulary checklist, the word count section of the measure. Parents were advised to mark words that their child is able to say on the checklist. A list of 672 words is given, broken down into 22 different categories. A copy of the British Adaptation may be found in the appendices (Appendix 9).

The MCDI was given to parents at the third video visit, when the child was aged between 22 and 26 months. The checklist was given as a paper form for parents to complete after the video had taken place. Parents were advised to record words that their children spontaneously used, including words that were not produced accurately. They were advised not to include words that the child did not use but only understood or could copy. Parents were reassured that there is a wide range in normal development, and advised not to worry if their child did not know many of the words. They were also asked to complete the whole form on the same day and to date the form, to avoid scores being inflated due to parents adding newly acquired words at later dates. Completed forms were then collected at a later appointment (usually around 1–2 weeks after the third research visit when the parents were given a copy of all the film taken of them as a gift for participating in the study). Advice and onward referral to speech and language therapy was offered to parents who reported that their child spoke less than 30 single words (in accordance with local speech and language therapy guidelines).

4.1.4: Data analysis

Once verified, participant characteristic information, primary outcome measure values, secondary outcome measures and additional measures reported above for post hoc analysis were entered onto SPSS version 21 for analysis of frequency distribution and statistical analysis. In order to establish the extent to which randomisation and the matched pairing of participants had minimised the effects of the known covariates (namely SES as measured by parental level of education and home
ownership status, as well as history of postnatal depression, discussed fully in Chapter 1 and also in Chapter 3, section 3.1) frequency of distribution of these factors was explored using SPSS (version 21) as described below.

In order to establish the appropriateness of using a parametric statistical test, as proposed in the research design stage (Chapter 3, section 3.1), the frequency distribution of the primary and secondary outcome measures were examined. This was carried out to ensure that the assumptions for parametric analysis were met. These assumptions are that the data is normally distributed, that there is homogeneity of variance across the groups, that the data is interval data and that there is independence across study participants (Field, 2005). The latter two assumptions were met through the study design (i.e. interval data was collected and the controlled randomisation of participants ensured independence across participants) but the former two assumptions needed re-examination after the data gathering stage through assessing the variance across the data.

4.1.5: Post hoc analysis

In order to examine the extent to which the data captured in this study met the theoretical underpinnings outlined in Chapter 1, namely that parental talk is related to child language outcomes, post hoc analysis was carried out to examine the correlation between overall parental talk and child vocabulary levels at age 2 years on the MCDI (Klee et al., 1999). For these correlations the overall talk was measured as total parent word tokens across the three measures. The relationship between word types and child vocabulary levels was also investigated using the mean number of word types across all three measures per participant.

Post hoc analysis was also carried out in order to examine the effect of the covariates reported in the literature to influence parental talk and child language outcomes (described above in Chapter 3,
section 3. 1). These were parental level of education, home ownership status, history of postnatal depression and sex of child on raw measures of parental word types to children at the baseline, post intervention stage and the 2 year follow up stage. The distribution of these covariates across the experimental groups was examined, and the effect of the BTHV on subgroups according to these covariates was also examined. For parental education level participants were categorised into 2 groups. Parents with 13 years or less were categorized as having a high school education and parents with 14 or above years were categorized as having a college education. For home ownership status, families in privately rented accommodation, council accommodation or other were grouped together. The distribution of variance for all outcome measures was then examined by experimental group for participants living in privately owned homes and participants in other accommodation separately.

4.2: Results

4.2.1 Recruitment

Participant flow

In accordance with the CONSORT statement (Schulz et al., 2010) a flow diagram shown in Figure 10 shows the recruitment, randomisation, intervention status and analysis for the primary outcome measure (parent word types). As shown in Figure 10, 69 participants were recruited overall, 35 were allocated to receive the BTHV and 34 to the control group. For the first follow up measure 3 participants were lost in the BTHV and 2 from the control group prior to the data analysis stage, resulting in a sample of 64 participants. For the 2 year follow up stage, a further 7 participants were lost from the BTHV group and 10 participants were lost from the control group, resulting in a sample of 47 participants. Reasons for loss of participants included participant withdrawal from the study (or in one case lack of consent on the part of the child to participate in the video session),
criteria for video not fulfilled (for example, more than one adult or child were present at the time of the video) and loss of contact with the participant.

For the secondary outcome measure, 9 participants were lost from the BTHV and 9 from the control group resulting in a sample of 51 participants. Reasons for loss were the same as for the primary outcome measure with one additional case where the participant lost the MCDI questionnaire.

Recruitment:
Recruitment took place between October 2011 and August 2013. Recruitment ended in October 2013 in order to complete the study within the timeframe agreed by the NIHR. As discussed in the methods section (section 4.1.2) there were significant delays to the recruitment procedure during this time with recruitment capabilities substantially reduced between January and June 2012. Participants were followed up until September 2014, again, in accordance with the timetable agreed by the NIHR.
Figure 10: Participant flow diagram for the primary outcome measure (based on the CONSORT statement template (Schulz et al., 2010)}
4. 2. 2: Data entry and verification

The distribution of frequencies for the known covariates stated in section 4. 1. 4 are described below.

*Parental level of education*

Descriptive statistics of the means, standard deviation and variance showed similar distribution of frequencies across the experimental and control groups for parental level of education as shown in Table 12 below. Both groups displayed a bimodal histogram, with modes at the two main levels of education (secondary and further education) as shown below in Figure 11.

**Table 12** Descriptive statistics showing variance of frequencies across experimental groups for parental level of education:

<table>
<thead>
<tr>
<th>Experimental group status</th>
<th>N</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean</th>
<th>Std. Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>BTHV</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of years parental education</td>
<td>35</td>
<td>10</td>
<td>18</td>
<td>14.17</td>
<td>2.526</td>
</tr>
<tr>
<td>Valid N (listwise)</td>
<td>35</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of years parental education</td>
<td>34</td>
<td>11</td>
<td>18</td>
<td>14.24</td>
<td>2.230</td>
</tr>
<tr>
<td>Valid N (listwise)</td>
<td>34</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Home ownership status

Analysis of descriptive statistics also revealed that home ownership status was equally distributed across the groups with similar numbers of participants residing in privately owned homes, council and armed forces accommodation. A substantial majority lived in privately owned accommodation (63.8%). The pie charts shown below in Figure 12 indicate equity of distribution:

Figure 12 – Distribution of home ownership status across experimental groups:
History of post-natal depression

There was a slightly larger proportion of participants with a reported history of postnatal depression in the control group (26.5% - 9 participants) compared to the BTHV group (14.3% - 5 participants).

Sex of child

Frequency analysis revealed an equal number of boys and girls in the control group, but a slightly higher distribution of boys to girls in the BTHV group (17 boys to 14 girls, that is a 60% - 40% distribution).

4. 2. 3: Distribution of data

Variance of frequencies for the primary and secondary outcome measures is shown in Figures 13-15 below through histograms.

Figure 13 - Frequency distributions by experimental group for measures of post intervention word types minus baseline word types.
Figure 14 - Frequency distributions by experimental group for measures of 2 year follow word types minus baseline word types

Figure 15 – Frequency distributions by experimental group for measures of expressive vocabulary (section A of MCDI – British adaptation)
Table 13, below, shows z scores for skewness and kurtosis by experimental group for the three measures as follows:

Table 13: skewness and kurtosis z scores by experimental group for post intervention – baseline word types, 2 year follow up – baseline word types MCDI and expressive vocabulary (significant scores at p< 0.05 highlighted with *).

<table>
<thead>
<tr>
<th></th>
<th>Word types post intervention minus baseline</th>
<th>Word types 2 year follow up minus baseline</th>
<th>MCDI words produced (Section A)</th>
</tr>
</thead>
<tbody>
<tr>
<td>z- skewness BTHV group</td>
<td>-1.72</td>
<td>0.48</td>
<td>-1.14</td>
</tr>
<tr>
<td>z – kurtosis BTHV group</td>
<td>3.75*</td>
<td>1.26</td>
<td>0.46</td>
</tr>
<tr>
<td>z – skewness control group</td>
<td>0.79</td>
<td>-0.36</td>
<td>0.78</td>
</tr>
<tr>
<td>z – kurtosis control group</td>
<td>0.68</td>
<td>0.37</td>
<td>-0.97</td>
</tr>
</tbody>
</table>

These measures show some abnormality in distribution, namely a leptokurtic distribution for the post intervention measure of word types in the BTHV group. The fact that z scores for the control group fall within the normal range also indicates some lack of homogeneity of variance across groups.

4. 2. 4: Review of appropriate statistical test

The fact that the data was not distributed normally (as highlighted in section 4. 2. 2) renders parametric analysis an inappropriate choice of statistical test. Furthermore, the overall sample size at 69 participants was considerably less than that predicted by the a-priori power calculation for the
parametric repeated measures Anova reported in Chapter 3 section 3. 2. The small sample size (in relation to the planned sample size and considering the variance of the primary outcome measure) reduces the power in the statistical test, therefore potentially increasing the risk of a Type II error. Analysis using the non-parametric Mann Whitney U test of distribution of two independent samples with Bonferroni-Holm corrections (Holm, 1979) was therefore justified as the appropriate alternative to the repeated measures ANOVA.

In addition to the Mann Whitney U tests, boxplots have been used to examine frequency distributions around the medians.

As the data was not normally distributed, for the post hoc tests nonparametric correlation analysis was selected to examine the effect of number of years parental education on the following datasets: parental talk to children at baseline, the post intervention stage and the 2 year follow up stage. The Mann Whitney U test of distribution of two independent samples with Bonferroni-Holm corrections (Holm, 1979) as appropriate was selected for the same datasets to examine the effects of home ownership status, history of postnatal depression and sex of child.

4. 2. 5: Randomised controlled trial results for primary and secondary outcome measures

Primary outcome measure

Hypothesis (1): Parents who receive the BTHV will use more word types in their talk to their children as measured in a 15 minute recording of the home environment than parents who do not receive the service.
Experimental results: There were no significant differences in the distribution of scores across the two experimental groups for measures of word types (less baseline scores) at the post intervention stage (mdn exp = -20, control = -11 U = 595, n=64, NS) or the 2-year follow up stage (mdn exp = 25, control = 22 U = 199, n=47, NS). As there was no evidence of a significant effect of the BTHV on measures of parental word types the null hypothesis of no difference has been retained.

Secondary outcome measure

Hypothesis (2): The children who receive the BTHV will show higher expressive vocabularies as measured on the MCDI – British Adaptation at age 22-26 months than the children who do not.

Experimental results: No significant differences were found in the distribution of scores across groups for words produced on the MCDI – British adaptation – section A (mdn exp = 303.5, control = 320 U=354, n=51, NS). Again, as no evidence of a significant effect of the BTHV on child vocabulary development at 2 years of age was found in this study the null hypothesis of no difference has been retained.

Figures 16 – 18 show boxplots for each of the outcome measures. The considerable overlap in frequency distributions between experimental groups illustrates the absence of a significant effect of the BTHV on any of the measures. The negative scores in figure 16 demonstrate that when related to the baseline measure participants in both groups spoke less to their babies in the post intervention measure. The positive scores in figure 17, however, demonstrate that participants spoke more to their children at the 2-year follow up in comparison to the baseline measure.

The boxplots for words produced on the MCDI,– British adaptation (Klee & Harrison, 2001) (figure 18) again illustrate the shared variance of scores across the experimental groups.
Figure 16: Boxplot showing distribution of frequencies for number of word types at the post-intervention minus baseline stage.

Figure 17: Boxplot showing distribution of frequencies for number of word types at the 2-year follow up minus baseline stage.
4. 2. 6: Post-hoc analysis

**Relationship between parental talk measures and expressive vocabulary at age 2 years**

Correlation analysis using the non-parametric Spearman’s Rho indicated that there was a highly significant relationship between overall parental talk (measured as the total number of parent word tokens spoken to children over the 3 measurement points) and words produced measures on the MCDI (Klee & Harrison, 2001) $Rho=0.519 \ p<0.001$. There was also a significant correlation between the mean number of word types spoken over the 3 measures and words produced on the MCDI $rho=0.358 \ p=0.017$.

**Parental education level**

Correlation analysis using the non parametric Spearman’s Rho test revealed that there was a significant positive relationship between number of years of parental education and number of parent word types spoken to children at the baseline measure $r_s (67) = .325, \ p=0.007$ and at the 2
year follow up measure $r_s (47) = .324$, $p=0.027$ but not at the post intervention measure $r_s (65) = .116$, NS. Furthermore, there was no significant relationship found between number of years parental education and number of words produced as reported on the MCDI $r_s (51) = .177$, NS.

The distribution of parental education level by experimental group indicated equal distribution across the experimental groups (as discussed above in section 4.2.1). Whilst the distribution was bimodal there was even distribution across the range of education levels with no significant skewness ($z$ score for skewness for overall sample = 0.107). Boxplots examining the effect of the BTHV on the primary and secondary outcome measures according to level of education revealed similar variance across all groups, and no meaningful differences according to level of education. These box plots may be found in the appendices (Appendix 10a).

*Home ownership status*

The distribution of covariates indicated that 63.8% of participants lived in privately owned homes. Analysis of distribution of frequencies using the independent samples Mann-Whitney U Test with Bonferroni–Holm corrections for four comparisons did not indicate any significant effects of home ownership status on the number of word types spoken to children at the baseline measure (median privately owned = 151.5, median other = 127, $U(67) = 333$, NS), the post intervention measure (median privately owned = 172.5, median other = 125, $U(65) = 284.5$, NS) or the 2 year follow up stage (median privately owned = 200.5, median other = 170, $U(47) = 133$, NS). Furthermore, there was no effect of home ownership status on number of words reported on the MCDI (median privately owned = 323 median other = 297, $U(51) = 219$, NS).
The distribution of home ownership status was found to be similar across experimental groups (as highlighted above in section 4.2.1). Boxplots illustrating distribution of variance for the primary and secondary outcome measures according to home ownership status are shown in the appendices (Appendix 10b). Amongst families not in privately owned homes there was a higher score distribution for the BTHV group in the post intervention minus baseline measure when compared to controls but this was not repeated in the 2 year follow up minus baseline measures. There appeared to be a similar effect for families in privately owned accommodation at the 2 year follow up, however, there was no evidence of an effect of the BTHV on MCDI words produced scores for either category of home ownership status.

Effect of history of postnatal depression on outcomes

The Mann-Whitney U test with Bonferroni –Holm corrections for four comparisons was also carried out to analyse the effect of reported history of post-natal depression on distribution (hPND) of frequencies on parent word types and scores on the MCDI (words produced and mean length of utterance in morphemes). There was a significant effect of hPND on number of word types spoken to the child at baseline (mdn yes = 97, mdn no = 146 U(67) = 509.5, p=0.012 pBonferroni, 4=0.048) but not at the post intervention measure (mdn yes = 136, mdn no = 167.5 U(65) = 461.5, NS) or at the 2 year follow up (mdn yes = 158.5, mdn no = 189 U(47) = 248.5, NS). Again, there was no effect of hPND on reported words produced on the MCDI (mdn yes = 216, mdn no = 323 U(51) = 250, NS).

The data verification reported in section 4.2.1 highlighted a slightly higher proportion of parents with hPND in the control group compared to the BTHV group. As with previous post hoc analyses, box plots examining the effect of the BTHV according to hPND, however, revealed similar variance across all groups, and no meaningful differences according to hPND. These box plots may be found in the appendices (Appendix 10c).
Effect of sex of child

Analysis of distribution of frequencies using the independent samples Mann-Whitney U Test with Bonferroni–Holm corrections for four comparisons revealed that there was no significant effect of sex on parent word types at baseline (median male = 127, median female = 157, U(67) = 709.5, NS), the post intervention measure (median male = 152.5, median female = 168, U(65) = 602, NS) or the 2 year follow up stage (median male = 194.5, median female = 185, U(47) = 268, NS). There was also no significant effect of sex on number of reported words produced on the MCDI (median male = 286, median female = 333, U(51) = 391, NS).

Verification of the data reported above in section 4.2.1 highlighted that there was a slightly higher proportion of boys in the BTHV group and an even distribution of boys to girls in the control group. Box plots examining the effect of the BTHV according to sex of child indicated that there were no meaningful differences according to sex of child. These boxplots may be found in the appendices (Appendix 10d).
Chapter 5: Overall study discussion, conclusions and directions for future research.

The aim of this study was to provide a contribution to the evidence base for speech and language therapy prevention services for primary language delay. With reference to the literature outlining current theory and empirical research on early language development, and particularly the role of the environmental input (Chapter 1), and mindful of current guidelines on the development of evidence based practice (Chapter 2, section 2.1) a systematic scoping review of the literature was carried out to identify current primary prevention practice in the UK (section 2.2). This review highlighted that a substantial degree of practice had taken place in recent years but there was very little underpinning evidence for these services. There was sufficient evidence at Levels 1 and 2 of the MRC (2000) framework to justify further investigation of the Babytalk Home Visiting Service and, following a feasibility study (Chapter 3, section 3.2) a randomised controlled trial into the effectiveness of the BTHV was carried out (Chapter 4). The randomised controlled trial did not provide evidence to support the effectiveness of the BTHV on parental talk to children or child language outcomes at age 2 (section 4.2). Although subgroup analysis indicated a possible short-term effect on parental talk for lower SES families, this was not sustained at the 2-year follow up stage, and there was no evidence of effectiveness of the service on child language outcomes.

The purpose of this chapter is to discuss how this research relates to the wider literature and the issue of environmentally based language delay with reference to the topics and issues raised earlier in this thesis. First, limitations of the randomised controlled trial are discussed (section 5.1). Second, the question of why the BTHV did not demonstrate evidence of effectiveness is discussed in the light of the model of service and the systematic review (section 5.2) and the underpinning theoretical approach (section 5.3). Finally, overall reflections on the study and the positioning of
prevention practice within the evidence based framework proposed by the MRC (2000, 2008) and clinical practice for speech and language therapy are discussed in section 5.4.

5.1: Limitations of the randomised controlled trial

5.1.1: Summary of results and study limitations

The results of this randomised controlled trial did not provide sufficient evidence to support the hypotheses tested. There was no evidence observed of an effect of the BTHV on the number of parent word types spoken in videoed parent-child interactions in the home setting, either shortly after the intervention (one to three months post intervention) or over the long term (that is, when the child reached age 2 years). There was also no evidence observed of an effect of the BTHV on the reported measure of child expressive vocabulary using the words produced section of the MCDI – British Adaptation (Klee & Harrison, 2001). Furthermore, the distribution of frequencies for each experimental group using boxplots indicated both a lack of effect size and a considerable level of shared variance across the experimental groups. Post hoc analysis was carried out to examine if there might be any effect on subgroups (according to home ownership status, education level of parent, sex of child or history of postnatal depression). Whilst there was some indication that the BTHV may have had an effect on families not resident in privately owned homes at the post intervention stage, the effect was not sustained at the 2 year follow up measure and there was no evidence of an effect of the BTHV on this subgroup on parent reported scores on the MCDI – British adaptation (Klee et al., 1999). Furthermore, when considering the two measurements of the primary outcome measure and the secondary outcome measures there was no consistent evidence of any effect of the BTHV on the outcomes for any other subgroup.

The most likely interpretation of these findings is to conclude that the BTHV is not an effective primary prevention initiative for supporting early language development through facilitating...
increased parental talk to children in the early years. It is first, however, judicious to explore any alternative interpretations to that given above.

There were a number of limitations in the study, which are described below. These limitations necessitate an enquiry into the extent to which a Type II error might have been made. A Type II error occurs when a study leads the researcher to conclude that there was no effect of the independent variable when, in fact, an effect exists (Breakwell & Rose, 2006). The potential limitations in this study are discussed below, with consideration to the likelihood of the limitation leading to a Type II error.

5.1.2: Recruitment and attrition of participants

Difficulties with recruitment have been described above in Chapter 4, section 4.1.2. Whilst the feasibility of recruiting the required number of participants to the study was explored in the pilot study (Chapter 3, section 3.2), changes to organisational and economic infrastructure within the local area resulted in lower than planned levels of recruitment, with its resultant effects on statistical power as discussed below in section 5.1.3.

Concerning attrition, the original research design predicted an attrition rate of 30%. The participant flow diagram shown in Figure 10 shows attrition levels in the study. From the 69 participants recruited to the study and randomised to groups, 64 participant measures were included in the post intervention analysis for the primary outcome measure and forty-seven for the two year follow up analysis for the primary outcome measure. This constitutes a 7.2% attrition rate at the post intervention stage and a 32% overall attrition rate for the 2 year follow up stage. The overall attrition rate was similar to that predicted in the study design. It may, therefore, be postulated that it was difficulties with recruitment, rather than attrition, that was a limitation in this study.
The recruitment difficulties experienced led to limitations with the sample size and sample characteristics in the study. These are discussed further, below.

5.1.3: Sample size

The difficulties with recruitment described above resulted in a lower than planned overall sample size. If inadequate numbers of participants are recruited, the power of the statistical tests is reduced, which may result in an increased likelihood of a Type II error occurring. In the case of this study, for the planned analysis (that is, using a repeated measures Anova) an a-priori calculation of the required sample size was carried out as part of the feasibility pilot study (see Chapter 3, section 3.2.4) but, as described above, inadequate numbers of participants were recruited.

It was also not appropriate to use a parametric statistical test as the assumptions for parametric assessment were not met due to a non-normal distribution of the data (see Chapter 4, section 4.2.2). Whilst the test was adjusted, it is accepted that power overall is reduced in non-parametric studies and is still influenced by effect size and sample size (Mumby, 2002). On this basis it would be, therefore, prudent to consider that due to the relatively small sample size and the effect sizes anticipated the risk of a Type II error occurring was increased.

This question of whether there was an effect of the BTHV was further informed, however, by analysis of variance using boxplots. Analysis of effect size and variance of outcomes between the experimental groups has been proposed in the literature as a more informative method of analysis than relying on the null hypothesis significance testing (NHST) method alone. According to Cumming (2012) there are two reasons for this. First, analysis of effect size is highly relevant to clinical studies, giving a clinically relevant outcome, whereas statistically significant result may be found for interventions that have a negligible effect size, especially in larger samples. Second,
analysis of effect size does not force conclusions to be made on the dichotomous parameters of significance or non-significance.

In the case of this study, this alternative approach was used to complement and further inform the results of the Mann-Whitney U tests through the examination of boxplots (Figures 16 - 18) and has been able to shed light on the possibility of whether a Type II error was made. The boxplots demonstrate that the variance across groups overlapped considerably. There was no evidence of an effect of any size of the BTHV for either of the outcome measures. Furthermore, there was no evidence of a consistent direction of effect for the BTHV on the primary outcome measure. To illustrate, the median for the BTHV compared to controls for the primary outcome measure was lower at the post intervention stage (as shown in Figure 16), but higher at the 2 year follow up measure (shown in Figure 17). For the secondary outcome measure, number of reported words on the MCDI (Klee et al., 1999) the frequency distributions almost completely overlap, suggesting a zero effect size.

It is possible that the BTHV had a small effect on the outcome measures that would have been observed in a larger population. In this case a Type II error may have occurred. The question of how big an effect is clinically relevant in this possibility, however, is raised. As noted by Cumming (2012), even very small and clinically irrelevant effect sizes may be proven to be significant using the NHST method if a large enough sample were obtained. This study was limited as the effect size deemed to be clinically appropriate (discussed in Chapter 3, section 3.2.4) required a larger sample size than that recruited. It is hypothesised, however, that even with a smaller sample, if the BTHV was effective analysis of the boxplots would have indicated trends towards an effect. The combination of NHST and analysis of effect size and variance using boxplots, therefore, provided a more comprehensive approach to data analysis than would have been achieved using NHST alone.
Whilst a Type II error based on a small sample size cannot be ruled out, the boxplots allow for greater levels of confidence in interpreting the results.

5.1.4: Sample characteristics

Another interpretation of these results might be that a Type II error has occurred because the BTHV is only effective for a subsection of the population that has been underrepresented in this trial. The MRC guidelines caution against this error (Medical Research Council, 2008), highlighting that consideration of underlying theory and research prior to a definitive trial is needed to inform for whom an intervention is likely to be effective. The BTHV was developed to support parents in facilitating their child’s language development in areas of low socio-economic status. Hart and Risley (1995) found that parents from low SES backgrounds spoke less to their children and this was related to their child’s own language development. It was hypothesised that if parents from low SES backgrounds could be supported to speak more to their children, this may in turn facilitate increased child language development. The BTHV is relevant, therefore, to families from low SES backgrounds.

The initial research design planned for families to be recruited from the 30% most deprived wards in the Portsmouth area (Office for National Statistics, 2015), through collaboration with the Health Visiting services and local Sure Start Centres. Due to the difficulties experienced with recruitment described in the methods section (Chapter 4, section 4.1.2) both the geographical area and the methods of recruitment needed to be adapted. Participants were recruited from all wards in Portsmouth using response letters as well as direct contacts. Health visitor and Children’s Centre support was reduced considerably during the recruitment period due to reduction in funding for Sure Start services. Analysis of the SES of those recruited to the study using data on levels of education and home ownership status (described in Chapter 4, section 4.2.1) indicated that the
proportion of high SES families was higher than that originally planned. This is postulated due to the high proportion of families living in privately owned accommodation, and the high proportion of families with a college or above level of education. It might be proposed, therefore, that the overall results were diminished if the BTHV was not as effective with families who already spoke more to their children.

Post hoc analysis of the data reported in Chapter 4, section 4.2.5 indicated that there was no significant evidence of an effect of home ownership status on the number of parent word types spoken to children. The boxplots analysis examining the effect of the BTHV on subgroups according to home ownership status (shown in Appendix 10b) indicated that there might have been an effect of the BTHV on families who did not own their own home at the post intervention stage. There was no evidence, however, that this effect was sustained for this subgroup at the 2 year follow up stage. Furthermore, there was no evidence of an effect on the reported number of words produced on the MCDI (Klee et al., 1999). As with the main outcomes, direction of effect was inconsistent across the two stages of measurement, and no trend indicating an effect for a subgroup of participants was evident. Furthermore, with the exception of the post intervention measure for the subgroup of non-home owners, variance across both groups overlapped considerably as with the main outcomes. Whilst further research to explore the short term effect of such advice on lower SES families would facilitate an increased understanding of the potential effect seen at the post intervention stage for non-home owners, the absence of evidence of an effect of the BTHV on parent word types at the 2 year follow up stage indicates that if there was an effect of the BTHV on this subgroup, that it may be temporary.

The other indicator of SES used in this study was parental level of education. As a widely used measure of SES it was parental level of education that was used to match pairs of dyads prior to randomisation. Post hoc analysis revealed an equal distribution of education levels across both
experimental groups. Parental level of education was not a significant predictor of parental talk post intervention or of child language outcomes on the MCDI – British adaptation (Klee & Harrison, 2001). There was also no evidence of an effect of the BTHV on the main outcomes for subgroups of either college educated or high school level educated participants. Other subgroups of interest included parents who reported a history of post-natal depression (PND) or the sex of the child. Again, for these variables analysis of the effect of the BTHV on subgroups using boxplots revealed no evidence of any effect.

The possibility that a Type II error has occurred due to sample characteristics cannot be ruled out, particularly when considering the possible effect seen on parent word types for non-home owners at the post intervention stage. For parent word types at the 2 year follow up stage and for reported words produced on the MCDI – British English adaptation (Klee et al., 1999), however, post hoc analysis results did not indicate any further evidence suggesting a lasting effect of the BTHV on parent talk or on child expressive vocabulary at age 2 years.

5.1.5: Fidelity of service delivered

When evaluating complex interventions, the extent to which a service may vary between participants is a factor which may contribute to a Type II error occurring (Medical Research Council, 2008). As neither of the two hypotheses have been supported in this study, the extent to which the service remained standard across all participants in the trial (that is, service fidelity) is questioned. Fidelity may be compromised through variation in the speech and language therapy assistant delivering the service, change in knowledge levels over the course of the trial, changes in supervision arrangements and characteristics of different participants receiving the service.
Whilst the extent to which variation in the service may have led to a Type II error could not be examined during the trial, a number of steps were taken at the research design stage to increase service fidelity. From a team of four speech and language therapy assistants, the two most experienced were selected to provide the BTHV for this trial. Both assistants had received full training and had achieved all the required competencies to deliver the service prior to the trial starting. This included a service-shadowing programme where the fidelity of the service across visits was examined. Throughout the trial the assistants received regular supervision and delivered the services to a semi-scripted protocol, with a checklist of the key information to be given at the service. Funding was secured from the NIHR to ensure that the same staff members were maintained throughout the duration of the trial during a time of economic and organisational change. These steps are in keeping with recommendations made by the Medical Research Council (2008) concerning service fidelity in randomised controlled trials and minimised the risk of low service fidelity. Whilst all these steps were taken, it was not possible to obtain evidence of service fidelity across participants during the trial. The assistant delivering each visit was not recorded in the study. Post hoc analysis of the effect of each assistant on the outcomes and a process evaluation into the delivery of the service to families may have informed the question of service fidelity further (Medical Research Council, 2008).

5.1.6: Hawthorne or Observer effects

The extent to which a Type II error may have occurred as a result of a Hawthorne effect also warrants consideration in this study. A Hawthorne effect is defined by Kohli et al (2009) as the tendency of a participant in an experiment to change their behaviour in some way simply due to their awareness of being observed. Hawthorne effects are alluded to in clinical trials within the speech and language therapy profession (e.g. Gibbard, 1992; Suskind et al., 2013). Also known as the observer effect (e.g. Yamamoto & Suzuki, 2012), ‘Hawthorne’ has been criticised as being too
ambiguous a term (e.g. Holden, 2001). It has been highlighted that ‘Hawthorne’ as a concept has been referred to in the literature in many different and contradictory ways and the appropriateness of its use has been questioned (Chiesa & Hobbs, 2008).

Cognisant of this debate, it is appropriate to question whether the nature of the experimental environment, particularly in this case where participants’ behaviour was being overtly observed through video recordings, has influenced the outcomes in any way. It is unlikely that the secondary outcome measure of reported expressive language was influenced by a Hawthorne effect, as this outcome was neither behavioural nor directly observed. The primary outcome measure of parental word types is a behavioural measure and so may have been at risk of a Hawthorne effect. If parent talk was artificially elevated during the video sessions, this may result in abating any effect of the BTHV as both groups are affected by the Hawthorne effect, leading to a Type II error. There are a number of different factors that aid consideration of this question, which are discussed below.

Research design and observations in pilot and main study

It is first necessary to reflect on the research design to establish to what extent a Hawthorne effect on measures of parent talk (including word types) was considered and accounted for. At the feasibility pilot study, questions concerning potential Hawthorne effects were raised and addressed. Participants were asked to what degree they felt their activities during video recordings represented everyday life. They reported that they felt the session was largely reflective of ‘life as normal’. Whilst this provides some indication of ecological validity of the activities, it does not provide evidence against a Hawthorne effect on parent talk. Analysis of word types measured in the feasibility pilot study indicated some effect during the first fifteen minutes of video recording compared to later segments (due to greater variance in the distribution of frequencies for first fifteen minute segments of video). This was taken into consideration in the main study design as the last fifteen minutes of the video recordings were transcribed for analysis. Again, the use of the later
segments of video minimises the risk of a Hawthorne effect to some degree but it does not rule out the possibility of the effect of being videoed on parent talk being sustained.

Another aspect of the research design implemented to reduce the risk of a Hawthorne effect was the information given to participants regarding the video sessions. Participants were advised that the researcher would video everyday activities and that the researcher was interested in whether the BTHV resulted in any changes to everyday life, but they were not given specific advice about the outcome measures. In particular, participants were not told that the researcher would analyse their talk. Given this, it would be reasonable to predict that any Hawthorne effect might be more likely to be observed within the BTHV group, as they would have been given specific advice to talk to their baby. The participants in the BTHV group may, therefore, be more likely to be aware of their own talk in the post intervention measure. It is also noteworthy that other behaviours did not appear to have altered as a result of being observed. For example, the television was left on in many homes throughout the trial, and parents used computers or smartphones during the recordings.

Measures of parent talk - comparison of measures with other measures in the literature.

Another way of examining if parents spoke more or less in the video sessions than they usually would is to compare measures of parent talk in this study with findings from other studies. This is problematic as the methods used in different studies vary in a number of ways. This analysis does shed light on the ecological validity of the results obtained in this study, however, which is pertinent to the question of a Hawthorne effect. In order to inform the Hawthorne question, therefore, the methods and findings of this comparison are described below.

Studies used for comparison

Five studies from the literature served as a comparison for this study; Hart and Risley (1995), Hoff and Naigles (2002), Greenwood et al. (2010), Weisleder and Fernald (2013) and Suskind et al.
Hart and Risley (1995) used audio recording as a method, Hoff and Naigles (2002) used video recording, whereas Greenwood et al. (2010), Weisleder and Fernald (2013) and Suskind et al. (2013) used the more recently developed LENA Pro, an audio digital language capture and analysis device (Lena Foundation, 2014). The duration and overall quantity of data captured also differed. Hart and Risley (1995) captured and analysed data per hour, Hoff and Naigles (2002) captured varying quantities of time, averaging 42 minutes and those using LENA Pro captured data over a longer period, for example, 10 hours reported by Weisleder and Fernald (2013).

Finding a comparable measure

In addition to the difficulties comparing studies with different data capture methods, it is also problematic to compare studies using parental word types as this measure cannot be easily scaled up and down to different time segments. To illustrate, the mean number of word types obtained overall from the main study is 169 words for a 15-minute period. This compares favourably with the mean number of word types found in fifteen-minute segments in the feasibility pilot study (174 word types). Further analysis of the feasibility study results, however, demonstrates that it is not possible to compare this figure with studies that have used different periods of time for their outcome measure. The mean word types for 45-minute segments found in the feasibility study were 316 word types. A quick calculation shows that a 45-minute estimate cannot be made by multiplying a 15-minute estimate by 3 (based on the feasibility study outcomes, scaling up the 15 minute mean in this way would result in an estimate of 522 word types; a substantial overestimation of the true value). As Hoff and Naigles’ (2002) mean of 316 word types was based on 42 minute segments and Hart and Risley’s reported 281 word types on one hour recordings, comparison of parent talk using word types is not possible. Furthermore, word type measures were not given for studies using the LENA Pro system.
It is possible, however, to compare measures of parent talk if the word tokens measure is used. Whilst this is not the measure used for the primary outcome measure in this study, it is a valid parent talk measure, which was automatically calculated by the SALT language analysis package (Miller & Chapman, 1985) during the data analysis process in this study. The feasibility study results demonstrate that the mean number of word tokens can be scaled up to enable a common time segment across studies and, therefore, allow a meaningful comparison (in the feasibility study the average number of word tokens per 15 minute segment was found to be 710 word tokens and the average for 45 minutes was 2129, demonstrating a linear relationship).

A comparison of the findings of this study with the studies reported above was therefore carried out to inform the question of whether a Hawthorne effect had been observed. Table 14, below, gives mean word tokens across the range of studies with figures calculated to a common 15-minute segment.

Table 14: mean word tokens across a range of studies with adjusted mean for 15 minutes

<table>
<thead>
<tr>
<th>Study</th>
<th>Method of data capture</th>
<th>Mean reported word tokens / time period</th>
<th>Adjusted mean for 15 minute time period</th>
</tr>
</thead>
<tbody>
<tr>
<td>This study (main)</td>
<td>Video</td>
<td>659 / 15 minutes</td>
<td>660</td>
</tr>
<tr>
<td>This study (feasibility)</td>
<td>Video</td>
<td>710 / 15 minutes</td>
<td>710</td>
</tr>
<tr>
<td>Hoff and Naigles (2004)</td>
<td>Video</td>
<td>1881 / 42 minutes</td>
<td>672</td>
</tr>
<tr>
<td>Suskind et al. (2013)</td>
<td>LENA (audio)</td>
<td>1400 / hour</td>
<td>350</td>
</tr>
<tr>
<td>Greenwood et al. (2010)</td>
<td>LENA (audio)</td>
<td>1095 / hour</td>
<td>274</td>
</tr>
</tbody>
</table>
It can be seen that the results obtained for this study are similar to those obtained by Hoff and Naigles (2002) but are considerably higher than the mean word tokens measured in other studies. The reasons for this discrepancy may be due to the difference in data capture methods. The increased measures captured in this and the Hoff and Naigles (2002) study may be evidence of a Hawthorne effect resulting from video use. It could be argued that being videoed is more intrusive and therefore may be more likely than audio recording or the LENA Pro device to result in a change in participant verbal behaviour. At the very least, it may lead participants to present what they consider to be their most optimal parenting strategies. Alternatively, the difference between studies may indicate differences in validity of the methods used. It is possible that due to greater intelligibility yielded from video analysis, a higher but more valid word count was achieved. It is possible that both of these possibilities influenced the results found in the different studies.

This possibility raises important issues for both the interpretation of previous studies (including this one) and consideration of the most appropriate methods to be used in future research. The question of whether video use results in a greater Hawthorne effect than audio recording and whether the results of video recordings are more valid than audio recordings due to the reduction of unintelligible segments warrants greater understanding before conclusions are made on the findings of studies using both these methods. Further research to investigate whether video recording results in a Hawthorne effect might involve comparing results from a range of measures of the same participant over time using different recording methods.

It is also possible that the participants’ behaviour was not falsely elevated as a result of being videoed but that parents were at their natural peak of talkativeness in the study, influenced by the act of being videoed, as highlighted above. Whilst this would represent a measure of that participant at their own ‘personal best’, it would not give a true measure of their typical ‘everyday’ talk. The Hart and Risley (1995) and LENA studies captured more samples over longer periods
than the present study or the Hoff and Naigles (2002) study, yielding significantly more data per participant. This was likely to have resulted in a much wider range of everyday activities being included in the data capture, some of which would have involved less parent to child interaction. Due to the time constraints of transcription, larger samples were not feasible in this study. The potential effect of smaller sample sizes on the ecological validity of the measures, however, is a limitation of this study.

**Summarising the factors - was there a Hawthorne effect?**

Considering all the above factors, whilst steps were taken at the research design stage and observations of other behavioural aspects indicated ecological validity of videoed activities, the possibility of a Hawthorne effect on the primary outcome measure having occurred cannot be ruled out. Further research examining the relationship between measures of parent talk, method of data capture and amount of time captured per participant might inform the validity of parent word types as a meaningful indicator of overall parent talk to children.

5. 1. 7: Blinding

In order to reduce bias in the study double blinding is recommended as part of the CONSORT standard (Schulz et al., 2010). Whilst the researcher remained blind to the experimental status of participants until after the data analysis stage, it was not possible to blind participants to their status after the intervention phase. A way to ensure against bias in this way would be to include an arm into the study where a non-specific service is provided (in the place of the BHTV). This is an approach reported in other randomised controlled trials of speech and language therapy interventions (e.g. Gibbard, 1992). Comparison of the BTHV experimental group against such a group would minimise the risk of bias in the study by exposing any placebo effect within the BTHV
group. As no evidence of effect was seen in this study, however, this limitation did not appear to influence the outcomes.

5. 2: Why was there no effect of the BTHV?

5. 2. 1: Possible limitations in the BTHV

Understanding why a complex intervention, such as the BTHV, has not demonstrated evidence of effectiveness is not easy due to the multiple components involved (Medical Research Council, 2000, 2008). It is, however, supported through modelling the service. In order to understand why a service may not be effective, an appraisal of the individual components may be instructive. Concerning the BTHV, the model of service delivery reported in Chapter 2 (section 2. 3) and shown in Figure 4, section 2. 3 is referred to in order to aid this appraisal. The model was divided into four parts, service delivery, target clientele, therapy components and staffing. Each of these parts is discussed separately, below.

Service Delivery

Service delivery components of the BTHV were the method of service (environmental and at the level of primary prevention), dosage (a one off 45 minute session) and method of delivery (home visit). The method of service delivery will be discussed in more detail in section 5. 4, as this applies to the wider question of environmentally based prevention services and not just the BTHV.

The question of dosage concerns the frequency, intensity and appropriate timing of the intervention. The timing of the intervention, that is, the optimum age to intervene is discussed below in this section. Concerning the frequency and intensity of dosage, the BTHV was a low dose intervention, with only one home visit delivered per client. It might be argued that this is not sufficient to result in a change in parental behaviour or child language development. It may be reasonable to assume
that a higher dose may be more effective, but the question then arises as to how high that dose would need to be to have an effect, two sessions, three or more? Fey, Yoder, Warren, and Bredin-Oja (2013) highlighted that there is little guidance in the literature on appropriate frequency and intensity of speech and language therapy interventions.

Two other prevention studies that have been recently reported may shed light on the question of dosage. Suskind et al. (in press) carried out a randomised controlled trial of a new non speech and language therapy prevention initiative, “Thirty Million Words”. They delivered 8 one hour home visit sessions to low SES families and found that parents’ total word count (measured as word tokens) increased during and immediately after the intervention. They found that the increase was not, however, sustained at 4 months post intervention. The subgroup analysis carried out in the BTHV randomised controlled trial also gave some indication that there may be a short but not longer term effect of the BTHV on parental talk for lower SES parents.

Suskind et al. (in press) also found an increase in measures of child vocalisation. No measure of later language development were taken, however, so assumptions cannot be made about longer-term child language outcomes. As child vocalisations were not measured in the BTHV RCT it is not possible to make a comparison concerning effects of dose on child outcomes at this short-term follow up stage.

The second study, reported by Wake et al. (2011) was a clustered randomised controlled trial on a preventative service for language development for children identified through a screen as being at risk of language delay. This was based on a programme called ‘Let’s learn language’, a modified version of the preventative programme: ‘You make the difference’ (Manolson, 1995). Six two hourly sessions were delivered to participants in this trial. This study did include measures of child
language acquisition, and no significant effect of the intervention was found. Measures of parent talk were not taken in this study.

Caution is needed when interpreting the results of the BTHV with reference to these two studies, as they are all complex interventions with the difficulties cited above. Two factors, however, appear to emerge from the results of these studies. First, there may be a temporary, short-term effect of preventative services for low SES families, and the effect may be increased with increased dosage. As both studies used similar measures a meta-analysis may inform the question of dosage further, but this would require access to the dataset of the Suskind et al. (in press) study. A meta-analysis would also be enhanced by a greater number of studies. The second factor that has emerged from the three studies is that there is currently no evidence of effectiveness at a longer-term level or on child language outcomes from the dosages examined. Due to the very small number of studies in this area, however, it is not possible to be confident with any conclusions, and further research examining different quantities and intensities of dosage may inform the question of whether behaviour can be changed over the longer term.

The third component listed under service delivery is ‘home visit’. The systematic review highlighted that, whilst home visits were carried out in a few cases, the preferable mode of delivery was group based. Home visits were justified for the BTHV on two grounds, to increase the reach of the service (important for universal services) and to facilitate individualised information giving. The question of reach was not addressed in this RCT and further research is required to establish the most appropriate mode of service delivery for family focussed universal speech and language therapy preventative services.

Concerning individualised advice the results of the three studies may also be informative. The BTHV and the Thirty Million words project (Suskind et al., in press) were both based around home
visiting whereas the Let’s learn Language programme reported by Wake et al (2011) was delivered through a group format. The home visit format may have contributed to the short-term effect on parental talk reported in the Thirty Million Words project, and also to the possible effect seen in the subgroup analysis for the BTHV study.

Suskind et al. (in press) report specific individualised quantitative target setting (for parental talk) as part of the therapy approach. Whilst the advice in the BTHV may be adapted to individuals in a home visit (for example, by focussing on different aspects of the information given), the language facilitation strategies promoted were general. Furthermore, as a one-off visit, the option of developing and working towards individualised targets was not appropriate. There may also be limitations to personal tailoring of the service as a result of the staff delivering the service. This is discussed below in this section.

Specific individualised targets have been highlighted as effective in other health promotion practice (National Institute for Clinical Excellence, 2015). Furthermore, specific individualised targets have been identified as a key component of other effective speech and language therapy services (e.g. Gibbard, 1992). The degree to which the individualised advice was the effective component on parental talk in the Suskind et al (in press) study warrants further investigation. Furthermore, the effectiveness of home visiting compared to other modes of service delivery for facilitating individualised advice is an area of interest for complex interventions.

**Target clientele**

The BTHV model is aimed at families of babies aged 6 – 18 months as a universal plus service. The justification for the age of children was on the grounds that from 0 -6 months parents have increased support from health visiting services and that other needs of parents and infants might diminish the effect of the messages about language development. Another justification was based
on the grounds that from around 6 months of age babies’ responses may be much more obvious to parents. They might, therefore, more easily see the effects of changes in their own behaviour on their babies at this age. Children who are older than 18 months may start to access other services, such as preschool and toddler groups. Also, in their second year their comprehension and expression of verbal language begins in earnest. A prevention service, therefore, might be more appropriately delivered before this age. There is not a clear indication from the literature, however, regarding the most appropriate age to offer prevention advice. It is possible that such a service might be more effective if delivered during pregnancy, within the first six months or even at a later stage when children are going through a rapid stage of development. As a sensitive period for language development in infancy has been proposed in the literature (e.g. Kuhl, 2004), it is possible that an intensive dosage intervention at the appropriate age might support the development of the language processing skills children need to acquire new language.

The systematic review did not address the question of the most appropriate age for intervention as the review questions did not address the age of clientele in the services reviewed. Some very limited information concerning the age of children targeted in services was available through the data synthesis, for example, Potter and Barner (2004) reported specific groups for toddlers and babies. The randomised controlled trial did not inform the question of age appropriateness of the service and the question of whether a service such as the BTHV might be more effective if given at a different age remains.

The survey into primary prevention services carried out by Fuller (2010) explored current practice at different ages. She identified a range of services delivered for children up to 12 months and for 13 months and over but again there was no evaluation of the appropriateness of this age. As the possibility of a temporary change in parent talk behaviour has been observed in this study through the subgroup analysis for lower SES families and in the Suskind et al. (in press) study, future
research might investigate whether this short term change might effect change in child language outcomes if the intervention were given at an optimal stage in development (e.g. during a sensitive period).

The target clientele section of the model also highlighted that the service would be delivered as a universal or universal plus service with reference to the Healthy Child Programme (Department of Health, 2009) discussed in Chapter 2, section 2.3. The justification for the universal plus service was based on the higher prevalence levels of primary language delay in social deprived areas, and the BTHV was originally developed to meet the needs of such an area in Portsmouth City. The systematic scoping review encompassed a broad and comprehensive search strategy, outlined in Chapter 2, section 2.2. From this, much of the practice identified was from the National Evaluation of Sure Start Website, highlighting that this practice took place within Sure Start areas, which were identified by the government based on an assessment of social need (Glass, 1999). This suggests that prevention practice is being or has been targeted towards vulnerable populations, as advised by the Royal College of Speech and Language therapists in their model of service provision (Royal College of Speech and Language Therapists, 2006).

Concerning the randomised controlled trial, the difficulties with recruitment highlighted in Chapter 4 have resulted in a larger proportion of higher SES families being recruited into the trial than originally planned. It is difficult, therefore, to draw firm conclusions on the evidence base for lower SES families. The subgroup analysis reported in section 4.2 indicates that there may be a temporary effect of the service on parent talk for families at the lower end of the SES continuum. In order to address questions arising from this study, such as those stated above around dosage and timing of service delivery, future studies involving larger samples of lower SES families would be required.
Service delivery components

The model of the BTHV specified that the service incorporate information, modelling and supplementary resources according to the BTHV protocol. Although the systematic review did not identify a large amount of specific information concerning the type of advice given in other prevention services, the information that was identified was in accordance with that given in the BTHV (e.g. information on language development, and advice on commenting on children’s interest). The results of the randomised controlled trial did not provide any evidence, however, that this information is effective as a general prevention strategy. As discussed above, the information was general language facilitation advice, based on the theoretical underpinnings reported in Chapter 2, section 2.3.1. The possible limitations of generalised advice compared to specific personalised targets was discussed above in this section. In order to explore the potential reasons why this information might not be effective, it is necessary to revisit the current theory on child language development. This discussion may be found below in section 5.3.

Staffing

The model of service delivery identified trained and supervised speech and language therapy assistants to deliver the BTHV. Two assistants delivered the service for the intervention arm of the randomised controlled trial. Given that the randomised controlled trial did not provide evidence to support the effectiveness of the BTHV, it is pertinent to question whether the BTHV might have been more effective if delivered by other staff, for example, qualified speech and language therapists.

The speech and language therapy profession frequently make use of other professionals in service delivery, with a consultative or indirect approach not uncommon in schools (Dockrell, Lindsay, Letchford, & Mackie, 2006). The systematic review did not inform the question of how much prevention practice takes place through third party professionals as the focus was on family
focussed interventions. Fuller (2010), however, noted that training of other professionals, such as Children’s Centres workers, does take place. The assistants involved in the delivery of the BTHV were both employed within the speech and language therapy service, had received full training and development to a knowledge and skills profile and received regular supervision. It might be proposed, therefore, that the quality and fidelity of the service delivery would be equal to or superior to that delivered by professionals working for other agencies who had been trained by speech and language therapists, such as Children’s Centres workers who have a similar qualification levels as the speech and language therapy assistants. It might be suggested, however, that the personalisation of the service is limited if delivered by staff with lower levels of qualifications that are trained to work to a protocolised formula.

The question of the level of qualifications needed in staff delivering prevention services has been raised in the literature for other professions. For example, the Family Nurse Project, a home visiting project aimed at supporting young mothers has demonstrated evidence of effectiveness when delivered by a qualified nurse but not when delivered by unqualified assistants (Olds et al., 2004). It is possible that, similarly, the BTHV might demonstrate more evidence of effectiveness if delivered by a qualified speech and language therapist. It is also possible that the service may be more effective if the information were delivered through a public health practitioner with a higher level of qualification who has a relationship with the family, such as a family nurse practitioner or health visitor. Such professionals may be better placed to identify potential difficulties experienced by families that may influence parent talk or child language development, for example, if a mother was experiencing post natal depression.

The need for further research on the effectiveness of services according to staffing is valuable to the profession. Services are challenged to demonstrate efficiency, particularly in the UK under the current commissioning structure (National Health Service, 2015). Without evidence to the contrary,
the pressure to demonstrate value for money may result in more services being delivered by staff
with lower levels of qualification. This is a particular risk when commissioners are faced with
services providing indicative evidence of effectiveness of services utilising staff with lower levels
of qualifications, such as was the case with the BTHV (Smith & Gibbard, 2011) before this trial.
The results of this study demonstrate that future research with appropriate levels of control, such as
a randomised controlled trial are required in order to support understanding of issues of staffing.

Summary
This discussion highlights that the lack of evidence of effectiveness for the BTHV may be due to
one or more of the components of this complex intervention. It is not possible to determine which
of these components might need to be addressed in order to support child language development.
Through consideration of the results of the randomised controlled trial in the light of other studies
and the systematic scoping review, however, it is possible to shed light on priorities for future
research and development, which are discussed in the next section.

5. 3: Revisiting the theory on language development

5. 3. 1: Review – the theoretical assumptions of the BTHV

The development of the BTHV was based on the theoretical assumptions that were outlined in
Chapter 1 section 1. 4. In summary these assumptions were based on an interactionist /
constructivist approach, with the concept of one process of development as opposed to a dual words
/ rules approach (Tomasello, 2005). The following theoretical assumptions were also made. First,
that one of the skills children bring to bear when developing a language is using statistical learning
(Kuhl et al., 2001; Tsao et al., 2004). Second, that this learning is shaped by social interactions
(Kuhl et al., 2001). The role of linguistic input is significant (Owens, 2012; Snow, 1994) and whilst
children use the input in different ways to construct language (Lieven, 1997), the quantity of
language input influences developing language processing skills (Hurtado et al., 2008; Weisleder & Fernald, 2013). Finally, whilst there is a substantial buffering effect for language learning, allowing many normally developing children to develop the basic core features of grammar despite varying levels of linguistic input (Snow, 1994), there is evidence of the effects of quantity of input, both in the speed of acquisition of vocabulary in the early years (Hart & Risley, 1995; Hoff & Naigles, 2002) and in the absence of more complex syntactic structures amongst children in lower SES communities in later childhood (Moyle et al., 2007).

With this theoretical approach as a basis, the hypothesised effectiveness of the BTHV was based on two assumptions. The first assumption was that, as an environmental feature, the quantity of parental talk to babies could be changed (and this was tested in the randomised controlled trial through the primary outcome measure). The second assumption was that increased parental talk would facilitate increased language gains in children (through providing a rich source of data to the developing child and facilitating development of language processing skills). This was tested through the secondary outcome measure. These two assumptions are discussed, below, in the light of the results of the randomised controlled trial.

Evidence to support theoretical assumptions

Before the assumptions on which the BTHV are based are discussed, it is necessary to consider whether the data obtained in this study provides any support for the underlying core theoretical assumptions. The data does, indeed, provide evidence to support previous research, particularly concerning the relationship between quantity of linguistic input and child language development. A highly significant correlation was found between overall parental talk and size of expressive vocabulary at age two years, and a significant relationship was also found between mean parent word types and child language development (reported in Chapter 4, section 4.2.5). This evidence does not inform further on the nature of the relationship or causation, but the data provides
additional evidence that the relationship exists at an early stage in language development, demonstrated through vocabulary levels at age 2 years.

*Can parental talk be increased?*

The BTHV was based on the hypothesis that it would be possible to change levels of parental talk. The subgroup analysis of the results of the randomised controlled trial found a possible short-term effect, increasing parental word types for families who did not own their home. If this finding were confirmed in larger studies, it may reflect the report by Suskind et al. (in press) that lower SES families in their study have demonstrated short term increases in their talk. Neither this study nor the Suskind et al. (in press) study, however, have demonstrated evidence of effectiveness of changing the quantity of parental talk over the longer term. This raises questions over the potential for any change brought about in parental talk to be maintained.

It is worth considering the comments made by Bishop (2014b) in the light of these findings. As other reports of the relationship between parental talk and child language in the literature are based on correlation studies a cause and effect relationship has not yet been identified. If, as is possible, a third factor is causing both child language and parental talk levels, such as genetic predisposition, then it may be very difficult to alter the parental linguistic behaviour over the longer term. The issue of causation (particularly involving the influence of the environment) needs further research in order to move forward in prevention practice. This is discussed below in this section, with recommendations given for future research. Concerning the potential for parents to change their talk behaviour over the long term, it is important to understand further the nature of parental talk to children within the context of that parent’s overall language abilities. Weisleder and Fernald (2013) reported that, unlike infant directed speech, speech that was not addressed to infants but simply overheard in the background was not related to child vocabulary outcomes. The levels of general talkativeness, however, within families may inform the question of a parent’s ability to talk more to
their infant. Studies exploring the relationship between a parent’s general talkativeness and the quantity of their child directed speech might indicate whether the issue is one of parental language levels or parenting practice behaviours. Furthermore, there have been many studies exploring the relationship between child directed speech and SES. Further research investigating general measures of adult speech (word types and word tokens) when related to SES may also inform this question.

The role of linguistic input in child language development

If a permanent change in parent talk had been observed, the results of the secondary outcome measure, that is child language development, might have informed the question of the role of input into language development further. The theoretical stance adopted in this study was that input does influence language outcomes. In this study, the change in parental talk within individuals and the subsequent differences in child language observed would have addressed the question of genetic predisposition to language levels. The role of genetic inheritance in language development is not disputed but the level of influence parental linguistic input brings to bear on overall child language levels is still debated in the literature (Dale et al., 1998; Snow, 1994). If parents had increased their talk, and this increase had affected child language, then this would have provided evidence to support the influence of linguistic input. As the randomised controlled trial, and the Suskind et al (in press) found only short term temporary gains for low SES families with no evidence of a longer term effect, however, this question remains largely unanswered.

Priorities for future research

The issues raised above place a challenge for prevention practitioners. Further research is needed into both the nature of parent talk and its potential for change and the relationship between linguistic input and child language development. It is suggested that there is enough evidence in the literature to demonstrate a significant role of linguistic input in supporting optimal language
abilities in young children to warrant further investigation into the nature of that role. The thorny issue of the role of genetic inheritance, however, needs to be addressed. This may be done in a number of ways. It would be instructive, for example, to build on the studies examining the relationship between input and language processing skills in parent / child dyads developed by Hurtado et al. (2008) and Weisleder and Fernald (2013) but using dyads without shared genes, such as adopted children and their parents. Another method might be to observe language processing skills in a laboratory setting using nonwords as a stimulus. Finally, studies investigating the long-term language skills of children of parents with an illness which may influence their child directed speech, such as postnatal depression might also inform this relationship further.

Reflections on how this study informs theory

As a piece of applied research, this study is limited in its ability to inform some of the theoretical questions highlighted above. Basic research, which is able to manipulate covariates within an experimental setting is more suited to address focussed questions, such as those examining the role of genetic inheritance and the role of linguistic input in child language development. As discussed above, the complex nature of the BTHV as an intervention results in many covariates being possible candidates responsible for retaining the null hypotheses.

The results of this study, however, do provide a contribution to the wider evidence being developed on parent talk and child language. As applied research, the aim of this study was to investigate a possible intervention to support language development in children identified as vulnerable. Taking a broader perspective than much basic research, therefore, this study has been able to highlight some of the priorities for research concerning both theory and clinical practice.
5. 4: The evidence base for speech and language therapy practice for primary language delay

5. 4. 1: How this study contributes to the evidence base for primary prevention

Before discussing the contribution of this study to the field of prevention of primary language delay in speech and language therapy, the reader is reminded that the focus of this study was particularly on practice that is delivered directly to the family, that is universally delivered (albeit within vulnerable populations), and is specific to speech and language therapy practice. Within these constraints, this study has contributed to the evidence base in two key ways. First, the systematic scoping review reported in Chapter 2, section 2. 2 provides a broad picture of current and recent clinical practice, particularly within the UK. The review also highlighted the limited evidence base in this field. Second, the randomised controlled trial failed to provide evidence to support the hypotheses that parent talk could be increased over the long term through the BTHV or that child expressive vocabulary could be increased at age 2 years by the BTHV. The RCT highlighted, however, a potential short-term effect on parental talk for parents from lower socioeconomic backgrounds.

Whilst this study cannot prove a null (that is, that the service is not effective) the lack of evidence when tested in this study is informative to the profession. In light of the discussion on evidence-based practice reported in Chapter 2, section 2. 1 of this thesis, studies that do not reject the null are considered to be valuable sources of information. This is evident in the academic and clinical arena. For example, the British Medical Journal welcome studies with negative results, provided that the study design is robust (British Medical Journal, 2015). As stated in Chapter 2, section 2. 1. 3, the risk of only promoting positive findings in the literature is that interventions which are potentially not effective may become part of routine clinical practice and even part of the ‘folklore’
of the profession (Lof, 2011). Goldacre (2014) goes as far as to state that when an ineffective service is provided where effective services are available, then this results in harm being done to clients.

The findings of the randomised controlled trial reported in this thesis may inform the evidence base further in the light of the two other initiatives discussed above in section 5.2, namely the adapted ‘You Make the Difference’ programme reported by Wake et al. (2011) and the “Thirty Million Words’ project reported by Suskind et al. (in press). These studies did not fulfil the criteria for the systematic scoping review because they were not delivered by speech and language therapists (Suskind et al., in press) or were based on a referred sample based on a language screen (Wake et al., 2011). The findings of these studies in conjunction with the results of the BTHV randomised controlled trial, however, may inform the overall discussion on the effectiveness of preventative services. Currently, despite these studies, there remains little evidence for the effectiveness of specific speech and language prevention initiatives targeted at facilitating the family environment.

The focussed nature of the inclusion and exclusion criteria in the systematic scoping review has enabled a clear picture of speech and language therapy provision to emerge. Consideration of the value of the studies reported above, however, does highlight a limitation in the review design. A way around this might be for future reviews not to isolate the service based on the profession but rather to target the intervention. Concerning systematic review methodology, however, it is inevitable that whichever way inclusion and exclusion criteria are framed, studies that may shed light on the review question may be omitted.
5. 4. 2: The way forward for prevention of primary language delay

Future research into the effectiveness of the BTHV in its current form is not justified as this study found inadequate evidence of long term effects on parental talk or on child language outcomes. Furthermore, the results indicate that low intensity, general advice services promoting parental talk to children are unlikely to effect change in parental linguistic behaviour or child language acquisition. Research into the effects of giving the information in a higher dosage, at a different stage of child development or through different staff, however, may inform the future development of prevention initiatives. The study also highlighted priorities for further basic research to understand the mechanisms underlying the relationship between parent talk and child language development (highlighted above in section 5. 3). Other areas of research might include investigation into specific activities which parents might be supported in which result in increased talk, e.g. book sharing, attendance at parent / toddler groups or singing nursery rhymes.

The field of prevention does not only include family focussed interventions. Further research is already demonstrating evidence of effectiveness of interventions that take place in early years settings (Dockrell, Lindsay, Roulstone, & Law, 2014; Farmer & Griffiths, 2006; Fricke, Bowyer-Crane, Haley, Hulme, & Snowling, 2013; Hobbs, 2006). Continued research into education setting based interventions, including the longer term follow up of children involved in interventions would be valuable to the field of prevention in speech and language therapy. Furthermore, as highlighted in Chapter 2 (section 2. 1), whilst an effective screening instrument has not yet been developed (Law et al., 1998; Maas, 2000; Nelson et al., 2006), efforts to seek ways to identify children at risk of SLI at an early stage, through continued research into the underlying language processing skills necessary for language development would also support preventative initiatives. This is particularly pertinent considering the highly influential role of genetic inheritance. Research examining genetic
and behavioural risk factors in the early years may inform appropriate provision for children identified as being at higher risk for SLI.

5.4.3: Reflection on developing and evaluating complex interventions using the MRC (2000, 2008)

The guidelines for developing and evaluating complex interventions have provided a framework for the development and evaluation of the BTHV. Using the framework as a template, it has been possible to chart the stages in the development of the service, and to gather appropriate information before moving on to the next stage (as in the case of the systematic review reported in section 2.2 and the feasibility pilot study reported in section 3.2). Reference to advice in the guidance, as well as guidance provided by the Cochrane Collaboration (Armstrong et al., 2011; Higgins & Green, 2011) and the CONSORT statement (Schulz et al., 2010) have resulted in the development, delivery and reporting of a robust, objective randomised controlled trial.

The need for controlled studies in speech and language therapy intervention research has been demonstrated in this study. The BTHV was previously considered to be potentially effective through indicative evidence (Smith & Gibbard, 2011). When subjected to a controlled and randomised study design, however, no evidence of effectiveness was found. Controlled studies, and particularly RCT’s remain relatively rare in speech and language therapy research. The value of quantitative research depends on the objectivity of study designs. As discussed in Chapter 2 (section 2.1), the potential for bias in many studies limits reliability of the outcomes. One of the strengths of this study is the reliability of the data through considered control of potential bias (through randomisation, blinding and reporting according to the CONSORT statement (Schulz et al., 2010). Given that the results of the RCT do not support the indicative evidence reported by Smith and Gibbard (2011), the effect of potential bias in the early evaluations has been highlighted,
therefore supporting calls in the literature for careful critical appraisal of current evidence, as well as appropriate research design for future studies (Lof, 2011). The tools used in this study have provided a robust framework for the systematic review and randomised controlled trial design and, in conjunction with qualitative studies, they are recommended for future speech and language therapy intervention research.

One potential area of development was highlighted in the systematic scoping review, which reported the use of parental evaluation forms as a common first stage in evaluation of innovative practice. The quality of these evaluation forms, however, could not be assessed due to a lack of information in the reports. Given that there is a recognised gap between clinical practice and research (Royal College of Speech and Language Therapists, 2014) it is suggested that early indicative evidence might be enhanced if clinicians adhered to robust methods of questionnaire based evaluation. Such guidance is readily available (Huxley & Mohamad, 1991; Tsai & Chai, 2005). Whilst parental feedback may not provide objective evidence of effectiveness, a well-designed and reported questionnaire would provide a reliable indication of parental views and satisfaction levels. This has a number of benefits. First, it contributes to the model of evidence based practice proposed by Dollaghan (2007) and highlighted in section 2.1, as it provides reliable evidence of the views of the clients. Second, it contributes to avoiding unnecessary waste as research based on interventions evaluated in this way would be reported to be relevant to service users. Third, some questionnaires may provide some initial indications of how an intervention may be effective, which may then be investigated further in objective studies.

Another potential area for development highlighted in this process is for the profession to support the modelling of complex interventions and evaluation of components of models. The modelling of the BTHV not only supported replicability, but also facilitated discussion of the results and aided consideration of priorities for future research. Development of specific guidance for speech and
language therapists seeking to build a model of their services would not only contribute to service fidelity but also supports the development of evidence according to MRC (2008) guidelines.

This study was a continuation of the development of evidence on effectiveness of the BTHV. Previous evaluations had suggested that the BTHV may be an effective service (Smith & Gibbard, 2011; and submitted). These previous studies provided evidence of positive parental feedback, and some indication of increased language development. They represented evidence at Phase II on the original MRC model of evidence based practice for complex interventions (Medical Research Council, 2000). Whilst the later guidance from the MRC (2008) emphasizes a more cyclic model without specific stages, it is generally accepted that there are different levels of quality of evidence. The earlier reports of the BTHV provided indicative evidence. As the RCT failed to provide evidence of effectiveness, however, the need for objective evaluation of clinical innovations at this level of evidence is highlighted, as stated above. The value of the MRC (2000, 2008) guidance on the development and evaluation of speech and language therapy services has therefore been demonstrated in this study.
6. 1: Conclusion: The contribution of this study to evidence based practice in prevention of primary language delay

The systematic scoping review of family focused preventative practice for primary language delay, and the development and evaluation of the BTHV has informed the evidence base for universal and targeted paediatric speech and language therapy services. The systematic review has demonstrated the scope of practice and highlighted the current state of the evidence base. The RCT has demonstrated that the BTHV in its current form may have a temporary effect on parent talk for parents who are from lower socioeconomic backgrounds. If this temporary effect is found in future research to affect child development (through being delivered in a different dose or at a different stage in the child’s development) this may warrant further research. In its current form, however, the results suggest that it is unlikely to change parental talk behaviour in the long term, or be effective in supporting child language development. In addition, analysis of the results in the light of the current theory, model of the BTHV and guidance on evidence-based practice has provided some clear avenues for potential future research, as discussed in Chapter 5. Finally, as stated above, it has demonstrated the critical role of controlled trials in service evaluation.

6. 2: Final and personal reflections

The implications of this research are valuable to the speech and language therapy profession. Within the UK, at a time of austerity and with the introduction of ever more competitive commissioning of services, speech and language therapists are being expected to do more with fewer resources. In addition, there have been calls to change practice to provide a more universally available service (Law et al., 2013). The systematic scoping review provided evidence that speech and language therapists have risen to these challenges. In this climate, it is tempting to provide low
cost interventions that, on the surface, appear to be effective and are valued by service users. The challenge for clinicians is to subject their innovations to scrutiny. Indicative evidence of effectiveness for services is informative and provides a platform for further development and evaluation of services. It is recommended, however, that establishment of evidence does not stop at the indicative stage as this study has demonstrated the potential for this early evidence to bias.

It is not easy for clinicians to investigate interventions using controlled trials. Currently, within the clinical environment, there are a considerable number of barriers to carrying out high quality research. First, the development of innovative practice has a personal element. It may be tempting to remain in a position where the very service one has developed, and potentially, therefore, has allegiance to, appears to be effective through an uncontrolled evaluation study. This barrier to evidence may be further enhanced if team members are also involved in service delivery or if the service has a brand that is of value to the organisation. The author was asked by concerned members of the speech and language therapy department on a number of occasions what would happen to the service if the trial found no evidence of effectiveness. Conducting this study has involved the challenge of sacrificing any personal pride in the development of the BTHV in the pursuit of robust evidence of effectiveness.

Other obstacles are also faced concerning the delivery of controlled trials in clinical practice. One of these is the fact that services such as the BTHV are often commissioned. If found to be ineffective, there is a risk of financial loss to organisations. There is, therefore, a pressure to provide positive evidence for services developed in clinical practice, which may have implications for bias in intervention evaluation studies. This is particularly pertinent in a competitive environment where many speech and language services are commissioned on the basis of indicative positive evidence. Another risk arises from the practical challenges of continuing a trial in a constantly changing political, economic and organisational landscape. These challenges provide very real obstacles to
research, as was found, particularly with recruitment, in this study. These barriers were present despite funding of the project by the NIHR and a formal declaration of support from the relevant organisations. A final challenge to research in clinical practice is that research may be considered by some to be an unnecessary luxury at times when clinical service commissioners and providers are under pressure to provide increased efficiencies in times of austerity.

The consequences of not promoting continued research and development according to the standards highlighted by the MRC, however, are that speech and language therapists cannot be sure of the effectiveness of the services delivered. Furthermore, lack of modeling of studies in conjunction with controlled research limits the ability to evaluate the critical components of complex interventions, such as the dosage, timing and resources required in interventions. It might be argued that, due to the constraints of the clinical environment, research is better situated within an academic environment. The benefits of research active clinical practice, however, include the development of a research active and research aware clinical workforce, appropriate critical appraisal skills amongst service providers, research developed that is relevant to clinical practice and an increased pool of potential research participants.

Cognisant of the barriers to research and development within clinical practice, therefore, it is necessary to foster a clinical environment that values research and considers it as an integral part of service delivery. In the UK, the NIHR is addressing this challenge by supporting clinical academic career pathways hosted within NHS Trusts (National Institute for Health Research, 2015). Despite the increased awareness of the need for evidence of effectiveness of therapy approaches, however, the gap that exists between clinical practice and research is still wide. It is postulated that until clinical research is embraced within the clinical environment and prioritised by commissioners, the gap will not close. This would be facilitated if provider organisations and NHS commissioning bodies worked together to further the development of a research active culture in within the clinical
environment. Funding organisations such as the NIHR might support this through recognition of or incentivising commissioning bodies. This would benefit both clients, through future research into best practice and practitioners through continued professional development.

Through this study it has been possible to gain experience in developing an evidence base for speech and language therapy services. The process is challenging but by opening up clinical services to robust scrutiny the speech and language therapy profession can continue to develop effective services for the benefit of their clients.
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LIST OF APPENDICES

Appendix 1  Checklist for developing a search strategy  254
(Naumann, 2007)

Appendix 2  Systematic Scoping Review Data Chart:  255
2a- Nature of Service Delivery
2b – Information given and method of evaluation

Appendix 3  Smith and Gibbard (2011)  259

Appendix 4  Smith and Gibbard (submitted)  275

Appendix 5  Documents approved by Berkshire REC  287
5a and b letters giving favourable ethical approval from Berkshire REC
5c Study protocol  292
5d Invitation letter (pilot study)  299
5e Study advertisement poster  300
5f Information sheet (pilot study)  301
5g Invitation letter (main study)  306
5h Information sheet (main study)  307
5i Consent form  312

Appendix 6  Pilot study: Boxplots showing variance of frequencies across participants measures of total utterances, word tokens and word types  314

Appendix 7  Video information sheet – main study  316

Appendix 8  An example of a standard measures report from SALT  317

Appendix 9  CDI – Words and Sentences (British Adaptation) (Klee & Harrison, 2001)  318

Appendix 10  Post hoc analysis boxplots  327
### Appendix 1: Checklist for developing a search strategy (Naumann, 2007)

<table>
<thead>
<tr>
<th>Checklist items</th>
<th>Completed for this study</th>
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</thead>
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<tr>
<td>1. Define text words</td>
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<td></td>
<td>Language delay</td>
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<tr>
<td></td>
<td>Children</td>
</tr>
<tr>
<td>2. Determine synonyms for the text words</td>
<td>Health promotion</td>
</tr>
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<td></td>
<td>Language disorder</td>
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<tr>
<td></td>
<td>Toddler</td>
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<tr>
<td>3. Control for different spellings or using appropriate truncations</td>
<td>Promot*</td>
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<td></td>
<td>Prevent*</td>
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<td></td>
<td>Child*</td>
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<td>Toddler*</td>
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<td>Infant*</td>
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<td></td>
<td>Language dev*</td>
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<td></td>
<td>Language delay*</td>
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<td></td>
<td>Language disorder*</td>
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<tr>
<td>4. Consider brand names when searching for a specific drug treatment</td>
<td>N/A</td>
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<td>5. Perform test searches – I</td>
<td>Language promotion</td>
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<td></td>
<td>Health promotion</td>
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<td></td>
<td>Prevention</td>
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<td>Language delay</td>
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<td>Language disorder</td>
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<td>Language development</td>
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<td>6. Identify “controlled vocabulary” (keywords) used for the indexing of databases (MeSH for MEDLINE, EMTREE for EMBASE)</td>
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<td>Health promotion</td>
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<td>Prevention</td>
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<td>7. Decide on whether to perform an “exploded” or a “focussed” search for keywords</td>
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<td>8. Check if all words are spelled correctly</td>
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<tr>
<td>9. Combine logically all search terms</td>
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<td>10. Perform test searches – II</td>
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<tr>
<td>11. Customise the syntax of your search strategy to the specific databases</td>
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### Appendix 2a: Systematic Scoping Review Data Chart - Nature of Service Delivery

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<th>Author</th>
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<th>Other group</th>
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<th>Training</th>
<th>Leaflets/CD/Toy/DVD</th>
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</tr>
<tr>
<td>The Fence at the top; Plymouth</td>
<td>2009</td>
<td>Conference, TTYB</td>
<td></td>
<td></td>
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<tr>
<td>Time to Talk, Warwickshire</td>
<td>2009</td>
<td>Conference, TTYB</td>
<td></td>
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<tr>
<td><strong>Totals</strong></td>
<td></td>
<td></td>
<td>13 18 1 10 2 6 3 15 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>
Appendix 3: Smith and Gibbard (2011) Babytalk Home Visits: Development and initial evaluations of a primary prevention service Child Language Teaching and Therapy 27(1) 66-83

Baby talk home visits: Development and initial evaluations of a primary prevention service

Clare Smith and Deborah Gibbard
Speech and Language Therapy Service, Solent Healthcare, Portsmouth, UK

Abstract
Language delay is a common developmental difficulty. Research indicates that it is influenced by environmental factors, particularly social deprivation, but that a parent’s interaction protects children’s language development against these factors. It is hypothesized that by supporting parents’ interaction, language development may be facilitated. This study aims to evaluate a preventative intervention for language delay. The Babytalk Home Visiting (BTHV) service was developed and delivered in Portsmouth, UK from 2003 to 2007. Two separate evaluations of the BTHV service were carried out, the first using parent questionnaires and the second using a comparative evaluation of parent ideas and child-language outcomes. In the first evaluation parents indicated that they valued the information given in the BTHV service, and 72.5% stated they would change their communication behaviour according to advice given. In the second evaluation, parents who reported receiving the BTHV service gave a significantly greater number of ideas on how to encourage language development, and reported a significantly higher child word count than parents who had not. The results of these evaluations suggest that this preventative initiative may be beneficial; however, limitations of the evaluation findings are discussed, and it is concluded that controlled comparative research is required to establish the effectiveness of such approaches.

Keywords
health promotion, language development, language delay, public health, socio-economic status

I Introduction
1 Prevalence of primary language delay:
Primary language delay remains one of the most prevalent developmental delays in early childhood (Hall and Elliman, 1996). The exact prevalence is debated, and Enderby and Pickstone (2005) cite a number of studies that give differing levels. Law et al. (1998) reviewed the literature and found

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Appendix 3: Smith and Gibbard (2011) Babytalk Home Visits: Development and initial evaluations of a primary prevention service Child Language Teaching and Therapy 27(1) 66-83

Smith and Gibbard

Prevalence figures ranging from 0.6% to 33.2%. It is also recognized that in some communities this figure is higher. For example, in an area of high social deprivation Locke et al. (2002) found that over 65% of children entered nursery with a mild language delay or worse. Pickstone (2004, cited in Enderby and Pickstone, 2005) found a prevalence in a disadvantaged area of 31%, based on direct testing.

2 Long-term implications for speech and language delay

The long-term outcomes for individuals with primary language delay have also been documented. Rescorla (2005) found that late talking toddlers fare worse at school than normally developing peers, but not as poorly as children with specific language impairment. In her summary of literature on outcomes for children with speech and language difficulties Clegg (2006) cites language difficulties, low socio-economic status (SES) and low IQ as particular risk factors for poor outcomes later in life.

Educational outcomes are not the only factors affected by language delay associated with low SES. Persisting speech and language difficulties can lead to emotional and behavioural difficulties (Qi and Kaiser, 2004; Stringer and Clegg, 2006). Furthermore, there is some evidence to suggest a link between speech and language difficulties and anti-social behaviour, and between language levels and employment prospects (Clegg, 2006). In a study by Bryan et al. (2007) a much higher prevalence of communication and language difficulties was seen in a sample of young offenders than is seen in the general population, indicating that language abilities may be a potential risk factor for antisocial and criminal behaviour.

3 Language development and environmental effects

It is widely accepted that a child’s environment influences his or her language development, and this is reflected in the increased prevalence of language delay reported in areas of low SES as stated above. The most significant factor in a child’s environment is his/her main caregiver, and the interactions that that caregiver has with the child. Hart and Risley (1995) found that the amount of language that children heard from their caregiver, and subsequently produced, was directly related to their SES. The negative effects of low SES, however, can be minimized by a protective caregiver environment. In a regression analysis Raviv et al. (2004) found that parenting factors (maternal sensitivity and cognitive stimulation) were partial mediators of the relation between SES and language skills. These findings are supported by other studies. For example, Gutman and Feinstein (2007) found that whilst parenting factors are influenced by SES, increased parental facilitation of language acted as a protective factor for language against the effects of SES. Sylva et al. (2004) also reported that parental participation outweighed the effects of social class or parental education. Blanden (2006) concurs that the level of parental interest is important in determining what enables those who are disadvantaged in childhood to succeed later in life, with this being linked to higher early test scores in children.

4 Facilitative factors in the caregiving environment

The studies discussed above illustrate that aspects of the parenting environment can support language development. Specifically, the amount of language spoken to children is shown to be related to their language development (Hart and Risley, 1995; Hoff and Naigles, 2002). The effect of interactional style has also been shown to influence language development, such as following a child’s lead in interaction, and commenting on a child’s topic of interest (Tomasello and Todd, 1983;
Appendix 3: Smith and Gibbard (2011) Babytalk Home Visits: Development and initial evaluations of a primary prevention service *Child Language Teaching and Therapy* 27(1) 66-83

### Table 1: Butler’s (1989) three levels of prevention

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary prevention</td>
<td>Focus on health promotion, in order to prevent the onset of a disease/impairment</td>
</tr>
<tr>
<td>Secondary prevention</td>
<td>Focus on early detection and intervention, to shorten the duration of impairment and therefore limit its effects on an individual</td>
</tr>
<tr>
<td>Tertiary prevention</td>
<td>Focus on reducing the impact of longer term impairment on an individual</td>
</tr>
</tbody>
</table>

Hoff-Ginsberg, 1987; Tamis-LeMonda et al., 1996). For example, in an experimental setting Tomasello and Farrar (1986) found that 17-month-old children learned words more easily when an item in their focus of attention was labelled, rather than an item not in their immediate focus. The effects of child-directed speech (CDS) are also debated in the literature. Tomasello (2003) concluded that CDC is not necessary for language acquisition, but it may speed up the process. Matychuk (2005) argues that CDS is the most important factor related to successful language development that an infant encounters.

There are also certain parenting activities that families engage in that are considered to support language development. These may link intrinsically with aspects of interaction in the parenting environment as described above. Ginsborg (2006) discusses the importance of play to a child’s cognitive, physical, social and emotional development, highlighting that play offers the opportunity for parents to engage fully with their children. Singing nursery rhymes has been associated with increased language outcomes (Bryant et al., 1989; Roulestone et al., 2002). Whilst the benefits of sharing books are debated in the literature (for a review, see Scarborough and Dobrich, 1994), sharing books with young children has been positively associated with language development, and with later academic achievement at school in a number of studies (Morag et al., 1998; Moore and Wade, 2003; Boyce et al., 2004). Dunning (1994) argued that it is aspects of adult-child interaction that takes place during book sharing that may be significant in promoting language development, a factor that had been overlooked in many studies.

### 5 Challenges for intervention

There is clearly therefore a need to address the speech and language needs of children in order to reduce the prevalence of persisting language delay, and therefore ameliorate the longer-term effects. Law argued that given the negative consequences of speech, language and communication difficulties on so many factors, the promotion of language development is a ‘public health issue requiring a public health response’ (Law, 2006: 141). Public health services have indeed been interested in the language development of young children, and universal health services such as health visiting have given advice on supporting language as part of their role for some time.

Speech and language therapy services have also been aware of the need to support language development at an early stage. The effectiveness of early intervention has been highlighted (Gibbard, 1994; Law et al., 2003). However, speech and language therapy advice has historically been available only for children for whom there is a developmental concern. To illustrate using Butler’s (1989) three levels of prevention (see Table 1), speech and language therapy has historically intervened at levels 2 and 3, with level 1, that is primary prevention, being provided by the universal services without speech and language therapy support.

Development of primary prevention initiatives within the speech and language therapy service in the UK has taken place within the last decade, largely as a result of external funding from government
sources, such as Sure Start. The nature of these services is diverse, consisting of training courses, work within nurseries, parent and toddler groups, large-scale public relations initiatives and home visits.

This article aims to describe the development, delivery and evaluation of a primary prevention speech and language therapy initiative that has taken place in a local Sure Start programme in Portsmouth, UK: the Babytalk Home Visiting (BTHV) service.

The BTHV service was developed in 2003 by the authors as part of the speech and language project for Sure Start Somerstown, a Sure Start programme in Portsmouth City, UK. Sure Start is a UK government funded multi-agency programme aiming to support parents and young children in order to reduce the negative effects of child poverty and social exclusion (Department for Children, Schools and Families, 2010).

It was hypothesized that by giving parents information about language development and how this can be facilitated at home through a preventative advice giving service, parents would increase their knowledge and skills in this area and would adapt their parenting environment to facilitate language development in their child. It was also hypothesized that this would lead to increased language levels in their child.

II Method

1. Procedure and service delivery:

The BTHV service was developed following initial consultation with local health and social care professionals with the following aims:

1. to increase caregivers’ awareness of language development, in particular developmental milestones;
2. to illustrate to primary caregivers the reasons why it is important to encourage language development in children;
3. to illustrate ways in which language development can be facilitated through interaction and parenting activities;
4. to support families in accessing the speech and language therapy service when appropriate.

2. Staff development

The service was delivered by the speech and language therapist (SLT) and a speech and language therapy assistant (SLTA) employed for the Sure Start Programme. The SLTA followed a development programme in line with a knowledge and skills profile, which outlined the following areas:

1. communication development from 0–2 years of age, covering play, attention and listening, non-verbal development, comprehension, expressive language and speech;
2. the effect of the environment and SES on language development;
3. aspects of interaction and activities highlighted in the literature as supporting language development;
4. the SLTA’s own communication skills, and engaging with parents;
5. administrative procedures and awareness of relevant policies, including lone working, confidentiality and safeguarding children.

A copy of the knowledge and skills profile is included as Appendix 1. Knowledge and skills in these areas were gained through attendance at courses, reading, workshops with the SLT and shadowing
other Sure Start programmes. The SLTA shadowed the SLT delivering the initial BTHV services. Her competence was then assessed using role-play sessions with the SLT and through a BTHV service delivered by the SLTA and shadowed by the SLT. At this stage, the SLTA was signed off as competent and began delivering the majority of the BTHV services. Over 90% of the BTHV service were delivered by the SLTA (the remainder by the SLT).

3 Participants

The service was marketed to all parents in the area through baby clinics and other parent groups, and referrals were received from Health Visitors. From 2004, the SLTA also attempted to contact all families on Health Visitor’s birth lists of children aged 6 months registered with the Sure Start programme who had not already been referred or requested a BTHV service. Whilst the aim of the service was to offer the visit to all families in the area with a baby, due to the high levels of transfer in and out of the area (25% mobility), this was not possible. It was also only possible to contact families registered with Sure Start Somerstown (due to data protection and information-sharing guidelines). However, as registration levels in Somerstown were high (over 80%), this meant that a large number of families were contacted.

4 The nature of the visit

The SLTA contacted families when the child was 6 months of age, and offered a home visit at a mutually convenient time. She then visited the family and spent around 60 minutes with the primary caregiver. The baby did not have to be present, but if he/she was, the SLTA would model activities with the baby. Advice was given to the parent on the following areas:

- normal language development from birth to two years, covering eye contact, non-verbal communication, turn-taking, cooing and babbling, comprehension of language and expressive language;
- benefits of caregivers encouraging language development, including increased vocabulary, increased attention and listening skills, narrative development and educational and social benefits;
- information on facilitative interaction, including following the child’s lead, copying babbling, special time, talking through everyday routines and child-directed speech;
- parenting activities that encourage language development, including sharing books, singing nursery rhymes, with examples of age-appropriate toys and books.

Families were given a CD of nursery rhymes, books and information leaflets to support the advice given in the BTHV service. They were also given information about local parent and baby groups. Finally, parents were advised how to contact the speech and language therapy department if they were concerned about their child. A record of the visit was completed for file in the health visitor’s case notes.

5 Monitoring and evaluation of the service

Monitoring of the number of BTHV services offered took place via the Sure Start monitoring database. The effectiveness of the BTHV service was evaluated in two ways:
Appendix 3: Smith and Gibbard (2011) Babytalk Home Visits: Development and initial evaluations of a primary prevention service *Child Language Teaching and Therapy* 27(1) 66-83

Smith and Gibbard

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*a Method 1: Parental feedback questionnaires*: Parents who received a BTHV service were given a questionnaire to complete (verbally or in writing) at the end of the visit. Translators or bilingual co-workers were involved when needed. Questions included whether the parent felt they knew more about language development and how to facilitate it, and whether they might do anything differently as a result of the visit. The questionnaire included an open section where parents were invited to record what they might do differently. The questions asked are provided in Appendix 2. Frequencies of response types were calculated for the yes/no questions. Responses to the open questions were grouped into themes (e.g. responses about talking to their child, looking at books, singing nursery rhymes), and percentages of overall responses calculated. Parents were also given an opportunity to give additional comments about the service.

*b Method 2: Language measures and additional questions*: The Revised Sure Start Language Measure (SSLM-R; Sure Start Unit, 2003) is a parental report of language that is carried out when a child is aged 22–27 months. The SSLM-R was developed for evaluation of Sure Start Programmes in the UK, and is derived from the Parental Evaluation of Developmental Status (PEDS; Glascoe, 1997) and the MacArthur parental inventory (Fenson et al., 2000). It contains questions about parental concern about general and language development as well as a list of 50 sample words. Parents report whether their child is able to say each of the 50 words. Additional information was also collected, such as educational level of parent and age of child in months. Collection of data on children’s language levels using the SSLM-R was required by all Sure Start programmes up to and including 2007 for regional and national evaluation of Sure Start targets.

During one financial quarter each year between 2004 and 2008 families living within the Sure Start area with a child aged between 22 and 27 months were contacted for the purpose of carrying out the SSLM-R. Families were selected from a database of families registered with the programme with children at the appropriate age. A minimum of 60 completed SSLM-Rs was required per year for the Central Sure Start Evaluation purposes (Sure Start Unit, 2003). In order to achieve this figure, all the children on the Sure Start Somerset database aged between 22 and 27 months during that financial quarter were contacted. As the primary requirements for collection of data using the SSLM-R were not to evaluate the BTHV service, families were not selected on the basis of receipt of a BTHV service, and the persons administering the SSLM-R did not know whether the families had received a visit or not prior to asking the parents.

In order to gain a more objective measure of the effect of specific initiatives developed by the speech and language project, however, including the BTHV service, additional questions were added to the SSLM-R in Portsmouth. These included questions such as ‘Have you had a Babytalk visit?’ The additional questions also included an open question ‘What do you think parents/carers can do to help their child learn to talk?’ A copy of the additional questions is provided in Appendix 3.

Responses to the question ‘What do you think parents/carers can do to help their child learn to talk?’ were assigned one mark for every different idea a parent gave that was in accordance with consensus from the speech and language therapy service (i.e. a parent would get one mark for ‘talk to your baby’, but not for ‘correct their speech’). Consensus was achieved through discussion between therapists within Portsmouth City, and with reference to the literature on facilitating language development. Table 2 outlines ideas that were considered by consensus to be beneficial or not beneficial for language development. A total score for number of different parent ideas was then given for each questionnaire.

In Portsmouth, all reports were gained verbally, with over 95% being obtained by face-to-face interview with the parent. Face-to-face interviews are reported to contribute to increased reliability
of the report (Roy et al., 2005). These interviews were carried out by a range of professionals who worked for projects commissioned by Sure Start Somerstown (seven separate projects with up to 10 staff). Inter-rater reliability tests were not carried out, but all staff involved followed the administration guidance stated in the SLM-R guidance manual (Sure Start Unit, 2003). Furthermore, staff were advised when asking the additional questions not to prompt parents or suggest ideas in response to the open question.

6 Data analysis for evaluation method 2

Data from the SLM-R and additional questions was entered, verified, and analysed using SPSS (version 14). Analysis of covariance (ANCOVA) was selected to assess the effect of receiving a BTHV service on the reported word count in the SLM, and the number of appropriate parent-generated ideas about language facilitation. This statistical test was selected because it enabled comparison of 2 groups (i.e. participants who had reported receiving a BTHV service with participants who had not), whilst partialling out the effects of covariates reported in the literature as influencing language development. A regression analysis was not selected due to the uneven group sizes, but ANCOVA was possible as the data in each group were normally distributed. To assess reported word count, the ANCOVA partialled out the effects of age of child, gender of child and education level of the main carer. Roy et al. (2005) found that gender and age in months had a significant effect on word count on the SLM-R. Furthermore, education level of the main carer is a widely reported influencing indicator of SES, which is also reported to affect language development (Hart and Risley, 1995).

To assess the number of appropriate ideas on language facilitation, the ANCOVA partialled out the effects of gender of child, education level of main carer, and position of child in family. The position of the child in the family was included as it was postulated that previous experience of parenting may contribute to increased knowledge of child development. The gender of the child was also included as a covariate as it has a significant effect on the child’s own language development (Roy et al., 2005), and therefore may affect the reciprocal interaction from the parent.

III Results

1 Monitoring

Between January 2003 and December 2007 350 visits were delivered in the Sure Start Somerstown area. This results in an average of 70.2 visits per year. A breakdown of number of visits given per year is as follows:

<table>
<thead>
<tr>
<th>Year</th>
<th>Visits</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003</td>
<td>100</td>
</tr>
<tr>
<td>2004</td>
<td>110</td>
</tr>
<tr>
<td>2005</td>
<td>120</td>
</tr>
<tr>
<td>2006</td>
<td>130</td>
</tr>
<tr>
<td>2007</td>
<td>140</td>
</tr>
</tbody>
</table>
Appendix 3: Smith and Gibbard (2011) Babytalk Home Visits: Development and initial evaluations of a primary prevention service Child Language Teaching and Therapy 27(1) 66-83

2 Evaluation method 1: Parental questionnaire

Of the 351 visits that were carried out, 349 questionnaires were completed by parents. When asked if they felt that they knew more about Language Development, 94.6% respondents answered that they did. 72.5% respondents stated ‘yes’ to the question ‘Will you do anything differently as a result of this visit?’ and 62.2% stated on the evaluation form what they would do; responses included talking more to their baby, spending a special time with their baby each day, singing nursery rhymes and reading books (see Figure 1). When asked if they knew how to get help if needed, 96.8% of respondents stated that they did.

When asked how satisfied parents were with the BTHV service, 91.1% rated their satisfaction at 5 out of 5, where 5 is most satisfied. Comments given by parents included: ‘I feel more confident about what I’m doing and have lots of ideas about new things to do’ and ‘Very helpful and I’ve learned a lot about baby language.’

3 Evaluation method 2: SLM-R with additional questions

Between 2003 and 2008 135 SLM-R reports with additional questions were collected for children living in the Sure Start area aged 22–27 months. Of these, 46 parents reported that they had received a BTHV service when their child was younger, and 87 parents reported that they had not.

a Effect of reported BTHV service on parent ideas to encourage language: One hundred and thirty-two SLM-R papers with additional questions were valid for analysis (three were not valid due to missing data). Parents who reported that they had received a BTHV service gave significantly more ideas to encourage language (mean = 3.15, SD 1.738) than those who reported that they did not (mean = 2.03, SD 1.536), when controlling for education level, gender of child, and position of child in the family ($F(1,127) = 8.00, p = 0.005$). Additionally, parents with a higher level of education had significantly more ideas than less educated parents ($F(1,127) = 8.192, p = 0.005$). There was no evidence to suggest that gender of child ($F(1,127) = 0.897, p = 0.345$) or position of child in the family ($F(1,127) = 1.820, p = 0.18$) had an effect on the amount of parent ideas given. The means of number of ideas with standard deviations for each group are shown in Table 3.

b Effect of BTHV service on child’s reported word count: A total of 133 questionnaires were analysed (with 46 stating that they had had a BTHV service, and 87 stating that they had not). Two questionnaires were not valid due to missing data. Children of parents who reported receiving a BTHV service had a significantly higher reported word count (mean = 30.70, SD 13.625) than children of parents who reported that they had not (mean = 25.38, SD = 11.755), when controlling for gender, age and parental level of education ($F(1,128) = 4.859, p = 0.029$). All covariates were also found to be significant: girls had a significantly higher word count than boys ($F(1,128) = 17.169, p = .000$); older children had a higher word count than younger children ($F(1,128) = 13.795, p = .000$), and children of parents with a higher level of education had a higher word count ($F(1,128) = 4.132, p = 0.044$). The means of reported child word count with standard deviations for each group are shown in Table 4.
Appendix 3: Smith and Gibbard (2011) Babytalk Home Visits: Development and initial evaluations of a primary prevention service *Child Language Teaching and Therapy* 27(1) 66-83

![Graph showing percentage of responses](image)

**Figure 1** Types of responses given to the question: "What, if anything, will you do differently as a result of this visit?"

<table>
<thead>
<tr>
<th>Activity</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Talk to child</td>
<td>29.00%</td>
</tr>
<tr>
<td>Look at books</td>
<td>15.00%</td>
</tr>
<tr>
<td>Sing rhymes</td>
<td>12.00%</td>
</tr>
<tr>
<td>Special time</td>
<td>11.00%</td>
</tr>
<tr>
<td>Listen to child/follow lead</td>
<td>9.00%</td>
</tr>
<tr>
<td>Go to groups</td>
<td>6.00%</td>
</tr>
<tr>
<td>Label things</td>
<td>5.00%</td>
</tr>
<tr>
<td>Other</td>
<td>4.00%</td>
</tr>
<tr>
<td>Spend more time</td>
<td>3.00%</td>
</tr>
<tr>
<td>Play</td>
<td>2.00%</td>
</tr>
</tbody>
</table>

**Table 3** Mean parental ideas with standard deviations

<table>
<thead>
<tr>
<th></th>
<th>Mean number of ideas to support language development</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reported receipt of BTHV</td>
<td>3.15</td>
<td>1.738</td>
</tr>
<tr>
<td>Reported no receipt of BTHV</td>
<td>2.03</td>
<td>1.536</td>
</tr>
</tbody>
</table>

**IV Discussion**

There is a case in the literature for facilitating language development through supporting the home environment. The BTHV service was developed with this aim in mind by giving parents or carers information about their child’s language development, and how they can support this in their daily lives. The BTHV service was also developed in response to a need to address the increased prevalence of language
Appendix 3: Smith and Gibbard (2011) Babytalk Home Visits: Development and initial evaluations of a primary prevention service Child Language Teaching and Therapy 27(1) 66-83

Table 4 Mean reported word count with standard deviations

<table>
<thead>
<tr>
<th>Reported receipt of BTHV</th>
<th>Mean reported child word count at 22-27 months</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reported no receipt of BTHV</td>
<td>25.38</td>
<td>11.755</td>
</tr>
</tbody>
</table>

delay found in areas of social deprivation. Based on findings such as those of Hart and Risley (1995), it was postulated that the increased prevalence of language delay in areas of low SES was based in part on factors in the home environment. The service therefore targeted the home environment for support.

The results of both evaluation methods indicate subjective and objective benefits of the BTHV service and support the hypotheses. The results of the comparative evaluation (method 2) support the perceptions given by parents in method 1. This was, however, a service evaluation, and not subjected to the controls of a research study. A number of methodological limitations should be considered and are discussed below.

1 Evaluation method 1: Parental feedback questionnaire

This is a report of parents’ own perception of the benefit of the BTHV service. Whilst many parents report that they felt that they had learned more about language development and how to facilitate this in their child, the evaluation does not give an objective measure of increase in knowledge and skills, as no baseline and post-intervention measures were taken. Furthermore, whilst many parents reported that they would change their behaviour in some way as a result of the BTHV service, and the changes suggested by parents were behaviours that are supported in the literature as being beneficial for language development, the evaluation does not indicate whether parents actually did implement this change in behaviour.

The questionnaire was given to the parent at the end of the BTHV service by the SLTA. This resulted in a high level of returns (over 99%). Parents indicated that they valued the service, and high levels of satisfaction were reported. It is possible, however, that parents felt compelled to write positive comments as the SLTA was present at the time. Whilst the positive additional comments received on the form suggest that the service is valued by parents, the use of third-party evaluators in the future may validate parental responses further.

Parents gave a number of responses to the open question ‘What will you do differently as a result of this visit’ as illustrated above. Responses were grouped into themes, and these are given in Figure 1. This open question method was selected (over a tick list) to ensure that the response was a genuine response, and not simply a response to prompts. The allocation to the themes was carried out by one SLT. Inter-rater reliability tests were not carried out. A test of reliability of the rating method would enable the method to be replicated, and future evaluations might include intra- and inter-rater reliability tests to validate the ratings of the responses.

2 Evaluation method 2: Comparative analysis using SSLM with additional questions

The results of the comparative analysis indicate a positive effect of report of receiving a BTHV service on parental ideas for language development and on reported child word count. As with method 1, however, there were methodological limitations, which are discussed below.
Appendix 3: Smith and Gibbard (2011) Babytalk Home Visits: Development and initial evaluations of a primary prevention service Child Language Teaching and Therapy 27(1) 66-83

78

Child Language Teaching and Therapy 27(1)

a Parental report: An adequate language measure?: The SLM-R is a parental based report of their child’s expressive language. Past studies have documented high correlations between parent report and children’s language development (Dale, 1991; Sure Start Unit, 2003). Future research might, however, examine the effect of the BTHV service on other measures of language, for example, standardized assessment or on direct observation of language development as used by Hart and Risley (1995).

b Control in the evaluation method: The two groups compared (i.e. families who had reported receiving a BTHV service and families who had not) were not controlled groups. There is, therefore, potential for additional variables to have influenced the results. Known factors, such as parental level of education were partialled out in the analysis. Other factors, however, such as a greater willingness to access services, or prior knowledge of language development, may also have influenced the outcomes. Furthermore, the evaluation relied on the parents’ report of whether they received a BTHV service or not. It is possible that some of the parents who had reported not receiving a visit may have actually forgotten receiving one. This may have biased the results, as a parent who did not remember receiving the visit may also not remember the advice given. Another factor that may introduce bias into the results is blinding to conditions. The staff involved in carrying out and analysing this evaluation were not blind to which parents reported receiving a BTHV service. Due to the order of questioning, when carrying out the SLM-Rs staff were not aware of whether a parent had received a BTHV service when asking about word count, but would have been told about receipt of BTHV service by the time they asked about parental ideas to support language. There is, therefore the risk of evaluator bias in these results, particularly concerning the parent ideas. Whilst this evaluation indicated a positive effect of receipt of the BTHV service for both child word count and parent ideas, a comparative research study with controlled groups, baseline measures and blinding to conditions is required before the effect of the BTHV service can be fully established.

A comparison was not made between the BTHV services carried out by the SLT and those carried out by the SLTA. As over 90% of visits were made by the SLTA, the results support service delivery by a team involving SLTs and assistants. Future research, however, could investigate the relative impact of services delivered by SLTs as compared to delivery by SLTAs.

V Conclusions

Primary prevention of language delay is a relatively new clinical area. Due to the emergence of new funding streams in the UK, such as Sure Start, this area is rapidly developing. There is little reported in the literature on the development, delivery and evaluation of primary prevention services that target the home environment. This is a report of such a service. The evaluations indicate benefits of the service, but are limited methodologically, and the results must be interpreted in the light of these limitations.

This report, however, provides a contribution to the literature for preventative services. It is hoped that more research on primary prevention takes place. If found to be effective, primary prevention would provide a valuable tool for tackling the inequalities in language abilities according to socioeconomic status.

Acknowledgements

The authors would like to acknowledge the following for their contribution to this project: Elaine Davis, Speech and Language Therapy Assistant, Portsmouth City Teaching (PCT), for her involvement in both the delivery and evaluation of this service; Margaret Meikle, Professional Adviser and Therapy Services Manager, Speech and Language Therapy Department, Portsmouth City Teaching Primary Care Trust; Jill Fitzgerald,
Appendix 3: Smith and Gibbard (2011) Babytalk Home Visits: Development and initial evaluations of a primary prevention service Child Language Teaching and Therapy 27(1) 66-83

Smith and Gibbard 79

Children’s Centre Strategy Manager, Portsmouth City Council, for commissioning this service in Sure Start Somerton; Amy Drakota, Research Fellow, School of Health Sciences and Social Work, University of Portsmouth, for her support with the statistical analysis and reporting of evaluation data.

References


Appendix 3: Smith and Gibbard (2011) Babytalk Home Visits: Development and initial evaluations of a primary prevention service Child Language Teaching and Therapy 27(1) 66-83

### Appendix 1: Knowledge and skills profile for sure start speech and language assistant

#### Language Development

<table>
<thead>
<tr>
<th>Item</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. To understand the pattern of normal language acquisition</td>
<td>Portfolio,</td>
</tr>
<tr>
<td>2. To understand the importance and role of non-verbal communication</td>
<td>Observation reports,</td>
</tr>
<tr>
<td>3. To be aware of issues surrounding language development and deprivation</td>
<td>Role play</td>
</tr>
<tr>
<td>4. To be aware of language development in bilingual families</td>
<td>Shadowed visits</td>
</tr>
<tr>
<td>5. To understand the concept of information carrying words</td>
<td></td>
</tr>
<tr>
<td>6. To understand a range of approaches for working with language:</td>
<td></td>
</tr>
<tr>
<td>- EIP</td>
<td></td>
</tr>
<tr>
<td>- Hanen</td>
<td></td>
</tr>
<tr>
<td>- Babyltalk/Wiltaar</td>
<td></td>
</tr>
<tr>
<td>- Use of Makaton</td>
<td></td>
</tr>
<tr>
<td>- Baby signing</td>
<td></td>
</tr>
</tbody>
</table>

#### Sure Start

<table>
<thead>
<tr>
<th>Item</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. To understand the aims of Sure Start</td>
<td>Portfolio</td>
</tr>
<tr>
<td>8. To be aware of the products and services offered by Sure Start Somerscown</td>
<td></td>
</tr>
</tbody>
</table>

#### Communication skills

<table>
<thead>
<tr>
<th>Item</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. To show an ability to communicate with parents in a way that:</td>
<td>Observation</td>
</tr>
<tr>
<td>- is non-judgmental</td>
<td>Role play</td>
</tr>
<tr>
<td>- is informative</td>
<td>Shadowed visits</td>
</tr>
<tr>
<td>- uses simple language</td>
<td></td>
</tr>
<tr>
<td>- is non-prescriptive</td>
<td></td>
</tr>
<tr>
<td>- lacks jargon</td>
<td></td>
</tr>
<tr>
<td>- is not patronising</td>
<td></td>
</tr>
<tr>
<td>- shows an awareness of differences in background and culture</td>
<td></td>
</tr>
<tr>
<td>- is flexible to the needs of different situation</td>
<td></td>
</tr>
<tr>
<td>- respects confidentiality</td>
<td></td>
</tr>
</tbody>
</table>

#### Administration

<table>
<thead>
<tr>
<th>Item</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. To understand and develop the administrative system for obtaining Babyltalk referrals in designated area.</td>
<td>Discussion with SLT</td>
</tr>
<tr>
<td>2. To show knowledge of guidance as set out in Babyltalk protocol</td>
<td>Reading</td>
</tr>
<tr>
<td>3. To show awareness of communication with Health Visitors regarding all Babyltalk visits</td>
<td>Training course</td>
</tr>
<tr>
<td>4. To understand the trusts policies on lone-working, confidentiality and consent</td>
<td></td>
</tr>
<tr>
<td>5. To be able to maintain a clear filing system for all Babyltalk documentation</td>
<td></td>
</tr>
<tr>
<td>6. To undertake training in Safeguarding Children</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 2  Parental feedback questionnaire for evaluation method

Tell us what you think of the baby talk visit

Was the visit at a convenient time for you?
yes       no       not sure

Did you find the information useful?
yes       no       not sure

Do you feel you know more about how babies learn to talk?
yes       no       not sure

Do you feel you know more about how to help your baby learn to talk?
yes       no       not sure

Do you think you will do anything differently with your baby because of this visit?
yes       no       not sure

If yes, please write what you would do below

Do you know how to get help if you are worried about your child’s talking?
yes       no       not sure

Overall, how satisfied are you with the service provided by this project?

How did you find out about the baby visit?

Please write any comments below:

.................................................................
Appendix 3: Additional questions for evaluation method 2

Before this visit, had you received any of the following products/services?

1. Babytalk visit  
   YES/NO

2. Come and sing  
   YES/NO

3. Nursery rhyme CD  
   YES/NO

4. Talking with your baby/toddler information leaflets  
   YES/NO

What do you think parents/carers can do to help their child learn to talk?  
(do not prompt the parent, if a parent says don’t know, that’s okay)

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

Name of staff member carrying out SSLM ..................................................
Appendix 4: Smith and Gibbard (submitted) Babytalk Service for Children’s Centres, a trans-agency collaboration

Keywords: Evidence-based practice, language development, parent education, Sure Start, late talkers

Abstract

Background: The need to bridge the gap between speech and language therapy clinical practice and research is widely acknowledged. This is especially the case for health promotion work for early language development, which has witnessed a rapid growth over the past fifteen years. Whilst this new practice reflects innovation it is not grounded within the framework for evidence-based-practice highlighted by the Medical Research Council. The Babytalk Home Visiting service (BTHV) is a public health speech and language therapy service delivered at the universal and universal plus levels of the Healthy Child Programme. This service has been reported in a replicable manner with positive outcomes. Requests to extend the BTHV using a multi-agency approach provided the need to model and evaluate the service further.

Aims: The aim of this project was to extend the BTHV service delivery using a multi-agency collaborative approach, without compromising the quality and effectiveness of the service.

Methods & Procedures: A model outlining the key components of the BTHV was developed using the existing protocol reported in the literature. A multi-agency service level agreement was drawn up with involvement from the speech and language therapy, health visiting and Children’s Centres services. Children’s Centres staff were employed and trained to deliver the BTHV and ongoing supervision was carried out by the speech and language therapy service. Extension of the service was evaluated using quarterly monitoring reports and contact monitoring data, and maintenance of quality was evaluated using development portfolios, supervision meeting minutes and parental questionnaires.

Outcomes & Results: Availability of the BTHV was successfully extended by 965% and actual contacts extended by 396% compared to a staffing increase of 288%. Development portfolios and parental evaluation forms indicated that the quality of service delivery was not compromised, although ongoing supervision was found to be a necessary component in maintaining quality.

Conclusions & Implications: Modelling and evaluating the BTHV has enabled service extension in a changing political and economic climate, and has provided foundations for future research into its effectiveness. It is argued that reporting and modeling of clinical practice development in this way may contribute to closing the gap between clinical practice and research by providing information from the bottom up, that is, by presenting current clinical development.
Appendix 4: Smith and Gibbard (submitted) Babytalk Service for Children’s Centres, a trans-agency collaboration

Background
Within the Speech and Language therapy profession in the UK, there has been a rapid development of primary prevention services for Early Language delay (Smith et. al, in preparation, Sawyer, Pickstone et al. 2007, Fuller 2010). Whereas around fifteen years ago pre-referral services for Speech and Language therapy were largely unheard of, primary prevention within the context of health promotion is now reported to be considered by speech and language therapists to be a core element of service delivery (Ferguson and Spence 2012). Indeed, Law et al (2013) have made a recent call to action for Speech and Language therapy services to be contextualised within a public health framework. They argue that primary prevention services, otherwise known as universal or universal plus services (DOH 2009), should be considered a key component of speech and language therapy service delivery.

This emergence of primary prevention services has arisen in the UK in response to the need to address the speech, language and communication development of children in areas of social disadvantage. The needs of these children are well documented in the literature; firstly, children in areas of social disadvantage are reported to be at higher risk of language delay than their more advantaged peers (Hart and Risley 1995, Locke, Ginsborg et al. 2002, Enderby and Pickstone 2005, Marmot 2010). Secondly, language disadvantage in the Early Years, coupled with the negative effects of low socio-economic status exacerbates disadvantage further, with negative long-term effects on education and employment (Stringer and Clegg 2006) and social and emotional wellbeing (Bryan, Freer et al. 2007). This is particularly relevant in Western Society where there is a greater dependence on communication skills for economic wellbeing in adulthood (DCSF 2008, Law, Reilly et al. 2013). Thirdly and finally, the environment, and the parenting environment in particular, has been found to mediate against the negative effects of social disadvantage (Hart and Risley 1995, Raviv, Kessenich et al. 2004, Gutman and Feinstein 2007). These findings are supported by the social interactionist theory of language development (Johnson 2007) and the concept of the intergenerational transmission of competence proposed by Hart and Risley (Hart and Risley 1995).

Whilst the justification of these services is based on sound theoretical and empirical underpinnings there is little evidence on the effectiveness of the services developed thus far (Smith, Williams et al. in preparation, Law, Reilly et al. 2013). As a clinical profession, speech and language therapists are guided by principles of evidence based practice (RCSLT 2006). The Medical Research Council’s guidance on the development of complex interventions (MRC 2008) has particular relevance for speech and language therapy interventions, which are known to have multiple components. There is therefore a need for the reporting of the development and early evaluations of interventions, in order to build evidence of effectiveness from the bottom up, and to bridge the gap between research and clinical practice.

This paper describes the second stage of evaluation and modeling of a primary prevention service previously reported in the literature, namely, the Babytalk Home Visiting service (BTHV) (Smith and Gibbard 2011).

Development of the Babytalk Home Visiting Service (BTHV).
The BTHV is a primary prevention initiative established in Portsmouth City, UK in 2003. It was developed by the speech and Language therapy service for a local Sure Start Programme,
Appendix 4: Smith and Gibbard (submitted) Babytalk Service for Children’s Centres, a trans-agency collaboration

part of a multi-agency national initiative designed to support early child development and combat against the negative effects of child poverty (Glass 1999).

The BTHV is a one off home visit delivered universally to families with babies aged between 6 and 18 months within a defined geographical location. Delivered by a trained speech and language therapy assistant, advice is given to parents on the pattern of normal language development, the effects of the home environment on language acquisition, and advice on ways to support language development in the home. Advice includes features of interaction and parenting activities reported in the literature as facilitative for expressive language development. For a full report of the service, see Smith and Gibbard (2011).

The BTHV was initially developed for delivery within a small area of high social disadvantage in Portsmouth City serviced by the local Sure Start programme. The population of this area was estimated to be around 800 children aged 0-5 years (local unpublished data). In 2004 the service was extended to a neighbouring Sure Start Centre with a similar population size, through growth of the speech and language therapy team. The service was delivered in this way between 2003 and 2013 for these geographical locations. It was evaluated using a parental questionnaire and a comparative evaluation of reported parental ideas to support language and child language outcomes using the Sure Start Language Measure - Revised (Sure Start 2002). This initial evaluation was reported by Smith and Gibbard (2011). In summary, findings from the questionnaire were as follows; parents who reported receiving the BTHV also reported high levels of satisfaction and perceived increase in knowledge about language development. 72.5% of respondents stated that they would do something differently as a result of receiving the service, with examples being parents reporting that they would talk more to their baby, sing rhymes and look at books. In the comparative evaluation, children of parents who reported receiving the BTHV also reported a significantly higher child word count on the SSLM-R than children who had not received the BTHV. Furthermore these parents were able to produce a greater number of appropriate ideas on ways to facilitate language development at home.

Service modeling for multi-agency extension of the BTHV.
Due to changes in the overall structure and funding of the local Children’s Centres in Portsmouth (which took place as a result of the national drivers to extend the number of Children’s Centres nationally) delivery of the BTHV was extended across an increased geographical location in 2008. This extension provided the incentive to develop the BTHV model of intervention further, and to evaluate components of the model. This process is described below:

Background to service extension:
In 2004 the UK government announced plans to increase the number of Children’s Centres across the UK (UK Parliament 2010). In Portsmouth City the number of Children’s Centres rose from 7 to 17 between 2007 and 2012, servicing a population of 10,619 0-5 year olds (local data). Mindful of the national drivers highlighting the speech, language and communication needs of young children (DCSF 2003, DCSF 2008) a multi-agency proposal was developed in the city with a remit of providing universal and universal plus services to support early language development. The proposal included the extension of the BTHV to all Children’s Centres, based on local parent involvement feedback and on the initial positive evaluations reported by Smith and Gibbard (2011).

Development of the model:
Appendix 4: Smith and Gibbard (submitted) Babytalk Service for Children’s Centres, a trans-agency collaboration

In order to extend the BTHV without compromising its quality or effectiveness a clear model, outlining the components of the service was developed and agreed by all parties. This model is shown below in Figure 1. The aim was to utilise existing staff within Children’s Centres to deliver the BTHV in the extended geographical locations. An extended referral process was also required, and the Health Visiting service was identified as the most appropriate professional body to make referrals. A multiagency service level agreement was therefore drawn up to enable a collaborative delivery of the BTHV. The most significant change in service delivery for the extended service was the agency delivering the interventions. The extended BTHV was to be delivered by Early Years workers employed by a local Children’s Centre (CC workers). The focus of evaluation therefore, was on the development of competence and ongoing supervision of these workers.

Figure 1: A model outlining the components of the BTHV

The staffing component of the BTHV model was developed further to facilitate quality processes in recruitment, training, professional development and supervision as follows:

**Participants:**
An initial competencies profile was developed and 5 staff representing 3 whole time equivalent staff were identified from a local Children’s Centre. These staff had proven knowledge and skills in child development (equivalent to NVQ level 3), experience of working in a nursery setting and experience of outreach work and home visiting.

**Materials:**
The Speech and Language therapy service developed the knowledge and skills framework from the original BTHV protocol detailing the key competencies needed to deliver the BTHV within the extended Children’s Centres. A framework for a portfolio of development was also established, and the CC workers each kept their own individual portfolio illustrating evidence of their knowledge and skills development.

278
Appendix 4: Smith and Gibbard (submitted) Babytalk Service for Children’s Centres, a trans-agency collaboration

The original BTHV protocol was extended to include administration procedures for the CC workers and information on the core Speech and Language Therapy service, including local NHS Trust policies (child protection, safe lone working, information sharing and confidentiality) and speech and language therapy referral information.

Staff training:
A full day’s training course was developed and delivered, covering language and social disadvantage, infant communication developmental milestones (focusing on 0-2 years of age), the effect of the home environment on language acquisition, and describing the BTHV in detail. A protocol of the BTHV was given to each Children’s Centre worker at this course, and other key aspects of the service were also covered, including interpersonal communication skills, lone home visiting and personal safety and administrative procedures.

In order to consolidate learning within a practical context a work-shadowing programme was established. Each CC worker shadowed a speech and language therapy assistant (SLTA) 3 times and observed the BTHV being delivered. They were then shadowed by the SLTA a further 3 times while they delivered the BTHV. Finally the CC worker was shadowed by the supervising specialist SLT, and following a one to one reflective practice tutorial, were signed off as competent if appropriate, or otherwise a period of continued shadowing with specific goals was recommended.

Supervision:
A monthly trans-agency group supervision meeting was established to explore issues arising from learning process and delivery of the BTHV. Issues discussed at these meetings included teething problems associated with interagency working, referrals and the administrative processes, adherence to the protocol and sharing challenges and best practice. In addition, a key related topic was discussed at each meeting (e.g. bilingualism, twin births, premature births and language development) to facilitate continued professional development.

Evaluation of the extended service: Methods
The aims of the evaluation were to assess the extent to which the service has been extended (evaluation of reach) and the extent to which perceived quality and effectiveness of service delivery has been maintained. Evaluation methods in relation to these aims are outlined below:

Extension of service:
Service availability was assessed through monitoring the promotion of the BTHV within Children’s Centres to parents and promotion of the service to multiagency professionals (assessed through quarterly service level agreement reports). Population data was used to estimate the increase in service availability. In addition, during quarter 4 of 2008 actual service delivery was assessed using contact monitoring data collected by the local Children’s Centres service.

SLT perceived quality of extended service:
Appendix 4: Smith and Gibbard (submitted) Babytalk Service for Children’s Centres, a trans-agency collaboration

The development of knowledge and skills was monitored through completion of the competencies profiles, monthly supervision, rating of service delivery in shadowed visits and evidence gained in individual portfolios.

The responsibility for quality of service delivery was held by the speech and language therapy service. The professional development portfolios were used to monitor the knowledge and skills and ongoing development of the trained Children’s Centre workers. It was anticipated that equivalent levels of competence would lead to equivalent levels of quality in service delivery.

Parental perceived quality and effectiveness of extended service:
In order to examine parental levels of satisfaction with the extended BTHV, the questionnaire developed in the previous evaluation (Smith and Gibbard 2011) was given to parents receiving the extended service. Percentage of ‘yes’ responses to the question ‘will you do anything differently’ from Children’s Centres worker questionnaires were compared with the outcomes reported by Smith and Gibbard (2011) for the original service. Responses to the open question ‘what will you do differently?’ were listed, grouped by topic and classified by SLTs as being either beneficial or not beneficial for language development. Classifications were based on empirical and theoretical underpinnings described above and by SLT consensus through inter-rater reliability testing. Responses are outlined in Table 1, below. The proportion of total responses classified as beneficial was calculated (as a percentage) for CC worker collected questionnaires and compared with questionnaires collected by the SLTAs. Again, it was anticipated that equivalent levels of parental satisfaction would indicate equivalence in quality of service delivery.

Table 1: Classification of beneficial and non-beneficial parental responses to the question ‘what will you do differently?’

<table>
<thead>
<tr>
<th>Beneficial responses</th>
<th>Non-beneficial responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Talk to baby</td>
<td>Buy more toys</td>
</tr>
<tr>
<td>Look at books</td>
<td>Non-specific comments about play</td>
</tr>
<tr>
<td>Sing nursery rhymes</td>
<td>Correct baby’s speech</td>
</tr>
<tr>
<td>Special time</td>
<td></td>
</tr>
<tr>
<td>Follow child’s lead</td>
<td></td>
</tr>
<tr>
<td>Go to local parent/baby groups</td>
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</tbody>
</table>

Finally, the questionnaire responses from the extended service were collated with responses from the initial evaluation, to give an overall parental evaluation of the BTHV.

Results

Extension of service: Service availability: From 2008 the service was promoted through posters in every Children’s Centre in Portsmouth City and flyers in all Children’s Centres registration packs. In addition the Children’s Centre workers visited local parent and baby groups, hostels and libraries, where they promoted the BTHV and booked appointments with parents. The supervising Speech and Language therapist also delivered service promotion presentations to Children’s Centres forums, parent forums and Health Visitor meetings to increase awareness of the universal availability of the service. The reach of the service in
terms of availability was therefore increased from the initial population of 2 Children’s Centre geographies (approximately 320 babies aged 6-18 months) to all families within the city of Portsmouth, a population of 1,540 6-18 month old babies. This represented a 965% increase in service availability from an increase in staffing of 288%.

**Service delivery:** In quarter 4 of 2008 25 BTHV were carried out by SLTAs and 74 by additional Children’s Centre Staff, resulting in 99 visits overall, reflecting a 396% increase in actual delivery for the quarter (again, from a staffing increase of 288%).

**Evaluation of supervising agency’s (Speech and Language Therapy Service’s) perceived quality of extended service.**

**Development of knowledge and skills:** The Children’s Centre workers demonstrated evidence of achieving the essential competencies for the BTHV within 6 months of commencing training, and many of the desirable competencies within 12 months of commencing training. Furthermore, they were able to demonstrate satisfactory performance on shadowed visits as rated by the supervising specialist SLT. This rate of development is similar to that expected of other newly trained but inexperienced staff, for example newly qualified SLTs for clinical practice, and also reflected time taken for newly recruited speech and language therapy assistants to develop to full competence.

Discussions minuted within the monthly supervision meetings demonstrated that the Children’s Centre workers continued to gain increased knowledge and skills through the training, work shadowing and knowledge and skills portfolio management established within the BTHV model. Children’s Centre workers demonstrated decreasing dependence on the SLT and SLT assistants for core information given and common home visiting issues arising (for example, safety in lone working, or communicating effectively with parents). Actions from the supervision meetings for the first 6 months included repeated requests for CC workers to adhere to the protocol for service delivery and record keeping, whereas minutes from later supervision meetings demonstrated a greater focus on sharing best practice and extended discussions around the key topic for that meeting.

**Evaluation of parental perceptions of quality and effectiveness of the service:**

Between 2008 and 2009 a total of 251 questionnaires were collected by CC workers delivering BTHV. Percentage responses for Children’s Centre worker collected questionnaires and questionnaires collected for the initial Smith and Gibbard (2011) are shown in Table 2 below.

For the extended service, 76.5% of respondents answered ‘yes’ to the question ‘will you do anything differently as a result of this visit, compared to 72.5% of respondents reported in the initial evaluation by Smith and Gibbard (2011).

174 of the 251 respondents (69.3%) gave concrete responses to the open question ‘what will you do differently?’ Of these responses, 86.2% of responses (and 59.7% of total responses) were classified as beneficial. In comparison, 217 (62.1%) of respondents in the initial evaluation gave responses, of which 84.8% (52.7%) were classified as beneficial.

A total of 596 parental questionnaires were collected for the BTHV. This response size was sufficient for a 95% confidence interval with a 5% margin of error, assuming a 50%
Appendix 4: Smith and Gibbard (submitted) Babytalk Service for Children’s Centres, a trans-agency collaboration

distribution and based on the given population of 1540 families in Portsmouth city (Raosoft 2014). From these questionnaires 74.6% respondents stated that they would do something differently as a result of the service, 65.1% stated what they would do and, of these, 86% (and 56% of the total respondents) were classified as beneficial responses. Parental reported satisfaction levels remained high (95.6%), as did parental reported perceptions of increased knowledge about child language development (94.3%).

Table 2: A comparison of parental questionnaire responses between the extended service and the initial evaluation (Smith and Gibbard 2011).

<table>
<thead>
<tr>
<th></th>
<th>Extended service evaluation</th>
<th>Initial evaluation (based on questionnaires collected by Smith and Gibbard 2011)</th>
<th>Total questionnaires collected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of questionnaires</td>
<td>251</td>
<td>349</td>
<td>596</td>
</tr>
<tr>
<td>Total number of respondents who</td>
<td>192 (76.5%)</td>
<td>253 (72.5%)</td>
<td>445 (74.6%)</td>
</tr>
<tr>
<td>reported that they would do something different (% of total questionnaires)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total number of respondents who</td>
<td>174 (69.3%)</td>
<td>217 (62.1%)</td>
<td>388 (65.1%)</td>
</tr>
<tr>
<td>stated what they would do</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>differently (% of total questionnaires)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total number of responses</td>
<td>150 (59.7%)</td>
<td>184 (52.7%)</td>
<td>334 (56%)</td>
</tr>
<tr>
<td>classified as beneficial (% of total questionnaires)</td>
<td></td>
<td></td>
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</table>

Discussion

Contribution to the development of evidence based practice for primary prevention initiatives in SLT: The BTHV has been developed as a primary prevention service in response to the national and local political drivers described above. Whilst the service is based upon sound theoretical underpinnings, it is argued that the drivers for this service development have largely been policy based in response to the government Sure Start initiative described above. This is reflective of much emergent practice, particularly within the field of primary prevention for early language delay (Smith et al, in preparation) as there is evidence of a range of developed services following government policy developments (Sawyer, Pickstone et al. 2007, Fuller 2010) but little evidence of effective practice (Smith et. al, in preparation, Law, Reilly et al. 2013).

Cognisant of the realities of these drivers for new intervention development, there is a need to attempt to ground service innovation within the principles of evidence based practice. The Medical Research Council highlights the importance of service modeling and evaluation at initial phases of the development of complex interventions (MRC 2008). This paper, in conjunction with the initial evaluations reported by Smith and Gibbard (2011) attempts to
Appendix 4: Smith and Gibbard (submitted) Babytalk Service for Children’s Centres, a trans-agency collaboration

provide a comprehensive account of the development and evaluation of the BTHV, thus providing a contribution for the speech and language therapy profession to the field of primary prevention of early language delay. The modeling and early evaluations of the BTHV are reported identifying the key components of the service, and providing the initial building blocks of evidence with early evaluations. Reports of parental satisfaction and perception of the value of the service reported in the initial evaluation report are built upon in this report, reinforcing confidence in the findings.

Benefits of modeling a complex intervention
The delivery of the original BTHV service has had to be adapted according to a changing political and economic climate within Portsmouth city and the UK. The development of the original protocol and modeling of the service enabled adaptations to be made to extend the service delivery, and the evaluations reported indicate that the quality of the service was not compromised. Furthermore, parental reports confirm that the service remained a valuable element of the local Children’s Centre portfolio.

As a component of the BTHV model, the SLT service developed measures to assess the competencies, knowledge and skills of the developing Children’s Centre workers. The combination of training, shadowing and monthly supervision provided a robust professional development package, and Children’s Centre workers demonstrated full competence within 12 months of recruitment to the service. The monthly meeting discussions highlighted that the training programme alone would not have been adequate for transmitting the knowledge and skills required to maintain the quality of service delivery previously established. Principles and processes discussed in training needed to be reinforced over a period of time with the Children’s Centre workers. This is reflective of supervision of any newly employed staff (including those working within the same department as the supervisor) and is therefore, not surprising. It is argued that quality of this service delivery was enhanced as a result of a robust protocolised model of the BTHV reinforced through regular specialist trans agency supervision. Such a model might be employed in other collaborative service delivery, such as the delivery of speech and language therapy programmes or embedding of aims and strategies by school staff, nurses or care workers.

Discussion of the evaluation methods and outcomes
Evaluation of reach of the service was reported using population and contact monitoring data. As primary prevention services are, by nature, targeted to a universal population the reporting of reach provides information on the feasibility and value of a service at a population level. The availability of the BTHV was reported to be successfully extended to a wider population, and this report describes the attempts that were made by the CC workers and the SLT service to promote the service. The extent to which families across Portsmouth were aware of the availability of this service, however, was not reported. A measure of public awareness of the BTHV would inform the success or otherwise of these attempts. An example of such a measure is reported by Abba and Hughes (2006) in their report on a health promotion campaign for language development. They used a poll, which found that 40% of those questioned were aware of their campaign.

This service extension was evaluated in part using a parental questionnaire. Whilst a questionnaire is unable to provide an objective evaluation of effectiveness, a well-designed questionnaire is able to provide evidence of parent perceptions of the value of a service. Views of service users are considered to be a key component of evidence-based practice (Rycroft-Malone, Seers et al. 2004), and it is argued that a robust questionnaire provides
information that is reliable. The questionnaire reported in this paper is an appropriate method for assessing parent views, is replicable and uses a range of question types suitable to the question asked. Furthermore, the number of responses is given. The confidence level validates the survey outcomes for the population of families with babies in Portsmouth city. It is worth noting that the parent questionnaire results for the extended service, whilst similar, were slightly more positive than those for the initial evaluations. This may be for a number of reasons. First, as more questionnaires were gathered for the initial evaluation over a longer period of time, the slightly lower results may be more reflective of the true perceptions of the BTHV. Second, the initial evaluation took place within the most deprived part of Portsmouth City. Responses may be reflective of a more disadvantaged demographic. Thirdly and finally, the results may be improved because more formal, frequent supervision and support was offered during the extension period as a result of developing this element of the BTHV model further. A comparative evaluation of the SLTA provision at the same time as the CC worker provision would give a clearer picture of the reasons for this increase.

**Indicators for future research**

This evaluation report, together with the initial Smith and Gibbard evaluation (2011) provides indicators for future research and development. Specifically, this evaluation highlighted that many parents report they would make behavioural changes in response to the advice given, with many reporting that they would talk more to their baby, read books, play together with their child and sing nursery rhymes. Future research into the effectiveness of the BTHV might explore whether parents do, in fact, make these changes. These evaluations have been instrumental in securing funding for a randomised controlled trial into the effectiveness of the BTHV on parent talk to children and child language outcomes, and primary and secondary outcome measures have been based on these findings and findings from the initial evaluations (Smith and Gibbard 2011).

**Conclusions**

The need to bridge the gap between research and clinical practice is recognised as a priority within the profession, and in the UK is the focus of the Royal College of Speech and Language Therapists’ annual conference in 2014 (RCSLT 2014). This paper is an example of an attempt to do this by providing information about clinical practice as it has developed in the work place. This ‘bottom up’ building of evidence is rooted in public involvement and has ecological validity. Chalmers and Glasziou (2009) cite a source of waste in research can arise through researchers asking the wrong questions (that is, questions that are not relevant to the service user). Early evaluations such as this can minimise this risk of waste by informing the direction of future research from parental evaluations.

**Acknowledgements**

The authors would like to thank the Speech and Language therapy assistants and Children’s Centres workers for their dedication to the BTHV, Portsmouth Children’s Centres strategic development team for their continued support of the service, the Willows Children’s Centre for hosting the Children’s Centres workers, Portsmouth City Health Visiting service and the many parents who were involved in the development and continued evaluation of the BTHV.

Declaration of Interest:
The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.
Appendix 4: Smith and Gibbard (submitted) Babytalk Service for Children’s Centres, a trans-agency collaboration

References:


Appendix 4: Smith and Gibbard (submitted) Babytalk Service for Children’s Centres, a trans-agency collaboration


Smith, C. Williams, E. and Bryan, K. (in preparation) Supporting Early Language Development; A systematic scoping review of preventative services to parents in the UK.


Appendix 5: Documents approved by Berkshire REC (5a – letter giving favourable ethical opinion to study).

National Research Ethics Service
Berkshire Research Ethics Committee
Building L27
University of Reading
London Road
Reading
RG1 5AG
Telephone: 0118 916 0553/1
Facsimile: 0118 916 0559

13 October 2009

Mrs Clare Smith
Senior generalist Speech and Language Therapist / PhD Student
Portsmouth City Teaching Primary Care Trust
Speech and Language Therapy Dept.
Battenburg Avenue Clinic
North End
Portsmouth
PO2 0TA

Dear Mrs Smith

Study Title: An investigation into the effectiveness of primary prevention of Speech and Language Difficulties through supporting the home environment.

REC reference number: 09/H0505/101
Protocol number: 1

Thank you for your letter of 02 October 2009, 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.

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

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).

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

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

This Research Ethics Committee is an advisory committee to South Central Strategic Health Authority.

The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England.
Appendix 5: Documents approved by Berkshire REC (5a – letter giving favourable ethical opinion to study).

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk. Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

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:

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<tr>
<th>Document</th>
<th>Version</th>
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<td>13 July 2009</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 (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

This Research Ethics Committee is an advisory committee to South Central Strategic Health Authority.

The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England.
Appendix 5: Documents approved by Berkshire REC (5a – letter giving favourable ethical opinion to study).

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

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.

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
- 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.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencesgroup@nres.npsa.nhs.uk

09/H0505/101 Please quote this number on all correspondence

Yours sincerely

Professor Nigel Wellman
Chair

Email: scsha.berksrec@nhs.net

Enclosures: “After ethical review – guidance for researchers”

Copy to: Professor Karen Bryan, Faculty of Health & Medical Science
Appendix 5: Documents approved by Berkshire REC (5b Letter indicating favourable ethical opinion for amendments).

20 July 2011

Mrs Clare Smith
Senior generalist Speech and Language Therapist / PhD Student
Portsmouth City Teaching Primary Care Trust
Speech and Language Therapy Dept
Battenburg Avenue Clinic
North End, Portsmouth
PO2 3TA

Dear Mrs Smith,

Study title: An investigation into the effectiveness of primary prevention of Speech and Language Difficulties through supporting the home environment.

REC reference: 09/H0595/101
Amendment number: 2
Amendment date: 27 June 2011

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.

Approved documents

The documents reviewed and approved at the meeting were:

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<td>Protocol</td>
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<tr>
<td>Notice of Substantial Amendment (non-CTIMPs)</td>
<td>2</td>
<td>27 June 2011</td>
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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.

This Research Ethics Committee is an advisory committee to the South Central Strategic Health Authority. The National Research Ethics Service (NRES) represents the NRES directorate within the National Patient Safety Agency and Research Ethics Committees in England.
Appendix 5: Documents approved by Berkshire REC (5b Letter indicating favourable ethical opinion for amendments).

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

09/H0505/101: Please quote this number on all correspondence

Yours sincerely

Mr David Carpenter
Chair

E-mail: scsha.berksrec@nhs.net

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

Copy to: Professor Karen Bryan, Faculty of Health & Medical Science

This Research Ethics Committee is an advisory committee to South Central Strategic Health Authority. The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England.
Title: An investigation into the effectiveness of primary prevention of Speech and Language Difficulties through supporting the home environment.

Summary: There is justification in the literature for promoting optimal child language development through advising and supporting parents. Theory and research evidence suggest that this approach may prevent some language delay, and the negative effects that delay has on a child’s educational, social and emotional development. Services of this nature are being developed in the UK; however, there is very little reported evidence of effectiveness of these services. This study aims to develop a language promotion service in accordance with theory and to investigate its effectiveness. A randomised controlled trial is planned with two experimental groups; a control group and a group which receives the language promotion service. The service will be given to families when the baby is approximately 1.0 years of age. Measures of parent talk to children and child language levels will be taken for each family before the intervention (baseline measure) and after the intervention at intervals until the child is aged 2:0 years. Mean scores for each experimental group (observed measures, and mean differences from the baseline measure) will be compared using independent t-tests. It is expected that parents who receive a language promotion service will increase the quantity and quality of their talk to their children, and that their children will also develop more language skills than parents from the control group. It is also expected that these effects will sustain and therefore be observed when the child is 2:0 years. If this service is found to be effective, it will provide a much-needed contribution to the evidence base for preventative services in speech and language therapy. It will also provide a cost effective solution to promoting language development in the early years, and contributing to a child’s social, emotional and academic development.

Aims: To develop a health promotion service for language development in accordance with theory, and to examine its effectiveness in terms of parental talk to children, and child language outcomes.

Background: Primary language delay, that is, language delay in the absence of other physiological or cognitive difficulties remains one of the most prevalent developmental delays in early childhood (Hall & Elliman 1996). It is also recognised that in some communities this figure is higher. For example, in an area of high social deprivation Locke et al (2002) found that over 65% of children entered nursery with a mild language delay or worse. Alongside these prevalence figures, many professionals involved in early years are concerned that language skills in children are declining. ICAN (2004) reported that 89% of nursery workers were concerned about an increase in language difficulties amongst the pre-school population.

The long-term educational implications of language delay have been documented (Clegg 2006; Leitao & Fletcher 2004; Rescorla 2005; Snowling et al. 2001). Furthermore, persisting speech and language difficulties can lead to emotional and behavioural difficulties (Huaqing Qi & Kaiser 2004; Stringer & Clegg 2006), and there
Appendix 5: Documents approved by Berkshire REC (5c – study protocol).

is some evidence to suggest a link between language difficulties and anti-social
behaviour, employment prospects and even criminality (Bryan et al. 2007; Clegg
2006). It is widely accepted that a child’s environment does have some influence on
their language development. Johnson (2007) used a social-interactionist approach to
describe how the on-going interaction between a child, his/her behaviour, the care
giving environment and societal expectations influence that child’s language
development.

The effect of the caregiver environment, specifically, has been found to have a
protective influence for language development (Gutman & Feinstein 2007; Raviv et
al. 2004; Sylva et al. 2003). Studies have shown that the amount of language
spoken to children is related to their language development (Hart & Risley; 1995,
Hoff & Naigles; 2002). The effect of interactional style has been shown to influence
language development, with factors such as following a child’s lead in interaction,
and commenting on a child’s topic of interest (Hoff-Ginsberg, 1987; Tamis-LeMonda
et al. 1996, Tomasello and Todd, 1983). There are also certain parenting activities
that families engage in that are considered to support language development. These
include play (Ginsborg 2006), singing nursery rhymes (Bryant et al.; 1989, Roulestone
et al. 2002) and sharing books (Boyce et al 2004, Moore & Wade, 2003; Morag et al;

Primary prevention of developmental delay has largely been the remit of public health
services, such as health visiting. However, a more focussed service is justified, on
the grounds of the high prevalence of language delay, its effects on future outcomes
for children, and the known effect of a facilitative environment. The development of
primary prevention initiatives within the speech and language therapy service in the
UK has taken place within the last decade, largely as a result of external funding from
government sources, such as Sure Start. Types of intervention include information
given at parent and child groups, home visits, training courses, public awareness
raising, input into other groups, production of leaflets CDs and DVDs and one off
events. The effectiveness of such services, however, particularly those targeting
parents and the home environment, remains largely unreported (Smith, paper in
preparation). One health promotion service for language development was
developed and evaluated in Portsmouth City (Smith & Gibbard; submitted). The
results of this evaluation indicated that parents who received the service were able to
give more ideas about how to encourage language development than parents who
had not received the service. Furthermore, the mean reported word count of children
whose parents had received the service was significantly higher than the mean
reported word count of children whose parents had not received the service. These
results suggest that there may be benefits in a health promotion service for language
development; however, Smith and Gibbard (submitted) stated that research under
controlled experimental conditions is required to confirm their findings. They also
stated that the long-term benefits of such a service remain unknown.

There is, therefore, a clear requirement for a stronger evidence-base of primary
preventative speech and language therapy services. There is justification for
development and delivery of a primary prevention service in accordance with theory
and current evidence, and evaluation of such a service under controlled experimental
conditions. As the overall aim of the service is to facilitate child language
development (and prevent environmentally based language delay) it is necessary to
measure child language outcomes. As the target of the service is parents, and their
talk to children, measures of parental interaction are also an essential component of the study. The longer-term effects of such a service should also be examined, in order to establish whether any gains are maintained or diluted over the course of a child’s development.

**Plan of investigation:** As stated above, the investigation aims to investigate whether a health promotion service for language development can affect lasting benefits in child language development (through effecting change in parent talk to their children). This research question will require quantitative data. A between subjects design has therefore been identified, as this enables comparison between families who receive such a service and families who do not.

**Pilot study.**

Aim: The aim of the pilot study is to validate the methods of data capture, measurement and analysis identified for the main study. The following hypotheses will be tested

Hypothesis (H)1: 45 minutes of videotape is adequate to yield 30 minutes of natural interaction.

H2: Snack/meal time and play time activities yield comparable data across participants.

H3: Video transcription enables analysis of identified quality features of interaction.

H4: Video transcription of 30 minutes of data takes 150 minutes to transcribe.

H5: Features of interaction identified are present in the participants across the age range of the children.

It is hoped that the pilot study observations will also highlight any additional meaningful features of interaction to be measured in the main study.

**Participants and Recruitment:**

6 parent/child dyads will be recruited for the pilot study. Inclusion and exclusion criteria are as for the main study.

3 dyads = child age 7 months
3 dyads = child age 22 months

**Method**

Each dyad will be videotaped in their own home on 2 occasions in the pilot study. The session will include 2 activities planned by the researcher and agreed with the parent beforehand:
Appendix 5: Documents approved by Berkshire REC (5c – study protocol).

1. Meal/snack time (this may include milk feeding if the child is not yet weaned onto solid foods, but will be agreed with parents before hand – parents do not have to agree to be videotaped breastfeeding if they do not wish)

2. Play activity with toys brought by the researcher.

Each session will last around one hour with approximately 45 minutes of videotaping. Parents will be instructed to act and talk to their child as they would normally. The first 10 minutes of videotaping will be of normal daily life. If the snack/meal activity is not taking place, either this or the play activity will be introduced around 10 minutes after the videotaping has begun (parental choice). After the first activity, the second activity will be introduced. The parent will be instructed to interact as she/he normally would with their child at the start of the videotaping. The second videotaping session will take place up to 1 month after the first session. This will be identical to the first session.

The data will be transcribed onto a speech analysis software package (SALT). The duration of this process will be timed for each transcription. Features of language that are supported in the literature as facilitating child language development will then be analysed. These include total number of words spoken to the child (word tokens) and number of different words spoken to the child (word types). Features of child interaction will also be analysed, these include amount of vocalisation and use of gesture in the younger children, and word types and tokens for the older children.

Results of the pilot study will be reported, and amendments to the main study recommended.

Main Study

Aims: To examine the effectiveness of a health promotion service for language development in terms of parental talk to children, and child language outcomes.

Hypothesis (H)1: Parents who receive a health promotion service specifically for language development, will show greater measures of quality and quantity of their talk to their children than parents who do not receive the service.
Null hypothesis (N01): There will be no difference between parents regardless of whether they receive such a service.

H2: The children of parents who receive a health promotion service for language will show higher language levels than the children of parents who do not receive such a service.
N02: There will be no difference between children regardless of whether their parents receive such a service.

H3: The effects on parents’ and children’s talk as a result of receiving a health promotion service for language development will be observed when the child is 2 years of age.
N03: There will be no difference between children and parents when the child is 2 years of age, regardless of whether the parents have received such a service.
Plan of investigation: As stated above, the investigation aims to investigate whether a health promotion service for language development can affect lasting benefits in child language development (through effecting change in parent talk to their children). This research question will require quantitative data. A between subjects design has therefore been identified, as this enables comparison between families who receive such a service and families who do not.

A randomised controlled trial has therefore been identified as it enables comparison between two groups as follows:

Group A: Control group; will receive child and family services as normal

Group B: Experimental group one; will receive child and family services plus one home visit where language development advice is given

Measures of parental talk to children will be based on quality interaction features identified in the literature and validated by the pilot study. These will include number of overall words spoken to the child per hour (word tokens) and number of different words spoken to the child per hour (word types). Measures of child language will also be carried out using features identified in the literature and validated by the pilot study. In addition, the child's language will be assessed using a standardised child developmental assessment. Baseline measures of all participants will be taken prior to the intervention (when child is aged approximately 1;0 year). The intervention will take place when the child is aged 1;1 years. Measures will then be taken at 1;2 years and 2;0 years.

Justification of sample size: The aim is to recruit 122 participants to form 2 experimental groups of 47. This accounts for a drop out rate of 30%. This leaves a total sample size of 97. A 30% drop out rate is determined, as although engagement with families will be high with each family having 3 hour long home visits (predicting therefore a low drop out rate), the longitudinal nature of the study poses an increased risk of families dropping out. A medium level drop out rate has therefore been proposed. The number of participants required to enable observation of a statistically significant result was calculated using GPower version 3 (Faul et al. 2007), and in consultation with an expert advisor on statistical methods at the university of Surrey.

Selection and exclusion criteria: Participants will be recruited from two geographical regions that are recognised as having a low socioeconomic status population. Two regions have been selected to ensure that enough participants may be recruited. Participants will be pseudonymised and randomly assigned to the 3 groups. Whilst socioeconomic status will be recorded, families from any socioeconomic background will be included.

Selection criteria will include:
* First time mothers (or main carers)
* Families where child spends at least 60% of waking hours with main carer at the start of the study
* Families where English Language is spoken routinely with the child
Appendix 5: Documents approved by Berkshire REC (5c – study protocol).

- Families where parent and child have no identified cognitive, language difficulty or sensori-neural deafness

Exclusion criteria will include:
- Parent or child has known congenital diagnosis affecting learning or language
- Parent or child has known sensori-neural deafness
- A language other than English is spoken routinely with the child
- Child spends less than 60% of waking hours with main carer at start of study

Intervention: The intervention will be carried for experimental group B within the family home. The intervention will be carried out by a trained professional (a speech and language, or learning support assistant employed within Children's Centres). The intervention will last around 1 hour.

Methods of data collection and analysis: Measures of parent talk and child interaction will be carried out by the researcher. To account for researcher bias, the researcher will be blind to which participants are in which experimental group. Measures will be taken at hour-long observations within the parent home (the parent talk to the child will be videotaped for 30 minutes as validated by the pilot study). Data will then be transcribed using SALT language analysis software (Miller & Chapman; 1985), which will calculate number of word tokens and types per hour (plus any additional parental interaction features validated from the pilot study).

The following data will then be compared between the experimental groups using independent samples t tests:

Baseline measures, means for each group
Pre intervention measure, means for each group
Difference between baseline and pre intervention measure – means for each group
Measures at 2;0 years, means for each group
Difference between baseline and measure at 2;0 years – means for each group

Measures of child language development will be taken at 2;0 years using a standardised child development assessment. Measures of the home environment will also be taken at this time. Features of child speech in the observations will also be transcribed and analysed. Mean standard scores will be compared using independent t tests. Statistical analysis will be carried out using SPSS version 14.

Time schedule:

The proposed time schedule is given in table one.

Dissemination of results:

The results of this study will be disseminated via publications in peer reviewed journals, conference presentation and also PhD thesis.

In addition, the results will be shared by poster and presentation with the research participants, and the Children's Centres and Child and Family Teams involved in the research project.
Appendix 5: Documents approved by Berkshire REC (5c – study protocol).

It is hoped that the results of this study contribute to the evidence base for early language development. If found to be effective, this intervention may provide a cost effective and sustainable means of supporting communication development, and its benefits for the educational, social and emotional wellbeing of children.

Key references:
Smith, C and Gibbard D (to be submitted to Child Language Teaching and Therapy April 09) Babytalk home visits: development and evaluation of a primary prevention service.

This research is funded by a Clinical Doctoral Research Fellowship from the National Institute of Health Research
Dear parent,

**Invitation to participate in a research project on services to help Child Development:** Examining the effects of health promotion for child development: Pilot study (Research ethics reference: 09/H0505/101)

I am writing to you to invite you to participate in a research project. We want to find out if certain health promotion services help families and their child’s development. You have been invited because you have a baby aged either 6 or 22 months of age. If you decide to participate both you and your baby would be involved in the first stage of the study (known as the pilot study). This stage of the study will take place over 3 months and you will be visited up to 2 times in your home by someone from the research team. You and your baby will be videoed carrying out everyday activities during these visits. More information is given in an information sheet, which will be given to you before you decide to take part in the study.

It is up to you to decide whether or not you want to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive from the NHS.

To say thank you for your time, we will give your baby a ‘little scientist’ T-shirt showing that he/she has been part of the study and a copy of the videos that we have taken of you and your baby.

If you are interested, please complete the attached form and return it to us in the enclosed stamped addressed envelope. Or you can email or text me with your details, and I will get in touch with you.

Yours faithfully,

Clare Smith
Researcher
University of Surrey
We’re carrying out a study into services for families and babies.

This study will look at the effect of information we give you on your baby’s development. Some families in the study will be given additional information about child development. If you take part in the study we will video you and your baby in your home. This will help us find out if and how the information helps families.

If you are interested contact Clare Smith by filling out this form and giving it to the group leader (or your Health Visitor). Or you can contact Clare direct on 07826 873937 or c.smith@surrey.ac.uk

This study has been reviewed and given favourable opinion by Berkshire Research Ethics Committee. Reference: 09/H0505/101
Examsining the effects of health promotion for child development: Pilot Study

We would like to invite you and your baby to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish.

Part 1 tells you the purpose of this study and what will happen to you and your baby if you take part. Part 2 gives you more detailed information about the conduct of the study. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Part 1 About the Study

The purpose of the study;

This study is being carried out as part of an educational qualification for the researcher, who is a PhD student.

We are interested in finding out if certain early health information services help your child’s development. Sometimes we don’t know which services are best. To find out, we need to compare different services. We intend to do this in our study. Before we can do this we need to check that we are using the right tools to measure these effects. We are carrying out a smaller study first to look at these tools. This is called a pilot study. After this pilot study, we will put people into groups and give each group a different service (the main study). The results will be compared to see if one is better. To try to make sure the groups are the same to start with, each person is put into a group by chance (randomly). The pilot study will help us to decide which tools to use in this main study.

Why have you and your baby been invited?

You and your baby have been invited to be part of the pilot study, because your baby is aged either 6 or 22 months of age. As our main study will be looking at services for babies at this age, we want to make sure we are able to measure effects before we start. If you decide to participate you and your baby would be involved in the pilot study. We hope that there will be around 6 families involved in this stage of the study (and around 90 in the whole study) in the Portsmouth region.
Appendix 5: Documents approved by Berkshire REC (5f: Information sheet – pilot study).

Do we have to take part?
It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you and your baby receive.

What will happen to me and my baby if I take part?
If you decided to participate in the study a researcher would visit your home twice over 3 months. The researcher is a qualified child health professional. Each visit will last about one hour. During these visits, the researcher would observe and video you and your baby carrying out normal everyday activities (such as snack/mealtimes and play). The researcher will then analyse this information and the video recordings, to ensure that she is using the right measures for the main study (the second stage).

What will happen after the study?
We hope that we can find out if and how certain health information services help parents and children. If we find a service to be helpful we will offer it to you and your baby. We will also be able to use this information to advise those who plan services for young children and their families.

Will I suffer any expenses? How will I be compensated?
We do not anticipate that you will suffer any expenses as a result of this study, as it will take place in your home. We do realise, however, that you are giving up your time to take part in this study. To say thank you for this, we will give your baby a T shirt showing that he/she has been part of the study, and a copy of the video that we take of you and your child.

What will I have to do?
During the visits described above we would like you and your baby to carry out a normal everyday activity. This will be either a meal/snack time or playing with your baby. The researcher will bring toys that she would like you and your baby to play with. We would like you to act as you would normally during these sessions, and we will not ask you to behave or play differently with your baby. We will video these activities.

What is the service being tested?
This stage of the study is testing the measures that we will use in the main study. You or your baby will not receive any medicines or services in this study.

What are the possible disadvantages and risks of taking part?
We do not expect any risks to your health as a result of taking part. You will be required to give up your time to be available for the study, but you will be able to carry out certain everyday activities with your child during this time.

If we discover that you or your child have a condition for which you are not aware, we would discuss this with you, and advise you accordingly.
Appendix 5: Documents approved by Berkshire REC (5f: Information sheet – pilot study).

We have a duty to safeguard children. If we notice anything that we are concerned about, we may discuss it with you, and will report it if necessary. We will always follow appropriate child protection guidelines. In such circumstances confidentiality will be broken. Further information on this is given in part 2.

**What are the possible benefits of taking part?**
It is hoped that the service given in this study will support parents and therefore help their child’s development. The service may also prevent certain developmental difficulties in some children. If you decide to take part, and the service tested in the main study is found to be effective, you will be given the information at the end of the study. There may be no benefit to you and your baby from taking part in this study.

**What happens when the research study stops?**
You and your baby will continue to receive all the usual child and family services you are entitled to after the research study stops.

**What if there is a problem?**
Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in part 2.

**Will my taking part in the study be kept confidential?**
We wish to inform your health visitor if you decide to participate in the study. You do not have to agree to this, but if you do not agree, you will not be able to participate in the study. All information we gather about you will be kept confidential. We will follow ethical and legal practice, and all information about you will be handled in confidence. The details are included in Part 2.

This completes Part 1. If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.
Part 2

What will happen if I don’t want to carry on with the study?
You are free to withdraw from this study at any time without giving a reason. If you do withdraw from the study, we will destroy all your identifiable information, but we will need to use the data we have collected up to your withdrawal.

What if there is a problem?
If you have a concern about any aspect of this study you should ask to speak to the researcher, who will do her best to answer your questions. She is a qualified Child Health Professional employed by Portsmouth City Teaching PCT, and a PhD Student at the University of Surrey. Her details are:

Clare Smith
PhD Student, Faculty of Health and Medical Sciences
University of Surrey
Telephone no: 07826 873937
Email: c.smith@surrey.ac.uk

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from your Health Visitor.

In the event that something does go wrong and you or your baby are harmed during the research and this is due to someone’s negligence then you may have grounds for a legal action for compensation against Portsmouth City Teaching Primary Care Trust or the University of Surrey, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in this study be kept confidential?
Information about you and your baby will be collected during the home visits, and through your health records. All the information will be stored securely on Portsmouth City Teaching PCT premises. The person responsible for your data storage is the researcher, who will abide by NHS guidelines on data storage. Any information about you which leaves these premises will have your name and address removed so that you cannot be recognised.

You will be given a code at the beginning of the study. The code will then be applied to all the information collected about you. This will help us to keep your details confidential. We will also remove any personally identifiable information when we report the study. If we wish to use video records of you in presentations, we will ask for your specific written consent.

If you join the study, some parts of your medical records and the data collected for the study will be looked at by authorised persons from the University organising the research. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Will you inform anyone if I decide to participate?
If you decide to participate we will inform your Health Visitor. We will not share any of the information we collect about you or your baby without your consent, except in
the cases of Safeguarding Children, where if a child is at risk of harm, it is necessary
to share information, and therefore confidentiality will be broken.

What will happen to the results of the research study?
We intend to report the study in academic journals, and also to present information to
local services (such as other professionals in the NHS or in Children’s Centres). Any
information we obtain about you will be confidential, and we will remove personally
identifiable information before writing reports or giving presentations. We may wish
to use some videos of families in our presentations, but we will not do this without
your specific written permission.

Who is organising and funding the research?
The research is being organised by the University of Surrey and is part of a PhD
programme. The research is currently funded by the Wessex Institute Education
Bursary Scheme.

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people, called a
Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This
study has been reviewed and given favourable opinion by Berkshire Research Ethics
Committee. Reference number: 09/H0505/101

A copy of this information sheet will be given to you, together with a copy of your
signed consent form to keep.

Further information and contact details:

For any further information about the research please feel free to contact:

Clare Smith
PhD Student
Faculty of Health and Medical Sciences
University of Surrey

Telephone: 07826 873937
Email: c.smith@surrey.ac.uk
Dear parent,

Invitation to participate in a research project on services to help Child Development: Examining the effects of health promotion for child development (Research ethics reference: 09/H505/101)

I am writing to you to invite you to participate in a research project.

We want to find out if certain health promotion services help families and their child’s development. You have been invited because you have a baby aged 6 - 12 months of age. If you decide to participate both you and your baby would be involved in the study. The study will take place over 18 months and you will be visited up to 5 times in your home by someone from the research team. You and your baby will be videoed carrying out everyday activities during these visits. More information is given in an information sheet, which will be given to you before you decide to take part in the study.

It is up to you to decide whether or not you want to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive from the NHS.

To say thank you for your time, we will give your baby a ‘little scientist’ T shirt showing that he/she has been part of the study, a toy at the end of the study and a copy of the videos that we have taken of you and your baby.

If you are interested, please complete the attached form and return it to us in the enclosed stamped addressed envelope. Or you can email or text me with your details, and I will get in touch with you.

Yours faithfully,
Clare Smith
Researcher
University of Surrey
Examining the effects of health promotion for child development

We would like to invite you and your baby to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish.

Part 1 tells you the purpose of this study and what will happen to you and your baby if you take part. Part 2 gives you more detailed information about the conduct of the study. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Part 1 About the Study

The purpose of the study;

This study is being carried out as part of an educational qualification for the researcher, who is a PhD student.

We are interested in finding out if certain early health information services help your child’s development. Sometimes we don’t know which services are best. To find out, we need to compare different services. We intend to do this in this study. We will be putting people into groups and we will give each group a different service. The results will be compared to see if one is better. To try to make sure the groups are the same to start with, each patient is put into a group by chance (randomly). You have a 50% chance of receiving one of the services we are studying. The study is a double blind trial. This means that neither you nor the researcher will know which service group you are in until the end of the study.

Why have you and your baby been invited?
You and your baby have been invited because your baby is approximately 6 - 12 months of age. We want to look at the effect of certain services on you and your baby. If you decide to participate both you and your baby would be involved in the study. We hope that there will be around 90 families involved in this study in the Portsmouth region.

Do we have to take part?
It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you and your baby receive.

What will happen to me and my baby if I take part?
The study would start when your baby is 6 - 12 months old. If you decided to participate in the study, you would continue to receive all the child and family services normally available to you. No service will be withdrawn from you. Some families will receive an additional health information service (half of the families in the study).

For all families, a researcher would visit your home 3 times over 12 - 18 months (when your baby is twice in the first 4 months and then once again when your child is 2 years of age). The researcher is a qualified child health professional. Each visit will last about one hour. During these visits, the researcher would observe and video you and your baby carrying out normal everyday activities, such as a snack/meal time and a play time. The researcher will also ask you some questions about you, and also about things you do with your child. The researcher will then analyse this information and the video recordings, and compare what she sees with the types of services you have received. The researcher will also carry out an assessment of your child’s development towards the end of the study.

What will happen after the study?
We hope that we can find out if and how certain health information services help parents and children. If we find a service to be helpful, and you were in a group that did not receive it, we will offer it to you and your baby. We will also be able to use this information to advise those who plan services for young children and their families.

Will I suffer any expenses? How will I be compensated?
We do not anticipate that you will suffer any expenses as a result of this study, as it will take place in your home. We do realise, however, that you are giving up your time to take part in this study. To say thank you for this, we will give your baby a T-shirt showing that he/she has been part of the study. This will happen after the first phase of the study (when your child is 9 months old). We also wish to say thank you for your long term support by giving your child a toy at the end of the study (when your child is 2 years old). We will also give you a copy of the video recordings that we have taken of you and your child.

What will I have to do?
The services you receive will give you information that may help you support your child’s development. During the additional visits described above, we would like you to answer some questions about you and your child. During the videotaping, we would like you to carry out two normal everyday activities with your baby. These may be a meal/snack time and playing with your baby. The researcher will bring toys that she would like you and your baby to play with. We would like you to act as you would normally during these sessions, and we will not ask you to behave or play differently with your baby.

When we carry out the child development assessment at the end of the study, we will ask you some questions, and may play with your child using certain toys.

What is the service being tested?
Appendix 5: Documents approved by Berkshire REC (Appendix 5h: Information sheet – main study).

The service is a health promotion service. It is an information-giving service, and does not involve giving any medicines or treatment. If you and your baby receive the service, you may be given some resources to help you with the information.

**What are the alternatives for the service?**
This is a new service. There are currently no alternatives, as it is intended to be an additional service for families. Information on child development can be obtained by parents, however, from their health visitor or from Children’s Centre services.

**What are the possible disadvantages and risks of taking part?**
We do not expect any risks to your health or your baby’s as a result of taking part. You will be required to give up your time to be available for the study, but you will be able to carry out certain everyday activities with your child during this time.

If we discover that you or your child have a condition for which you are not aware, we would discuss this with you, and advise you accordingly.

We have a duty to safeguard children. If we notice anything that we are concerned about, we may discuss it with you, and will report it if necessary. We will always follow appropriate child protection guidelines. In such circumstances confidentiality will be broken. Further information on this is given in part 2.

**What are the possible benefits of taking part?**
It is hoped that the service given in this study will support parents and therefore help their child’s development. The service may also prevent certain developmental difficulties in some children. If you decide to take part, you may receive this service when your child is a baby. If you do not, and the service is found to be effective, you will be given the information at the end of the study (when your child is 2 years old).

**What happens when the research study stops?**
You and your baby will continue to receive all the usual child and family services you are entitled to after the research study stops.

**What if there is a problem?**
Any complaint about the way you or your baby have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in part 2.

**Will my taking part in the study be kept confidential?**
We wish to inform your health visitor if you decide to participate in the study. You do not have to agree to this, but if you do not agree, you will not be able to participate in the study. All information we gather about you will be kept confidential. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This completes Part 1. If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.
Part Two:

What will happen if I don’t want to carry on with the study?
You are free to withdraw from this study at any time without giving a reason. If you do withdraw from the study, we will destroy all your identifiable information, but we will need to use the data we have collected up to your withdrawal.

What if there is a problem?
If you have a concern about any aspect of this study you should ask to speak to the researcher, who will do her best to answer your questions. She is a qualified Child Health Professional employed by Portsmouth City Teaching PCT, and a PhD Student at the University of Surrey. Her details are:

Clare Smith
PhD Student, Faculty of Health and Medical Sciences
University of Surrey
Telephone no: 07826 873937
Email: c.smith@surrey.ac.uk

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from your Health Visitor.

In the event that something does go wrong and you or your baby are harmed during the research and this is due to someone’s negligence then you may have grounds for a legal action for compensation against Portsmouth City Teaching Primary Care Trust or The University of Surrey, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in this study be kept confidential?
Information about you and your baby will be collected during the home visits, and through your health records. All the information will be stored securely on Portsmouth City Teaching PCT premises. The person responsible for your data storage is the researcher, who will abide by NHS guidelines on data storage. Any information about you which leaves these premises will have your name and address removed so that you cannot be recognised.

You will be given a code at the beginning of the study. This code will then be applied to all the information collected about you. This will help us to keep your details confidential. We will also remove any personally identifiable information when we report the study. If we wish to use video records of you in presentations, we will ask for your specific written consent.

If you join the study, some parts of your medical records and the data collected for the study will be looked at by authorised persons from the University organising the research. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Will you inform anyone if I decide to participate?
If you decide to participate we will inform your Health Visitor. We will not share any of the information we collect about you or your baby without your consent, except in
Appendix 5: Documents approved by Berkshire REC (Appendix 5h: Information sheet – main study).

the cases of Safeguarding Children, where if a child is at risk of harm, it is necessary to share information, and therefore confidentiality will be broken.

What will happen to the results of the research study?
We intend to report the study in academic journals, and also to present information to local services (such as other professionals in the NHS or in Children’s Centres). Any information we obtain about you will be confidential, and we will remove personally identifiable information before writing reports or giving presentations. We may wish to use some videos of families in our presentations, but we will not do this without your specific written permission.

Who is organising and funding the research?
The research is being organised by the University of Surrey and is part of a PhD programme. The research is currently funded by the Wessex Institute Education Bursary Scheme.

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by Berkshire Research Ethics Committee (Reference: 09/H0505/101).

A copy of this information sheet will be given to you, together with a copy of your signed consent form to keep.

Further information and contact details:

For any further information about the research please feel free to contact:

Clare Smith
PhD Student
Faculty of Health and Medical Sciences
University of Surrey

Telephone: 07826 873937
Email: c.smith@surrey.ac.uk
Appendix 5: Documents approved by Berkshire REC (5i: Participant consent form).

Centre Number: 1  
Study Number: 1  
Patient Identification Number for this trial: ....

CONSENT FORM: Version 2  
Date: 29th September 2009

Title of Project: Examining the effects of a health promotion service for child development.  
[Research ethics reference: 09/H505/101]

Name of Researcher: Clare Smith  
Researcher  
Faculty of Health and Medical Sciences, University of Surrey  
Guildford, GU2 7XH  
Telephone: 07826 873937, Email: c.smith@surrey.ac.uk

Please initial box

1. I confirm that I have read and understand the information sheet dated 13th July 2009 (version 1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my health care or legal rights being affected.

3. I understand that relevant sections of my health records and data collected during the study may be looked at by individuals from the University of Surrey, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

4. I agree to my child’s Health Visitor being informed of my participation in the study.

5. I agree to take part in the above study.
Appendix 5: Documents approved by Berkshire REC (5i: Participant consent form).

6. I give consent for my child to take part in the above study.

☐

7. I give consent to data obtained about me and my child being used in publications and presentations about the study, and I understand that this data will be anonymised.

☐

8. I give consent to video recordings of me and my child being taken and used for data analysis for this research project.

☐

9. I give consent to video recordings of me and my child being used in presentations and training about the study, and I understand that my name and my child’s name will be changed for this purpose, and any identifiable information additional to the video will be removed prior to use.

☐

_______________________  ____________  ________________________
Name of Participant    Date         Signature

_______________________  ________________________
Name of carer

_______________________  ________________________
Name of Child          Date         Signature of carer

_______________________  ________________________
Name of person taking consent Date         Signature
Appendix 6: Pilot study: Boxplots showing variance of frequencies across participants measures of total utterances, word tokens and word types
## Appendix 7: Video information record

### Video session information sheet

<table>
<thead>
<tr>
<th>Participant information code:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Video session number:</td>
<td></td>
</tr>
<tr>
<td>Date:</td>
<td></td>
</tr>
<tr>
<td>Time:</td>
<td></td>
</tr>
<tr>
<td>Verbal consent given?</td>
<td></td>
</tr>
<tr>
<td>Child age:</td>
<td></td>
</tr>
<tr>
<td>Present:</td>
<td></td>
</tr>
<tr>
<td>Was that what you normally would have done?</td>
<td></td>
</tr>
<tr>
<td>Are there any words your child says that may be hard for me to recognise?</td>
<td></td>
</tr>
<tr>
<td>Other notes</td>
<td></td>
</tr>
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</table>
Appendix 8: An example of a standard measures report from SALT

M12
STANDARD MEASURES

<table>
<thead>
<tr>
<th></th>
<th>Mother</th>
<th>Child</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TRANSCRIPT LENGTH</strong></td>
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<td></td>
</tr>
<tr>
<td>Total Utterances</td>
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</tr>
<tr>
<td>Analysis Set (C&amp;I Verbal Utts)</td>
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</tr>
<tr>
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</tr>
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</tr>
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<td></td>
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<tr>
<td>MLU in Words</td>
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<tr>
<td>MLU in Morphemes</td>
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<tr>
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</tr>
<tr>
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</tr>
<tr>
<td>% Responses to Questions</td>
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</tr>
<tr>
<td>Mean Turn Length (words)</td>
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<td>0</td>
</tr>
<tr>
<td>Utterances with Overlapping Speech</td>
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<td>0</td>
</tr>
<tr>
<td>Interrupted Other Speaker</td>
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<td>0</td>
</tr>
<tr>
<td><strong>INTELLIGIBILITY</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% Intelligible Utterances</td>
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</tr>
<tr>
<td><strong>MAZES AND ABANDONED UTTERANCES</strong></td>
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<td></td>
</tr>
<tr>
<td>Utterances with Mazes</td>
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<td>0</td>
</tr>
<tr>
<td>Number of Mazes</td>
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<tr>
<td>Number of Maze Words</td>
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</tr>
<tr>
<td>Maze Words as % of Total Words</td>
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<td>---</td>
</tr>
<tr>
<td>Abandoned Utterances</td>
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<td>0</td>
</tr>
<tr>
<td><strong>VERBAL FACILITY AND RATE</strong></td>
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<td></td>
</tr>
<tr>
<td>Words/Minute</td>
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<td>---</td>
</tr>
<tr>
<td>Within-Utterance Pauses</td>
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</tr>
<tr>
<td>Within-Utterance Pause Time</td>
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</tr>
<tr>
<td>Between-Utterance Pauses</td>
<td>0</td>
<td>---</td>
</tr>
<tr>
<td>Between-Utterance Pause Time</td>
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<td><strong>OMISSIONS AND ERROR CODES</strong></td>
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<td>Word-level Error Codes</td>
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<td>Utterance-level Error Codes</td>
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# Calculations based on C&I Verbal Utts
Appendix 9: The CDI – Words and Sentences British Adaptation (Klee & Harrison, 2001): used in this study with permission from the author

Child’s Name: ____________________________  Sex: __________
Date of Birth: ____________________________ Age: __________  Today’s Date: __________

The MacArthur
Communicative
Development
Inventory: Toddlers
British English Adaptation

A. VOCABULARY CHECKLIST
Children understand many more words than they say. We are particularly interested in the words your child SAYS. Please go through the list and mark the words you have heard your child use. If your child uses a different pronunciation of a word (for example, “rafe” instead of “giraffe” or “ketti” for “spaghetti”), mark the word anyway. Remember that this is a “catalogue” of all the words that are used by many different children. Don’t worry if your child only knows a few of these right now.

1. SOUND EFFECTS AND ANIMAL SOUNDS

<table>
<thead>
<tr>
<th></th>
<th>Sound Effects</th>
<th>Animal Sounds</th>
</tr>
</thead>
<tbody>
<tr>
<td>baa baa</td>
<td>● meow</td>
<td>● uh ch</td>
</tr>
<tr>
<td>choo choo</td>
<td>● moo</td>
<td>● vroom</td>
</tr>
<tr>
<td>cockadoodledoo</td>
<td>● ouch</td>
<td>● woof woof</td>
</tr>
<tr>
<td>gir</td>
<td>● quack quack</td>
<td>● yum yum</td>
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2. ANIMALS (Real or Toy)

<table>
<thead>
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<tbody>
<tr>
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<td>● duck</td>
<td>● owl</td>
</tr>
<tr>
<td>ant</td>
<td>● elephant</td>
<td>● penguin</td>
</tr>
<tr>
<td>bear</td>
<td>● fish</td>
<td>● pig</td>
</tr>
<tr>
<td>bee</td>
<td>● frog</td>
<td>● pony</td>
</tr>
<tr>
<td>bird</td>
<td>● giraffe</td>
<td>● pupoy</td>
</tr>
<tr>
<td>bunny</td>
<td>● goose</td>
<td>● sheep</td>
</tr>
<tr>
<td>butterfly</td>
<td>● hen</td>
<td>● squirrel</td>
</tr>
<tr>
<td>cat</td>
<td>● horse</td>
<td>● teddybear</td>
</tr>
<tr>
<td>chicken</td>
<td>● insect/ fly</td>
<td>● tiger</td>
</tr>
<tr>
<td>cockerel</td>
<td>● kity</td>
<td>● turkey</td>
</tr>
<tr>
<td>cow</td>
<td>● lamb</td>
<td>● turtle</td>
</tr>
<tr>
<td>crocodile</td>
<td>● lion</td>
<td>● wolf</td>
</tr>
<tr>
<td>deer</td>
<td>● monkey</td>
<td>● zebra</td>
</tr>
<tr>
<td>dog</td>
<td>● moose</td>
<td></td>
</tr>
<tr>
<td>donkey</td>
<td>● mouse</td>
<td></td>
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</tbody>
</table>

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Appendix 9: The CDI – Words and Sentences British Adaptation (Klee & Harrison, 2001): used in this study with permission from the author

THE MACARTHUR COMMUNICATIVE DEVELOPMENT INVENTORY: TODDLERS
British English Adaptation

3. VEHICLES (Real or Toy)
- aeroplane
- bicycle
- boat
- bus
- car
- fire-engine
- helicopter
- train
- motorbike
- pram
- tractor
- tricycle

4. TOYS
- ball
- balloon
- bat
- block
- book
- bubbles
- chalk
- crayon
- doll
- glue
- jigsaw
- pen
- pencil
- play dough
- present
- story
- toy

5. FOOD AND DRINK
- apple
- applesauce
- banana
- beans
- biscuit
- bread
- butter
- cake
- carrots
- cereal
- cheese
- chewing gum
- chicken
- chips
- chocolate
- coffee
- coke
- cracker
- crisps
- doughnut
- drink
- egg
- fish
- food
- grapes
- green beans
- hamburger
- ice
- ice cream
- ice popsicle
- jam
- jelly
- juice/fizzy juice
- lollipop
- meat
- melon
- milk
- muffin
- noodles
- nut
- orange
- pancake
- peanut butter
- peas
- pickle
- pizza
- popcorn
- potato
- pretzel
- pudding
- pumpkin
- raisin
- salt
- sandwich
- sauce
- soup
- spaghetti
- strawberry
- sweetcorn
- sweet
- toast
- tuna
- vanilla
- vitamins
- water
- yogurt

6. CLOTHING
- bead
- belt
- bia
- boots
- button
- coat
- dress
- glove
- hat
- jacket
- jeans
- jumper
- mittens
- nappy
- necklace
- pyjamas
- scarf
- shirt
- shoes
- shorts
- slipper
- sock
- sweatshirt
- tights
- trainers
- trousers
- underpants
- zip

Appendix 9: The CDI – Words and Sentences British Adaptation (Klee & Harrison, 2001): used in this study with permission from the author

<table>
<thead>
<tr>
<th>THE MACARTHUR COMMUNICATIVE DEVELOPMENT INVENTORY: TODDLERS</th>
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<tbody>
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<td><strong>7. BODY PARTS</strong></td>
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<tr>
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<td>○</td>
<td></td>
</tr>
<tr>
<td>arm</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>belly button</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>buttocks/bottom*</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>cheek</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>chin</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>ear</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>eye</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>face</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>*or word used in your family</td>
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<td><strong>8. SMALL HOUSEHOLD ITEMS</strong></td>
<td></td>
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</tr>
<tr>
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<td>○</td>
<td></td>
</tr>
<tr>
<td>blanket</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>bottle</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>bowl</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>box</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>brush</td>
<td>○</td>
<td></td>
</tr>
<tr>
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<td>○</td>
<td></td>
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<tr>
<td>camera</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>can</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>clock</td>
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</tr>
<tr>
<td>comb</td>
<td>○</td>
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<tr>
<td>cup</td>
<td>○</td>
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<td>dish</td>
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<td>fork</td>
<td>○</td>
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</tr>
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<td>glass</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>glasses</td>
<td>○</td>
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</tr>
<tr>
<td><strong>9. FURNITURE AND ROOMS</strong></td>
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<tr>
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<tr>
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<td>○</td>
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<tr>
<td>col</td>
<td>○</td>
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<tr>
<td>door</td>
<td>○</td>
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<td>○</td>
<td></td>
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<tr>
<td>dryer</td>
<td>○</td>
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<td><strong>10. OUTSIDE THINGS</strong></td>
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</tr>
<tr>
<td>cloud</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>flag</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>flower</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>garden</td>
<td>○</td>
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<td>grass</td>
<td>○</td>
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<td>hose</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>ladder</td>
<td>○</td>
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<td>lawn mower</td>
<td>○</td>
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</tr>
<tr>
<td>moon</td>
<td>○</td>
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<td>pavement</td>
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Appendix 9: The CDI – Words and Sentences British Adaptation (Klee & Harrison, 2001): used in this study with permission from the author

**THE MACARTHUR COMMUNICATIVE DEVELOPMENT INVENTORY: TODDLERS**

**British English Adaptation**

### 11. PLACES TO GO

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<td>school</td>
<td></td>
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<tr>
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<td>house</td>
<td>shop</td>
<td></td>
</tr>
<tr>
<td>church*</td>
<td>outside</td>
<td>woods</td>
<td></td>
</tr>
<tr>
<td>circus</td>
<td>park</td>
<td>work</td>
<td></td>
</tr>
<tr>
<td>city centre, town</td>
<td>party</td>
<td>yard</td>
<td></td>
</tr>
<tr>
<td>country</td>
<td>petrol station</td>
<td>zoo</td>
<td></td>
</tr>
<tr>
<td>farm</td>
<td>picnic</td>
<td></td>
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<tr>
<td>film</td>
<td>playground</td>
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*or word used in your family

### 12. PEOPLE

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<tr>
<td>aunt</td>
<td>doctor</td>
<td>child’s own name</td>
<td></td>
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<tr>
<td>baby</td>
<td>fireman</td>
<td>people</td>
<td></td>
</tr>
<tr>
<td>babysitter</td>
<td>friend</td>
<td>person</td>
<td></td>
</tr>
<tr>
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<td>girl</td>
<td>pet’s name</td>
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<td>boy</td>
<td>grandma*</td>
<td>police</td>
<td></td>
</tr>
<tr>
<td>brother</td>
<td>grandpa*</td>
<td>postman</td>
<td></td>
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<tr>
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<td>sister</td>
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<td>man</td>
<td>teacher</td>
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</tr>
<tr>
<td>cowboy</td>
<td>mummy*</td>
<td>uncle</td>
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<tr>
<td>daddy*</td>
<td>nurse</td>
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</table>

*or word used in your family

### 13. GAMES AND ROUTINES

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<tbody>
<tr>
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<td>lunch</td>
<td>shopping</td>
<td></td>
</tr>
<tr>
<td>breakfast</td>
<td>nap</td>
<td>snack</td>
<td></td>
</tr>
<tr>
<td>bye</td>
<td>night night</td>
<td>so big!</td>
<td></td>
</tr>
<tr>
<td>dinner</td>
<td>no</td>
<td>thank you</td>
<td></td>
</tr>
<tr>
<td>give me five!</td>
<td>patty cake</td>
<td>this little piggy</td>
<td></td>
</tr>
<tr>
<td>gonna get you!</td>
<td>peekaboo</td>
<td>turn around</td>
<td></td>
</tr>
<tr>
<td>go potty</td>
<td>phone</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>hi</td>
<td>please</td>
<td></td>
<td></td>
</tr>
<tr>
<td>hello</td>
<td>shh/shush/hush</td>
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### 14. ACTION WORDS

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</tr>
<tr>
<td>blow</td>
<td>drive</td>
<td>hurry</td>
<td>ride</td>
</tr>
<tr>
<td>break</td>
<td>drop</td>
<td>kick</td>
<td>rip</td>
</tr>
<tr>
<td>bring</td>
<td>dry</td>
<td>kiaa</td>
<td>run</td>
</tr>
<tr>
<td>build</td>
<td>dump</td>
<td>knock</td>
<td>sing</td>
</tr>
<tr>
<td>bump</td>
<td>eat</td>
<td>lick</td>
<td>sit</td>
</tr>
<tr>
<td>brush</td>
<td>fall</td>
<td>like</td>
<td>sit</td>
</tr>
<tr>
<td>carry</td>
<td>feed</td>
<td>look</td>
<td>sit</td>
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<td>catch</td>
<td>find</td>
<td>listen</td>
<td>sit</td>
</tr>
<tr>
<td>chase</td>
<td>finish</td>
<td>look</td>
<td>sit</td>
</tr>
<tr>
<td>clap</td>
<td>fit</td>
<td>love</td>
<td>sit</td>
</tr>
<tr>
<td>clean</td>
<td>fix</td>
<td>make</td>
<td>skates</td>
</tr>
<tr>
<td>climb</td>
<td>get</td>
<td>open</td>
<td>sleep</td>
</tr>
<tr>
<td>close</td>
<td>give</td>
<td>paint</td>
<td>sleep</td>
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<tr>
<td>cook</td>
<td>go</td>
<td>pick</td>
<td>slides</td>
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<td>cover</td>
<td>hate</td>
<td>play</td>
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<td>cry</td>
<td>have</td>
<td>pour</td>
<td>watch</td>
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<td>cuddle</td>
<td>hear</td>
<td>pretend</td>
<td>stay</td>
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<td>cut</td>
<td>help</td>
<td>pull</td>
<td>stand</td>
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<tr>
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<td>hide</td>
<td>push</td>
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<td>draw</td>
<td>hit</td>
<td>put</td>
<td>sweep</td>
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</table>

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THE MACARTHUR COMMUNICATIVE DEVELOPMENT INVENTORY: TODDLERS
British English Adaptation

15. DESCRIPTIVE WORDS

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<tr>
<td>asleep</td>
<td>gentle</td>
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<td>awake</td>
<td>good</td>
<td>pretty</td>
</tr>
<tr>
<td>bad</td>
<td>green</td>
<td>quiet</td>
</tr>
<tr>
<td>better</td>
<td>happy</td>
<td>red</td>
</tr>
<tr>
<td>big</td>
<td>hard</td>
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<td>brown</td>
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<tr>
<td>careful</td>
<td>hurt</td>
<td>soft</td>
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<td>clean</td>
<td>last</td>
<td>sticky</td>
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<tr>
<td>cold</td>
<td>little</td>
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<td>long</td>
<td>thirsty</td>
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<tr>
<td>dark</td>
<td>loud</td>
<td>tiny</td>
</tr>
<tr>
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<td>mad</td>
<td>tired</td>
</tr>
<tr>
<td>dry</td>
<td>naughty</td>
<td>wet</td>
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<td>nice</td>
<td>windy</td>
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<tr>
<td>fine</td>
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16. WORDS ABOUT TIME

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<td>before</td>
<td>night</td>
<td>tomorrow</td>
</tr>
<tr>
<td>day</td>
<td>now</td>
<td>tonight</td>
</tr>
<tr>
<td>later</td>
<td>time</td>
<td>yesterday</td>
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17. PRONOUNS

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<td>her</td>
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18. QUESTION WORDS

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<th>Why</th>
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<td>what</td>
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<td>who</td>
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</table>

19. PREPOSITIONS AND LOCATIONS

<table>
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<tr>
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<th>On top of</th>
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</thead>
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<td></td>
<td></td>
</tr>
<tr>
<td>above</td>
<td>for</td>
<td></td>
</tr>
<tr>
<td>around</td>
<td>here</td>
<td></td>
</tr>
<tr>
<td>at</td>
<td>inside/in</td>
<td>there</td>
</tr>
<tr>
<td>away</td>
<td>into</td>
<td></td>
</tr>
<tr>
<td>back</td>
<td>next to</td>
<td>under</td>
</tr>
<tr>
<td>behind</td>
<td>of</td>
<td></td>
</tr>
<tr>
<td>beside</td>
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<tr>
<td>by</td>
<td>on</td>
<td></td>
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</table>

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Appendix 9: The CDI – Words and Sentences British Adaptation (Klee & Harrison, 2001): used in this study with permission from the author

THE MACARTHUR COMMUNICATIVE DEVELOPMENT INVENTORY: TODDLERS
British English Adaptation

### 20. QUANTIFIERS AND ARTICLES

| a | each | other |
| all | every | same |
| a lot | more | some |
| an | much | the |
| another | not | too |
| any | none | |

### 21. HELPING VERBS

| am | does | need/need to |
| are | don't | try/try to |
| be | gonna/going to | want to |
| can | gotta/got to | was |
| could | hatta/have to | were |
| did | is | will |
| did you | lemm/me le me | would |
| do | |

### 22. CONNECTING WORDS

| and | but | so |
| because | if | then |

### B. HOW CHILDREN USE WORDS

<table>
<thead>
<tr>
<th>Not Yet</th>
<th>Sometimes</th>
<th>Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Does your child ever talk about past events or people who are not present? For example, a child who went to the circus last week might later say circus, clown or band.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Does your child ever talk about something that’s going to happen in the future, for example, saying “choo choo” or “aeroplane” before you leave the house for a trip, or saying “sway” when you are going to the park?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Does your child talk about objects that are not present such as asking about a missing or absent toy, referring to a pet out of view, or asking about someone not present?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Does your child understand if you ask for something that is not in the room, for example, by going to the bedroom to get a teddy bear when you say “where’s the bear”?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Does your child ever pick up or point to an object and name an absent person to whom the object belongs? For example, a child might point to mammy’s shoe and say ‘mammy’.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

PART II – SENTENCES AND GRAMMAR

### A. WORD ENDINGS/PART I

<table>
<thead>
<tr>
<th>Not Yet</th>
<th>Sometimes</th>
<th>Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. To talk about more than one thing, we add an ’s’ to many words. Examples include cars (for more than one car), shoes, dogs and keys. Has your child begun to do this?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. To talk about ownership, we add an ’s’, for example, Daddy’s key, kitten’s dish and baby’s bottle. Has your child begun to do this?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. To talk about activities, we sometimes add ’ing’ to verbs. Examples include looking, running and crying. Has your child begun to do this?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. To talk about things that happened in the past, we often add ‘ed’ to the verb. Examples include kissed, opened and pushed. Has your child begun to do this?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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323
Appendix 9: The CDI – Words and Sentences British Adaptation (Klee & Harrison, 2001): used in this study with permission from the author

THE MACARTHUR COMMUNICATIVE DEVELOPMENT INVENTORY: TODDLERS
British English Adaptation

B. WORD FORMS
Following are some other words children learn. Please mark any of these words that your child uses.

<table>
<thead>
<tr>
<th>NOUNS</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>children</td>
<td>o</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>feel</td>
<td>o</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>men</td>
<td>o</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mice</td>
<td>o</td>
<td></td>
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<tr>
<td>teeth</td>
<td>o</td>
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</table>

<table>
<thead>
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</thead>
<tbody>
<tr>
<td>ate</td>
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<td>fell</td>
<td>o</td>
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<tr>
<td>made</td>
<td>o</td>
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<td></td>
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<tr>
<td>blew</td>
<td>o</td>
<td></td>
<td></td>
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<tr>
<td>flew</td>
<td>o</td>
<td></td>
<td></td>
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<tr>
<td>ran</td>
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<tr>
<td>bought</td>
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<tr>
<td>lost</td>
<td>o</td>
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</tr>
</tbody>
</table>

C. WORD ENDINGS/PART 2
Young children often place the wrong endings on words. For example, a child might say “Auntie gook home”. Mistakes like this are often a sign of progress in language. In the following lists, please mark all the mistakes of this kind you have heard your child say recently.

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<tr>
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<table>
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<tr>
<td>makeled</td>
<td>o</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

HAS YOUR CHILD BEGUN TO COMBINE WORDS YET, SUCH AS “NOTHER BISCUIT”, OR “DOGGIE BITE”?  
Not Yet   o   Sometimes   o   Often   o

IF YOU ANSWERED NOT YET, PLEASE STOP HERE. IF YOU ANSWERED SOMETIMES OR OFTEN, PLEASE CONTINUE.

D. EXAMPLES: Please list three of the longest sentences you have heard your child say recently.

1.  
2.  
3.  

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### E. COMPLEXITY

In each of the following pairs, please mark the one that sounds MOST like the way your child talks right now. If your child is saying sentences even longer or more complicated than the two provided, just pick the second one.

<table>
<thead>
<tr>
<th>Two shoe. Two shoes.</th>
<th>Baby blanket. Baby’s blanket.</th>
<th>Read me story. m/ummy. Read me a story. m/ummy.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daddy car. Daddy’s car.</td>
<td>That’s my lorry. That’s my lorry.</td>
<td>Want more juice. Want juice in there.</td>
</tr>
<tr>
<td>(Talking about something happening right now) Kitten sleep. Kitten sleeping.</td>
<td>(Talking about something that already happened) Daddy pick me up. Daddy picked me up.</td>
<td>There a kitten. There’s a kitten.</td>
</tr>
<tr>
<td>(Talking about something that already happened) I fall down. I fell down.</td>
<td>(Talking about something that already happened) Doggie kiss me. Doggie kissed me.</td>
<td>Where m/ummy go? Where did m/ummy go?</td>
</tr>
<tr>
<td>These my tooth. These my teeth.</td>
<td>You fix it. Can you fix it?</td>
<td>I no do. I can’t do.</td>
</tr>
<tr>
<td>Turn on light. Turn on the light so I can see.</td>
<td>Where’s my dolly? Where’s my dolly name Sam?</td>
<td>Don’t read book. Don’t want you read that book.</td>
</tr>
<tr>
<td>Want biscuits. Want biscuits and milk.</td>
<td>Lookit me! Lookit me dancing!</td>
<td>We made this. Me and Paul made this.</td>
</tr>
<tr>
<td>Biscuit m/ummy. Biscuit for m/ummy.</td>
<td>Lookit! Lookit what I got!</td>
<td></td>
</tr>
</tbody>
</table>

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Appendix 10: Post hoc analysis

10a: Variance of frequencies by experimental group according to parental level of education.

Figure 1: Outcomes for word types post intervention minus baseline

Figure 2: Outcomes for 2 year follow up minus baseline
Figure 3: Outcomes for MCDI words produced
Appendix 10b: Variance of frequencies by experimental group according to home ownership status

Figure 1: Outcomes for word types post intervention minus baseline

Figure 2: Outcomes for 2 year follow up minus baseline
Figure 3: Outcomes for MCDI words produced
Appendix 10c: Variance of frequencies by experimental group according to parental history of postnatal depression.

Figure 1: Outcomes for word types post intervention minus baseline

Figure 2: Outcomes for 2 year follow up minus baseline
Figure 3: Outcomes for MCDI words produced
Appendix 10d: Distribution of variance of outcome measures broken down by sex of child.

Figure 1: Distribution of variance of word types measured at baseline according to sex of child.

![Figure 1: Distribution of variance of word types measured at baseline according to sex of child.](image)

Figure 2: Distribution of variance of word types measured post intervention according to sex of child.

![Figure 2: Distribution of variance of word types measured post intervention according to sex of child.](image)
Figure 3: Distribution of variance of word types measured at 2 year follow up according to sex of child.