A pilot study to evaluate the effectiveness of an individualised and cognitive behavioural communication intervention for informal carers of people with dementia.

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The thesis is submitted in partial fulfilment of the requirements for the award of the degree of Doctor of Philosophy of the University of Portsmouth.

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<th>Description</th>
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<tbody>
<tr>
<td>ACQOL</td>
<td>The Adult Carers Quality of Life Scale</td>
</tr>
<tr>
<td>CCS</td>
<td>The Communication Competence Scale</td>
</tr>
<tr>
<td>CMHN</td>
<td>Community Mental Health Nurses</td>
</tr>
<tr>
<td>CSES</td>
<td>The Communication Self Efficacy Scale</td>
</tr>
<tr>
<td>DoH</td>
<td>The UK Department of Health</td>
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<tr>
<td>GSES</td>
<td>The General Self Efficacy Scale</td>
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<tr>
<td>HADS</td>
<td>The Hospital Anxiety and Depression Scale</td>
</tr>
<tr>
<td>MMSE</td>
<td>The Mini Mental State Examination</td>
</tr>
<tr>
<td>NHS</td>
<td>The National Health Service</td>
</tr>
<tr>
<td>NICE</td>
<td>The UK National Institute for Health and Care Excellence</td>
</tr>
<tr>
<td>OPMH</td>
<td>The Older Person’s Mental Health Service</td>
</tr>
<tr>
<td>OT</td>
<td>Occupational Therapy/Therapist</td>
</tr>
<tr>
<td>PWD</td>
<td>A person with dementia</td>
</tr>
<tr>
<td>RCSLT</td>
<td>The Royal College of Speech and Language Therapists</td>
</tr>
<tr>
<td>SIG</td>
<td>Special Interest Group</td>
</tr>
<tr>
<td>SLT</td>
<td>Speech and Language Therapy/Therapist</td>
</tr>
<tr>
<td>TEI</td>
<td>The Therapeutic Engagement Index</td>
</tr>
<tr>
<td>TS</td>
<td>The Talking Sense Program</td>
</tr>
<tr>
<td>UK</td>
<td>The United Kingdom</td>
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First and foremost I would like to thank my wife and children, Debi, Emily and Sam for your faith, patience, love and constant support – I dedicate this work to you.

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Dissemination

Publications

Barnes, C., & Markham, C. (in preparation). A systematic review of communication based, psychosocial interventions, for informal carers of people with dementia.


Findings from this study have contributed to this author’s co-authorship of the following publications:


**Poster Presentations**

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Portsmouth University Aging Network conference (November 2012).

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**Oral Presentations**

TARGET GP training event (November 2012). Portsmouth clinical commissioning group.

Royal College of Speech and Language Therapists Special Interest Group Meeting (May 2014). Royal College of Speech and Language Therapists, White Hart Yard, London.

Solent NHS Medical Education Meeting (September 2014). Solent NHS Trust, Portsmouth.

Solent NHS Trust adult SLT department study day (March 2015).

Presentation to the Solent NHS Trust research conference (July 2015).

University of Portsmouth research seminars programme (July 2015).
Declaration

Whilst registered as a candidate for the above degree, I have not been registered for any other research award. The results and conclusions embodied in this thesis are the work of the named candidate and have not been submitted for any other academic award.

Signed: ......................................................  Date: .........................................

Word Count = 67,115 excluding references and appendices.
Abstract

**Background:** People with dementia and family carers experience difficulties communicating. This research aimed to review and contribute to the theory and evidence-base for single component, psychosocial interventions that address these difficulties.

**Methodology:** A systematic review identified and critically appraised controlled trials addressing dementia carer communication difficulties. The best evidence identified by this review supported the one-to-one, individualised, cognitive behavioural approach used in the previously developed Talking Sense manual.

A pilot, randomised controlled trial then compared 27 carers who completed three 1:1 individualised sessions using Talking Sense with 25 carers who received a single, knowledge-only, control session. The primary outcome was measured by the Hospital Anxiety and Depression Scale. Semi-structured interviews were conducted with 15 purposively selected carers from the treatment group. Finally, a concurrent mixed methods analysis identified similarities and differences in data sets which are synthesised in the final discussion.

**Results:** Some statistically significant results suggested carers receiving the Talking Sense intervention had fewer communication difficulties happening and felt more valued by their relatives. A score close to significance suggested they perceived their relatives to be more communicatively competent. There were no significant differences for the primary outcome measure of carer anxiety and depression as well as carer quality of life, general and communication self-efficacy.

Thematic analysis of the interviews suggested that carers benefitted from meeting with an expert and an individualised programme. Carers reported changes in feelings, thinking and reactive communication and positive changes in their relative’s communication but had difficulty recalling specific learning, developing self-insight and describing implementation intention-setting.
The mixed methods analysis supported changes in person with dementia competence and communication difficulties happening, and the absence of changes in anxiety and depression.

**Conclusion:** The results of this research support the use of Talking Sense by expert interventionists. The mixed methods analysis suggests that at least part of the change in person with dementia communication was attributable to actual or perceived change by that person. The potential for change in the person with dementia, associated with changes in carer thinking and behaviour, is the most significant finding from this programme of research.
Outline of the Thesis

This section provides an outline of the thesis. In addition, separate overviews are provided at the beginning of each chapter.

Communication can be difficult when it doesn’t make sense to the speaker or the listener. Attempts to make sense of communication can include consideration of the meaning of words and actions, our beliefs about why something is happening or what we should do in a particular situation. People with dementia and their relatives can be more or less aware of experiencing communication difficulties and of attempts to make sense of them when they are together. This programme of research has taken a mixed methods approach to evaluate a novel intervention, the Talking Sense manual, designed for professionals working with carers of people with dementia, to help them make sense of the communication difficulties they experience with their relatives.

The thesis is divided into seven chapters: (1) an introduction, (2) a systematic literature review, (3) an overview of the programme of study and the intervention (4) a pilot randomised controlled trial, (5) a semi-structured interview study, (6) a mixed methods analysis and final discussion and (7) a conclusion.

Chapter one – Introduction: This chapter is divided into four sections. The first section provides the background to people with dementia and their carers detailing types and prevalence of dementia and the range of dementia symptoms including changes in memory, behaviour and mood. Hereafter, the term carers is used to refer to informal family carers who provide the majority of care for people with dementia. The second section describes communication difficulties from the perspective of both the person with dementia and their carer. Theories of communication difficulty in dementia are also presented. The third section introduces general interventions for people with dementia followed by a more detailed framework for carer focused psychosocial interventions. From this framework, psychosocial interventions are described as either multi-component or single component (e.g. communication) interventions. One key
evidence-based intervention approach, cognitive behaviour therapy, is also introduced. The fourth section introduces the range of outcome measures typically used in psychosocial intervention research.

**Chapter two - Systematic literature review:** This chapter is divided into 5 sections. The first section details a specific focus for the review, namely single communication component controlled studies for dementia family carers. The review chapter also includes a summary of the literature for major communication component and multi-component interventions, qualitative research on communication interventions and previous systematic reviews considering both single communication component and multi-component interventions. The second section of this chapter describes in detail the methods used to search, evaluate and rate included studies. In the third section, eight studies are described in detail using a synopsis and synthesis approach. The fourth section of this chapter introduces a recent UK based psychosocial carer study (Livingston et al., 2013) which is used throughout the thesis for comparison of design and results. The final section identifies clinical and research implications for psychosocial interventions and in particular, those that address communication difficulties. These recommendations form the basis of the research programme design and intervention detailed in chapter 3.

**Chapter three - An overview of the programme of research and an introduction to the intervention: the Talking Sense manual:** This chapter contains 4 sections. The first two sections provide an overall aim, to determine the effectiveness of the Talking Sense intervention, followed by an overview of mixed methods. This research used a concurrent mixed methods design which included a pilot randomised controlled trial and a series of semi-structured interviews. The second section of this chapter describes the development of the Talking Sense manual with examples of content. The Talking Sense manual was developed prior to this programme but modified for face to face delivery in this research. The third section explains the importance of developing theories of delivery and effect (mechanisms of action) for psychosocial interventions. A number of
theories are presented which were identified when Talking Sense was developed.

Chapter four – The pilot randomised controlled trial: The format of this chapter follows the CONSORT checklist (Moher et al., 2010) for the reporting of randomised controlled trials. The chapter contains four sections. The first, introduction, section provides background information and context as well as the objectives of the RCT component. The second, methods, section explains decisions made in the design of this study, outcome measurement selection and specific details including ethical approval, the processes for participant selection, randomisation, intervention delivery and outcome measurement. In the third section, the quantitative results of the pilot study are presented and summarised highlighting significant differences between the control and treatment group. The fourth, discussion, section considers only the quantitative results of the pilot study. Results are discussed under three headings; limitations, generalisability and implications. Specific research and clinical implications are included alongside the mixed methods discussion in chapter 6.

Chapter five – Qualitative study: This chapter contains five sections and follows a similar structure to chapter 4. This chapter provides specific detail for a series of semi-structured interviews that were conducted with 15 purposively selected carers after they had received the Talking Sense intervention. The first section provides an overview of qualitative research. The second section then provides an overview of the limited qualitative research available in this field. The third, methods, section details the aims of the semi-structured interviews as well as the process of conducting the interviews using a third party interviewer. The use of purposive selection and the concept of data saturation are also explained. This section explains in detail the framework approach of thematic data analysis used. The fourth section presents the interview results in six main themes including relevant quotes from carers. The fifth, discussion, section begins with the limitations of this interview study, and then uses a number of summarised points from the main interview themes to consider the generalisability and
implications of these findings. Many of these implications are detailed in the combined clinical and research implications recorded in chapter 6.

Chapter six – Mixed methods analysis and final discussion: This chapter contains three, main components; the mixed methods analysis, the mixed methods discussion and the final discussion. These components are divided into eight sections. The first two sections detail the mixed methods analysis, results and key topics discussion. Using a defined mixed methods analytical approach, the results from chapters 4 and 5 are combined where possible and also compared to findings detailed in chapters 1 and 2. Consideration is also given to the proposed theoretical mechanisms of action for the Talking Sense intervention detailed in chapter 3. The third section aims to summarise the overall programme of research. Following this, two further sections consider theoretical and methodological implications from this overall programme of research. A further section then summarises the main strengths of this programme of research. The final two sections provide a detailed breakdown of clinical and research implications and recommendations based on the discussions in this and previous chapters.

Chapter seven – Conclusion: This chapter acts as the conclusion for the overall programme of research. It aims to address the aims or research questions contained within the programme of research and the implications of the programme's findings. This chapter also includes the primary recommendations for future research.
1 Chapter One: Introduction

This chapter aims to provide an introduction to dementia and the people that live with it, their family carers and the communication difficulties they experience together.

The chapter is divided into four sections:

- Background information about dementia and carers
- Communication difficulties for people with dementia and their carers
- Interventions in dementia care
- Outcomes in psychosocial intervention research

In the broad context of interventions in dementia care, a more specific framework for psychosocial interventions for dementia carers is introduced (see 1.3.2). This framework will be used in this programme of research to consider a specific approach, called “Talking Sense”, which has been designed to address carers’ communication difficulties.

1.1 BACKGROUND

This section provides background information about the prevalence, presentation and prognosis of dementia. This includes distinctions between types of memory affected, behaviour changes and the incidence of depression. This is followed by demographic information about family carers, referred to thereafter as carers. The varied experience of carers, including what they can feel and think, is introduced alongside evidence of differences between sub-groups of carers. The relatively high incidence of carer depression is highlighted as well as the significant cost of caring for people with dementia.

1.1.1 About Dementia

The diagnostic and statistical manual (5th edition) of the American Psychiatric Association (2013) defines dementia as “a major neuro-cognitive disorder resulting in cognitive deficits that interfere with independence”. The previous
edition of this manual (American Psychiatric Association, 2000) included a more detailed description of dementia as:

“a memory impairment coinciding with related changes in another cognitive domain such as language, judgement or abstract thinking of sufficient severity to cause impairment in social and occupational functioning which is a decline from previously higher levels of functioning” (American Psychiatric Association, 2000).

1.1.1.1 Types of dementia
There are as many as 75 different conditions that can cause dementia. These include dementia associated with conditions such as Parkinson’s disease, Huntington’s disease, progressive supranuclear palsy (PSP) and HIV- Aids (Bourgeois & Hickey, 2009).

Alzheimer’s disease is the most common form of dementia, thought to affect 62% of people with dementia. During the course of the disease, plaques and tangles develop in the structure of the brain caused by the build-up of certain proteins, leading to the death of brain cells. Vascular dementia, which includes arteriosclerotic changes in blood supply to the brain, cerebrovascular disorders and ischemic haemorrhages, is thought to affect 17% of people with dementia. Types of dementia can also co-exist. The incidence of mixed dementia (Alzheimer’s and vascular) is estimated to be 10% of cases (Alzheimer’s Society, 2014).

1.1.1.2 Prevalence of dementia
There are approximately 800,000 people with dementia in the UK. This figure is expected to rise to one million by 2021. Two thirds of these people live in the community (Alzheimer’s Society, 2014).

The prevalence of dementia increases with age, affecting 1 in 1400 people between 40 and 64, 1 in 100 between 65 and 69, 1 in 25 between 70 and 79 and 1 in 6 above 80 years of age (Alzheimer’s Society, 2014).
Determining the life expectancy and rate of decline in dementia is difficult. On average, people with Alzheimer's disease live for eight to ten years after the onset of symptoms. However, life expectancy varies considerably dependant on age at onset. For example, people diagnosed in their 60s and early 70s can expect to live for around seven to ten years, whereas someone diagnosed in their 90s will, on average, live for about three years. Life expectancy will also depend on whether the disease was diagnosed early or in the later stages (Alzheimer’s Society, 2013).

1.1.1.3 Memory difficulties
Memory difficulties in dementia vary by type of dementia but typically affect working and short term memory earlier in the progression of the disease, whilst long term and procedural memory are more preserved (Bourgeois & Hickey, 2009).

Bourgeois and Hickey (2009) describe short term memory difficulties in dementia as “a disruption in the automatic unconscious nature of storing relevant information for later retrieval”. Whilst this is typically thought of as an inability to learn new information, they argue that some individuals with milder difficulties can still learn new information if they use appropriate training strategies.

Procedural memory has been referred to as the “how to” rather than the “what” of information. Many activities of daily living e.g. cooking, bathing, eating, and grooming rely on procedural memory and are often more preserved in the early stages of dementia. It is thought that this preservation of procedural memory comes from the over-learning that occurs by repetition of tasks and skills throughout life (Bourgeois & Hickey, 2009).

1.1.1.4 Changes in behaviour
Difficulties with memory are often associated with changes in behaviour for people with dementia. Behaviour changes in dementia can present as disorientation and confusion, repetitive verbal and physical behaviours, aggression and apathy. The frequency, intensity and severity of behaviour change vary as a function of the individual, the stage and aetiology of the
dementia and a variety of environmental factors including the responses of others (Bourgeois & Hickey, 2009).

1.1.1.5 Depression in dementia
Clinical depression is also relatively common in dementia. Enache, Winblad and Aarsland (2011) report an incidence of depression of between 20 to 30% of people with Alzheimer’s disease. This proportion seems to be relatively similar across dementia stages and is thought to be higher in patients with vascular dementia and Lewy body dementia. In a large UK population study, the incidence of depression in 2,500 comparable people without dementia was calculated to be 8.6% (Winblad et al., 2004).

1.1.2 About carers
Care for people with dementia is provided by both professional paid carers and informal, unpaid and most often, family carers.

1.1.2.1 Who cares
The Princess Royal Trust for Carers (2014) calculated that there are almost seven million family carers in the UK. They expect this number to increase by 3.4 million over the next 30 years. Of these seven million, there are an estimated 670,000 people in the UK acting as primary family carers for people with dementia (Alzheimer’s society, 2014). Unless otherwise stated, the term carer is hereinafter used in this thesis to refer to family carers of people with dementia.

The majority of care for people with dementia is provided by their family (Walker, 1995). Of these informal carers, approximately 60% are women (Carers UK, 2013). One person will usually and often by default take the role of principle carer (Pesiah, 2006). The average age of a family carer of someone with dementia in the UK is between 60 and 65 years old (Princess Royal Trust for Carers, 2014).

1.1.2.2 What carers do
Schulz (2000) points out that the provision of support or assistance from one family member to another is a normal aspect of human interaction. For example,
when a wife provides care to her husband with dementia by preparing his meals or cleaning the house, she may be doing tasks she has always done within their home and relationship. Assistance with feeding, bathing and dressing or provision of medication are more typical of the extraordinary care provided by carers which exceeds the boundaries, in this example, of what is typical for spousal relationships. Consequently, caring can be defined as providing extraordinary care, beyond the bounds of what has previously been established. This may explain why adult children sometimes report more caring burden than spouses, despite providing fewer hours of actual care (Schulz, 2000).

1.1.2.3 Carer feelings, anxiety and depression
Between 18 to 47% of dementia carers report feelings of anxiety and related depression (Akkerman & Ostwold, 2004; Charlesworth, 2001). This appears to be influenced by factors such as time spent caring, outside pressures, increased isolation, feelings of disappointment and poorer health of the carer (Andren & Elmstahl, 2008). Savundranayagam and Montgomery (2010) also reported carers feeling a loss of companionship and reciprocity and feelings of frustration and sadness all related to changes in the quality of social interactions both with their relative with dementia, and more broadly, due to changes in the nature of interactions within their family and social networks. Consequently, it would seem that carers under significant pressure are more likely to evaluate their caring role as inadequate, ultimately leading to providing care for a shorter period (Charlesworth & Reichelt, 2004).

1.1.2.4 Carer beliefs
Qualitative researchers have explored the belief systems of carers of people with dementia. In one example, Paton, Johnston, Katona and Livingston (2004) identified carers that attributed cognitive, behavioural and psychological symptoms of dementia to causes other than the dementia. They found carers often believing that the person with dementia had control over their behaviour, with a substantial number of carers believing that the person could still return to normal. Paton et al. (2004) argued that carers are unlikely to seek information and skills to approach difficulties that they don’t attribute to the illness.
1.1.2.5  Carer health
The 2011 Census for England and Wales (UK Office for National Statistics, 2011) identified that both male and female carers are between 2 and 3 times more likely to have “not good” general health if they are providing 50 hours or more unpaid care per week than if they provide no unpaid care. Males had higher ratios of poor reported health than females, suggesting male health is affected more by providing unpaid care than female health.

1.1.2.6  The cost of caring
The overall cost to UK society of dementia is estimated to be £23billion. The value to the UK of care work provided by family carers is estimated at £8billion (Alzheimer’s society, 2014).

1.2  COMMUNICATION DIFFICULTIES FOR PEOPLE WITH DEMENTIA AND THEIR CARERS
This section provides information about the presentation and progression of communication difficulties for people with dementia and the effect that this has on carers. Theories of communication difficulty and communication differences between sub-groups of carers are introduced, as well as the relatively high priority given by carers to address communication difficulties.

1.2.1.1  Communication difficulties for people with dementia
Communication difficulty is one of the earliest presenting features for most people with dementia (Bourgeois & Hickey, 2009). The most common early language symptoms of a typical presentation are word-finding, naming and verbal-description difficulties. Phonology (the production, selection and sequencing of speech sounds), syntax (grammar) and the ability to interpret non-verbal communication (communicating without words using gestures, facial expression, tone of voice, touch and distance) remain relatively intact until the later stages of most dementia presentations (Bourgeois and Hickey, 2009). People in the middle to later stages of dementia can experience considerable difficulty engaging in meaningful conversation when the focus is on content or meaning, though they may have preserved ability to interact at a non-verbal,
People with mild dementia typically report difficulty thinking of names and words, difficulty understanding and remembering requests and difficulty thinking of topics for conversation. As well as forgetfulness, their family often notice they have become quieter or alternatively more talkative, with subtle changes in social appropriateness. They may also become harder to persuade and reason with, often repetitive and sometimes develop blaming or accusatory behaviour (Bourgeois & Hickey, 2009).

Every communication interaction carries messages, often implied and non-verbal, about the relationship between communicators. This relationship message conveys information about the degree of intimacy and the power balance (Hendryx-Bedalov, 1999). When families experience dementia, the content and understanding of this message can change for the person with dementia and the carer.

1.2.1.2 Communication difficulties for carers

Communication difficulties are one of the most frequent and hardest to cope with experiences for family carers (Nolan, Ingram, & Watson, 2002; Egan, Berube, Racine, Leonard, & Rochon, 2010). Carers of people exhibiting communication and behaviour difficulties have been found to be twice as likely to have their own psychiatric distress (Gilleard, Belford, Gilleard, Whittick, & Gledhill, 1984). Carers suffering from more depressive symptoms have also been found to use less positive communication themselves (Braun, Mura, Peter-Wright, Hornung, & Scholz, 2010). How long an informal carer of a person with dementia provides care has also been strongly correlated with their experience of challenging behaviours and communication difficulties (Searson, Hendry, Ramachanrdan, Burns, & Purandare, 2008).

Knowing how to respond to changes in communication is very difficult. Carers report feeling exhausted by having to think more about what to say (Killick & Allan, 2001; Haley, Wadley, West, & Vetzel, 1994). They often take more
responsibility for what is talked about and avoid subjects that cause distress (Killick & Allen, 2001). Carers can experience verbal challenging behaviours from people with dementia or, when frustrated, even launch their own verbal attack (Santo Pietro, 1994). This can contribute towards the feelings of guilt they often report (Steffen, McKibbin, Zeiss, Gallagher-Thompson, & Bandura, 2002). Carers that do find themselves criticising their relative, perhaps in an attempt to help them remember, tend to feel more burden than those that use encouragement liberally (Charlesworth & Reichelt 2004). Having said this, it is important to note that many carers experience moments of joy, pleasure and humour from caring (Searson et al., 2008).

1.2.1.3 Communication theories in dementia

A number of theories of communication difficulty in dementia have been proposed:

**The communication predicament of old age** is a theory, formulated by Lubinski (1995) which describes a downward negative cycle of communication experience for the person with dementia. The components include use of “elderspeak” (Hummert, Shaner, Garstka, & Henry, 1998), presumed incompetence and learned helplessness of the person with dementia. Elderspeak is a style of speech typically used by young adults to address the elderly with accommodations including the use of shorter sentences, simpler vocabulary and repetition. For some it aids understanding whilst for others it can be interpreted as infantilizing and patronising.

Young, Manthorp and Howells (2011) describe this as a cycle where, the more the person with dementia is subjected to “elderspeak”, the less likely they are to communicate in a truly adult and engaged way. The less they are seen to communicate in a truly adult and engaged way, the less others then attempt to engage with them in this way.

**Communication accommodation theory** suggests that we adjust our verbal and non-verbal communication in response to circumstances (Giles & Ogay, 2006). We are said to converge (become more like) or diverge (less like) the person we
are speaking to. Young et al. (2011) adds that the study of convergence has shown that people converge not towards a reality of a person, but towards a stereotypical idea of that person or the group they are felt to belong to. Using “elderspeak” is an example of carers converging to speak in a way they imagine the person with dementia needs them to speak.

1.2.1.4 Differences between carers sub-groups
There are also reported communication differences between sub-groups of carers. Studies suggest that spouse carers tend to have a greater awareness of how communication is affected, whilst adult child carers can experience more difficulty communicating across distances (e.g. on the telephone) or combining quality communication with essential tasks (Marwit, Meuser, & Bryer, 2005). Male carers are more content with limited communication (Marwit et al., 2005), tend to receive more praise for their caring (Chang, 1999) and are more likely to purchase outside support (Corcoran, 1992), which potentially increases access to communication partners. Some cultures e.g. Asian and Afro-Caribbean have more of a tradition of caring within the family, which can influence their expectations (Jolley et al., 2009; Gray, Jimenez, Cucciare, Tong, & Gallagher-Thompson, 2009). Although these traditional carers can find it harder to ask for help.

1.2.1.5 Carer information needs and support
When asked about their information and support needs, carers have rated communication difficulties and related strategies highly. Wackerbath and Johnson (2009) identified “communicating with the care receiver” as the third (out of 22) most important topic, whilst 83% of carers in a study conducted by Rosa et al. (2009) rated communication skills as the most important topic to address.
1.3 INTERVENTIONS IN DEMENTIA CARE

This section introduces the range of interventions provided in dementia care, approaches to supporting carers in addressing communication difficulties and more specifically the group of interventions known as psychosocial carer interventions. One specific intervention approach, “cognitive behaviour therapy”, which is used in the study that follows, is also introduced.

Contemporary medical treatment for people with dementia is directed at early assessment and intervention (UK Department of Health, 2009a). Over the last decade, there have been advances in the provision of drugs, particularly for Alzheimer’s disease, that for some people reduce the rate of memory decline. There have also been high profile drives for more conservative use of medication to manage behavioural symptoms (Royal College of Psychiatrists, 2013).

Non-pharmacological treatments for people with dementia include information provision, counselling, behaviour therapy, memory aids and strategies, and cognitive stimulation therapy. These are typically provided in individual or group formats (Bourgeois & Hickey, 2009).

The literature contains diversity in the terminology used to define interventions specifically for carers. Taking this into consideration, support for carers of people with dementia can be broadly divided into psychosocial support and more practical support e.g. home care, day centre and residential respite. A large proportion of carer support occurs in group settings (Schulman & Mandel, 1988; Thompson, Spilsbury, Hall, Birks, Barnes, & Adamsom, 2007). Some carers may also have access to health and social care professionals, counsellors, advice telephone lines, community nurses, books, leaflets and films (Dementia UK, 2010).

1.3.1.1 Communication advice and approaches

The most common way of addressing communication difficulties with carers is to provide a list of general guidelines aimed at supporting successful communication, such as “slow your speech” or “use yes/no questions” (Small, Gutman, & Makela, 2003) and recommended approaches such as “validation
therapy” (Bleathman & Morton, 1996) or “reminiscence” (Powell, Hale, & Bayer, 1995). Validation therapy, for example, is an approach suitable only for people with more advanced dementia that relies on the communication partner valuing the quality of the interaction above the content. Validation is achieved by mirroring the perceived underlying meaning of what is being said, repeating key words and asking vague questions very much in the style of a newspaper reporter (Feil, 1995).

A number of communication guides for supporting informal carers of people with dementia have been published (e.g. James, 2008; Straus, 2001). Typically, these combine a range of strategies for maintaining and maximising communication. However, very few of these guides provide evidence on the efficacy of the guide as an intervention, whilst many have little evidence to support the selection of strategies included in the guide. The systematic review that follows (chapter 2) includes examples of evidence based programmes.

McGilton et al. (2010) suggest that all carer interventions should have a theoretical framework to explain the mechanism by which they work. Unfortunately, Charlesworth and Newman (2006) suggest theoretical frameworks are often not made explicit within guides or research publications.

1.3.2 Psychosocial interventions

Psychosocial interventions in dementia care are defined by the INTERDEM group, a pan-European network of dementia researchers, as:

“interventions that involve interactions between people to improve psychological or social functioning” (Moniz-Cook, Vernooij-Dassen, Woods, Orrell, & Interdem Network, 2011).

This can include interventions as diverse as one off education sessions, telephone help lines and residential courses (Charlesworth & Newman, 2006). Subcategories of psychosocial interventions including education, support, counselling, individual or group, cognitive behavioural, skills training, case
management and multi-component have all been used in different combinations in systematic reviews (Charlesworth & Newman 2006).

Schulz (2000) provides a useful framework for considering carer interventions:

**Component(s) being targeted**: The intervention may be targeting specific change in one or more component (multi-component interventions). Examples of components include communication, person with dementia behaviour, use of day services, stress management, activities and carer thinking.

**Domain(s) being targeted**: Schulz (2000) defines these as knowledge, skills, behaviour or affect of the carer or person with dementia.

**Delivery system characteristics**: This considers aspects of the intervention such as frequency, face-to-face or group, and individualisation or standardisation (e.g. use of a generic package) of delivery.

**Mechanisms of action**: These are the theoretical processes which could be used to describe why the intervention might bring about a specific outcome. Examples could include learning theory, stress process models, motivational theories, behaviour change theories and personal construct or cognitive behavioural theory (Schulz, 2000).

Using this framework, each psychosocial intervention can be described by a unique combination of components, domains targeted, delivery methods and theoretical methods of action. A theoretical framework for the Talking Sense intervention used in this study is introduced in chapter 3.

Schulz (2000) introduces a further distinction between single component and multi-component psychosocial interventions. An example of a multi-component intervention would be Livingston et al. (2013), who used a manual-based coping strategy programme to address components which included education, stress, emotional support, behaviour management, assertive communication, relaxation, future planning, activity management and skill maintenance. In
contrast, a single component intervention is designed to address just one topic; the study by Liddle et al. (2012) is a single component intervention which addresses communication difficulties alone.

The INTERDEM manifesto (Moniz-cook et al., 2011) suggested that it is important to identify the relative value of each component and the characteristics of carers who are most likely to benefit from addressing it.

1.3.3 Cognitive Behaviour Therapy
Cognitive behavioural therapy (CBT) is considered to be the most evidence-based psychotherapy and behaviour management approach in popular use today. It is used for a wide range of conditions, though especially for the treatment of anxiety and depression (Cooper, Balamurali, Selwood, & Livingston, 2006; Wells, 2008).

A simplified interpretation of the cognitive behavioural model suggests that events lead to thoughts, thoughts lead to feelings and physiological changes, which then result in actions or responses (i.e. a cyclical process). Thoughts in particular are influenced by our beliefs and assumptions (Wells, 2008). This model of CBT is illustrated in Figure 1-1 below.
CBT is an interactive therapy which relies on the participant’s involvement in goal-setting and identifying areas for discussion. Another element of CBT is the use of the Socratic dialogue which uses questions and summary statements to explore the meaning of the participant’s experience (Wells, 2008). The aim of CBT is to address and change unhelpful thinking and behaviour.

The NICE (National Institute for Health and Care Excellence, 2006) clinical guidelines for dementia suggest that;

“Carers of people with dementia who experience psychological distress ..... should be offered psychological therapy, including cognitive behavioural therapy, conducted by a specialist practitioner.”
1.4 OUTCOMES IN PSYCHOSOCIAL INTERVENTION RESEARCH

This section introduces outcomes that have been used in psychosocial intervention research.

A number of outcome measures have been used in carer research; these include carer burden, depression, quality of life, observations of communication, knowledge evaluations, self-efficacy and reports of carer experience, as well as a range of measures considering the experience, cognition, ability and behaviour of the person with dementia (Charlesworth & Newman 2006; Schulz, 2000).

To identify suitable outcomes, Schulz (2000) suggests asking if the outcome is important to the individual and to society, and secondly evaluating how large any change would need to be in order for the change to be considered significant. Gwyther (1997) suggests that people with dementia prefer outcomes that generate normalcy, inclusion, meaningful activity, quality of life, reduction of anxiety and enhancement of comfort.

Nurock and Wojciechowska (2007) asked carers about what outcomes mattered to them. They described significant outcomes as follows; improved cognition and memory for their relative, reduced challenging behaviour, reduction in carer stress, prolonged life of their relative, a better trained higher quality professional workforce and the ability to communicate better with the person they care for.
2 Chapter Two: Systematic Literature Review

The primary aim of this chapter is to present findings of a systematic literature review designed to identify the evidence base for dementia carer psychosocial interventions and in particular, single communication component interventions i.e. studies where the intervention only addressed communication difficulties. The review considers only interventions provided for informal carers arguing that the activities, needs and culture of professional carers are significantly different. The secondary aim is to identify and present implications for clinical practice and recommendations for future research, which informed the development of the intervention and research methods described in the chapters that follow.

The chapter is divided into five sections:

- Focus of the systematic review
- Review method
- Review results (synopsis and synthesis)
- A comparative contemporary study
- Implications for clinical practice and future research

This review includes discussions of previous systematic reviews for single component communication studies as well as systematic reviews for more general multi-component interventions. Findings from these multi-component reviews are included because they represent a significantly larger evidence base for psychosocial carer interventions. This chapter also introduces a contemporary UK dementia carer psychosocial intervention study which is used for detailed comparison of design and results in this thesis (Livingston et al., 2013).

2.1 FOCUS OF THE SYSTEMATIC REVIEW

This section starts by giving a broad definition of a systematic review. The specific focus of this review is then given, which includes questions addressed by this review. Terminology used during the review process is also introduced.
2.1.1 Definition of a systematic review

The Cochrane Collaboration (2011) define a systematic review as one that aims to collate all evidence that fits defined eligibility criteria in order to answer a specific research question. It uses explicit and systematic methods with the intention of minimizing bias, and therefore provides more reliable findings.

The key elements of a systematic review are:

- a clearly stated set of objectives including pre-defined eligibility criteria for studies
- an explicit and reproducible methodology
- a systematic search that attempts to identify all studies that would meet the eligibility criteria
- an assessment of the validity of the findings of the included studies
- a systematic presentation, and synthesis, of the characteristics and findings of the included studies

2.1.2 Focus of this review

This review has only considered psychosocial interventions provided for informal carers of people with dementia. Whilst many interventions may be suitable for use with both professional and informal carers, the experience of informal carers is considered to be significantly different to that of formal carers in terms of emotional and practical experience, attachment, role, history, expectations and objectives (Ward-Griffin, 2002). Levine and Murray (2004) describe a culture clash between informal and professional carers as well as professional carers and policy makers, primarily driven by differing values and priorities. They suggest that this culture gap is particularly noticeable in the areas of communication and especially with truth-telling. For example, they argue the use of “therapeutic lies” is most acceptable to family carers and least acceptable to policy makers (Levine & Murray, 2004).

This review also only considers interventions that address communication difficulties occurring between the informal carer and the person with dementia. This single component focus (Schulz, 2000) was chosen to make it easier to
identify the likely mechanisms of action from a more homogenous intervention and to make any recommendations more relevant and reproducible for clinicians working specifically to address the communication needs of carers. This approach was also chosen to inform the development of the research programme detailed in this thesis (see chapter 3 onwards).

This review includes comparisons to previous systematic reviews for single component communication interventions to help establish rigour and the contemporary nature of this review. Reference is also made to systematic reviews for the much larger evidence base of multi-component interventions, in order to compare findings and consider a broader evidence base for working with carers.

2.1.3 Review structure
This review has followed a structure recommended by Aveyard (2011) which is in keeping with contemporary approaches for review writing in the speech and language therapy profession as discussed by Marshall, Goldbart, Pickstone and Roulstone (2011), as well as previous approaches to review writing in the field of psychosocial interventions for dementia carers (e.g. Thompson et al., 2007). The use of narrative synopsis and synthesis follows guidelines published by Popay et al. (2006).

This review has only considered English language publications. There is some evidence to suggest that there are similarities between English-speaking carer populations in the UK, USA and Australia which is sufficient to make research published there comparable (Burns et al., 2010).

2.1.4 Questions addressed by this review
This review asks:

- Do interventions for informal carers of people with dementia that specifically address communication difficulties generate outcomes that are significant for professionals and carers?
• How does this evidence compare and relate to the wider research evidence for all dementia carer psychosocial interventions?
• What are the methodological weaknesses in existing research and therefore implications and recommendations for future research and intervention development?

2.1.5 Definitions
The following definitions were used in this review;

*Carers or Caregivers* (a term primarily used by American publications) refers to non-paid relatives or friends of the person with dementia. Carers could be co-habiting or visiting spouses/partners, children or friends. No minimum contact or communication time was used to define caring as this has rarely been reported in studies and may not necessarily indicate communication quality.

*People with dementia* refers to people with a primary diagnosis of a form of dementia including Alzheimer’s disease and vascular dementia.

*Communication* refers to the verbal and non-verbal interactions that occur between the carer and the person with dementia. Communication difficulties can be experienced by the person with dementia or the carer, leading to frustration, anxiety and difficulties carrying out tasks or sharing meaning and experiences (Andren & Elmstahl, 2008a).

2.2 REVIEW METHOD
This section provides specific detail of the method used in this review including: search terms, inclusion criteria, examples (with rationale) of excluded studies, the method for assessment of study quality and details of studies not available.

Electronic searches were conducted using the databases AMED, BNI, CINAHL, MEDLINE, PSYCHINFO, EBSCO HOST, SCIENCE DIRECT and PROQUEST.

Searches were also conducted using Google Scholar. A manual search was also conducted on The Gerontologist journal, which has a history of publishing dementia carer studies. After the initial collection of studies was obtained, a
further search was conducted for studies cited but not yet identified, by reviewing reference lists from identified studies and reviews published within the last 5 years. Searches sourced articles published up to the end of December 2014.

The initial review searches were first conducted between September 2010 and September 2011 (i.e. prior to the onset of the study detailed in chapter 3 onwards). Searches for newly published systematic reviews and single communication component interventions were repeated regularly until January 2016.

Systematic reviews published since the year 2000 (i.e. ten years before the initial searches were first conducted) considering either specific communication interventions or all psychosocial interventions for dementia carers, were also identified during this search process.

2.2.1 Search terms
A combination of the following search terms and Boolean operators was used:

Dementia OR Alzheimer*

Carer* OR Caregiver* OR Family OR Relative

Communication OR Behaviour OR Interaction*

Support OR Training OR Intervention* OR Program* OR Counselling

*represents a wildcard

2.2.2 Inclusion criteria for treatment studies
No time limit on publication date was applied to treatment studies in order to allow for maximum inclusion and an appreciation of changes in design, outcome measures and findings over time.
Studies were included if:

- the primary recipient of the intervention was an informal carer
- the cared-for people had a primary diagnosis of dementia
- symptoms, behaviour and experiences attributable to dementia and being a carer were the subject of the interventions
- the intervention was described as delivered individually or in groups, face to face, telephone or by media (e.g. books, dvd, etc)
- interventions appeared to have either a single or significant component (Schulz, 2000) addressing communication difficulties occurring between the carer and person with dementia
- study design included randomised or non-randomised controlled trials
- studies were published in English

Studies were excluded if:

- the carer was not the focus e.g. studies looking only at the effectiveness of communication approaches such as reminiscence or validation therapy
- interventions were delivered to a mixed group of informal and professional carers

2.2.3 Examples of studies excluded from initial searches

Some carer intervention studies describe physical treatments such as prescription of antidepressants, exercise, sleep or respite. These were excluded from this review. However, much of the support for dementia carers involves talking to them. In keeping with previous reviews, talking with carers or even facilitating conversation between carers and relatives with dementia is not a communication intervention in the terms of this review (Eggenberger, Heimerl, & Bennett, 2012). For this reason, Ulstein, Sandvik, Wyller, & Knut (2007) was excluded as their intervention, in a medium size RCT, involved teaching carers about dementia and the use of problem solving skills. They enabled
communication between the carer and person with dementia but didn’t explicitly discuss communication difficulties or strategies.

Murphy and Oliver (2013) however did look at carer and client communication, using a “Talking Mats” approach. Their study was excluded because, whilst informal carers were enabled (i.e. provided with topics and resources) to use the Talking Mats technique in a combined evaluation session with a therapist, they were not taught or evaluated using it independently. This was interpreted as an experiential evaluation rather than a skills or knowledge learning evaluation.

Finally, whilst every effort has been made in this review to identify interventions that address communication difficulties, it was apparent from the early stages of this review that most psychosocial interventions are insufficiently described to allow for accurate identification of components. This creates difficulty, not only with component identification and comparison, but also clinical replication.

2.2.4  **Assessment of study suitability and quality**

Studies were reviewed initially by title and then abstract. Single and multi-component intervention studies and systematic reviews likely to include communication components were read in full.

Studies were first sorted using an MS Excel spreadsheet (Microsoft, 2007a), detailing year of publication, experimental method, proportion of communication as single or significant component and domains targeted (Schulz, 2000) along with a brief description.

The majority of studies described the interventions used by either listing components covered, time spent or number of sessions spent. A significant communication component was operationally defined as greater than 25% of components covered, time or sessions delivered. Studies were then sorted into single communication component, significant communication component (>25%), minor communication component (<25%) and no communication component studies.
Katrak, Bailocerkowski, Massey-Westropp, Saravana-Kumar and Grimmer (2004) identified 121 tools used for critical appraisal and concluded there was no gold standard tool available. This review has therefore used tools which were considered the best fit for purpose as measures of quality and evidence (Gough, 2007). The tools selected had also been used in recent reviews (Egan et al., 2004; Thompson et al., 2007) allowing for some comparison of rating. Consequently, studies and reviews were evaluated using quality criteria from the critical appraisal skills programme (CASP, 2013), ratings of quality from the SORT taxonomy (Ebell et al., 2004) and a 5 point rating of study quality (Thompson et al., 2007).

Criteria evaluated from the CASP (2013) programme included checks for:

- randomisation and allocation procedure
- control group used & defined
- groups treated equally
- delivery one to one and/or individualised
- intervention described
- time taken to deliver was reported
- carers and people with dementia defined
- setting described
- intention-to-treat analysis conducted
- groups similar and representative at outset
- blinding
- use of objective established measures
- flow of subjects described and attrition reported
- outcomes used and reported
- follow-up periods
- differences in groups at conclusion described
- treatment effect size reported
- statistical adjustments described and justified
- validity and reliability reported
conclusions made

The SORT (Ebell et al., 2004) taxonomy included the following levels and criteria:

- level 1 studies are high quality, randomised, controlled, trials including concealed allocation, blinding, intention-to-treat analysis, sufficient power, adequate follow up (>80%).
- level 2 studies are lower quality clinical trials, cohort studies or case-control studies
- level 3 studies are case series studies, consensus guidelines or opinion

The 5 point rating scale for quality used by Thompson et al., (2007) gave one point for each of the following; random allocation, no significant differences between treatment and control group on sample characteristics at outset, sample size of more than 20 (10 in each group), attrition rate of less than 10% and use of well validated outcome measures.

For included studies, study quality was rated by this author and the academic supervisor independently, to provide for a means of inter-rater reliability and agreement as encouraged by Marshall et al. (2011).

Previous systematic reviews were sorted into groups including single communication component only reviews and multi-component psychosocial intervention reviews. Systematic reviews were evaluated for quality using the CASP (2013) programme systematic review checklist. When considering systematic reviews, particular attention was given to the review question, included studies, relevance of studies, search period, review procedures, inclusion and exclusion criteria, focus of interventions and outcomes considered.

2.2.5 Studies not available

One study, Ripich, Kercher, Wykle, Sloan and Ziol (1999b) was unavailable in print but described in part by other Ripich studies (Ripich, Ziol, & Lee, 1998; Ripich, Kercher, Wykle, Sloan, & Ziol, 1999a) and summarised in Ripich and Horner (2006). A summary of the findings from this study are discussed alongside
the other Ripich studies (Ripich et al., 1998; Ripich et al., 1999a) in the section below.

2.3 RESULTS OF THE SYSTEMATIC REVIEW

This section starts by examining four previously published systematic reviews, of single communication component interventions, identified during this review process.

A detailed breakdown of identified individual studies is then given. Studies that had a major communication component (i.e. >25% of time taken or intervention content) are described briefly prior to a detailed breakdown of the eight single communication studies identified by this review. Further consideration of major component studies is not attempted due to difficulties identifying the exact nature of interventions delivered. The eight single communication component studies are described using a synopsis and synthesis approach. Limited qualitative data from these eight studies is also presented.

For comparison and additional consideration, a summary of evidence identified from the highest quality and most recent systematic reviews for multi-component psychosocial interventions is also given.

A conclusion aims to summarise the results from all the evidence detailed in this review.

2.3.1 Previous systematic reviews addressing single component communication interventions for dementia carers

Only four systematic reviews were identified which have previously considered single communication component psychosocial interventions for informal carers.

Egan et al. (2010) looked at a broad range of quantitative studies published up to June 2009, grading studies by SORT criteria (Ebell et al., 2004). Thirteen treatment studies were identified, however they excluded those that were not designed to specifically improve the communication of the person with dementia and therefore studies which measured carer wellbeing or depression alone were excluded. The review also included a mix of studies with formal and informal
carers. They recommended that all future research should include measures of communication change in the person with dementia.

Zientz, Rackley and Bond Chapman (2007) conducted a systematic review of interventions for informal carers up to 2002, adding additional information on three further studies for professional carers. After considering seven informal carer studies, they identified a number of methodological concerns around internal validity, external validity and dose response characteristics. Their recommendations included the need for future research to look at social outcomes for the person with dementia, quality of life for carers, generic versus individualised training and the effects of training at different stages of dementia.

Aizawa (2010), a published MSc thesis, examines four publications in a narrative style looking at strengths and limitations in detail. The recommendations included the need for research which compares the effect of addressing communication in comparison to other components or areas of need.

In the most recent review, by Eggenberger, Heimerl and Bennet (2012), the authors also included interventions for formal and informal carers. As well as evidence of effect, they examined in more detail the content of the interventions listing the most common topics covered. However, Eggenberger et al. (2012) identified only three of the five studies included in this review which were published prior to 2010. In their conclusion, they recommend more consistent use of validated outcome measures in future studies. Similar to Ripich et al. (1999a), they also recommend that interventions should include periodic refresher or booster sessions for carers over time.

The review which follows aims to be more contemporary, specific and rigorous than previous reviews.

The research study which follows from chapter 3 onwards has taken into account, where possible and appropriate, the recommendations for future research made above.
2.3.2 Studies identified during the review

In total 90 treatment studies were identified for inclusion in this review. The flowchart in Figure 2-1 gives a breakdown of these studies and those included or excluded.

![Flowchart illustration](image)

**Figure 2-1: Flowchart illustrating the selection of studies in the systematic review process.**
Four studies were excluded as they did not involve direct intervention with carers.

Thirty carer intervention studies were then excluded as they included no mention of communication within the description of the intervention.

A further 54 studies were then examined using the review methodology. Of these, 31 studies were excluded from the review as having only a minor (less than 25%) component of communication intervention described.

Of the remaining 25 studies, 14 were identified as single component communication interventions and 11 as using multi-component interventions containing a significant communication component that constituted between 25% and 50% of the interventions listed, time or sessions provided, although this was often difficult to measure with any certainty.

### 2.3.3 Major communication component within multi-component studies

Of the multi-component studies that contained a major communication component (>25%), the highest quality research was detailed in Gitlin, Winter and Dennis (2010a) and Gitlin, Winter, Dennis, Hodgson and Hauck (2010b). These were judged to be level 1 (SORT), quality grade 4 (Thompson et al., 2007) studies. Both studies provided one-to-one individualised treatments, within an RCT for over 200 people. Both studies led to significant changes including less depressive symptoms and improved well being for the carer and, for Gitlin et al. (2010b), small but significant improvement in activity engagement for the persons with dementia.

Further analysis of major communication component studies was not pursued as the communication specific component was rarely described in sufficient detail. The overall effect of multi-component interventions was considered from systematic reviews alone.
2.3.4  Single communication component studies

Thirteen studies were identified which appeared to evaluate single communication component interventions with informal carers. Only four studies (McCallion, Toseland, & Freeman, 1999; Liddle et al., 2012; Done & Thomas, 2001; Bourgeois, Burgio, Schulz, Beach, & Palmer, 1997) included any qualitative data and analysis which in each case was limited in detail (see section 2.3.7.).

After further reading, two studies were excluded; Tanner and Daniels (1990) was excluded as, although they described a communication workshop provided for carers, only baseline measures of communication difficulties experienced including therapist rated observations, were recorded and therefore significant outcomes were not reported. Weinrich, Jensen and Hughes (2006) was also excluded as the majority (10/16) of carers were professional carers whereas this review is only concerned with family carers.

Three further studies were then excluded from consideration as they were either in-depth single case studies (Spilkin & Bethlehem, 2003; Orange & Colton-Hudson, 1998) which employed conversational analysis techniques, or a small (n=7) case series design with no control group (Roque, Ortiz, Araujo, & Bertolucci, 2009).

The most recent single component communication study by Small and Perry (2013) was also excluded, primarily because it is not a controlled trial. Small and Perry (2013) detail the development of the TRACED training programme for family carers. This programme is informed by a theoretical model of compensating for communication limitations on a relational level, enhancing expression of self and recognising the importance of family communication patterns. To date, these authors have only published the results of a 6 participant uncontrolled pilot study, with limited details of results and recommendations for modifications to the intervention and further research.

2.3.4.1  Controlled trials detailed in this review

Of the remaining single component communication studies identified, eight were controlled trials, described in the text and tables (2.1 and 2.2) that follow.
Table 2.1 below compares the number of participants, severity of dementia and content of the intervention provided in these studies.

**Table 2-1: A comparison of number of participants, severity of dementia and interventions provided for single component communication studies.**

<table>
<thead>
<tr>
<th>Study</th>
<th>Total number of carers</th>
<th>Number in treatment arm</th>
<th>Mean (SD) MMSE score at entry</th>
<th>MMSE Range</th>
<th>Content of Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ripich et al., 1998</td>
<td>37</td>
<td>19</td>
<td>16.63 (4.9)</td>
<td>NP</td>
<td>FOCUSED manual plus video, role play, handouts and reminder cards (see figure 2.2)</td>
</tr>
<tr>
<td>Ripich et al., 1999a</td>
<td>54</td>
<td>32 (10 people had boosters)</td>
<td>16.2 (5.3)</td>
<td>NP</td>
<td>As for Ripich et al., (1998) except the booster group were sent a set of reinforcers including a tape.</td>
</tr>
<tr>
<td>Haberstroh et al., 2011</td>
<td>22</td>
<td>9</td>
<td>19.3 (5.6)</td>
<td>3-28</td>
<td>Step by step approach. Looked at presentation, attention, comprehension and remembering. Includes personal examples, discussions and role play.</td>
</tr>
<tr>
<td>Done and Thomas, 2001</td>
<td>45</td>
<td>30</td>
<td>NP</td>
<td>NP</td>
<td>Not provided.</td>
</tr>
<tr>
<td>McCallion et al., 1999</td>
<td>64</td>
<td>32</td>
<td>5.81 (6.3)</td>
<td>NP</td>
<td>Verbal and non verbal communication and visit structure</td>
</tr>
<tr>
<td>Bourgeois et al., 1997</td>
<td>14</td>
<td>7</td>
<td>13.07 (4.8)</td>
<td>4-20</td>
<td>Learned about antecedents and consequences of behaviours. Learnt to use written cues.</td>
</tr>
<tr>
<td>Liddle et al., 2012</td>
<td>29</td>
<td>13</td>
<td>17</td>
<td>7-22</td>
<td>RECAPS and MESSAGE programme addresses communication and memory difficulties and strategies.</td>
</tr>
<tr>
<td>Kouri et al., 2011</td>
<td>50</td>
<td>25</td>
<td>Above 20</td>
<td>20-28</td>
<td>Contains five modules. Four self efficacy strengthening strategies were included.</td>
</tr>
</tbody>
</table>

Key: NP= Not provided.

2.3.4.2 Randomisation

Six studies were described as randomised controlled trials. McCallion et al. (1999), Kouri, Ducharme, and Giroux (2011) and Liddle et al. (2012) described random allocation occurring, but did not define how this was undertaken. Liddle (2013) confirmed that
allocation was made by a computer based random sequence generator. Done and Thomas (2001) used cluster block randomisation with a pragmatic approach, whereby the first two out of three groups assembled received the intervention. Haberstroh, Neumeyer, Krause, Franzmann and Pantel (2011) set out to randomly assign to groups but were unfortunately unable to achieve this after two participants asked to change groups.

2.3.4.3 Use of blinding
McCallion et al. (1999), Kouri et al. (2011) and Liddle et al. (2012) were the only studies to use any form of blinding, which was single blinding of assessors.

2.3.4.4 Rates of attrition
McCallion et al. (1999), Haberstroh et al. (2011), Kouri et al. (2011) and Liddle et al. (2012) reported attrition rates of 14%, 8%, 12% and 19% respectively. Attrition was not reported in other studies.

2.3.4.5 Participant characteristics
There are some noticeable differences between the groups of participants included in these studies. Nearly all of the studies used the Mini Mental State Examination (MMSE) (Folstein, Folstein, & McHugh, 1975) as an indicator of dementia severity. However, McCallion et al. (1999) included more severely impaired persons with dementia than other studies i.e. an MMSE score of less than 10 (mean 5.8). The majority of other studies were focused on people with dementia scoring between 15 and 20 on the MMSE test although not all studies reported the range of MMSE scores included. Where MMSE score range was reported, it was often wide; for example Haberstroh et al. (2011) reported a range of 3-28/30, suggesting the inclusion of a heterogeneous population. This makes it difficult to draw conclusions about which subgroups of carers or people with dementia are most likely to benefit from these interventions.

As expected, studies that reported carer sex had a higher proportion of female carers ranging from 67% to 83%. There were also some significant demographic differences between treatment groups in some studies which are described later. Done and Thomas (2001) contained no descriptive information about the people with dementia and family carers involved.

2.3.4.6 Sample size calculations
Only Kouri et al. (2011) and Liddle et al. (2012) included any sample size calculations to
determine the minimum number of participants required to achieve statistical significance.

2.3.4.7 Reliability and validity
Attempts to establish reliability were limited to the use of treatment manuals for McCallion et al. (1999), Ripich et al. (1998 and 1999a), Bourgeois et al. (1997), Kouri et al. (2011), training for treatment deliverers for McCallion et al. (1999) and training for carers in use of outcome measures for Bourgeois et al. (1997).

Attempts to establish validity were limited, ranging from using a proportion of established outcome measures with records of validity to processes of determining social validity (Bourgeois et al., 1997; Kouri et al., 2011). Most studies made no reference to validity. Done and Thomas (2001) used all newly designed or modified measures with no record of validity established. Kouri et al. (2011) designed two new measures which were reviewed by experts for content validity.

2.3.4.8 Interventions and individualisation
All interventions addressed communication occurring in the home environment, with the exception of McCallion et al. (1999) which was conducted in five large nursing homes and addressed visitor communication.

Descriptions given by Haberstroh et al. (2011), McCallion et al. (1999), Bourgeois et al. (1997) and Kouri et al. (2011) all indicate a degree of individualisation of the intervention. Individualisation is defined by Schulz (2000) as the process of adapting an intervention to an individual as opposed to delivering a generic or highly structured intervention in the same format for each person or group.

Only the interventions delivered by Liddle et al. (2012) and Ripich et al. (1996, 1998 and 1999a) are available in sufficient detail for clinical replication. Both programmes use acronyms to aid recall of specific strategies. As an example, Figure 2-2 below illustrates strategies from the FOCUSED programme (Ripich & Wykle, 1996).
<table>
<thead>
<tr>
<th>F = Face</th>
</tr>
</thead>
<tbody>
<tr>
<td>Face the person directly</td>
</tr>
<tr>
<td>Call him or her by name</td>
</tr>
<tr>
<td>Touch the person</td>
</tr>
<tr>
<td>Gain and maintain eye contact</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>O = Orient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orient the person to the topic by repeating key words</td>
</tr>
<tr>
<td>Simplify and shorten sentences</td>
</tr>
<tr>
<td>Use names of objects and people</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>C = Continue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restate the topic throughout the conversation</td>
</tr>
<tr>
<td>Use signals when you are starting a new topic</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>U = Unstick</th>
</tr>
</thead>
<tbody>
<tr>
<td>Help the person by suggesting the word he or she is looking for</td>
</tr>
<tr>
<td>Repeat the person’s sentence using the correct word</td>
</tr>
<tr>
<td>Ask, “Do you mean?”</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>S = Structure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Structure your questions so the person will recognize choices</td>
</tr>
<tr>
<td>Provide two simple choices at a time</td>
</tr>
<tr>
<td>Use yes or no questions</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>E = Exchange</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keep up normal everyday conversation by taking turns talking</td>
</tr>
<tr>
<td>Keep conversation going by saying, “That’s great” or “Tell me more”</td>
</tr>
<tr>
<td>Do not “test” them by asking questions such as, “What day is it” or “Who is our Prime Minister?” Instead ask questions like, “Did you have a dog when you were growing up?”</td>
</tr>
<tr>
<td>Give the person clues about how to answer your question</td>
</tr>
</tbody>
</table>

Figure 2-2: Strategies from the FOCUSED programme (Ripich & Wykle, 1996).
Table 2-2 below illustrates, in date order, the eight single component communication studies included, starting with group interventions and concluding with one-to-one interventions. Due to the diversity of interventions and outcomes used, no other significant groupings or themes were possible. The table also provides further information about the outcome measures used in each study and includes the SORT (Ebell et al., 2004) levels and quality ratings (Thompson et al., 2007).
Table 2-2: Outcome measures, SORT and quality ratings from single component communication studies.

<table>
<thead>
<tr>
<th>Study</th>
<th>Outcome Measures used (carer status self-reported unless stated)</th>
<th>Measurement period</th>
<th>SORT level</th>
<th>Quality rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ripich et al., 1998</td>
<td>Mood, depression, health, general hassles, communication hassles, knowledge.</td>
<td>Baseline, immediately post intervention, 6 months and 12 months.</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Ripich et al., 1999a</td>
<td>Use of carers questions open-ended questions.</td>
<td>Baseline, 6 months and 12 months post intervention.</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Haberstroh et al., 2011</td>
<td>Mood, strategy use, burden, proxy person with dementia quality of life.</td>
<td>Baseline and immediately post intervention. Diaries completed throughout.</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Done and Thomas, 2001</td>
<td>Knowledge, communication difficulties, distress, stress, satisfaction.</td>
<td>Baseline and six weeks post intervention.</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>McCallion et al., 1999</td>
<td>Carer skills, hassles and visit satisfaction. Person with dementia functioning, depression, behaviour and social interaction. Nursing time and strategy use for challenging behaviours.</td>
<td>Baseline, 3 and 6 months post intervention.</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Bourgeois et al., 1997</td>
<td>Knowledge, satisfaction, repetitive verbalizations, carer self efficacy.</td>
<td>Baseline, post intervention, 24 and 36 weeks.</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Liddle et al., 2012</td>
<td>Knowledge, burden, positive perceptions, person with dementia depression, satisfaction, communication difficulties.</td>
<td>Baseline, post and 3 months after intervention.</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Kouri et al., 2011</td>
<td>Self efficacy, communication difficulties, knowledge, skills.</td>
<td>Baseline, 1 and 6 weeks post intervention.</td>
<td>1</td>
<td>4</td>
</tr>
</tbody>
</table>

Key: Outcomes underlined yielded significant reported between group differences.
2.3.5 **Synopsis of single component communication studies – interventions and outcomes**

This synopsis summarises the intervention and results for each of the single component communication studies included in this review in a comparable way (Popay et al., 2006). The implications of the results from these studies are detailed in the synthesis that follows (see section 2.3.6).

2.3.5.1 Studies by Ripich et al.

Ripich and colleagues have published four studies using the FOCUSED communication training programme. One is not included in this review (Ripich et al., 1995) as it includes professional carers. The three studies included in this part of the review do not report being related and use different measures; however there is some indication in the text that participants from the earlier study (Ripich et al., 1998) were involved in the second (Ripich et al., 1999a).

Another of the studies (Ripich et al., 1999b) was not available for review, but is reported in Ripich and Horner (2006). In this adaptation of the FOCUSED programme (see Figure 2-2), a comparison was made between white American and African American carers. Both groups demonstrated increased knowledge post-training, though African American carers showed greater positive effect than white carers. African American carers also showed a decline in reported hassles whilst white carers did not. These findings may be more relevant to services that provide carer support for specific ethnic and socioeconomic groups.

Ripich et al., (1998 & 1999a) used the FOCUSED communication treatment in a group format, delivered over four sessions. The earlier study (1998) used only co-resident carers whilst the later study (1999a) included all family members. In both studies, the control group is described as people who were invited to participate in the FOCUSED groups, but were unable to do so because of distance and time commitments. This appears to introduce a significant bias and difference between groups. For outcome measures, the Ripich et al. (1998) study used a number of published scales, some of which were modified prior to use.
The Ripich et al. (1999a) study looked specifically at observations of a 10 minute conversation task with the patient carer dyad.

Findings from the Ripich et al. (1998) study showed that carers had a significant decrease in communication hassles over time, and an increase in knowledge. The decrease in communication hassles was maintained at 12 month follow up. However, no changes were noted in carer affect, depression, health or general hassles (Ripich et al., 1998).

The Ripich et al. (1999a) study identified the use of fewer open ended questions and fewer failed responses following the intervention. This effect was strongest in the first 6 months of the study, with no effect evident at the 12 month follow up. There was no significant difference between the treatment and booster groups. This study is a good example of looking at a very specific strategy but it is dependent on the assumption that the use of open ended questions is always a negative communicative interaction. This author would suggest that some open ended questions (e.g. “what do you like?”) enable validation (Feil, 1995) and thus the experience of successful communication. In this example, the answer can be validated as anything the person with dementia likes.

This series of trials produced by Danielle Ripich and colleagues (1998, 1999a & 1999b) provide a good example of research which has sought to determine the effect of an intervention under different conditions, changing variables such as time and carer subgroups, presumably to identify the optimum potential for the FOCUSED (Ripich & Wykle, 1996) intervention.

2.3.5.2 Haberstroh et al. (2011)
Haberstroh et al. (2011) includes detailed intervention content, which was manualised, delivered in a group format over five sessions and theorised to use a psycho-educative mechanism of action. The control group included people with dementia on a waiting list, which essentially was ‘no treatment’. Whilst designed as a randomised trial, changes in subject allocation made this a controlled trial only. There were also noticeable demographic differences between groups on characteristics at baseline, with the treatment group containing only spouses
whilst the control group included 30% adult children carers and significantly fewer female carers. The authors did not state whether they adjusted for these differences. Outcomes were measured using carer mood diaries with established inter-rater reliability of r>0.80. Care receiver’s proxy rated quality of life and carer burden were also measured using established scales. Sub factor analysis was used to identify possible relationships and found that carers in the treatment group reported greater use of communication strategies, consistently higher carer mood on training days and increased quality of life of the care receiver but no changes in carer burden in comparison to the control group.

2.3.5.3  Done and Thomas (2001)
Done and Thomas (2001) used a group workshop intervention. However, they provided only limited information on the persons with dementia, carers and period of study, which would therefore make the intervention or study difficult to replicate. They do not state whether the groups of carers were comparable or if any adjustments were made. In addition, the majority of outcome measures (3/4) used in the study have no evidence of validation. There is also no indication of whether carers in the control group read the booklet provided. The overall intervention period of 2 hours is also relatively short. The main finding from this study was a significant difference in carer knowledge.

2.3.5.4  McCallion et al. (1999)
The strongest evidence in support of single component communication training for family carers is detailed in McCallion et al. (1999) and Kouri et al. (2011). These studies are graded at level 1 SORT (Ebell et al., 2004) with a quality grading (Thompson et al., 2007) of 3/5. Interestingly, these two studies address significantly different situations in terms of person with dementia severity, age and residence.

McCallion et al. (1999) evaluated the content and structure of visits by informal carers to residents of five nursing homes. The informal carers, some of whom were friends, were trained over a 9 hour period using “the functional visit education programme” in both a group and an individual intervention. After
random allocation, nursing staff in the home were blinded to which persons with dementia had relatives that had received training. In comparison with the other studies discussed above, the people with dementia were older (mean age 86; sd 6) and more impaired with an MMSE score of below 10 (Folstein et al., 1975). There were also some identified differences between the control and treatment group, which suggested the treatment group residents were more impaired and less likely to benefit from the intervention. A ‘treatment as usual’ control condition was used.

The functional visit education programme was associated with 21 significant effects. To minimise the effect of chance, only those with .01 level of significance were reported. At this level of significance, the intervention had a positive impact on resident’s symptoms of depression, ideational disturbances and levels of irritability. Findings converge to also suggest that this intervention led to a slower rate of increase in irritation, fewer verbal challenging behaviours and less physical challenging behaviour. There were, however, no significant changes in the nurses’ behaviour and limited support for any changes in the carer relatives’ behaviour. Some significant changes, recorded in the use of encouragement by relatives at 3 months, were not sustained at 6 months. This study suggests that training to facilitate changes in visiting carers’ communication brought about positive changes in the residents’ communication and behaviour. Interestingly this study, unlike all others, records the number of visits and time spent communicating with residents, which increased significantly for carers and relatives with dementia in the treatment group (mean of 18 visits per month).

2.3.5.5 Bourgeois et al. (1997)
The Bourgeois et al. (1997) study was part of a larger trial evaluating the use of a behavioural management program using written communication aids to manage behaviour. This study used a mixed workshop and individualised one-to-one intervention, over 14 hours. A ‘treatment as usual’ control condition was used. The study focused on and only measured the frequency of repetitive verbalisations. They identified a reduction in these behaviours and a delayed improvement (after 3 months) in carer self efficacy. However, there was a high
degree of within and between subject variability on verbal behaviours throughout the study. Whilst reliability measures were used to monitor carer self-recording, two of the seven carers were shown to be inconsistent in recording.

2.3.5.6 Liddle et al. (2012)
Liddle et al. (2012) examined the use of a brief intervention based on the individual use of two DVD packages called MESSAGE and RECAPS, which are now freely available for use on a “YouTube” channel (www.youtube.com/UQDementiaCare). This intervention, which is delivered one-to-one over a 1.5 hour period, focuses primarily on the carer’s communication and dementia knowledge, allowing for a small amount of time for discussion with the treatment deliverer. A ‘treatment as usual’ control condition was used. As part of a larger study, the authors acknowledge it is underpowered and attribute the relatively high rate of attrition to ill health. This study has a relatively high level of established measures (5/7). The results identified a significant improvement in carer’s knowledge, a reduction in care recipient disruptive behaviours and increased carer perceptions of positive aspects of caring at a level approaching significance. However, the training group also had an increased frequency of verbally communicated depressive behaviours from the person with dementia, in comparison to the control. The frequency of observed depressive behaviours was not significantly different between groups.

2.3.5.7 Kouri et al. (2011)
Kouri et al. (2011) provided a generic intervention package delivered one-to-one over a period of 12 weeks. This was compared with a leaflet given to the control group. Only a brief description is available of the intervention, though a detailed theoretical framework for mechanisms of action, based on knowledge and self-efficacy, is given. The study used outcome measures of carer self efficacy, rated communication-related problems, reported carer communication knowledge and reported carer communication skills. The results suggested a significant increase in knowledge, no difference in perceived communication difficulties, a decrease
in perceived communication disturbance, increase in self-efficacy and an increase in use of communication skills. The increase in knowledge was significant at one week post intervention and greater again at the follow up period of 6 weeks post intervention. Kouri et al. (2011) suggested this increase in knowledge over time may have been related to their provision of a programme document which was regularly reviewed.

2.3.6 Synthesis of single component communication studies

Meta-analysis of the findings from these studies is not possible due to the diversity of outcome measures used. Therefore, a narrative synthesis of the results of the included studies is detailed below. Whilst it can involve the manipulation of statistical data, the defining characteristic of a narrative synthesis is a textual approach, which tells the story of the findings from the included studies (Popay et al., 2006).

2.3.6.1 Mechanisms of action and the theory of change pathway

McGilton et al., (2010) challenge researchers to identify a mechanism of action for their intervention. Although only the most recent studies (Haberstroh et al., 2011; Liddle et al., 2012; Kouri et al., 2011) have suggested a formal mechanism of action, there are many common themes influenced by choice of intervention and outcome which occur across studies.

As part of this synthesis, a pathway (see Figure 2-3) was developed to illustrate how interventions are proposed to have a more or less direct effect at different levels. The development of this pathway, which only includes elements from the eight single communication component studies detailed above, has been influenced by the “Theory of Change” model (Anne E. Casey Foundation, 2004). The Center for Theory of Change (2014) suggests that the Theory of Change defines all of the building blocks needed to bring about a given long-term goal. This set of connected building blocks (interchangeably referred to as outcomes, results, accomplishments, or preconditions) is depicted on a map known as a pathway of change/change framework, which is a graphic representation of the change process.
Within this pathway (Figure 2-3), the ultimate goal or outcome may be a change in communication experience for carer or the person with dementia, though a sub outcome, more directly related to the input, could be a change in carer knowledge. Direct effects are postulated to occur when there is only one level distance between intervention and effect (e.g. interventions leading to level 1 effects). Effects across more than one level, are considered to be indirect effects. The interventions and effects are listed (left to right) in order of prevalence from the single component communication studies detailed in the review. This pathway could be developed further to include other effects such as length of time spent caring or receiving care.
**Intervention provides**

<table>
<thead>
<tr>
<th>Information</th>
<th>Strategies</th>
<th>Role play</th>
<th>Discussion</th>
<th>Peer influence</th>
<th>Materials</th>
<th>Goals</th>
<th>Reminders checks</th>
</tr>
</thead>
</table>

**Level One: Carer develops**

<table>
<thead>
<tr>
<th>Knowledge</th>
<th>Competence</th>
<th>Skills</th>
<th>Self-efficacy</th>
<th>Insight</th>
</tr>
</thead>
</table>

**Level Two: Carer experiences**

<table>
<thead>
<tr>
<th>More positive interactions</th>
<th>Less conflict</th>
<th>Less burden and depression</th>
<th>Better quality of life</th>
<th>Less frustration</th>
<th>More positive perception of care-giving</th>
<th>More communication or visits</th>
</tr>
</thead>
</table>

**Level Three: Person with dementia experiences**

<table>
<thead>
<tr>
<th>More positive interactions</th>
<th>Improved behaviour</th>
<th>Less frustration</th>
<th>Better quality of life</th>
<th>Less distress</th>
<th>Longer home care</th>
</tr>
</thead>
</table>

**Level Four: Other effects**

<table>
<thead>
<tr>
<th>Fewer nursing interventions</th>
<th>Carry over of skills to other situations</th>
</tr>
</thead>
</table>

*Figure 2-3: A theory of change pathway, developed from a synthesis of proposed mechanisms of action, from eight single communication component studies.*
2.3.6.2 Differences between carers
When considering differences between groups of carers, all of the studies in this review included a mixed group of family carers (e.g. age, sex, education, residence, relationship etc). Ripich et al. (1999b) was the only study which set out to compare subgroups of carers. The only subgroup differences evident are a stronger outcome effect for African Americans in comparison to white Americans in Ripich et al. (1999b) and the absence of (indirect) effect on nursing staff in comparison to significant positive effect on family carers from Bourgeois (1997).

2.3.6.3 Effect size
When comparing effect size between studies, Popay et al. (2006) warn reviewers to take care with “vote counting”. In terms of effect direction, none of the studies show any significant negative effects. The most common significant differences for outcomes between control and treatment groups appear to be in increases in carer knowledge and carer self-efficacy, and decreases in carer reported communication difficulties.

Effect size is only mentioned in one study (Liddle et al., 2012). The effect size of reported significant differences generally appears small (Bowling, 2009) though this is relative to the typically small sample sizes used. Examining the raw data provided, there is some indication that the effect size was greater for outcomes measuring carer knowledge and more specific interventions/measures e.g. the change in use of open-ended questions targeted and measured by Ripich et al. (1999a).

These findings suggest that selecting people with a specific difficulty, delivering a specific intervention which addresses that difficulty and measuring an outcome directly related to that target is more likely to generate a positive outcome. Using the pathway in Figure 2-3 above, it could be hypothesised that outcomes in level one, immediately below the intervention, are more likely to change significantly than outcomes in the indirect levels below. However, it is worth considering the value of change at level one alone: Charlesworth and Newman (2006) suggested that studies which focused only on educating carers could
show improvements in knowledge but very little corresponding change in carer’s well-being. Graham, Ballard, & Sham (1997) have even suggested that developing carer knowledge alone can increase carer anxiety.

2.3.6.4  Effects over time
The single communication component studies varied in how they measured effects over time, with final outcomes ranging from 6 weeks to 12 weeks after baseline measures. When considering effects over time, studies show examples of both consolidation (e.g. Ripich et al., 1998 generated better results at 6 months than immediately post treatment) and decay (e.g. Ripich et al., 1999a generated reduced results at 12 months in comparison to 6 months). Given the variability in interventions, there is insufficient information to identify an optimum time for effect, duration or delivery of intervention. However, given the specific nature of the intervention strategies (reducing open-ended questions) used by Ripich et al. (1999a) their results could indicate that more specific activities are less adaptable to changes over time. A similar effect was identified by Barnes (1998) who found that even at four week follow up, carers though pleased that very specific recommendations (e.g. “bring flowers when you visit your mother”) had been effective, were already seeking alternatives, primarily to provide variety for themselves. This would suggest that carers may be better equipped for the long term with a wider skill set that can be applied to new or changing situations.

Another factor evident in longitudinal studies was the difficulty in accommodating expected deterioration due to dementia over the long term. Interestingly, Ripich et al. (1998) suggested increased “hassles” reported from the control group may have just reflected expected change over time whereas stability or no change of outcomes in the treatment group may have reflected maintenance of ability due to the treatment. One way to control for this effect in longer term studies would be to include a third no treatment group though this may present ethical challenges to clinical services.
2.3.6.5 Feasibility
When considering facilitators and barriers to implementation, very little is mentioned about the feasibility of these studies and in particular rates of recruitment in comparison to participation. Ripich et al., (1998) used a control group comprised of people who were unable to attend, suggesting some felt burdened by inclusion in a research study. Where mentioned (McCallion et al., 1999, Haberstroh et al., 2011, Kouri et al., 2011 and Liddle et al., 2012), the rate of attrition was not low (range 8-19%) in comparison to the rate set (<10%) for quality studies by Thompson et al. (2007). There is no clear pattern from these studies indicating that attrition increased with duration or intensity as might be expected. Although Liddle et al. (2012) had the shortest intervention and a relatively short follow up period they had an attrition rate of 19%. This may indicate a weakness in design such as difficulties with the process for gathering completed outcome measures.

2.3.6.6 Confounding variables
There are some indications in these studies, from carer or author reports, that confounding variables may have influenced effects. These variables included having general group support (Ripich et al., 1999), a supportive visitor (Bourgeois et al., 1997) the process of tracking behaviour (Bourgeois et al., 1997) and the act of writing reflections (Haberstroh et al., 2011). This raises issues about study design and the potential for using further controls to avoid bias in a clinical environment without impacting on care provided.

2.3.6.7 Time spent talking
One factor which is not well defined (except in Bourgeois et al., 1997) in these studies is the amount of communication the people with dementia received. This may have influenced the effect of these interventions significantly and would be valuable data to collect in future studies. However, the direction of this effect may not always be clear as time spent communicating could increase the risk of conflict as much as raise quality of life. Obtaining data for time spent talking may also be burdensome for carers and difficult to measure, particularly for carers that live together who often interact in a less structured way.
2.3.6.8 Delivery mechanisms

The included studies contain a wide range of interventions and subjects. Subjective comparison appears possible only between group and individual interventions and between generic and individualised interventions. There are no obvious indications that one delivery mechanism affected outcomes more than another. However the authors’ conclusions from the group-based intervention studies (Ripich et al., 1998; Ripich et al., 1999a; Haberstroh et al., 2011; Done and Thomas, 2001; McCallion et al., 1999; Bourgeois et al., 1997) suggest that the group setting may have provided more opportunity for peer influence but less for individualisation of the intervention.

A wide range of materials were used, including manuals, videos, audio tapes, cards and handouts, though insufficient information is available to consider their relative value to the carer and the treatment deliverer. Liddle et al. (2012) were the only authors to include carers’ comments on the intervention materials in the qualitative data (see 2.3.7.). This could also be considered in future research.

2.3.7 Qualitative data from included studies

Four of the studies included in this review gathered qualitative data, limited to no more than a paragraph of text in each publication, typically by including a free comment field on evaluation questionnaires. Authors referred to themes, though no qualitative methodology was included in any of these studies.

Done and Thomas (2001) reported themes of carers describing the intervention as having given them confirmation for what they were already doing, and as something which may have helped earlier in their caring journey.

Bourgeois et al. (1997) reported themes that carers were able to generalise the strategy to other approaches, but that having the visit was more helpful than the actual intervention.

Liddle et al. (2012) reported that carers found the intervention accessible and relevant, and particularly liked role-play and examples. Their carers also reported
an increased feeling of awareness and felt they had more options. They also indicated they would like this intervention as early as possible.

McCallion et al. (1999) reported that the intervention changed their beliefs in what they and the person with dementia do. They also described that the intervention helped them to understand their relative.

This very limited qualitative research hints at potential themes (e.g. early intervention and the development of insight) which would help researchers and clinicians understand the mechanisms of action in this form of carer support. Further reliable qualitative research would help clinicians understand not just how but why these interventions work. A mixed methods approach would also help interpret the results of quantitative outcomes (Medical Research Council, 2000).

### 2.3.8 Evidence from systematic reviews of general psychosocial support for dementia carers

Evidence identified from higher quality systematic reviews for all psychosocial dementia carer interventions, a significantly larger evidence base, is considered below. More recent reviews and review findings which have clinical relevance to communication therapy are highlighted. Some, often more recent, systematic reviews were excluded from inclusion in this section of the review as they focused on specific aspects of psychosocial interventions e.g. education only (Jensen, Agbata, Canavan, & McCarthy, 2014) or dyadic interventions where the person with dementia and carer were seen together (Van’t Leven et al., 2013).

Seven higher quality systematic reviews (described below) were identified using the CASP (2013) checklist; these focused on information, skills training and support interventions with dementia carers. These interventions included multi-component, individual and group treatments, information and skills training, behaviour management training, counselling and psychotherapy and technological approaches using DVD, telephone or internet based support.
The most recent of these reviews set out to evaluate the quantitative and qualitative evidence for psychological support of dementia carers. The authors (Elvish, Level, Johnston, Cawley, & Keady, 2012) included the additional category of technology-based support and describe attempting to build on the most recent similar reviews (e.g. Gallagher Thompson & Coon, 2007). It is surprising (see Goy, Kansagara, & Freeman (2010) below for comparison) that they have limited the inclusion in their review to only 20 studies. They do however make interesting suggestions for future research, including strengthening of treatment fidelity through training and supervision of deliverers. Their conclusion was that the majority of evidence or supportive studies could be described as psychoeducational skill building and that these interventions can impact on depression, well being, quality of life, attitudes towards caring and anxiety.

Goy et al. (2010) examined 11 previous systematic reviews. From these they identified 231 RCTs. However, after including only good quality rated studies, with sample sizes greater than 50, they were limited to 37 studies for consideration. In comparison to previous systematic reviews this was the most comprehensive and rigorous. Overall, Goy et al. (2010) found no evidence that dementia carer interventions had any adverse effects. They identify no consistently strong evidence for carer interventions. However, they suggest that those interventions that appear to be more effective tend to be individually tailored treatments which are more resource intensive (such as behaviour management therapy) multi-component interventions designed after individual in-home assessment. Interestingly, one other review (Spijker et al., 2008), suggested that a combination of involvement and choice (individualisation) seemed to be the main characteristic that distinguished effective programmes from ineffective ones.

Selwood, Johnston, Katona, Lyketsos, & Livingston (2007) looked at psychological interventions for carers up to July 2003. They identified 62 studies, 10 of which were graded at level 1 (on a levels 1-3 scale similar to SORT). All interventions focused on the psychological health of the carer but were diverse in nature ranging from generic telephone lectures to single sessions of individual support.
and up to 18 weeks of group reminiscence therapy. They identified six level 1 (SORT) RCTs supporting the use of individual behavioural management therapy. Interventions in these studies focused on the care recipient’s behaviour and significantly reduced carer symptoms immediately and for up to 32 months. Teaching carers coping strategies also appeared to be effective in reducing psychological symptoms, though just teaching behaviour change principles appeared to be ineffective. Group interventions were reported to be less effective than individual, whilst education about dementia, group behavioural therapy and supportive therapy did not appear to be effective carer strategies.

Gallagher-Thompson and Coon (2007) conducted a similar more contemporary review looking specifically at 19 psycho-educational, psychotherapeutic and multi-component studies. They agreed with the evidence for providing behavioural management interventions supported by three studies which met their criteria for evidence based treatment. They also identified specific evidence with relatively high effect sizes to support the use of cognitive behavioural therapy as a form of psychotherapy, in particular when delivered individually for carers with significant levels of depression.

Looking more specifically at cognitive behaviour therapy, the most recent Cochrane collaboration review published on this subject by Vernooij-Dassen, Draskoiv, McCleery, and Downs (2011) again identified a beneficial effect of cognitive reframing (or cognitive behavioural therapy) on dementia carers’ psychological morbidity, anxiety and depression from 11 treatment studies. No effect was found for carers coping, appraisal of burden, reaction to their relatives’ behaviour or time to institutionalisation.
2.3.9  Review conclusion

This review has concentrated on the findings from controlled studies, for psychosocial interventions, with dementia carers and in particular those interventions that address communication difficulties.

The review questions were:

1. Do interventions for informal carers of people with dementia that specifically address (single component) communication difficulties, generate outcomes that are significant for professionals and carers?

2. How does this evidence compare and relate to the wider research evidence for all dementia carer (multi-component) psychosocial interventions?

3. What are the methodological weaknesses in existing research and therefore indications and recommendations for future research and intervention development?

Given the significance of the informal carer role in dementia care, the research evidence for working with these carers still remains limited. When trying to establish positive effects from working with carers it is important to remember that carers vary considerably in situation and response and that one of the primary sources of difficulty (the symptoms of dementia) cannot easily be resolved. By definition, the person with dementia will experience deteriorating cognition over time.

When considering SORT, level one evidence (CASP, 2013), the best quality evidence for all psychosocial interventions supports the use of individualised behaviour management therapy, such as cognitive behaviour or reframing therapy (Selwood et al., 2007; Gallagher-Thompson & Coon 2007; Vernooij-Dassen et al., 2011). The most likely outcome from this form of intervention appears to be a reduction in carer reported depression (Thompson et al., 2007).

Returning to Schulz’s (2000) framework for interventions, the research evidence would appear to support interventions that combine domains of knowledge, skill, behaviour change and cognition.
Looking specifically at psychosocial interventions with single and major communication components, there is significantly less evidence available with only four level one identified studies (McCallion et al., 1999, Gitlin et al., 2010a and 2010b and Kouri et al., 2011). As already mentioned, a number of other studies may have been included and made more easily replicable if more detailed intervention descriptions had accompanied findings.

These studies indicate that communication specific interventions with dementia carers have the potential to influence their knowledge, self efficacy and experience of communication difficulties. However, our understanding of how this works, the mechanisms of action, is very limited.

2.4 A comparative contemporary study

This section introduces a large scale multi-component intervention trial conducted in the UK, detailed in four publications, that was reported initially in 2013. The RCT detailed in Livingston et al. (2013) was used for comparative purposes during the methods design, the results and the discussion of the programme of research that follows in chapters 3 onwards. More specifically, this enabled comparison of outcome measures used, recruitment, carer demography and results.

This multi centre trial recruited 260 carers of people with dementia from 472 referrals, making a recruitment rate of 55%. Recruits were randomised to receive 8 sessions of carer support or routine clinical treatment as usual. They employed (relatively low cost) psychology graduates to deliver a manual-based coping strategy programme (START, STrAtegies for RelaTives) which was based on the previously evaluated American “Coping with Care-giving” manual (Gallagher-Thompson et al., 2002). This intervention was delivered over 8 sessions which were attended in full by 72% of participants.

The primary outcome measure from this study was the Hospital Anxiety and Depression Scale (Zigmund & Snaith, 1983). Their results suggested small but significant differences between groups in both carer depression and carer quality of life but no significant differences in person with dementia quality of life or any
significant difference in reported difficult behaviours. A further publication, Knapp et al. (2013) suggests that this intervention, when added to treatment as usual, was cost effective compared with treatment as usual alone, by reference to outcome measures of affective symptoms for family carers and carer based QALYs (quality of life years).

In 2014, Sommerlad, Manela, Cooper, Rappaport and Livingston published further qualitative findings from the participants of the above study. They collected self-completed structured questionnaires with free text fields from 75 participants of the START study treatment group two years after study entry. Their results suggested that two thirds of carers were using techniques from the intervention at a two year follow up.

A further study published by Li, Cooper, Barber, Rappaport, Griffin, and Livingston (2014) examined the relationship between coping strategies and outcomes from the START programme in the same (n=260) trial. They found that increased emotion-focused coping mediated intervention effects for carers with baseline case levels of psychological morbidity (i.e. HADS scores above 16). This suggested that the intervention worked in different ways for carers who were already depressed and anxious in comparison to those that weren’t.

In the chapters that follow, comparison of recruitment, results and experience between these studies and the present programme of research will be made.

2.5 Implications for clinical practice and future research

This section details indicators and recommendations for the clinical use of psychosocial interventions, in particular those that address communication, and research that aims to determine their effectiveness. These recommendations are based on the findings from the systematic review above and were used to select and design the programme of research detailed in chapter 3 onwards.

2.5.1 Indicators and recommendations for clinical practice

When considering how to provide psychosocial carer support services, systematic reviews appear to support the use of intensive, one to one,
individualised therapy, following home-based assessment combined with an element of skills training (Goy et al., 2010). Carer organisations suggest a similar approach. In a review of recent research, the Rosalyn Carter Caregiver Institute (2010) suggests that carer support will be most effective when providing “contact with a helper who has specific protocols to follow, interventions tailored to the carer’s specific needs and interventions that combine knowledge, skill building, problem solving and counselling”. The inclusion of counselling is also supported by Farren, Loukissa, Perraud, & Paun (2004) who suggest that addressing emotional as well as informational needs increases the likelihood of lasting change. However, this form of support is likely to be the most costly in terms of service provision and carer time, which paradoxically may make it less likely to succeed in clinical settings where cost effectiveness and carer burden are primary influences. However, individualised interventions informed by assessment may still allow for the most effective use of clinical and carer time by addressing only those topics that are necessary.

With recent drivers to deliver cost effective health care (UK Department of Health, 2010), policy makers are interested in who provides interventions and at what cost. Within any intervention, there is likely to be some effect caused by the personality and expertise of the interventionist. Considering expertise, Burger et al. (2010) identified that expert nurses were better able than novices to integrate roles, organise their time, communicate more effectively, deal with interruptions and use cognitive strategies. The psychosocial intervention studies reviewed above have not referred specifically to cost and experience of the interventionist; however Livingston et al. (2013) have addressed this issue by using newly qualified graduates as interventionists in order to determine the generalisability of their results to use by novice workers (see section 2.4). However, their results do not indicate whether experts would have yielded greater or even more cost effective outcomes.

There is some evidence from Liddle et al. (2012) that carers liked delivery systems using role play and examples. There also appears to be merit in using a treatment manual to provide structure (Ripich et al., 1996; Liddle et al., 2012).
The use of a manual also enables interventionist training, treatment planning, adherence monitoring and replication of clinical and research findings (Addis, 1997).

The key indicators for clinical practice of communication interventions with dementia carers suggested by the above review are summarised in Table 2-3 below. This table is revisited in chapter 6.

Table 2-3: Key indicators and recommendations for clinical practice of psychosocial interventions for dementia carers.

<table>
<thead>
<tr>
<th>Key Indicators and Recommendations for Clinical Practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Early intervention</td>
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<tr>
<td>b) Intensive Therapy</td>
</tr>
<tr>
<td>c) One to one delivery</td>
</tr>
<tr>
<td>d) Home based assessment</td>
</tr>
<tr>
<td>e) Individualised content tailored to carers needs</td>
</tr>
<tr>
<td>f) Specific protocols to follow e.g. a manual</td>
</tr>
<tr>
<td>g) Focus on self-efficacy and insight development</td>
</tr>
<tr>
<td>h) Combines knowledge, skills building, problem solving, counselling i.e. CBT</td>
</tr>
<tr>
<td>i) Includes role play and practical examples</td>
</tr>
</tbody>
</table>

2.5.2 Key indicators and recommendations for future research

A number of methodological issues from the included studies were recognized during the systematic review above, though a significant improvement in rigour is noticeable in more recent studies. Common issues identified by this author and supported by previous commentators (Charlesworth & Newman 2006; Schulz, 2000) include relatively small sample sizes (often with no accompanying power calculations), limited attempts to establish validity and reliability of interventions and outcome measures and poor description of participant flow. A number of studies also introduce complexity and bias by focusing their outcomes on the carers whilst making their selection of participants purely on the basis of the characteristics of the cared for. As well as inadequately defined interventions, many of the studies fail to provide adequate description of the
control (often ‘treatment as usual’) intervention. Future research should address these weakness and follow the example of higher quality studies (e.g. Gitlin et al., 2010a) incorporating guidance from the Cochrane Collaboration (2011) and guideline statements such as CONSORT (Moher et al. 2010).

Even single component psychosocial interventions are complex interventions. The Medical Research Council (MRC) (MRC, 2000) defines a complex intervention as an intervention built up from a number of components, which may act both independently and interdependently. These components usually include behaviours, parameters of behaviours (e.g. frequency, timing) and methods of organising and delivering those behaviours. Complexity can also occur within the range of possible outcomes and the potential for variability in the target population (MRC, 2006). Campbell et al. (2000) along with Schulz (2000) recommend a mixed qualitative and quantitative methods approach to evaluating complex interventions.

Looking for examples of mixed methods research, Lewin, Glenton, & Oxman (2009) identified qualitative components in 30 out of 100 RCT’s which considered issues such as knowledge, attitudes, practices and process. They were supportive of mixed methods, but critical of some researchers for poorly describing the qualitative methods used and making little effort to integrate qualitative and quantitative data. This lack of qualitative methodology was evident in single component studies included in the review above. To improve this situation, O’Cathain, Murphy and Nicholl (2010) recommend a method for integrating data from mixed methods studies using meta-themes and a mixed methods matrix. By combining qualitative and quantitative data in a matrix, researchers are better able to look for patterns in a qualitative cross case analysis (O’Cathain et al., 2010). Future research would benefit from taking a mixed methods approach.

Some authors have studied carer: patient dyads using observational methods (Ritchie & Lewis, 2012) including discourse and conversational analysis or reported case studies and case series design (e.g. Spilkin & Bethlehem, 2003; Roque et al., 2009). These research methods provide a greater depth of
understanding which can inform the development of expertise and interventions, though are less likely to support the generalisability of an intervention to a wider population. A mixed methods approach to research should provide both a depth of understanding and naturalistic perspective, from qualitative research, alongside the controlled and factual testing of a causal hypothesis that comes from quantitative research (Bowling, 2009).

The McCallion et al. (1999), Gitlin et al. (2010a and 2010b) and Kouri et al. (2011) studies demonstrated significant benefits from carer interventions for the person with dementia and the carer, but highlighted that without further intervention these benefits were only short term. Given that the day to day experience of people with dementia and carers changes over time, these studies would seem to support the idea that interventions should be repeated and adjusted to changes in circumstances at regular intervals. However, this would add further to resource and time demands. With this in mind, none of these studies have considered at what point in time these interventions would be most effective, though there is a noticeable trend when comparing older with newer studies to provide intervention in the earlier stages of dementia. Assessing which carers benefit the most is difficult due to the tendency in many studies to include a relatively heterogeneous population of people with dementia and carers. Future research would benefit from evaluating interventions with a more homogenous population of carers and people with dementia, as well as some consideration of effect between sub groups of carers and persons with dementia.

In comparison to some treatment studies where all participants start off with the same illness, it will remain difficult to establish large, significant effects from treatment of carers as not all research participants will present with significant levels of the measurable outcome (e.g. depression). Future research outcomes may be more sensitive to change by providing single component interventions for carers that report difficulty with that component (e.g. difficulty with communication). Aizawa (2010) also suggests that some consideration in future research should be given to the relative importance of a communication component in comparison to other possible components.
Egan et al. (2010) highlight the importance of including outcome measures that consider changes to the person with dementia. However, the ethical issues involved in including people with dementia may limit this form of research. This author would also argue that interventions which aim to improve the carers experience and quality of life should have value in their own right. If carers can be helped, evidence suggests that those who experience fewer communication difficulties are more likely to care for longer, communicate more positively and have better personal mental health which in turn should have significant benefits for their relative with dementia (Searson et al., 2008; Braun et al., 2010).

Outcome measures that consider carer knowledge, self efficacy and communication experience most commonly yield significant changes. For future comparison of the effects of all psychosocial interventions with communication specific interventions, the use of outcome measures of carer thinking and behaviour, mood and anxiety should also be encouraged.

Further research in the area of communication interventions for dementia carers is clearly needed. Given the significance of communication difficulties, clinically repeatable intervention studies with relevant outcomes are called for. However, interventions in this area will always be complex. If studies were reduced to so few elements as to allow for easy analysis (e.g. one component, one domain, one mechanism of action etc) they are then likely to be less relevant to clinicians that have to provide more generic services for very mixed groups of people.
A summary of key recommendations for future research is provided in Table 2-4 below. This table is revisited in chapter 6.

Table 2-4: A summary of key implications and recommendations for future research.

<table>
<thead>
<tr>
<th>Communication intervention research for dementia carers should include;</th>
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</thead>
<tbody>
<tr>
<td>a) Larger sample sizes with power calculations</td>
</tr>
<tr>
<td>b) Attempts to establish validity and reliability</td>
</tr>
<tr>
<td>c) Adequate descriptions of participant flow and interventions</td>
</tr>
<tr>
<td>d) Adequate description of the randomisation process</td>
</tr>
<tr>
<td>e) Selection based on carer and person with dementia criteria</td>
</tr>
<tr>
<td>f) Provision for a more homogenous population</td>
</tr>
<tr>
<td>g) Interventions that address carer needs</td>
</tr>
<tr>
<td>h) Adequate description of the control condition</td>
</tr>
<tr>
<td>i) A mixed methods approach</td>
</tr>
<tr>
<td>j) Integrated qualitative and quantitative data</td>
</tr>
<tr>
<td>k) Long term follow up and consideration of optimum delivery timing</td>
</tr>
<tr>
<td>l) Outcome measures that include carer thinking, behaviour, mood and anxiety</td>
</tr>
</tbody>
</table>
3 Chapter Three: An overview of the programme of research and an introduction to the intervention: the Talking Sense manual.

This chapter aims to provide an initial overview of the programme of research and the intervention used, both of which were informed by the recommendations made in chapter 2 (see Table 2-3 and Table 2-4). The aim of these studies was to determine the effectiveness of the Talking Sense manual (Barnes, 2011). Talking Sense was developed shortly before the programme of research commenced and therefore its development did not form part of the programme of research.

This chapter contains four sections:

- Aim of the programme of research
- Overview of the programme of research
- Overview of the development of the Talking Sense manual
- Introduction to theoretical models and mechanisms of action used in the development of the Talking Sense intervention

This chapter also introduces the theory of mixed methods research design and analysis. The mixed methods approach used in this study is described in a purpose statement (see 3.2.2).

3.1 AIM OF THE PROGRAMME OF RESEARCH

This programme of research aimed to review, then contribute to the theory and evidence-base for communication specific dementia carer psychosocial interventions by using a mixed methods approach to determine the effectiveness of the Talking Sense intervention.

3.2 OVERVIEW OF THE PROGRAMME OF RESEARCH

The purpose of this section is to provide an introduction and overview for the programme of research detailed in chapters 4 and 5.
Following on from the systematic review (see chapter 2), a pre-existing intervention, the Talking Sense manual (Barnes, 2011), was selected for use in this research programme. The Talking Sense manual was designed and adapted to meet the recommendations detailed in Table 2-3.

In this research programme, Talking Sense was delivered as an intervention:

- to family carers of people with dementia
- in their own home
- seen alone
- in an individualised way with topics determined by discussion and joint selection
- over three one-hour sessions within an eight week period
- incorporating elements of knowledge, skills, behaviour and thinking

The Talking Sense intervention was compared to a single individualised control intervention that addressed carer knowledge alone, providing recommendations in a “treatment as usual” format.

The effectiveness of these interventions was considered in a mixed methods research study, designed to meet the recommendations for future research detailed in Table 2.4.

3.2.1 Theory of research design
Addis (1997) defines treatment manuals as empirically validated approaches, designed to maximise internal validity. Within research, manuals also allow for an evaluation of the adherence and competence of delivery (Addis, 1997). Within clinical practice, they allow for the definition of treatment goals and establish standards of care (Carroll & Nuro, 2002). Carroll and Nuro (2002) describe three stages of research in developing and evaluating manuals:

- Stage one: a pilot study looking at adherence and competence
- Stage two: a controlled clinical trial making a comparison to treatment as usual (Addis, 1997)
Stage three: further study considering transportability into clinical practice and overall cost effectiveness

The Talking Sense intervention presented here is also considered to be a complex intervention. The Medical Research Council (2000) define a complex intervention as something built up from a number of components, which may act both independently and interdependently. These components usually include behaviours, parameters of behaviours (e.g. frequency, timing) and methods of organising and delivering those behaviours. Complexity can also occur within the range of possible outcomes and the potential for variability in the target population (Medical Research Council, 2006).

Campbell et al. (2000) along with Schulz (2000) recommend a mixed qualitative and quantitative methods approach to evaluating complex interventions. The Medical Research Council (2000) framework suggests that the qualitative component is helpful for understanding why and how something happens whereas quantitative data provides statistical evidence, within the limitations of the sample and outcome used, to determine whether significant effects and differences can be generalised to similar interventions and populations.

A number of research designs have been used in carer psychosocial research including case studies, case series, non-randomised controlled trials and conversation analysis. Few studies however, in a pilot study, have combined a mixed methods approach.

In particular, case studies and conversation analysis approaches, which take a micro-analytical approach, are thought to add significant depth to the field of enquiry. They identify not just the skill deficit, but also the detailed interactions (verbal and non-verbal) that occur (Chatwin, 2014). In the context of this research programme however, they would require ethical approval to recruit both a carer and the person with dementia, and are criticised for being subjective, open to interpretation and therefore difficult to generalise from (Chatwin, 2014). More specifically, conversation analysis has been criticised for analysing and interpreting actions and not the thoughts behind those actions.
(Chatwin, 2014). The ability to consider changes in carer thinking is important in the case of a cognitive behavioural intervention such as Talking Sense.

Randomised controlled trials, on the other hand, are referred to as the “true experimental method” (Bowling, 2009). The use of a control group allows the researcher to minimise the confounding effects of variables other than the independent variable. The use of randomisation safeguards against bias in allocations and minimises differences between groups of people being compared (Bowling, 2009).

3.2.2 **Introduction to mixed methods research**

This programme of research used a mixed methods design. Creswell and Plano Clark (2011) define this approach as “one in which the researcher collects, analyses and integrates both quantitative and qualitative data in a single study or multiple studies in a sustained programme of enquiry”.

Craig et al. (2008) in an update to the MRC intervention framework state that “wherever possible, evidence should be combined from a variety of sources that do not share the same weaknesses”. Green, Caracelli and Graham (1989) give the following reasons for choosing a mixed methods design:

- **Triangulation** – findings are combined in order that they can be mutually corroborated
- **Offset** – the weaknesses of one method are offset by the strengths of another
- **Completeness** – mixed methods allows for a more comprehensive account
- **Process** – whilst quantitative research shows structures, qualitative research provides a sense of process (the how and why)
- **Explanation** – one method helps to explain findings from the other
- **Credibility** – using both methods enhances the integrity of findings
- **Illustration** – qualitative findings can be used to illustrate quantitative data
Utility – qualitative data improves the usefulness of findings in e.g. clinical applications

Mixed methods research includes at least one qualitative and one quantitative strand. When selecting a design, four issues are particularly relevant. These include the level of interaction between strands, the relative priority of each, the timing and the procedures for mixing data from each strand. Mixing in this case suggests that data from one strand influences the other either at design, data collection or analysis stages.

In the case of this programme of research, the mixed methods design selected used one quantitative and one qualitative strand. They were given equal priority with mixing limited to the analysis stage. Data collection was concurrent (collected during the same phase of the study). This could be described as a convergent parallel design (Cresswell & Plano Clark, 2011).

The strengths and weaknesses of the convergent design are described as:

- it makes intuitive sense
- it is efficient as data can be collected at the same time
- data can be analysed separately which lends itself to team research
- sample size differences are likely and need to be taken into account in interpretation
- it can be challenging to merge data in a meaningful way
- it can be difficult to unpick data if it does not agree

Cresswell and Plano Clark (2011) recommend that researchers use a mixed methods purpose statement. The statement for this programme of research is as follows:

This mixed methods study addresses the effectiveness of the Talking Sense intervention. A triangulation mixed methods design was used, a type of design with different but complimentary data collected on the same topic. Separate aims are reported in chapters 4 and 5 for the quantitative and qualitative strands respectively. The aims of collecting
both quantitative and qualitative data were to bring together the strengths of both forms of research to determine the extent to which both sets of data converge, contradict, illustrate and explain the process of the intervention and experience of carer participants in this programme of research.

3.2.3 Introduction to research design

Once ethical approval was given, carers were recruited either from this authors’ existing clinical caseload, from attendance at existing carer support groups or by referral from third party professionals working in the Portsmouth Older Persons Mental Health service. Detailed inclusion criteria are given in chapter 4. Study participants were typically family members of someone with dementia scoring between 21 and 27/30 on the MMSE test (Folstein et al., 1975).

When carers were recruited for participation, they were randomly allocated to receive either the Talking Sense intervention or a single “treatment as usual” control intervention (see Appendix 7). Further details about the materials used, ethical aspects, selection of the control condition, referral, recruitment and randomisation processes are detailed in Chapter 4. This author delivered all interventions.

Carer participants self-completed a number of validated outcome measures at the time of recruitment and two weeks after the last intervention. One new outcome measure, the Communication Self Efficacy Scale (CSES) was developed for the purpose of this study. Details of the selection of outcome measures and the results obtained are provided in chapter 4. The outcomes measured included:

- the primary outcome measure* - Carer reported depression and anxiety (HADS)
- carer-reported expectations
- carer therapeutic engagement and readiness (TEI)
- carer-reported quality of life (ACQOL)
• carer communication self efficacy - the extent to which communication difficulties happen and how the carer believes they manage them (CSES)
• carer general self efficacy (GSES)
• carer-reported person with dementia communication competence (CCS)

*The primary outcome measure was selected in part for comparison with Livingston et al. (2013) who used the same primary outcome measure.

Additional information gathered included carer and person with dementia demographic details, severity and type of dementia, carer health and stress and carer and person with dementia support and service use.

Fifteen carer participants, who were randomised to the Talking Sense treatment group, were purposively selected after completion of outcome measures, to participate in semi-structured interviews. In an attempt to reduce bias, these interviews were conducted by a third party interviewer. The results of these interviews were analysed using a framework approach (Ritchie & Lewis, 2012). Further detail about the methodology, results and conclusions from these interviews is given in chapter 5.

Findings from the randomised controlled trial and interview components of this research programme are discussed individually at the end of chapters 4 and 5. The results and discussion from the mixed methods analysis are detailed separately in chapter 6.

**3.3 THE DEVELOPMENT OF THE TALKING SENSE MANUAL**

This section provides an overview of the development of the Talking Sense manual.

Taking into account Table 2-3 above, the author preceded this research programme by developing a treatment manual for use with carers of people with dementia. This manual was called Talking Sense (Barnes, 2011).

Talking Sense is a treatment programme designed for dementia care professionals to use, working in a one to one and individualised way with carers
of people with dementia to address communication difficulties. It was developed between October 2009 and January 2011. The development of Talking Sense was funded by a grant from NHS Education South Central.

Prior to the onset of this research programme, Talking Sense was developed by:

- taking into account findings from an earlier MA thesis pilot study (Barnes, 1998) using a carers communication intervention entitled Chatter Matters (Barnes, 2003)
- incorporating comments on 10 questionnaires returned from members of the Royal College of Speech and Language Therapists special interest group in psychiatry that had used the Chatter Matters (Barnes, 2003) approach
- incorporating comments on communication experiences and carer work approaches from 30 dementia carers who had completed a questionnaire circulated to all local carers groups
- conducting a literature search for articles and books using search terms including “communication, conversation, talk, challenging behaviour, training, education” AND “carers, caregivers, relatives, family” AND “dementia, Alzheimer’s disease”
- conducting a literature review of over 300 articles and 35 books including all the currently published books on communication and dementia for carers (See Appendix 1)
- merging all ideas identified into a series of 24 themes which were then ordered into a logical sequence of 9 stages for the treatment approach (see Figure 3-2)
- developing a 5 point severity of dementia and communication difficulty scale (called VEMAS) which is used to heighten the carer’s awareness but which is also matched to the majority of strategies and approaches detailed in the programme (See Appendix 2). Appendix 6 details the contents of each stage of the Talking Sense programme and how these were matched to the VEMAS scale
• conducting a content validity exercise with 20 national experts in dementia care to consider the descriptive accuracy of the VEMAS scale and its match to the topics included in Talking Sense

• arranging review of the completed manual by 5 local experts in dementia care and one carer

During the development of Talking Sense, the title and cover picture (see Figure 3-1) were discussed informally with three groups of carers. They were chosen to illustrate the idea of steps, the communication barrier between people with dementia and their carers, the difficulty carers and people with dementia have making sense of communication and the use of a sensible discussion based approach to working with carers.

Talking Sense was first produced as an A4 size book with over 100 pages. For more practical use as a one to one intervention in this programme of research, a modified version of Talking Sense was developed which included a series of 71 Powerpoint (Microsoft, 2007b) landscape slides printed in colour onto individual A4 presentation cards.

Figure 3-1 below illustrates the Title page of the Talking Sense manual and Figure 3-2 the nine steps of developing a Talking Sense. Talking sense is designed to be used step by step, starting off with the bottom step (Knowledge). Examples of slides from steps one to six of Talking Sense are included as appendices 3 to 5.

Returning to the Schulz (2000) framework for psychosocial interventions, Talking Sense can be described as follows:

**Component(s) being targeted:** Communication

**Domain(s) being targeted:** Carer knowledge, carer skills, carer behaviour, carer thinking and carer affect.

**Delivery system characteristics:** One to one, manual driven but individualised, in the carer’s home delivered over 3 hour long sessions (in the context of this study).
**Mechanisms of action:** Anticipated mechanisms of action are detailed in the following section.
Talking Sense

A communication programme for family carers of people with dementia

Figure 3-1: The title page of the Talking Sense manual.

Figure 3-2: The nine steps of the Talking Sense programme.
3.4 INTRODUCTION TO THEORETICAL MODELS AND MECHANISMS OF ACTION

The purpose of this section is to highlight the importance of using theoretical models for mechanisms of action, and to describe the models that were used to inform the development of the Talking Sense intervention. These models are referred to again in the discussion sections of chapters 4 to 6 to consider the evidence for the mechanisms that were identified and observed in the pilot randomised controlled trial and semi-structured interview studies.

Gitlin et al. (2000) report that in general there is poor understanding of how psychosocial interventions work. This is confounded by a history of poor documentation of intervention content as well as theory of delivery and effect (Charlesworth & Newman, 2006).

A number of researchers have encouraged the use of theoretical models or frameworks to explain how and why carer psychosocial interventions may have effects (McGilton et al., 2010; Charlesworth & Newman, 2006; Schulz, 2000). In the systematic review above (see chapter 2), only one study (Kouri et al., 2011) attempted to describe the anticipated effects from their intervention using a theoretical framework built around theories of self-efficacy. Although all of these studies were designed with outcome measures such as carer depression, burden and quality of life, no attempt was made to explain the process by which change was expected beyond using words such as training, skills, behaviour, psycho-educative and counselling (Bourgeois et al., 1997; Done & Thomas, 2001; Haberstroh et al., 2011; McCallion et al., 1999; Orange & Colton Hudson, 1998; Ripich et al., 1999; Spilkin & Bethlehem, 2003; Tanner & Daniels, 1990 and Weinrich et al., 2006).

Zarit and Femia (2008) suggest that a careful examination of the mechanisms by which a treatment is theorised to work will clarify which treatment approaches are best for a particular outcome and which outcome measures are best with a particular treatment. They add that this process is made more complex in the context of dementia carer interventions by understanding firstly that caring is
not a disorder; secondly that “symptoms” of caring (e.g. depression) do not occur for all; thirdly that carer: patient dyads have heterogeneous profiles for risk factors, and fourthly therefore; treatments need to be tailored to the specific circumstances of the carer: person with dementia dyad (Zarit & Femia, 2008). Schulz (2000) suggests that a theoretical model for intervention delivery and effect should enable us to identify which carer: patient situations are most likely to respond and benefit.

In the development of Talking Sense, theoretical models were used in two areas:

1) To provide theories for delivery of the intervention
2) To provide theories for the effect of the intervention

The description of models is not intended to be exhaustive. The models described in this section are only those considered during the development of the Talking Sense manual.

3.4.1 Theories for the delivery of Talking Sense
Psychosocial studies use a wide range of combinations of delivery methods. Talking sense incorporates a number of unique design features:

3.4.1.1 Interdependence of steps
Talking Sense presents materials in a series of steps (See Figure 3-2). The material within the steps can be individualised, though the programme is designed to be delivered in a set, step-by-step order. This is based on the principle that the steps are interdependent i.e. insight (step two) is dependent on knowledge (step one), thinking (step three) is dependent on insight (step two) etc.

3.4.1.2 Multi-modal learning
Research shows that many carers lack essential knowledge about dementia which leads to misunderstandings and misguided expectations (Paton et al., 2004). Studies have also shown that effecting changes in knowledge does not necessarily lead to changes in behaviour (similarly people change their behaviour without knowing or being able to describe why). However, the Talking Sense
approach has been written with the premise that accurate knowledge forms the foundation for development.

The primary theory adopted in Talking Sense is that of multimodal learning which has its origins in Edgar Dale’s (1969) early work. Dale (1969) identified that we remember very little of what we read but considerably more of what we discuss, say and do. Other authors such as Honey and Mumford (1982) have identified that individuals can have different preferences for learning. An additional tenant of this theory is that successful communication relies on skills which have to be learnt and established.

Therefore, in the context of using Talking Sense as an intervention, carers are encouraged to learn by hearing, discussing, doing and rehearsing.

3.4.1.3 Communication from the outside in
Talking Sense steps three to eight address communication from a converging perspective. This principle assumes that it is best to first consider the effect of the environment and the person’s resources (equipment) before moving on to look specifically at what is happening between people. The analogy of designing a stage play “set first and lines last” is used.

3.4.1.4 Cognitive behaviour therapy (CBT)
CBT has already been introduced in chapter one. In the delivery of Talking Sense, the use of CBT focuses on the here and now and relies on the therapist and carer developing a shared view of the problems they perceive and experience. This leads to identification of personalised, usually time limited, goals which are continually monitored and evaluated. This approach is intended to be empowering in nature, enabling the carer to tackle difficulties by harnessing their own resources. As well as discussion and developing formulations of shared theories, CBT in the context of Talking Sense can include homework such as completing thought diaries, activity records or carrying out experiments.

Typically, CBT, which is intended to be relatively brief, explores concepts such as:

- core or underlying beliefs e.g. “you should never lie or argue”
- dysfunctional assumptions (e.g. “if I do this then that will happen”)
- automatic/hot or instantaneous thoughts (e.g. “I’m useless”)
- vicious (and virtuous) circles

3.4.1.5 Developing Mindfulness
In the context of Talking Sense, mindfulness is used to refer to the process of paying attention in a particular way, stepping back and viewing unhelpful thoughts from a decentred perspective. This is essential for participation in the CBT approach. In therapy, this starts with encouraging people to become more aware of their thoughts (Westbrook, Kennerley, & Kirk, 2008).

One theory put forward by Teasdale (1996), is that CBT could have an effect not just by changing the content of people’s negative cognitions, but more by enabling people to identify their thoughts and evaluate the accuracy of those thoughts. Therefore, those carers who are less able to identify their own thoughts may have more difficulty engaging in the CBT process.

3.4.1.6 Developing self efficacy
Alongside the use of CBT, the development of self efficacy is one of the primary theories used in the Talking Sense approach.

The concept of self efficacy is attributed to Albert Bandura (1997) who defined it as “an individual’s belief in their ability to perform a specific behaviour or task” (rather than their actual ability to do so). Self efficacy has been found to play a significant role in predicting health behaviour. It is thought to influence how people feel, think and act.

Schwarzer and Fuchs (1995) suggest that a strong sense of personal efficacy is related to better health, higher achievement and more social integration. Self efficacy is thought to be related to the adoption, initiation and maintenance of health behaviours (Shwarzer & Fuchs, 1995). A low sense of self efficacy is associated with depression, anxiety and helplessness. Once a decision has been made to change an action, highly self efficacious persons are thought to invest
more effort and persist longer in maintaining change than those with low self efficacy. When setbacks occur, the former recover more quickly and maintain commitment to their goals. Perceived self-efficacy has also proven to be a powerful personal resource in coping with stress (Lazarus & Folkman, 1984).

Self-efficacy allows people to select challenging settings, explore their environments or create new situations. A sense of self-efficacy or competence can be acquired by mastery experience, vicarious experience, verbal persuasion or physiological feedback. Self efficacy is not the same as positive illusions or unrealistic optimism as it is based on experience and does not lead to unrealistic risk taking (Connor & Norman, 2009).

In establishing a rank order of direct paths that lead to intention, Schwarzer and Fuchs (1998) suggest that self-efficacy dominates followed by outcome expectancies and threat or risk perceptions.

3.4.1.7 Active use of encouragement

This is one feature of Talking Sense that may influence self-efficacy. The previous small scale M.A. study (Barnes, 1998) which included interviews with five carers, highlighted the importance of actively encouraging carers. Carers reported benefit from being encouraged for what they were already doing and had achieved, as opposed to being overwhelmed by what they hadn’t. Talking Sense intervention sessions are intended to include frequent active encouragement.

Figure 3-3 below illustrates the components of the Talking Sense intervention.
The following theories were identified during the development of Talking Sense to describe the mechanisms of action (Schulz, 2000) which were thought likely to occur.

3.4.1.8 Therapeutic alliance and engagement

Westbrook et al. (2008) argue that the therapeutic relationship is an essential foundation for therapy. Orlinsky, Grawe, & Parks (1994) provide good evidence linking the quality of therapeutic relationship to therapeutic outcome. Bordin (1979) analysed the therapeutic relationship and identified 3 essential components for a successful alliance:

- agreement on the task – what needs to be done in therapy
- agreement on therapy goals – what is being sought from therapy with client and therapist each contributing personal commitment to goals
a positive therapist-client bond typified by mutual liking, respect, trust and commitment

Although a therapeutic alliance is necessary, it is not sufficient in itself to account for the beneficial effect of CBT (Westbrook et al., 2008). Evidence suggests that the strongest predictor of outcome for CBT is the nature of the client’s participation or engagement in treatment (Burns & Nolen-Hoeksema, 1991).

In the context of Talking Sense, this model challenges the therapist to generate engagement and participation in therapy, as well as development of the therapeutic relationship.

3.4.1.9 Protection motivation theory
This model considers two appraisal processes: coping appraisal and threat appraisal. Coping appraisal involves assessing action-outcome efficacy and self efficacy. The concept of threat is partly associated with fear. Threat appraisal components have tended to be less predictive of intentions/action and seem to have their greatest influence earlier in the decision making process (Boer & Seydel, 1995). Adaptive responses are held to be more likely if the individual perceives themselves to be facing a threat which they believe they are susceptible to and which they believe is likely to be severe. Schwarzer and Fuchs (1998) also describe how a minimum level of threat or concern is required for people to start contemplating the benefits of certain actions.

In the context of the Talking Sense intervention, this theory is concerned with whether carers believe themselves and their relatives to be experiencing difficulty with communication and whether this is of sufficient severity to be considered a threat. The therapist may be able to influence these beliefs through the development of knowledge and insight.

3.4.1.10 Health locus of control
The health locus of control theory has its origins in Rotter’s (1954) social learning theory. The locus of control refers to the extent to which individuals believe they can control events affecting them. In the context of communication support, we
can make a distinction between carers as “internals” and “externals”. Internals are seen to believe that events are a consequence of their own actions whereas externals are seen to believe that events are unrelated to their actions and therefore out of their control. This is distinct from self-efficacy. Health locus of control has been found to be a relatively weak predictor of health behaviour (Abraham & Sheeran, 2009).

In the context of Talking Sense, the therapist explores whether the carer believes it is possible that their actions could affect a change; and whether the carer can influence those beliefs.

3.4.1.11 Implementation intentions and health behaviour
Abraham and Sheeran (2009) suggest that several theories that have been used extensively to predict health behaviours construe the person’s intention to act as the most immediate and important predictor of subsequent action. Implementation intentions are defined as instructions that people give themselves to perform particular behaviours or to achieve certain goals (goal intentions). They are seen as the culmination of the decision-making process and signal the end of deliberation. Intention-behaviour consistency is attributable to participants with positive intentions who subsequently act (inclined actors) and to participants with negative intentions who do not act (disinclined abstainers). Research suggests that inclined abstainers rather than disinclined actors are principally responsible for the intention-behaviour gap (Abraham & Sheeran, 2009).

In practical terms, implementation behaviour is about not just setting a goal – what I am going to do – but planning when, where, how and in response to what. They are “if-then” plans that require identification of a response, which will lead to goal achievement and anticipation of a suitable occasion to initiate that response. The real value of implementation intentions is that they become immediate, efficient and do not require conscious intent (Abraham & Sheeran, 2009).
Further evidence suggests implementation plans benefit from cognitive rehearsal. Other evidence suggests that goal intentions are more prone to wearing off over time than implementation intentions (Abraham & Sheeran, 2009).

3.4.1.12 Summary of theories for the intended effect of Talking Sense

In summary, the Talking Sense intervention aims to enable changes in carer’s knowledge, thinking, skills and behaviour. This process is collaborative between the therapist and carer. These theories of effect suggest that change is more likely if the therapist and carer are allied and engaged and if the carer appraises the threat as likely and of sufficient severity and consequence to warrant change that they and others will value. Carers will need to believe that they have control over change, are capable of implementing change, and have the resources to do so. Change will also require the setting and delivery of implementation intentions.
4 Chapter Four: Pilot, randomised controlled trial

This chapter includes the methods, results and discussion for the pilot, randomised controlled trial (RCT) study. The section headings follow the checklist for randomised controlled trials developed by CONSORT (Moher et al., 2010).

This chapter contains four main sections:

- Introduction
- Methods
- Results
- Discussion

The results of this study are discussed in this chapter, although, where comparable, results are also incorporated into a mixed methods discussion in chapter 6. The discussion section also follows the CONSORT (Moher et al., 2010) recommendations by reporting limitations, generalisability and implications of the results. Clinical and research recommendations are combined and incorporated into chapter 6.

4.1 INTRODUCTION

Chapter 1 of this thesis introduced communication difficulties in dementia and the effects these can have on family carers. Chapter 2, a systematic review of previous communication specific psychosocial interventions, identified recommendations for further research (see Table 2-4) using well documented evidence based interventions (see Table 2-3). Chapter 3 explained the development and content of the Talking Sense manual, used to deliver the treatment intervention in the study that follows. Talking Sense was developed, with theoretical mechanisms of action defined, to meet these recommendations.

4.1.1 Title

The title of this study was “A pilot study to evaluate the effectiveness of an individualised and cognitive behavioural communication intervention for informal carers of people with dementia.”
4.1.2 Background
This study was designed as a pilot study in contrast to a feasibility study. Lancaster, Dodd and Williamson (2004) suggest that the terms pilot and feasibility are often misunderstood. The National Institute for Health Research (2014a) describes a feasibility study as one that is conducted before a main study to answer the question “can this study be done”. Feasibility studies are used to estimate parameters, practicalities and resources that are needed to run and design the main study. In the case of this programme of research, the author had previously conducted a five subject mixed methods trial of a knowledge based intervention for dementia carers as part of an M.A. dissertation (Barnes, 1998) and therefore, had unpublished evidence of feasibility.

In contrast, the National Institute for Health Research (2014b) defines a pilot study as a version of the main study run in miniature, to test whether the components of the main study can all work together. It focuses on processes but also tests outcomes, potentially identifying trends that would support the investment required for further recruitment. Data from an internal pilot study may also be used in the final analysis of a subsequent larger study (Lancaster, Dodd, & Williamson, 2004).

The use of a pilot study in this research programme is in keeping with recommendations for phase two of the Medical Research Council (2000) complex interventions development and evaluation framework and stage two from the Carroll and Nuro (2002) model for the development of manual based treatment.

4.1.3 Aim and objectives
The main aim of this study was to determine the effectiveness of the Talking Sense intervention. This aim was intended to be realised by the following objectives:

- Test recruitment of anticipated number of carers in accordance with ethical principles, achieving low rates of attrition, minimal burden and no harm identified.
• Test delivery of the Talking Sense intervention in keeping with recommendations for clinical practice identified by the systematic literature review (see Table 2-3).
• Test acceptability of outcome measures selected by recommendations for future research (see Table 2-4), a review of previous outcome measures, consideration of established measures, and for comparison with the contemporary study Livingston et al. (2013).
• Test outcomes for significance or trends that reject the null hypothesis, that the Talking Sense intervention will be no more effective than the control intervention.
• Test the potential for mixed methods comparison (in chapter 6) with the series of semi-structured interviews detailed in chapter 5.
• Consider the potential for extending this pilot study in future research and identify recommendations for future clinical use of the Talking Sense intervention.

4.2 METHODS

This section describes and justifies the trial design, ethical considerations, participant selection, interventions and outcomes measured.

4.2.1 Design

The design chosen for this pilot study was a randomised controlled trial:

• in keeping with recommendations by Carroll and Nuro (2002) and the Medical Research Council (2000) for researching complex and manualised interventions
• as best fit for ethical and clinical requirements within the context of the clinical services where the study was undertaken
• in order to reduce the effect of bias and confounding variables and generate outcomes that would allow generalisation to the broader population of dementia carers as well as comparison with other research in the psychosocial interventions field
4.2.2 Research Governance and Ethics

4.2.2.1 Trial database registration
This study was registered on the international database clinicaltrials.gov
(Identifier: NCT01481363) coordinated by the US National Institute of Health.

4.2.2.2 The research steering group
Prior to submitting a formal proposal and seeking ethical approval, a research
steering group was formed. This group included the author, the academic
supervisor, a consultant psychiatrist who would act as a liaison with the Older
Persons Mental Health service, the SLT service manager and two experienced
carers of people with dementia. The members were chosen for reasons of
accountability and representation of interested parties.

The responsibilities and objectives of the steering group were to:

- Meet quarterly during the planning and recruitment phase of the study
- Record minutes which were distributed to all members
- Question the author to ensure the study protocol was being followed
- Monitor spending of research grants to ensure that funds were being
  used as proposed
- Monitor recruitment, intervention and outcome measurement to ensure
  the study was in keeping with existing SLT service and NHS trust policies
- Monitor, question and discuss referral rates, early findings, declines and
  withdrawals and positive and negative experiences to ensure the study
  was safe to proceed and in keeping with research objectives and ethical
  guidelines
- Identify and act on any concerns in conjunction with the SLT service
  manager, psychiatrists and university supervision

The results of the pilot study were presented for discussion at the final meeting
of the steering group in August 2014.
4.2.2.3 Ethical approval

After the research proposal was independently reviewed and amended, a detailed submission was made to the IRAS (Integrated Research Application System) research ethics committee in December 2011. Approval from the research ethics committee and local NHS research department was granted in April 2012 (see Appendix 8). Appendix 31 is also included as the University of Portsmouth (UPR 16) ethical checklist. The IRAS ethical declaration of the end of study is included as Appendix 32.

Ethically the study could be considered intrusive (research which would normally require consent), but not invasive (physically taking something to or from a person’s body) research (UK. Department of Health, 2008) and was not a clinical medical trial (Medical Research Council, 2007). The study design followed the World Medical Association ethical principles for medical research involving human subjects, detailed in the declaration of Helsinki (World Medical Association, 2013). The study design employed the following ethical principles (Pannbacker, Middleton, & Vekovius, 1996):

- Autonomy - commitment to respect the individual’s independent choice and actions
- Beneficence - obligation to convey benefits and help others to further legitimate interests
- Confidentiality - understanding that information divulged will be kept safe and not revealed to other persons
- Nonmaleficence - obligation not to inflict harm or risk of harm to others.
- Professional responsibility - obligation to observe the rules of professional conduct with patients and colleagues

The interventions were judged likely to be of benefit to carers and their relatives with dementia, in proportion to burden. The models of intervention were based around contemporary methods of good practice. Any potential for distress was likely to be limited to a short term effect, though the author needed to be mindful of the carers’ privacy and psychological well-being.
4.2.2.4 Participant Information

The extent of written information provided for potential carer participants was balanced so as to avoid stress caused by excessive information (British Society of Gerontology, 2008). Consideration was also given to the person with dementia’s awareness of their diagnosis and therefore literature referred to “memory difficulties” rather than dementia (Wilkinson, 2002).

A participant information sheet (see Appendix 10) was produced which followed best practice for design detailed by the National Research Ethics Service. This, and other purpose written documentation for participants, was measured for grammatical complexity (recorded on the document) using the FOG index (Panix, 2013). In these documents (Appendices 9 and 10), a grammatical complexity equivalent to a reading age of no greater than 12 years old was achieved.

A consent document (see Appendix 9) was used as a signed agreement to participate. The consent form included consent to the use of audio recording equipment for all sessions, storage of audio, electronic and paper data and monitoring of carer support by means of the OPMH service electronic records system. Materials were marked stating that the study was not approved for the participation of people without capacity to consent for themselves (UK Department of Health, 2009b).

4.2.2.5 Capacity and consent to participate

Carers were under no pressure to participate in this study. The carer gave informed consent to the author having demonstrated that they have a full understanding of what was involved (Alzheimer’s Association, 1997). Carers were free to involve another person in judging whether to participate (Alzheimer’s Association, 1997). They were also encouraged to ask questions (Alzheimer’s Association, 1997). Consent was checked and confirmed on every visit by the author and research interviewer (Wilkinson, 2002).

Carers were encouraged to be seen alone wherever possible. People with dementia were not participants in this study, but could be present as observers if they co-habited with the carer and preferred not to be absent. In this situation,
the author acted in the best interests of the person with dementia. Arrangements were also available for supervision of the person with dementia at an NHS day centre whilst the carer was seen alone nearby.

In keeping with the Mental Capacity Act (UK Government, 2005), the carer’s capacity to participate was assumed unless established otherwise. Compliance did not indicate capacity (UK Department of Health, 2009b). Capacity for carers was judged specifically in relation to understanding, retention, using or weighing information and communicating (Medical Research Council, 2007). Initial consideration of the carer’s capacity to participate was based on informal assessment by referrer and approval from the carer’s relative’s psychiatrist. Participants were free to withdraw from this study at any time. In addition, participation was cancelled or delayed if a person with dementia present did not appear to assent, actively expressed discomfort or distress, or indicated in any other way that they did not wish for the visit to continue (UK Department of Health, 2009b).

4.2.2.6 Confidentiality

The participant information sheet (see Appendix 10) included a condition stating that this was a confidential study and that disclosure of information would only take place to the person with dementia’s named psychiatrist if information revealed was related to a high degree of risk, personal loss or harm to the person with dementia or carer. The study design stated that carer participants would be informed prior to any disclosure.

No personally identifiable information was included in transcripts or publications. All recordings, written records and transcripts as well as treatment records were kept as part of the patient or carer record and therefore stored in keeping with the data protection act (UK Government, 2003) and local NHS policies.

A randomly generated six digit code produced from a webpage (www.randomcodegenerator.com) was used instead of personally identifiable information to identify carer participants on all paperwork. The key to this code
was stored securely in a locked drawer in the Speech and Language Therapy
department for the duration of the study.

4.2.3 Participants and interventions

4.2.3.1 Inclusion criteria
Carers were included in this study if they were:

• spouses, co-habiting partners or children of the person with dementia, in
  contact with their relative with dementia for more than two hours per
  week
• caring for a relative with a diagnosis of Alzheimer’s disease, vascular
dementia or Lewy body dementia
• reporting or acknowledging “current difficulties with communication”
  between themselves and their relative
• demonstrating capacity to understand and consent to participation for
  the duration of the study
• considered suitable for participation in this study by the approving or
  referring psychiatrist, with particular attention to mental wellbeing*
• caring for a person with dementia with a recent score of between 21 and
  27 out of 30 on the M.M.S.E. test (Folstein et al., 1975) (or functional
  ability typical of someone scoring in this range) **

*As anxiety and depression are common amongst carers, carers demonstrating
symptoms or a history of these conditions were not excluded. Their suitability for
participation was judged by the referrer, the author and the approving
psychiatrist.

**Although the Talking Sense manual was suitable for the widest range of
communication difficulties in dementia, this study limited its use to a cohort of
people within the range of mild dementia as defined in the National Institute for
Health and Care Excellence (NICE) clinical guidelines for dementia (2006). This
could include people with dementia graded as V, E or M on the VEMAS scale (see
Appendix 2). This followed the principle (see Table 2-4) that, in a relatively small
scale study, use of a more homogenous group of carers was more likely to enable identification of differences in response between carer subgroups. The inclusion of people with functional ability typical of MMSE scores above 21/30, allowed the referral of people who had scored below 21/30 or above 27/30, but in all other ways, were typical of people within that range.

4.2.3.2 Exclusion criteria

Carers were excluded from participation if they:

- did not meet the inclusion criteria
- were caring for someone with a primary communication impairment which was either associated with fronto-temporal dementia, Parkinson’s disease or a stroke, as it was expected that their presentation and experience would be significantly different from the majority of people with dementia (Nicolaou, Egan, Gasson, & Kane, 2010)
- had already received a significant form of individualised communication therapy e.g. with a speech and language therapist, psychologist or occupational therapist

4.2.3.3 Setting and location

This trial was conducted amongst carers of people with dementia living in Portsmouth and known to the Solent NHS trust speech and language therapy and older person’s mental health services.

The author was employed as a speech and language therapist specialising in dementia care and was assisted by a third party interviewer who was a trained speech and language therapist. Other support was provided by the speech and language therapy administrator (who produced interview transcripts), a therapy assistant (who helped four carers complete outcome questionnaires) and a student volunteer (who assisted in the compilation of outcome measure data).

The Portsmouth Older Persons Mental Health service (OPMH) provides diagnostic, medical and follow-up care for people across the full age and severity range of dementia as well as other types of mental illness for older people over
65. The service also provides individual and group support for carers. The OPMH service includes consultant psychiatrists, community mental health nurses, occupational therapists and a psychologist.

The sampling frame included urban and suburban areas and ethnic and social class diversity. In the 2011 census (UK Office for National Statistics, 2011), the Portsmouth area ranked highly for indicators of poverty and was home to approximately 25,000 people, out of 205,000 (i.e. 12%), born outside of the UK. Census statistics for Hampshire suggest that 93% of households use English as the main spoken language.

4.2.3.4 The referral process
Schulz (2000) encourages researchers in this field to market their interventions in an honest and factual way in order to ensure they reach those who most need them. He recommends a framework based around the following four elements:

- **Product**: Complex interventions are more difficult to comprehend which can lead to poorer recruitment and retention. To aid understanding, a promotional leaflet (see Appendix 11) was developed for potential participants and a guide for potential referrers (see Appendix 23).
- **Price (for participants)**: The promotional leaflet explained what might be gained from participation and offered some flexibility to minimise the time required for participation e.g. home visiting.
- **Place**: Flexibility regarding location of delivery of the intervention was also offered to maximise convenience.
- **Promotion**: Early participants were asked (where willing and appropriate) why they had chosen to participate in this study in order that future promotion was informed, appropriate and maximised.

Carers were not approached directly by the author. All referrals for participation came from third parties or following an explanation of the study by a third party.

Prior to commencing this study, the author met with over 20 potential referrers including consultant psychiatrists, community mental health nurses,
occupational therapists and a GP. Potential referrers were provided with a referrer’s guide (Appendix 23) that explained inclusion and exclusion criteria and the process of referral, a referral (marketing) leaflet (Appendix 11), a brief referral form (Appendix 12) and envelopes addressed to the author.

All potential referrers were sent a monthly email, during the recruitment phase of this study, which detailed referrals received to date, participation rates and targets. The email also included a periodic reminder on inclusion and exclusion criteria.

Recruits were also identified from the author’s existing caseload if approved by the overseeing psychiatrist.

The process of recruitment is illustrated in Figure 4-1 below.
Figure 4.1: The process of recruitment to this study.

**Talking Sense Study Flowchart A (see also more detailed study procedures).**

**Recruitment to study**

- **During nurse or consultant appointment:**
  - Carer reports or is asked if communication with their relative with dementia is a difficulty.

- **Referrers check suitability for inclusion in this study.**
  - Carer says Yes
  - Carer says No
  - Carer not suitable

- **Information leaflet on study passed to carer.**
  - Carer asked if their details can be passed to researcher.
  - Carer agrees.
  - Details passed to researcher

- **Researcher sends interested carer details of study.**
  - A week later
  - Carer suitable and agrees

- **Researcher telephones carer to explain and discuss.**
  - Carer declines

- **Treatment as usual from older persons and speech therapy services.**
  - Carer declines or unsuitable

For senior nurse referrals only. Overseeing consultant approval for participation sought.

See flowchart B
After receiving the promotional leaflet, carers were referred to this author by the referrer completing a brief referral form (Appendix 12). Telephone and secure email referrals were also accepted. Carers were asked, by the referrer, if their name and contact details could be passed to this author.

4.2.3.5 Recruitment process

All carers referred were then contacted by the author by telephone to explain the nature of participation and to screen for inclusion and exclusion criteria. Any carers declining at this point, or later, were recorded on a separate log which detailed reason for non-participation if provided.

Eligible carers indicating a desire to participate, were first sent a participant information sheet and consent form by post (See Appendix 9 and Appendix 10). Allowing time for postage and reading, a home visit then was arranged with the carers to discuss participation and answer any questions or concerns. At the start of this visit, the participant information sheet and consent form were explained verbally to the carers prior to their consent, taking into account their interests, needs, beliefs and priorities (Medical Research Council, 2007). If carers were still interested in participation, they were invited to sign the consent form. Carers were able to delay consent to another occasion if they required further time for consideration.
Figure 4.2: The participant’s experience and intervention delivery.
4.2.4 Interventions

Figure 4-2, on the previous page, illustrates the participant’s experience of interventions after recruitment and randomisation.

After carers consented to participate and had completed the baseline measures (see Appendices 15 - 21), all interventions were planned to be completed within 8 weeks of initial consent. Carer involvement in this study was intended to last no longer than 12 weeks.

Carers were offered appointments with a high degree of flexibility regarding appointment date, time and place to minimise burden. This included home visits, appointments at day centres and in hospital clinics. All appointments were planned to last no longer than one hour.

This author delivered all of the interventions. The intervention sessions used the following resources:

- VEMAS levels of difficulty scales (Appendix 2)
- Talking Sense key topics presented as single laminated slides (see examples in Appendix 13 and Appendix 14)
- Topic monitoring and planning form (see Appendix 6). This allowed the author to make a record of topics/slides discussed as well as to plan topics for future sessions
- Clinical record sheets to record issues raised

4.2.4.1 The Talking Sense intervention

The development of the Talking Sense manual is described in section 3.2. The Talking Sense intervention addresses the full range of domains described by Schulz (2000) including knowledge, thinking, skill and behaviour:

- Knowledge was addressed by providing description, explanation and discussion
- Thinking was addressed by introducing the CBT framework (in Talking Sense step 3), discussing and challenging beliefs and assumptions with the carer
• Behaviour change was addressed by identifying actions or activities for the carer to trial, discussing implementation intentions, and then reviewing progress in a later session

• Skills were addressed primarily through role play and rehearsal

The Taking Sense intervention was delivered by this author using a series of modified A4 laminated colour slides adapted from the original Talking Sense manual (Barnes, 2011). After a separate recruitment visit, the carer was seen, typically at home, on three separate occasions. The Talking Sense intervention was based primarily around discussion of the topic slides.

The content of each session followed the steps of the Talking Sense programme, though individual slides and topics were selected by discussion with the carer and this author. The author used the contents planner (see Appendix 6), carer difficulties descriptions and VEMAS level described by the carer (see Appendix 2) to guide the carer in selecting topics.

At the start of the initial intervention session, carers were asked to describe the communication difficulties they were experiencing and assign their relative a level of communication difficulty using the VEMAS scale (Appendix 2).

After the third session, carers in the Talking Sense intervention group were sent a letter summarising ideas, individualised recommendations and strategies identified.

4.2.4.2 The Control condition
Existing speech and language therapy service provision allowed for variability in carer therapeutic support ranging from providing leaflets to group contact and individual one off or regular support. For the purpose of this study, a consistent control condition was required to minimise confounding effects. Therefore a range of options for the control group condition were identified and discussed with service managers, referrers and the research steering group. These included:
• using a waiting list control group made up from people waiting to attend an existing carers’ information course
• providing carers with an information only leaflet or booklet
• providing a single individual face to face contact following existing methods of working from SLT

It was agreed that the most suitable condition, which maintained both research and clinical standards, would be providing a single SLT face to face contact.

A detailed description of what would be provided by this author during the control intervention was documented (see Appendix 7). During this single home visit intervention session, issues identified by carers at the point of referral were discussed using individualised and generic information. The primary distinguishing feature of the control intervention was that it did not use any manual or leaflets and did not refer to, or address, carer thinking. In addition, the single session did not provide for the opportunity to review behaviour change or practice skill development through role play.

During the study, the student volunteer listened to a random selection of five control session audio recordings to consider the author’s adherence to the control definition (see Appendix 7). In each of these 5 cases, the criteria for providing the control intervention was considered met.

4.2.4.3 Therapeutic support after research participation
Carers in both groups were able to request further SLT support after their involvement in the study. In keeping with ethical principles, carers in the control group were not able to request the Talking Sense treatment until the overall results of the study were confirmed.
4.2.5 Outcomes

The section starts by explaining why specific outcome measures were chosen before introducing the outcome measures used in this pilot study.

4.2.5.1 Theory of outcome measures in psychosocial interventions

Schulz (2000) describes seven main outcome measurement domains used in carer research:

- health effects
- carer characteristics and contextual measures
- service utilisation
- burden
- positive aspects of caring
- quality of care provided
- measures related to normative carer transitions such as institutionalisation

Carer characteristics and service utilisation were expected to be recorded in this study (see Appendix 15 and Appendix 16 and section 4.2.5.10). Within the Talking Sense programme, there was also already a section which asked the carer to consider positive aspects of care-giving. This information was recorded on both the digital audio files and clinical record sheets.

Carer burden measures such as the subjective measure of carer burden (Montgomery, Gonyea, & Hooyman, 1985) have been replaced in more recent carer studies by the more positive and broader perspective taken by quality of life scales (Moniz Cook et al., 2008). Moniz Cook et al. (2008) also reported that few studies yield positive changes in burden following intervention, suggesting that carer burden was a less sensitive measure.

Quality of care in this context would relate to quality of communication delivered by the carer or experienced by the person with dementia. With the exception of approaches like Dementia Care Mapping (Brooker, 2005), observation of communication in dementia carer studies has been limited to short interactions.
such as the use of the RMICS (Rapid Marital Interaction Coding System) during a ten minute observation in Braun et al., (2010). Using such outcomes would only be valid if extensive observations could be made of, and consent could be obtained from, people with dementia. Whilst valid, this level of measurement and the direct involvement of the person with dementia were considered to be outside of the remit of this pilot study. Recommendations for the use of conversational analysis and observation approaches are made in the discussion (see chapter 6).

A further approach not mentioned by Schulz (2000) was measuring carer knowledge. This approach has recently been used by Williams (2011) and Kouri et al. (2011). However, a study in the related field of training carers of adults with learning disabilities, demonstrates that changes in knowledge do not necessarily equate to changes in practice (Chadwick, Joliffe, & Goldbart, 2002).

One element which previously does not appear to have been considered in communication intervention studies is what Schulz (2000) refers to as carer transitions. He gives examples of transitions such as the carer accepting formal care support in the home, the move to institutional care, and the death of the person with dementia. The most likely transition relevant to participants in this study was identified as “loss of successful communication”. Whilst people with dementia were not active participants in this study, a proxy rated measure of communication competence was thought likely to identify perceived changes in communicative ability and provide information for comparison with qualitative themes.

Returning to the recommendations from the systematic review (see section 2.5 and Table 2-4), the most significant factors identified as likely to influence long term outcomes for the carer and person with dementia appeared to be the carer’s psychological health (Schulz, 2000), the carer’s self efficacy and the communication and behavioural characteristics of the person with dementia.

Therefore, consideration of possible outcome measures suggested that this study should measure outcomes of carer depression and anxiety, carer quality of
life, carer communication self efficacy and person with dementia communication competence.

4.2.5.2 Outcome measure collection time points
Each of the following outcomes was completed by carers for baseline immediately after consent and, by post, two weeks after the final intervention session.

4.2.5.3 Primary outcome measure - The Hospital Anxiety and Depression Scale (HADS)
The primary outcome selected for this study was carer anxiety and depression measured using the HADS (Appendix 17).

Anxiety is relatively common in later life with some authors suggesting that generalised anxiety is more common than depression. Anxiety commonly co-occurs with depression. Anxiety and depression in later life are thought to be under-detected and under-treated (Laidlaw, Thompson, Dick-Siskin, & Gallagher-Thompson, 2009).

A large number of scales for measuring anxiety and depression exist. The Hospital Anxiety and Depression Scale (HADS) (Zigmund & Snaith, 1983; Snaith, 2003) was selected for the following reasons:

- It is familiar. The HADS is one of the most commonly used contemporary anxiety and depression scales in psychiatric care and research. Its use facilitates understanding amongst academic and clinical readership.
- It is comparable with and supported by other contemporary researchers. It was the primary outcome measures used in the contemporary comparison study (see chapter 2.4) by Livingston et al. (2013) thus enabling direct comparison of results.
- It is well established. It has detailed validity records and proven use amongst elderly and psychiatric case groups in over 750 published papers (Bjelland, Dahl, Haug, & Neckelmann, 2002). The HADS appears to have high internal and external validity. In their review, Bjelland et al. (2002)
found a mean Cronbach’s alpha for the two HADS subscales of 0.82 (range 0.40 to 0.90). They describe sensitivity and specificity scores of approximately 0.80 and correlations with other commonly used questionnaires ranging between 0.49 and 0.83.

- It is minimally burdensome and feasible. It is self-administered over a relatively short time period, minimising burden to the carer and reducing the risk on incomplete data.
- Normal data is also available. Crawford, Henry, Crombie and Taylor (2001) conducted a study with 1792 members of the general adult population to identify normal scores for the HADS which gave a mean total score of 9.82. They found “caseness” (a score between 8 and 10 representative of clinical anxiety or depression) in the general population of 20% for anxiety and 7.8% for depression.

The HADS scale (Appendix 17) contains 14 questions for self completion. Seven questions are designed to identify anxiety and seven to identify depression. Each question scores between 0 and 3 making a total potential score range of between 0 and 42. The scale takes between 2 to 5 minutes to administer (Snaith, 2003) and identifies single scores for anxiety and depression as well as a total score.

4.2.5.4 Secondary outcome measures – Adult Carers Quality of Life scale (ACQOL)

One of the secondary outcome measures was carer self-rated own quality of life measured using the ACQOL (Appendix 18).

Carer-rated person with dementia quality of life is considered to be of less and questionable value primarily due to disparities between the carer and the patient’s perspectives (Ready & Ott, 2003). With this in mind, the author reviewed a number of established recommended scales for carer self-rated own quality of life (Jenkinson, Peters & Bromberg, 2011) which were:

- PIXEL (Thomas et al., 2006)
- SQLC (Glozman, 2004)
• COPE (McKee et al., 2003)
• DEMQOL (Smith et al., 2007)
• ADRQL (Rabins, Kasper, Kleinman, Black, & Patrick, 1999)
• EQ5D (Cheung, Oemar, Oppe, & Rabin, 2010)

These scales were reviewed to consider if they were fit for purpose, sufficiently reliable and valid. The author had experience of using the COPE and DEMQOL as clinical outcome tools in an ongoing carers support group; consequently, both of these measures had been criticised by carers as a poor reflection of their experience and as being difficult to complete. None of the other measures detailed above were selected because of similar difficulties with content and design.

During 2011, a newly published measure was identified which had been used by its authors as a clinical outcome measure in carers groups. The adult carer quality of life questionnaire (ACQOL) (Elwick, Joseph, Becker, & Becker, 2010) had been published as a scale, though a further article detailing its development was awaiting publication. The authors provided a pre-publication copy of this article which has since been published (Joseph, Becker, Elwick, & Silburn, 2012) and which included extensive data supporting face and construct validity, internal consistency reliability, utility and convergent validity. The ACQOL is described as valid for use with people with dementia and for carer self completion (see Appendix 18). After consideration as to whether the ACQOL was fit for purpose, it was selected for use in this study.

The ACQOL scale contains 40 questions in eight domains. A sub score for each domain can be calculated as well as a total score. A higher score equates to a higher quality of life. Each question scores from 0 to 3 making a total potential score range of between 0 and 120. No normative data has been published.
4.2.5.5 Secondary outcome measures – The Communication Self Efficacy Scale (CSES)

In keeping with the recommendations detailed in section 2.5 of this thesis, a secondary outcome measure of self efficacy was added to this study and measured using the Communication Self Efficacy Scale (CSES) (Appendix 21).

Talking Sense was designed (see section 3.3) specifically to address carer self efficacy, particularly in relation to communication.

Kouri et al. (2011) are the only other authors of a research trial in this field to refer to the concept of self efficacy. Carers in the intervention arm of their trial demonstrated a significant improvement in self efficacy. They refer to using a caregiver self efficacy scale from Bandura’s (1997) book on the subject. However, no such scale could be identified in available copies of this book. A revised version of the same scale was quoted in Steffen et al. (2002) which is called The Revised Scale for Care-giving Self Efficacy. This scale was evaluated, but ruled as unfit for purpose because one third of the questions were specific to obtaining respite, whilst other questions focused on scenarios, few of which related specifically to communication.

A literature search was conducted for similar communication-specific self efficacy scales and only one potential scale was found. Farran et al. (2011) had developed the Caregiver Assessment of Behavioural Skill (CABS-SR). This was also ruled out as too situation specific, with less than 50% of the seventeen questions being related to communication scenarios.

Therefore, the decision was made to develop a communication self-efficacy scale. This was based on the steps of the Talking Sense programme and common communication issues that were reported in the carer communication difficulty questionnaires completed (n=30) during the earlier development of Talking Sense (Chapter 3). This measure was designed to capture whether specific communication difficulties occurred, as well as the extent to which the carer believed they were able to manage them.
A guide for constructing self-efficacy scales (Bandura, 2001) was consulted. Once an early version of this scale had been developed, face (n=3) and construct validity (n=14) exercises were conducted. One question was removed from the early version of this measure as it achieved less than 58% essential rating using the Lawshe (1975) method of evaluating content validity. Full details of the development of this scale are recorded in Appendix 25. The scale is detailed in Appendix 21. Internal and external reliability results for this scale are reported in section 4.3.5.8.

Each scenario was scored by the carer for how often it happened and how well they believed they managed in that situation. Subtotal scores for “happens” and “manage” were reported separately. A total score was not used as this would be less meaningful than the separate subtotals.

A five point Likert scale was used (scoring 1 to 5), as recommended by Bandura (2001). Dawes (2008), in a comparison of Likert scale formats, found that 5 or 7 point scales produce slightly, though significantly, higher mean scores than 10 point scales. However the choice of 5, 7 or 10 points caused no significant difference in variation around the mean, skewness or kurtosis. A 5 point scale was also chosen, in contrast to 7 or 10 points, to reduce descriptive complexity and burden on the carer.

Higher scores indicated the scenario happened less and the carer managed better. The potential score range for each subsection of the nine question version of the CSES was between 9 and 45.

The CSES scale used at the outset of this study contained 10 negative communication scenario questions. Question two was later removed (see section 4.3.5.4 for rationale).
4.2.5.6 Secondary outcome measures – The General Self Efficacy Scale (GSES)

General self efficacy was measured alongside communication self efficacy using the published General Self Efficacy Scale (GSES) (Schwarz & Jerusalem, 1995) (Appendix 19).

The GSES was chosen to enable correlation of results with the CSES in an attempt to establish validity. The GSES was designed to assess a general sense of perceived self-efficacy with the aim of predicting coping with daily hassles as well as adaptation after experiencing stressful life events (Schwarz & Jerusalem, 1995).

Detailed psychometric properties of the GSES are published in Scholz et al. (2002). In samples from 23 nations, Cronbach’s alphas ranged from 0.76 to 0.90 with the majority in the high 0.80s. Criterion-related validity is documented in numerous correlation studies where positive coefficients were found with favourable emotions, optimism and work satisfaction. Negative coefficients were found with depression, anxiety, stress, burnout and health complaints (Schwarz, 2014). The GSES asks 10 questions with answers scoring between 1 and 4, giving a potential score range of 10 to 40. A single total score is calculated. A higher score indicates greater general self efficacy.

4.2.5.7 Secondary outcome measures – The Communication Competence Scale (CCS)

In keeping with Schulz’s (2000) recommendations for measuring transitions, a communication competence scale, the CCS (Appendix 20) was used in this study.

Wiemann (1977) defined communication competence as:

“an ability to choose among available communicative behaviours to accomplish one’s own interpersonal goals during an encounter, while maintaining the face and line of fellow interactants within the constraints of the situation.”
A number of communication competence measures were reviewed (Rubin et al., 2009) for best fit with the study aims and their psychometric properties. The Communicative Competence Scale (CCS) (Wiemann, 1977; Query & James, 2009; Gilchrist, 2009) was considered the most suitable for completion by carers to consider what could be interpreted as a change in experience and/or belief (see Appendix 20). For mixed methods analysis (see Chapter 6), the results of this measure were intended to be compared to reports of communication experience collated during the intervention process and the semi-structured interviews.

This measure has also previously been used with dementia carers for self rated competence by Weathers, Query and Kreps (2010). For reliability of the CCS, Wiemann (1977), McLaughlin and Cody (1982), Jones and Brunner (1984) and Cegala, Savage, Brunner and Conrad (1982), report co-efficient alpha scores of between 0.96 and 0.86. Evidence of construct and concurrent validity are also reported in the above studies. The CCS scale contains 36 questions and results in a single summary score. It uses a five point Likert scale (scoring 1 to 5) making a potential total score range of 36 to 180. A higher score equates to greater competence.

4.2.5.8 Secondary outcome measures – The Therapeutic Engagement Index (TEI) and Readiness

In order to monitor engagement and allow for cross comparison with other outcomes and mixed methods comparison (see Chapter 5 and 6), this study measured engagement using the Therapeutic Engagement Index (TEI) developed by Chee, Dennis and Gitlin (2005). A 4 point measure of readiness was also used, as recommended by Chee et al. (2005) and added to the recording page used for the TEI (see Appendix 22).

Chee et al. (2005) point out that patient engagement and adherence to treatment are strongly associated with outcomes. In a study with 105 carers, where they delivered a carer skill building intervention, Chee et al. (2005) identified that carers with better physical health, greater treatment exposure, more problem areas addressed, and who used active therapeutic techniques
(e.g. role play) demonstrated greater adherence. They concluded that modifiable carer and treatment implementation factors, including active engagement of carers, were associated with adherence, whereas patient characteristics were not.

A set of operational definitions for the TEI were developed specifically for this study to improve intra-rater reliability (see Appendix 24). Immediately after each treatment and control session the author completed the TEI. The TEI is described (Chee et al., 2005) as internally consistent and valid. Strong test-retest reliability and intra-class correlations have been demonstrated. The TEI consists of three interrelated components: openness, connectedness and involvement. A score is also produced for questions that are described as “combined openness and involvement”. This 14 item, 5 point Likert scale (scoring 0 to 4) produces subscores (see Appendix 22) and a total score with a potential range of 0 to 56. Higher scores suggest higher engagement.

The four levels of readiness included:

- One: pre-contemplation e.g. hearing but not listening
- Two: contemplation e.g. trying to understand
- Three: preparation e.g. being willing to listen
- Four: action/maintenance e.g. actively participating in the intervention and modifying strategies.

Higher scores for readiness (range 1-4) suggested the carer was more actively following recommendations.

4.2.5.9 Baseline and outcome measures completion and collection method

After consent to participate (see Figure 4-2) and prior to randomisation, carer participants were asked to complete demographic and characteristics information and baseline measures. For most carers, this occurred during the initial consent visit. Carers were also able to complete these measures alone and return by post if preferred.
All measures were self-administered. Bedard, Molloy, Guyatt and Standish (1998) demonstrated that carer self-administered instruments are valid and that carers may be more responsive in this situation than with interviewer administered forms. In a small number of instances (n=4) where carers had sight difficulties, the SLT assistant visited the carer to passively assist in completing the outcome measure forms.

Carers were sent outcome measures to be completed two weeks after their last intervention session. The return of posted outcome measures was tracked in a diary. Carers received a single telephone reminder call if outcome measures were not received within two weeks of original provision.

4.2.5.10 Carer and person with dementia characteristics and service receipt information

Carer and person with dementia characteristics and a description of previous service provision for the carer and person with dementia, were gathered from carers using questionnaires. This provided data on the effects of possible confounding variables and differences between intervention groups.

These questionnaires were completed after carers consented to participate and prior to the first intervention session. They included a carer background information questionnaire (see Appendix 15) and a service receipt inventory (see Appendix 16). Carers also completed a service receipt inventory with their outcome measures to record service use during the period of their participation in this study.

Carer and person with dementia characteristics information requested included:

- carer age and sex
- carer relation to person with dementia (description)
- time spent talking (hours)
- cohabitation and days per week together (yes/no and number)
- carer general health (rating scale)
- support from others (yes/no and number)
• carer education and occupation (rating scale)
• carers stress and treatment for depression (yes/no)
• ethnic background and use of other languages (description and yes/no)

The service receipt inventory asked how much contact (number of appointments), since the onset of the dementia, carers had received from:

• their GP
• the psychiatrist
• a community mental health nurse
• a psychologist or counsellor
• an occupational therapist
• a social worker
• a speech and language therapist

Carers were also asked if they have attended a carers group, a patient support group (for their relative), used respite care or if they had received any support or advice or read any information about dementia or communication in dementia.

4.2.5.11 Audio recordings
All treatment and control sessions were recorded using Twin (Zoom H1) digital audio recorders. This reduced the author’s reliance on making written records for clinical and research purposes. It also provided a mechanism for monitoring the time spent on each session.

4.2.5.12 Author reflective diary
During the course of this study, the author kept a digital reflective diary using Microsoft Word (Microsoft, 2007a). Reflection follows a cycle suggested by Kolb (1984) which is illustrated in Figure 4-3 below. In reflective practice, experiences are considered and thoughts recorded in an active process which combines attempts to make sense with theories and further investigation. This can lead to plans and action after which further observation and reflection takes place.
The aim of the diary was for the author to record and reflect on communication situations described, carer coping, thinking identified and recommendations made. Reflections were also recorded about the research process.

4.2.6 Sample size

Cooper et al. (2006) identified a mean HADS anxiety score of 7.2 (SD=4) in a pilot study amongst dementia carers. Their interpretation of the HADS and their own previous research suggested a decrease of 2 points in mean to be a clinically significant improvement in mental well-being. They calculated that in order to achieve this reduction, with 90% power, at 5% level of significance, 75 participants per group were needed. They then applied a design effect factor to allow for clustering and subsequently planned to recruit 260 carers (Livingston et al., 2013).

At the outset of this pilot study, it seemed unlikely that 150 participants could be recruited and treated with an intensive intervention within the resources available to the author. Therefore a realistic estimate of 60 recruits allowing for
attrition at a rate of 10% was proposed, with the expectation that if the study proved feasible and trends were identified, the pilot study could be continued as a larger clinical trial. This estimate was determined in a discussion with the SLT service manager and based on the experience of previous studies, SLT service referral rates, clinical time available, number of potential referrers and the numbers attending carers groups.

4.2.7 Randomisation

Campbell et al., (2000) recommend using cluster randomisation in complex studies. A similar approach was used by Livingston et al. (2013). However, cluster randomisation requires a significantly greater sample size (Kerry & Bland, 1998). Therefore, this pilot study used simple random allocation (Bowling, 2009) anticipating 30 carers per group.

4.2.7.1 Sequence generation

The randomisation sequence was generated using the following procedure adapted from Bowling (2009):

- A list of 30 randomly generated numbers between 1 and 60 were produced in isolation by a third party colleague using a true random number generating system on the website random.org. The remaining numbers between 1 and 60 formed the control group.

4.2.7.2 Concealment

In order to ensure that the randomisation codes were concealed from the author and participants (prior to consent) the following procedure was used:

- A set of 60 cards, labelled “control” or “treatment” were folded and secured in such a way that the randomisation could not be seen. The third party colleague then labelled the outside of these cards 1-60, to match the random allocation sequence. This allocation was checked by another third party colleague. The cards were stored securely by the author. The original allocation list was stored securely by the SLT administrator.
4.2.7.3 Allocation

Once carers had consented to participate and baseline forms were completed, carers observed the author opening the next sealed card in sequence (numbered between 1 and 60). The carer was shown the text inside the envelope which stated either “treatment” or “control”.

4.2.7.4 Implementation

Once carers were shown their allocation, this was recorded on their consent form and in the referrals log. Typically, at the end of the first visit, arrangements were made with the carer to book appointments for delivery of the treatment or control intervention. Participants were handed information letters confirming their allocation and the date(s) arranged for future appointments.

4.2.8 Blinding

Blinding, when participant and or researcher(s) are not aware of allocation to intervention or control groups, is an attempt to reduce bias (Bowling, 2009). Without blinding, participants may be influenced by their expectations of the intervention and researchers by their expectations of the participant.

In this study, blinding of participants was not possible due to the nature of the information and intervention provided. Blinding of the author during quantitative analysis was also not possible, since the author was familiar with the relatively small sample of research participants, who were potentially identifiable from their answers.

4.2.9 Statistical methods

4.2.9.1 Data collation and input

A codebook was developed for collation of data from each participant (see Appendix 26). This defined the scoring methods for each of the outcome measures. All measures were scored by the author (see 4.2.9). All data was input by this author to SPSS Version 21 database (IBM, 2012).
4.2.9.2 Data checking, missing data and cleaning

The first thirty completed sets (baseline and post intervention) of carer outcome measures were also scored independently by the student volunteer and then checked by the author. The remaining sets of scores were checked twice by the author. Once input to SPSS, data sheets were printed and checked by hand for missing data and any inputting errors. A small number (<10) of inputting errors were identified and corrected by this author.

Only three examples of missing data occurred. One form (ACQOL) was returned to the carer for completion after telephone discussion and agreement. This form was promptly returned completed. In the other two cases, one item was missing from the ACQOL scale (eight domains, five items per domain). An average score for other four items within the respective domain for that individual was calculated and added to the data set. Wang and Bakhai (2006) suggest other options for dealing with missing data including analysing only complete cases, only all available data or the use of multiple imputation methods to produce an estimate. Whilst analysing only complete cases can be more accurate it leads to a loss of research efficiency. In this case, the two missing values represented only 1/40\textsuperscript{th} of the score from the ACQOL for that individual. The other four items (used for the average score) were theoretically related and therefore the bias that could potentially be introduced by this method (regression to the mean) was considered to be within acceptable limits.

4.2.9.3 Distribution of data

Initial analysis was conducted using the SPSS Explore function (Tabachnick & Fidell, 2013). The mean difference from baseline scores were analysed between groups.

Distribution of data was considered for each outcome by group using visual evaluation of normal Q-Q plots, box plots and histograms. Statistical tests for distribution included the Shapiro-Wilk test ($p>0.05$) as well as hand calculation of skewness and kurtosis $z$ values (between -1.96 to 1.96) (Pallant, 2010; Tabachnick & Fidell, 2013). Levene’s test, for the homogeneity of variance...
(p>0.05) (Pallant, 2010) verified the equality of variance in the parametric samples, calculated using the SPSS ANOVA procedure (IBM, 2012).

4.2.9.4 Data analysis

The correct choice of test is important, as incorrect tests can produce misleading results which can over or under emphasise effect (McCrum-Gardner, 2008). For normally distributed, parametric data, independent t-tests were used. For non-parametric data, the Mann-Whitney U test was used. Interpretation of distribution, choice of statistical test and interpretation of results were later checked and discussed with the academic supervisor and university statistician. No adjustments were applied to the data following comparison of groups.

The Consort group guidelines (Moher et al., 2010) and other authors (Austin, Manca, Zwarenstein, Juurlink, & Stanbrook, 2010) are critical of statistical testing for comparison of groups at baseline, suggesting the results are only an assessment of the results of something which is known to have occurred by chance. For this reason, baseline statistical comparison has not been included.

The aims of a pilot study are to trial study processes and identify any statistical trends that would warrant further study (National Institute for Health Research, 2014b). In this pilot study, the sample size was likely to be underpowered. For these reasons, statistical significance has been reported at 95%, though results have also been reported that are close to significance. Close to significance, in this case, is defined operationally by results where p<0.10. The reporting of results, for those close to significance, has followed the approach recommended by Tabachnik and Fidell (2013) who warn against over reliance on p values and suggest that authors should report effect size as well as visual inspection and description of the data.

4.3 RESULTS OF THE PILOT RANDOMISED CONTROLLED TRIAL

This section details the results from the pilot study. Here, participant flow, sources of referral and reasons for non participation are described. Baseline carer and person with dementia characteristic data is detailed and used to
consider differences between groups. The results from each outcome measure are summarised then detailed.

4.3.1 Participant flow
The study participant flow diagram recommended by the Consort group (Moher et al, 2010) has been included below, modified for this study as Figure 4-4.

![Participant flow diagram](image)

**Figure 4-4: Participant flow diagram**

4.3.2 Recruitment
The study was opened to recruitment in April 2012. A recruitment period of 18 months was agreed with the SLT service manager, primarily due to clinical pressures. Therefore, as expected, recruitment closed in early October 2013. All interventions and outcome measures were completed by December 2013.
This study received 111 referrals over an 18 month period. This equated to 6 additional referrals per month to a clinical service that previously received an average of 18 referrals per month.

From referrals received, 55 people participated in the study and 56 did not. The recruitment target was 60 people. The 55 carers recruited were randomly allocated: 28 to the treatment arm and 27 to the control arm.

4.3.2.1 Source of referrals
A breakdown of source of referrals is detailed Figure 4-5. The most common source of referral (37%) was carers groups. Two thirds of participants reported attending a carers group at least once (see Table 4-1). This included ongoing general carer support groups (15 participants) and an information course (coordinated by the author) for carers who had a newly diagnosed relative (27 participants). Carers who attended the information course were near equally represented in each intervention group (48% control; 50% treatment).

![Figure 4-5: A breakdown of sources of referral, showing percentage of numbers referred, to the Talking Sense pilot study.](image)

4.3.2.2 Waiting time from referral to first contact
During the course of the study, there was a variable duration waiting list for carer contact, never exceeding 8 weeks from the point of referral. However, for
practical reasons e.g. holidays, some carers at first contact requested a longer delay before participation.

In some situations the carer and person with dementia’s circumstances changed between point of referral and carer contact. A review of the person with dementia circumstances was conducted prior to carer contact using the OPMH electronic records system as per usual clinical practice.

4.3.2.3 Intervention and outcome completion and attrition
All treatment and control carers completed all interventions. Two control and one treatment carer failed to complete the outcome measures after one reminder. The outcome data from these three individuals was not included in data analysis. This equated to an attrition rate of 5.5%.

4.3.2.4 Referrals unsuitable for participation
Fourteen referrals were judged, by the author, as not suitable for participation between receipt of referral and telephone contact with the carer.

Reasons for the carer and/or person with dementia not being suitable are given below:

- 2 people with dementia had since died
- 5 people with dementia had since moved to residential care
- 2 people with dementia had MMSE (Folstein et al., 1975) scores and functional ability that were significantly below the inclusion criteria
- 1 person with dementia was considered too able (MMSE score and functional ability above inclusion criteria)
- 2 carers were too unwell to participate (one with memory difficulties and one with moderate depression)
- 1 person with dementia was in general hospital

Excluding the two persons that died, referral suitability was calculated as 89%.
4.3.2.5 Referrals declining to participate

Forty two people were considered suitable, but declined to participate. Of these;

- 13 carers (4 males/9 females; 7 partners/6 adult children) reported they
didn’t need help - either because communication difficulties did not occur
or because they could manage those that did occur without help.
- 14 carers reported they were not able to participate - often because of
time limitations or an anticipated negative reaction from the person with
dementia.
- 15 carers (8 males/7 females; 8 partners/7 adult children) did not want to
participate - either in research or other therapy support.

Therefore, the true decline rate (i.e. those people referred who didn’t want to
participate) was 15%. It is difficult to judge this accurately, as some people gave
more than one reason or vague reasoning. Those people judged as “didn’t want
to participate” included those who failed to respond to telephone messages and
follow up letters. For this group, there may have been other reasons for non-
participation including the person with dementia or carer not being suitable.

Despite accounting for only 31% of referrals, male carers made up 53% of the
“didn’t want to” responses. Male carers were more challenging to recruit and
appeared more likely to decline participation than state they didn’t require help.
This trend was highlighted to potential referrers and the research steering group
during the recruitment phase of the study.

4.3.3 Baseline data

Table 4-1 below, gives carer and person with dementia characteristics for the 55
carers recruited and randomised to the treatment and control groups of the
Talking Sense study. This information was gathered using Appendix 15.

Included in Table 4-1 is a measure of baseline caseness (indication for clinical
diagnosis and treatment) for anxiety and depression. This follows the approach
used by Livingston et al. (2013) who suggested that a score equal to or greater
than 9 for the anxiety or depression sub-scores on the HADS (Zigmund & Snaith, 1983) would suggest clinical caseness of anxiety or depression (or both).

Table 4-1 also includes a column detailing demographic results from Livingston et al. (2013) (see 2.4) where comparable data was reported. Although data from the HADS was comparable, Livingston et al. (2013) used an alternative measure of cognitive impairment to the MMSE scale. The table also makes reference to carers who had previously attended the six week carers’ course run by the author.

Table 4-1: Results of demographic information for all recruits from Talking Sense including comparison with results from Livingston et al. (2013).

<table>
<thead>
<tr>
<th>Description</th>
<th>Talking Sense Treatment Group (N=28)</th>
<th>Talking Sense Control Group (N=27)</th>
<th>Talking Sense Total Recruits (N=55)</th>
<th>Results From Livingston et al. (2013) (n=260)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carer Characteristics</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean carer age (SD)</td>
<td>67 (11.8)</td>
<td>68 (14.3)</td>
<td>67 (12.9)</td>
<td>56/62 (12.3/14.6)</td>
</tr>
<tr>
<td>Range of carers ages</td>
<td>42-88</td>
<td>30-89</td>
<td>30-89</td>
<td>27-88</td>
</tr>
<tr>
<td>Male carers (n)</td>
<td>30% (8)</td>
<td>16% (4)</td>
<td>23% (12)</td>
<td>32%</td>
</tr>
<tr>
<td>Carers who were partners (n)</td>
<td>63% (17)</td>
<td>72% (18)</td>
<td>67% (35)</td>
<td>42%</td>
</tr>
<tr>
<td>Carers who were children of PWD (n)</td>
<td>33% (9)</td>
<td>24% (6)</td>
<td>29% (15)</td>
<td>44%</td>
</tr>
<tr>
<td>White British carers</td>
<td>100%</td>
<td>92%</td>
<td>96%</td>
<td>81%</td>
</tr>
<tr>
<td>Carers attending carers groups</td>
<td>68% (19)</td>
<td>70% (19)</td>
<td>69% (38)</td>
<td>N/A</td>
</tr>
<tr>
<td>Carer and relative with dementia interaction</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cohabiting carers and PWD (n)</td>
<td>59% (16)</td>
<td>72% (18)</td>
<td>65% (34)</td>
<td>57%/65%</td>
</tr>
<tr>
<td>Mean number of days spent together</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>Not reported</td>
</tr>
<tr>
<td>Range of days spent together</td>
<td>2-7</td>
<td>3-7</td>
<td>2-7</td>
<td>Not reported</td>
</tr>
<tr>
<td>Carer Mental Health</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carers receiving treatment for Depression (n)</td>
<td>19% (5)</td>
<td>24% (6)</td>
<td>21% (11)</td>
<td>Not reported</td>
</tr>
<tr>
<td>Baseline HADS Caseness for Anxiety (&gt;=9) (n)</td>
<td>44% (12)</td>
<td>44% (11)</td>
<td>44% (23)</td>
<td>55%/49%</td>
</tr>
<tr>
<td>Baseline HADS Caseness for Depression (&gt;=9) (n)</td>
<td>18.5% (5)</td>
<td>24% (6)</td>
<td>21% (11)</td>
<td>20%/21%</td>
</tr>
<tr>
<td>Persons with dementia (PWD) characteristics</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range and (SD) of PWD ages</td>
<td>62-89 (7.5)</td>
<td>55-91 (9.1)</td>
<td>55-91 (8.2)</td>
<td>53-96 (9.9/8.3)</td>
</tr>
<tr>
<td>PWD with Alzheimer Disease with Vascular Dementia</td>
<td>48% (13)</td>
<td>32% (8)</td>
<td>40% (21)</td>
<td>Not reported</td>
</tr>
<tr>
<td>with Mixed Dementia</td>
<td>19% (5)</td>
<td>16% (4)</td>
<td>17% (9)</td>
<td>Not reported</td>
</tr>
<tr>
<td>30% (8)</td>
<td>40% (10)</td>
<td>35% (18)</td>
<td>Not reported</td>
<td></td>
</tr>
<tr>
<td>Average PWD MMSE scores (SD)</td>
<td>24/30 (3.9)</td>
<td>24/30 (4.5)</td>
<td>24/30 (4.2)</td>
<td>Not used</td>
</tr>
<tr>
<td>Range of PWD MMSE scores</td>
<td>15-29/30</td>
<td>12-29/30</td>
<td>12-29/30</td>
<td>Not used</td>
</tr>
</tbody>
</table>
Additional demographic and service use data collected but not analysed are illustrated in histograms generated by SPSS (IBM, 2011) in Appendix 28.

4.3.3.1 Comparison between groups at baseline
Visual comparison of carer and person with dementia characteristics suggests the groups were similar, with the treatment group containing more males, and slightly more cohabiters and male people with dementia.

Further examination of service receipt data, beyond counting the total number of professional and SLT contacts (see Appendix 16 and Appendix 28), was not attempted due to probable inaccuracy of the data. Reflective records show that many carers completing the service receipt inventory had difficulty recalling the numbers of contacts received and distinguishing between the professionals they had seen. This omission from data analysis was agreed with supervision and research steering group.

4.3.4 Numbers analysed
Figure 4-4 illustrates how 3 cases (1 from the treatment group and two from the control group) were excluded from analysis because they failed to return outcome measures after receiving one reminder. This resulted in 27 treatment and 25 control cases being analysed.

4.3.5 Outcomes
4.3.5.1 Summary of quantitative results
Table 4-2 below summarises the results of primary and secondary quantitative outcome measures used in the Talking Sense study. Difference in mean scores (the difference between mean outcome and baseline scores) are shown with actual baseline and outcome measure mean scores given in brackets. Confidence intervals are reported for normally distributed data.
Table 4.2: Results of the primary and secondary outcome measures.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Difference means</th>
<th>Control</th>
<th>Confidence Intervals (low to high)</th>
<th>Test (*) result and p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Treatment (actual means)</td>
<td>Control (actual means)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HADS Total Score</td>
<td>-0.2 (13.9-13.7)</td>
<td>+1.3 (13.3-14.6)</td>
<td>-0.5 to 3.58</td>
<td>* Not significant, p=.133</td>
</tr>
<tr>
<td>• Anxiety sub score</td>
<td>-0.3 (8.1-7.8)</td>
<td>+0.5 (7.9-8.4)</td>
<td></td>
<td>† Not significant, p=.100</td>
</tr>
<tr>
<td>• Depression sub score</td>
<td>+0.1 (5.8-5.9)</td>
<td>+0.8 (5.4-6.2)</td>
<td></td>
<td>† Not significant, p=.122</td>
</tr>
<tr>
<td>ACQOL Total Score</td>
<td>+4.3 (69.6-73.9)</td>
<td>-0.2 (69.4-69.2)</td>
<td>-10.6 to 1.5</td>
<td>* Not significant, p=.138</td>
</tr>
<tr>
<td>• Support sub score</td>
<td>-0.1 (8.6-8.5)</td>
<td>-0.3 (7.7-7.4)</td>
<td></td>
<td>† Not significant, p=.912</td>
</tr>
<tr>
<td>• Choice sub score</td>
<td>+0.9 (7.6-8.5)</td>
<td>+0.6 (7.2-7.8)</td>
<td></td>
<td>† Not significant, p=.933</td>
</tr>
<tr>
<td>• Stress sub score</td>
<td>-0.1 (10.1-10.0)</td>
<td>+0.1 (10.2-10.3)</td>
<td></td>
<td>† Not significant, p=.978</td>
</tr>
<tr>
<td>• Money sub score</td>
<td>+0.3 (10.6-10.9)</td>
<td>-0.2 (10.4-10.2)</td>
<td></td>
<td>† Not significant, p=.219</td>
</tr>
<tr>
<td>• Growth sub score</td>
<td>+1.1 (6.9-8.0)</td>
<td>+0.5 (6.4-6.9)</td>
<td></td>
<td>† Not significant, p=.571</td>
</tr>
<tr>
<td>• Value sub score</td>
<td>+0.6 (7.8-8.4)</td>
<td>-0.6 (8.8-8.2)</td>
<td>-2.3 to -0.02</td>
<td>* Significant difference p= 0.046, eta² = 0.09.</td>
</tr>
<tr>
<td>• Ability sub score</td>
<td>+0.7 (9.4-10.1)</td>
<td>-0.1 (9.5-9.4)</td>
<td></td>
<td>† Not significant, p=.155</td>
</tr>
<tr>
<td>• Satisfaction sub score</td>
<td>+0.3 (9.0-9.3)</td>
<td>-0.3 (9.2-8.9)</td>
<td>-1.9 to 0.7</td>
<td>*Not significant, p=.357</td>
</tr>
<tr>
<td>CSES Total Score Happens</td>
<td>+1.3 (25.7-26.9)</td>
<td>-0.7 (25.7-25.0)</td>
<td>-3.5 to -0.3</td>
<td>* Significant difference p= 0.046, eta² = 0.09.</td>
</tr>
<tr>
<td>CSES Total Score Manage</td>
<td>+2.1 (29.7-31.8)</td>
<td>+0.7 (29.0-29.7)</td>
<td>-3.6 to 0.6</td>
<td>* Significant difference p=.152</td>
</tr>
<tr>
<td>GSES Total Score</td>
<td>-0.4 (31.9-31.5)</td>
<td>+0.1 (31.4-31.3)</td>
<td>-1.2 to 1.8</td>
<td>* Not significant, p=.702</td>
</tr>
<tr>
<td>CCS Total Score</td>
<td>+4.0 (107.9-111.9)</td>
<td>-2.1 (112.5-110.4)</td>
<td>-12.2 to 0.6</td>
<td>* Close to significance, p=.052, eta² = 0.09.</td>
</tr>
</tbody>
</table>

Key for table 4.2: Confidence intervals are reported for parametric data only. Tests used are independent t-test (*) for parametric data and Mann-Whitney U test (†) for non-parametric data. Higher score indicates increased anxiety and depression (HADS), higher quality of life (ACQOL), difficulties happened less (CSES happens), carers managed better (CSES manage), the carer was more generally self efficacious (GSES) and the person with dementia was more communicatively competent (CCS).
4.3.5.2 Results from the primary outcome measure – Hospital Anxiety and Depression Scale

There was no significant difference for HADS total score \( (p = .133) \) from comparison of the mean difference from baseline score, using an independent-samples t-test.

There were no significant differences for HADS anxiety sub-scores \( (p = .100) \) or HADS depression sub-scores \( (p = .122) \) from comparison of the mean difference from baseline score, using the Mann-Whitney U test.

4.3.5.3 Results from secondary outcome measures: Adult Carers Quality of Life Scale

There was no significant difference for ACQOL total score \( (p = .138) \) from comparison of the mean difference from baseline, using an independent-samples t-test.

The ACQOL scores were analysed for each of the eight sub-scores (support, choice, stress, money, growth, value, ability, satisfaction). These scores are detailed in table 4.2 above.

4.3.5.4 Results from secondary outcome measures: Communication Self Efficacy Scale

After consultation with the research steering group, data from question two of the CSES was excluded as reflective records identified a number of carers had suggested this question was ambiguous. The question mentioned a reduction in person with dementia communication which was considered to be a communication difficulty. However, some carers described an increase in talking from the person with dementia, which in itself caused communication difficulties between them. Therefore, all of the CSES results reported exclude question two.

The CSES “happens” total score was significantly different in favour of the treatment group \( (p = 0.046) \) from comparison of the mean difference from
baseline, with a narrow range of confidence intervals. The effect size was moderate (eta squared = 0.09).

The CSES “manage” total score was not significantly different (p=.152) from comparison of the mean difference from baseline.

4.3.5.5 Results from secondary outcome measures: General Self Efficacy Scale
The GSES total score was not significantly different (p=.702) from comparison of the mean difference from baseline, using an independent-samples t-test.

4.3.5.6 Results from secondary outcome measures: Communication Competence Scale
The CCS total score was close to significance in favour of the treatment intervention (p=.052) from comparison of the mean difference from baseline, using an independent-samples t-test. The effect size was moderate (eta squared = 0.09).

4.3.5.7 Results from the therapeutic engagement index and readiness scale
There was no statistically significant difference between groups for therapeutic engagement (p=.530). However, the control group appeared significantly more ready (from the readiness scale) (p=.012) than the treatment group with a moderate effect size (Cohen, 1988). Comparisons were made between groups after session one, since data was only collected for the single session of the control group.

A Friedman test was used to consider “within group differences” for the treatment group between the first, second and third treatment session. There was a statistically significant increase in both engagement $\chi^2(2, n=27) = 8.68$, p=.13) and readiness $\chi^2(2, n=27) = 29.6$, p=.000) across these three time points.

Further non-parametric analysis, using a Mann-Whitney U test, comparing control group results at session one with treatment group results at session three was conducted. There were no significant differences in engagement (p=.156) but a significant difference in readiness in favour of the treatment group
These results should be interpreted cautiously due to the subjective nature of the measure and the potential for bias introduced by researcher completion.

4.3.5.8 Reliability of the CSES

As a newly developed measure, statistical analysis was conducted using SPSS (IBM, 2012) to evaluate the reliability of the CSES.

By examining a combination of baseline and outcome scores internally (a sample of 104 completions) the questions in the CSES generated a Cronbach’s alpha of 0.868 for “happens” and 0.941 for “manages”. This suggested a high level of internal reliability.

For external reliability, correlations were conducted with the most similar baseline scores collected during the Talking Sense study. A Spearman RHO test for ordinal data was used. In this test, Cohen (1988) suggests that a score of between $r=.10$ and $.29$ indicates a small relationship, $r=.30$ to $.49$ a medium relationship and $r=.50$ to $1.0$ a large or strong relationship. A negative $r$ score indicates a negative correlation i.e. as one increased the other decreased. At 95% significance (n=52), the CSES “manage” total appeared to be significantly correlated to the HADS total score ($r=-.351, p=.011$), GSES total score ($r=.552, p=.000$) and ACQOL total score ($r=.484, p=.000$). This suggested that, at the outset, carers with higher communication self efficacy beliefs tended to have lower HADS scores, higher general self efficacy and higher quality of life scores.

The CSES “happens” score was also significantly correlated (at 95% significance) to the last MMSE score ($r=.283, n=51, p=.044$), VEMAS score (for treatment group) ($r=-.381, n=27, p=.050$) and CCS score ($r=.658, n=52, p=000$). This suggested that, at the outset, carers with lower “happens” scores (i.e. happens more often) had lower MMSE scores, higher VEMAS scores and lower communication competence scores.

The results suggest the CSES (excluding question two) was a valid and reliable measure of communication self efficacy in this study, though further evidence of validity and reliability is required for more extensive use.
4.3.6 Adverse events

No significant adverse events or harm to carers or persons with dementia was reported or observed during the course of this study. Consequently, there was no requirement to disclose information to the overseeing psychiatrist.

4.3.7 Summary of quantitative results

Fifty five carers were recruited from 111 referrals. All carers completed their allocated intervention. Three carers failed to complete outcome measures. Analysis of mean difference from baseline was based on 27 carers in the treatment group and 25 in the control. Demographic data suggests carer subjects were comparable between groups and, overall, to those recruited in the UK by Livingston et al. (2013).

There were no significant differences in anxiety and depression from the primary outcome measure (HADS).

For quality of life (ACQOL), there was a significant difference in one subscale only, an increase for the treatment group, for the “value” subscale from the ACQOL. There was no significant difference in total quality of life.

For carer communication self efficacy (CSES), there was a significant difference suggesting that carers in the treatment group reported fewer difficulties happening. There was no significant difference in their managing scores. Initial analysis suggested the CSES was internally and externally reliable.

There were no significant differences in carer general self efficacy (GSES).

For proxy rated person with dementia communication competence, a score close to significance with a moderate effect size was identified in favour of the treatment group.

The treatment group demonstrated a significant increase in engagement and readiness across the three contact sessions.
4.4 PILOT STUDY DISCUSSION

This section discusses the results detailed above. It follows the CONSORT group (Moher et al., 2010) recommendations to discuss limitations, generalisability and interpretation. Further consideration of these results, where comparable with the results of the semi-structured interviews (see chapter 5), are discussed in chapter 6 using a mixed methods approach.

4.4.1 Limitations of the pilot RCT study

This section details limitations of the pilot study including weaknesses in design, potential bias and confounding variables. The strengths of this study are detailed in section 4.4.3.9. Limitations discussed below are introduced at the beginning of each paragraph with a summary statement.

4.4.1.1 Limitations in research design

This section considers limitations in research design which may have influenced results.

4.4.1.1.1 Sample size

The sample size was small causing low statistical power. Button et al. (2013) argue that small sample sizes with low statistical power reduce the chance of detecting a true effect, and the likelihood that a statistically significant effect reflects a true effect by exaggerating the magnitude of that effect. Using data from this pilot study to calculate a larger and adequately powered sample size for future research should reduce the likelihood of type one and two errors. The potential for missing or exaggerated effects from this pilot study should be taken into consideration when designing future studies.

4.4.1.2 Inclusion criteria

The eligibility inclusion criteria did not sufficiently identify the target population. The pilot study eligibility criteria stated that suitable carers were those “experiencing current communication difficulties with their relative”. The mean CSES baseline scores for happens and manage of between 25 and 29/45
suggested many carers were close to a mean score of 27, which would indicate only occasional communication difficulties happening, which were managed adequately. Likewise, the inclusion of people with lower engagement and readiness scores suggests that some carers, once assigned to the treatment group, would not have met typical clinical criteria i.e. were not sufficiently ready or engaged, for the ongoing therapy (3 visits) that the study required. Therefore it can be suggested that the study protocol and consequent study recruitment was not sufficiently selective. Future clinical use of Talking Sense and future research would benefit from more selectively identifying the target population. Carers experiencing communication difficulty, in need of support and likely to engage in this intervention could potentially be identified by a referrer screening tool.

4.4.1.1.3 Perspective

The results of this study were limited to the carer’s perspective. Whilst this study aimed to address carer needs, it is important to remember that the views measured (e.g. communication competence) are only those of the carer. We should not assume that the person with dementia is not able to add to our understanding of difficulties occurring and the effect of any intervention. This raises the importance of (and potential for) including people with dementia in future research.

4.4.1.1.4 MMSE score

The MMSE (Folstein et al., 1975) score was not contemporaneous and as such not necessarily an accurate reflection of dementia severity. One of the primary screening indicators for inclusion, aside from “reported difficulty with communication”, was the MMSE score. Since people with dementia were not consented to participate in this study, their MMSE scores were identified from clinical records which were in some cases, were more than 6 months old. Clark et al. (1999) in a review of MMSE scores, suggested that a change of 3 points is clinically significant, whilst a mean loss of 3-4 points per annum for people with early Alzheimer’s was to be expected. The MMSE is also problematic because it relies heavily on language skills for completion, at the cost of assessing other
areas of cognition e.g. executive function, and lacks sensitivity to very mild presentations of dementia (Simmard, 1998). It is suggested therefore that future research should use alternative screening measures for person with dementia difficulty, which ideally are conducted at the point of referral. Where people with dementia are not able to participate in research, one recommendation would be to develop and extend the sensitivity of the VEMAS scale as a carer rated level of difficulty measure.

4.4.1.5 Confounding variables

**Confounding variables may have influenced outcomes.** Confounding variables are extraneous factors, not controlled for, which can influence results (Bowling, 2009). Psychosocial research, especially when conducted within an existing clinical service, is difficult to conduct in a fully controlled or isolated way. Access to literature, carers groups and support from OPMH also had the potential to have a positive effect on outcomes from this study. Having supportive contact from a professional, irrespective of the intervention provided, may also have had some effect. Performance bias may also be introduced by the total intervention time difference (3 sessions in comparison to 1) between the treatment and control groups. Future research should aim to minimise these influences and differences. In a larger clinical trial, these factors could also be adjusted for in the statistical analysis or considered as stratification variables at the point of randomisation.

4.4.1.6 Follow up

**The period of follow up was relatively short.** Sommerlad et al. (2014) in their qualitative evaluation of the Livingston et al. (2013) study, found that 2/3 of carers reported continued use of strategies at 2 year follow up. Future extension of this RCT study could evaluate any long term effect, though this would also require consideration of the effect of carer circumstances and person with dementia change over time.
4.4.1.7 Blinding

**Limited blinding may have introduced bias.** The participants in this study were not blinded to assignment whilst the outcome assessor (the author) was not blinded during outcome scoring. It is possible that carers may have consciously or unconsciously completed outcomes more positively to reflect their appreciation or expectation that participation in the treatment group would be more effective. The therapeutic engagement index in particular, completed by the author immediately after intervention sessions, had the potential to be influenced by the author’s expectations and increased familiarity with carers in the treatment group. Blinding of the outcome assessor and more objective measurement could also be introduced in future research design. One method employed by Lock et al. (2001) used third parties and a process of inter-rater reliability testing to judge video recordings of the person with dementia and carer interacting.

4.4.1.8 Validity of outcome measures

**A number of outcomes used did not directly measure the anticipated effect, i.e. were too distant from the intervention (see Figure 2-3).** Hobart et al. (2007) suggest that rating scales, such as the outcome measures used in this study, are the main dependant variables on which decisions are made that influence patient care. They describe a number of difficulties in relying on these scales, one being that we often do not know what variables the scales are really measuring. They argue that scales and the constructs they claim to measure are rarely underpinned by theory. They propose that scale development would benefit from having a bottom up (construct definition) rather than top down (grouping of items) approach. Aside from administration and design issues, it is clear that many of the scales used in this study were measuring something too distant from the communication-specific outcomes expected (i.e. more general self efficacy quality of life, anxiety or depression). Hobart et al. (2007) emphasise the importance of consulting qualitative and quantitative information when designing rating scales. The development of the communication self efficacy scale (see Appendix 21) used in this study positively demonstrates the feasibility
of developing theory based scales that measure the intended outcome. Future research could benefit from using other such theory based scales.

4.4.1.2 Clinical limitations
This section considers limitations in the Talking Sense intervention which may have reduced effectiveness and results.

4.4.1.2.1 Assessment and intervention links
The link between assessment, nature of difficulties and intervention was limited. Table 2-3 suggests that the intervention should address carer needs. Results from the CSES will be discussed below, though reflective records suggest that both the “happens” and “manage” component of this scale provided a relatively accurate impression of the difficulties with communication and efficacy that the carer was experiencing. These reflections include the suggestion that the initial results of the CSES could have been used more actively to determine which components of the Talking Sense intervention were used. Similarly, the CSES could have been used during and at the end of the intervention to discuss their progress with the carer. Discussing the content of an outcome measure whilst engaged in a research study introduces the potential for bias, though the CSES may have utility as a clinical tool to help plan and measure the effect of therapy.

4.4.1.2.2 Intervention intensity
The intervention was relatively brief. Whilst most authors (Wells, 2008; Laidlaw et al., 2009) are reluctant to prescribe an exact number of sessions for CBT, one of the underlying principles of CBT is that therapy is time limited. Some authors (Papworth, Marrinan, Martin, Keegan, & Chaddock, 2013) refer to low intensity CBT which is intended to be carried out over a short number of sessions. As well as reducing burden for the client, this form of therapy, assuming it yields outcomes, is more cost effective for deliverers. However, communication difficulties, carer understanding, self efficacy and competence are complex issues which may in reality take more time to effect. Future research may also consider a more intensive intervention.
4.4.1.3 Effects of non-attendance, adverse events, carer burden and attrition

Complaints, incidents, reported burden, attendance and adherence rates are indicators of limitations in the effectiveness of a study design and intervention.

Throughout this study, no complaints or incidents occurred or were recorded in the clinical notes, research records or the reflective diary.

Every participant (n=28) in the intervention group of this study (i.e. 100%) attended all three treatment sessions. In comparison, Livingston et al. (2013) report only 72% of carers in their treatment group attending all 8 sessions of their intervention. This suggests that less intense interventions and/or research participation may result in higher compliance and clinical efficiency. Unfortunately, none of the studies detailed in the systematic review (see chapter 2) include data on treatment adherence. Attendance may be influenced by length of involvement, increasing the potential for adverse events, though one explanation for non-attendance is burden.

The studies included in the systematic review (chapter 2) reported attrition occurring in a range from 8% to 19%. This study achieved an attrition rate of only 5.5%. This attrition was wholly attributable to the non-return of self-completed outcome measure questionnaires which, in terms of time at least, appears less burdensome than attending intervention sessions. Overall, there is no obvious indication from these results that this study design or intervention was significantly burdensome to carers.

4.4.2 Generalisability

This section considers the extent to which the sample recruited was representative of people with dementia and their carers, comparable to those recruited in other studies and therefore the extent to which results are generalisable.

4.4.2.1 Type of dementia

The Alzheimer’s society (2014) estimate that of those with dementia, 62% have Alzheimer’s disease, 17% have vascular dementia and 10% mixed (Alzheimer’s
and vascular) dementia. Other studies detailed in this thesis have not reported type of dementia recruited. This study recruited 17% of people with vascular dementia as expected. However, a recruitment rate of 40% Alzheimer’s disease and 35% mixed dementia suggests that the diagnosis of mixed dementia (Vascular and Alzheimer’s combined) is given more commonly in Portsmouth (i.e. people that were traditionally diagnosed with just Alzheimer’s are now being diagnosed with mixed Alzheimer’s and vascular dementia). Wilson et al. (2011) suggest that prevalence rates are indeed strongly influenced by the diagnostic process. Interestingly, the Portsmouth area is recognised as having the highest formal diagnosis rate of dementia, outside of London, in the south of England. This rate of approximately 64% (of the expected population of people with any form of dementia) compares to a national average of 48% (Alzheimer’s Society, 2014).

One other factor which may influence the diagnosis of mixed dementia in particular is the availability of anti-cholingeric medication, also considered high in Portsmouth (Alzheimer’s Society, 2014). This medication is licensed for Alzheimer’s’ disease and mixed dementia, but not Vascular dementia.

It is not expected that the mix of diagnosis in this study has influenced the results in comparison to other studies.

4.4.2.2 Carer characteristics

The Princess Royal Trust for Carers (2014) put the average age of a family carer for someone with dementia between 60 and 65 years old. The carers in the Talking Sense study (mean 67 years) were older than those in the Livingston et al. (2013) study (mean age 52 in the treatment group). This may have been influenced by recruitment (at daytime carers groups) and provision of an intervention during the day on weekdays making access to the interventions more difficult for working age carers. Future research may seek to include a wider range of carers.

Given that combined anxiety and depression rates amongst dementia carers are reported to be in a range between 18% and 47% (Akkerman & Ostwold, 2004;
Charlesworth, 2001) the caseness rates of 21% for depression and 44% for anxiety alone (toward the higher end of this range) suggests this study attracted carers who were more anxious and depressed than typical, possibly as a consequence of the difficulties with communication they were experiencing. Livingston et al. (2013), who were specifically targeting carers with anxiety, recruited a group of carers with even higher prevalence of anxiety (55% in the treatment group). Given that the primary outcome measure of both the Talking Sense study and Livingston et al. (2013) was changes in depression and anxiety, it is likely that a more anxious cohort of participants would have the potential for greater change. However, there may be more severe degrees of anxiety where this is not the case. Future research could examine outcomes in different cohorts e.g. levels of anxiety.

4.4.2.3 Representation of male carers

Male carers were under-represented in the recruitment to this study creating an element of selection bias. Suitable males were more than twice as likely to decline to participate in this study, than females. In contrast, Livingston et al. (2013) appear to show no difference between male and female (40% and 42%) decliners respectively. Livingston et al. (2013) included 32% male carers (and 68% female carers), which is significantly above the 23% male carer participants in the Talking Sense study. Where reported, the studies included in the systematic review had between 17% and 33% male carers. Carers UK suggest that 40% of informal carers of people with dementia are men (Carers UK, 2013). It would seem that male carers may be generally under-represented in carer psychosocial research though particularly so in this pilot study.

It is possible that male referrals to this pilot study were more likely to decline for a number of reasons which may include but not be limited to:

- they did not want to participate in research
- they did not want to receive the intervention offered
- they did not want to be treated by the (male) interventionist
- they did not believe the intervention would help them
Literature on male carer participation in research is sparse and inevitably biased towards the views of those that did participate rather than those that didn’t. However, equal recruitment between male and females in the Livingston et al. (2013) study would suggest that participation in research alone was unlikely to be the primary factor for decline to participate in this pilot study.

In a recent review of male caring, McDonnell and Ryan (2013) identified that male carers were more likely to adopt a task orientated and problem solving focused approach to caring. They also identified that male carers were less likely to experience emotional distress than females. One study (Gant, Steffen, & Lauderdale, 2007) found that the male carers preferred informational and skill development interventions over emotional focused interventions.

Given that the suitable male carers who declined to participate in this study equates to only 8 people, it would be unwise to make any assumptions other than to suggest that the primary reason for declining to participate was likely to be the nature of intervention and not the research process. Further comparison between this study and Livingston et al. (2013) would suggest that Livingston’s intervention was potentially more task and skill orientated than the Talking Sense intervention with its focus on CBT. Consequently, men may have been less inclined to meet to discuss their thinking and feelings and more inclined to practise strategies. This raises clinical implications for interventions with male carers and the potential to adapt the Talking Sense intervention for male carers. Further research on the reasons for decline could be attempted, including more detailed information recorded in a screening log.

4.4.3 Interpretation
This section interprets the results particularly in relation to other relevant evidence.

4.4.3.1 Discussion of recruitment
The breakdown of sources of referral (see Figure 4-5), suggests that 50% of referrals were identified by the author after approach by third parties (carers groups, own caseload and self referrals), whilst the other 50% were from third
parties only (consultants, nurses and early onset dementia service). Whilst carers groups provided a valuable source of referrals, they also introduced a confounding variable i.e. receiving other support. The majority of carers (69%) in this study had already received some form of support. The influence of this variable (support received before and during) could be measured, controlled further or adjusted statistically in future studies though randomisation should balance out the effect of “other support” if sample sizes are sufficient.

This combined method of identifying potential recruits appears to have maximised recruitment. By relying on author or referrer only recruitment, this study would not have achieved satisfactory recruitment. The approach to recruitment taken in this study illustrates the importance of establishing, informing and maintaining networks with access to potential participants. Although the referral network contained more than 20 professionals, it was significant that approximately 20% of referrals were received from the four consultant psychiatrists who provided clinical leadership for the majority of professionals in the referral network. This illustrates the value of maintaining the involvement of key personnel in the referral network. A lack of support from clinical leadership may have significantly reduced referrals received.

Referral suitability was calculated to be 89% in contrast to 96% achieved by Livingston et al. (2013). Gitlin et al. (2010) report a screening process in which they identified an 80% suitability rate. None of the single component communication studies included in the review (Chapter 2) detailed referral suitability rates. Although this study still achieved a high suitability rate, one reason for the higher rate achieved by Livingston et al. (2013) may be referrer familiarity. Referrers to the Livingston et al. (2013) study were seeking carers who had signs of anxiety for an intervention that targeted carer anxiety. Many of the Livingston et al. (2013) referrers, as mental health professionals, would have been familiar with clinical caseness for anxiety and experienced users of the HADS (Zigmund & Snaith, 1983) making the identification of anxiety a relatively concrete process. In contrast, referrers to the Talking Sense pilot study were seeking to identify a less familiar and more abstract scenario of “communication
difficulties”. This highlights the importance of referrers being familiar with both the condition under study and the intervention being delivered. Future research would benefit from developing referrer knowledge and providing feedback to increase accuracy. If future research included a multisite study, the development of referrer knowledge could include site visits and reviews.

This study achieved a recruitment rate from referrals received of 50% which is comparable to the 55% achieved by Livingston et al. (2013). Of the studies detailed in the review above, only three report their recruitment rates; Gitlin et al. (2010) experienced a recruitment rate of 73%, McCallion et al. (1999) 45% and Kouri et al. (2011) 81%. These rates were further reduced by post-recruitment attrition, which for Kouri et al. (2011) was 12%. These figures illustrate the difficulties inherent in recruiting carers for research participation. Many authors do not report their experience of and difficulties with recruitment which may explain why some authors (e.g. Wilcock et al., 2007) are concerned when they do not achieve the sample size anticipated from their power calculations.

Cooper, Ketley and Livingston (2013) in a systematic review of higher quality dementia patient intervention studies (primarily medication related), calculated that 26% of people with dementia receiving medication were eligible for participation in research of whom 43% were likely to agree to participate. These figures combined suggest that only 11% of people with dementia are likely to participate in research (that involves taking medication) if approached. Clinical trials that do not include invasive medical procedures (non-CTIMPs) typically have fewer exclusion criteria (for CTIMPs these are often related to co-morbidities and safety concerns) in which case the participation rate is likely to be higher. The national target, set by the Prime Minister’s dementia challenge, is for 10% of people with dementia to participate in research (Cameron, 2013). Researchers should rise to meet this challenge, though should also be realistic about the relatively small proportion of carers and people with dementia who are likely to participate. Also, where research is developed nationally and locally with the involvement of patients and carers, higher acceptability and relevance may positively influence participation.
The recruitment results give some indication of reasons for non-participation (see 4.3.2.5). Requirements to minimise burden and offer choice make it difficult to establish in more detail why carers declined to participate. Sommerlad et al. (2014), in a qualitative evaluation of the Livingston et al. (2013) study, sought more information from carers who withdrew from their study mid-intervention though received only one reply. Future research could develop a mechanism for looking more specifically at reasons for decline and non-participation in both carer research studies and clinical interventions.

4.4.3.2 Clinical versus statistical significance

The results above and discussion for this pilot study below focus on statistical significance at one point in time. Man-Son-Hing et al. (2002) point out that statistically significant results can be clinically insignificant and vice versa. They describe the minimal clinically important difference (MCID) as the smallest treatment efficacy that would lead to a change in a patient’s management. For the HADS, Livingston et al. (2013) have determined an MCID (see below 4.4.3.3). No similar objective, expert or patient subjective opinion is available for the ACQOL, CSES or CCS. A higher effect size has been given for each of the significant values described though future research would benefit from further clinician, carer and patient, statistical, economic and longitudinal measures to determine whether results obtained are clinically valuable and meaningful (Man-Son-Hing et al., 2002). In this programme of research, the qualitative results and mixed methods analysis (chapters 5 and 6) will also enable interpretation of these results.

4.4.3.3 Discussion of Hospital Anxiety and Depression Scale results

Livingston et al. (2013) used the HADS (Zigmund & Snaith, 1983) as their primary outcome measure. They considered a decrease of 2 points and 0.5 change in standard deviation to be clinically significant by expert consensus. The baseline HADS scores reported by Livingston et al. (2013) are given in Table 4-3 below:
Table 4-3: Comparison HADS scores from Livingston et al. (2013).

<table>
<thead>
<tr>
<th>Livingston Scores</th>
<th>Control (mean, SD)</th>
<th>Treatment (mean, SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HADS Anxiety Baseline</td>
<td>9.3 (4.3)</td>
<td>8.1 (4.4)</td>
</tr>
<tr>
<td>HADS Anxiety Outcome (4 months*)</td>
<td>8.6 (4.2)</td>
<td>7.5 (4.2)</td>
</tr>
<tr>
<td>HADS Depression Baseline</td>
<td>5.5 (3.9)</td>
<td>5.4 (3.8)</td>
</tr>
<tr>
<td>HADS Depression Outcome (4 months)</td>
<td>5.7 (4.0)</td>
<td>4.9 (3.9)</td>
</tr>
<tr>
<td>HADS Total Baseline</td>
<td>14.8 (7.4)</td>
<td>13.5 (7.3)</td>
</tr>
<tr>
<td>HADS Total Outcome (4 months)</td>
<td>14.3 (7.4)</td>
<td>12.4 (7.4)</td>
</tr>
</tbody>
</table>

*Livingston et al. (2013) also recorded 8 months post treatment outcomes. Only four month scores are shown for comparison to the Talking Sense results.

Livingston et al. (2013) reported that these results showed a mean difference of \(-1.80\) points (95% confidence interval \(-3.29\) to \(-0.31\) points; \(P=0.02\)) in favour of the intervention. They made statistical adjustments for centre and baseline score and for factors related to outcome (caregiver’s age and sex, neuropsychiatric inventory score, and Zarit burden interview score).

The results from using the HADS in this pilot study were in a similar range to the results achieved by Livingston et al. (2013). Table 4-1 also shows similar levels of caseness for anxiety (44%) and depression (21%). Crawford et al. (2001) identified a mean normal total HADS score of 9.82. They found caseness in the general population of 20% for anxiety and 7.8% for depression. Comparison suggests that the caregivers involved in the Talking Sense pilot study were more anxious and depressed than people in the general population.

When considering why this pilot study did not achieve similarly significant results from the HADS outcome measure in comparison to the Livingston et al. (2013) study, four main factors appear likely: it was underpowered as expected (for a pilot study), recruitment was less selective, the intervention was less effective and/or the intervention was inadequately intensive. Future research should address these issues, though it is worth highlighting and protecting the potential
economic and burden-reducing value of a less intense intervention e.g. by changing this element last.

As an example, the GSES measures general self-efficacy in contrast to the communication specific self efficacy measured by the CSES. Results suggest that the CSES was more sensitive to change from this intervention than the GSES. In the same way, the HADS (Zigmund & Snaith, 1983) measures general depression and anxiety, it does not focus specifically on communication. Pederson, Tkachuk and Allen (2008) highlight the value of measuring communication specific anxiety and depression introducing an outcome measure that achieves this, the PRCA 24, though this was not developed specifically for dementia. Future research may benefit from the development of a scale specifically designed to measure communication related depression and anxiety in dementia. Research conducted by Ornstein, Gaugler, Devanand, Scarmeas, Zhu and Stern (2013) recommends that person with dementia depression should also be measured. Their study suggested that person with dementia depression was more strongly correlated to carer depression than person with dementia behaviour.

4.4.3.4 Discussion of the Adult Carers Quality Of Life scale results
The total result for the ACQOL was not significant. However, the value subscale did identify a significant difference in favour of the treatment group. Interestingly, the five questions from the value subscale focus primarily on the sense of value the carer receives from their relative with dementia.

One of the difficulties with quality of life scales is that they often measure different interpretations of what constitutes quality of life (Charlesworth & Newman, 2006). When considering the subsections of the ACQOL, it is less likely that a communication intervention would influence more practical topics like money (questions 16-20) and future caring choice (questions 6-10) (see Appendix 18). Inclusion of unlikely effects in an outcome measure dilutes the overall influence of more likely effects.

Significant changes in value may be a closer reflection of what carers experienced in the Talking Sense programme and warrant comparison to the
semi-structured interview results (chapter 5), in the mixed methods discussion (chapter 6). The results of this comparison may have implications for future research.

4.4.3.5 Discussion of the Communication Self Efficacy Scale results
The results of the CSES suggest that carers in the treatment group had significantly fewer communication difficulties happening but experienced no significant difference in their ability to manage these difficulties. This is a promising outcome, which may in fact be measuring more directly the intended aim of the intervention (to reduce communication difficulties). It is interesting when considering the theory of change pathway (see Figure 2-3) that a level 3 (happens) change was identified when a level one was not (manage). What the results do not reveal is how the “happens” scores interact with the “manage” scores, for instance if something happens less often, does the carer manage better when it does happen or are they less aware of their ability to manage?

However, these results require cautious interpretation because this measure (CSES) was used whilst unproven. For validity, further comparison with qualitative data in the following chapters will help determine if the content of the CSES matched the reported experience of carers. This comparison may also help determine the mechanisms of action that occurred between intervention, carer and person with dementia leading to a scale underpinned by theory as suggested by Hobart, Cana, Zajicek and Thompson (2007).

The CSES now appears to have limited evidence of face validity, internal and external reliability. Reflective records suggest there were no obvious difficulties with its completion after removal of one ambiguous question. This raises a number of potential opportunities for use of the CSES in future research, in clinical assessment and clinical outcome measurement.

4.4.3.6 Discussion of the General Self Efficacy Scale results
The results of the GSES identified no significant differences or trends in this study.
The author of this scale (Schwarzer, 2011) published normal data which, for an equally distributed (by sex) US American adult population, produced a mean score of 29.48. The group mean from the Talking Sense study was slightly above this (31.5). This suggests that the GSES did not identify carers in this study as noticeably less (generally) efficacious that the general population, despite their higher rates of anxiety, depression and reported difficulties with communication.

This measure proved useful as one of the measures used to establish reliability of the CSES. However, it appears to be measuring an effect more distant from the aim of the intervention, and does not relate directly to caring or communication difficulties. It is possible that successful implementation of communication strategies and helpful ways of thinking may influence a carryover into general self-efficacy. However, if the GSES has the potential to identify this change a below normal initial score would have been expected.

Whilst the results from the GSES correlate to the CSES (see above), the author’s reflective diary records a number of situations where carers were observed to complete this scale scoring “3=moderately true”, which sits in the midline of the questionnaire, for the majority the questions (see Appendix 19). This tendency to opt for the midline answer also appeared influenced by carers’ difficulties with understanding some of the language used in the GSES. Since outcome measures were completed by carers alone, these observations suggest there was some effect of questionnaire design limiting the range of responses given by carers using the GSES. Visual inspection of SPPS histograms for GSES data and positive kurtosis scores from the analysis confirm this pattern of favouring mid scale scores. For these reasons, the GSES is not recommended for future research in this specific field. If future research outside of this field sought to include a general self efficacy scale, a review of the GSES or similar scales would benefit from the inclusion of patient and carer opinions to make the language and design more accessible.
4.4.3.7 Discussion of Communication Competence Scale results

The CCS total score was close to significance in favour of the treatment intervention with a moderate effect size. It is interesting to consider what direction these results took. Although not statistically significant, visual comparison of the outcome results between groups, suggests a trend whereby carers in the control group appear to consider their relatives less competent, whilst those in the treatment group, appear to consider their relatives more competent. It is possible that increased knowledge (the primary focus of the control intervention) may have led carers to identify more incompetence in their relative. Reductions in communication difficulties happening (as suggested by the CSES Happens score for the treatment group), may be associated with a perceived improvement in person with dementia competence. However, visual comparison should be undertaken cautiously due to the effect of magnitude i.e. mean scores were above 100. The difference between group means at outset (112.5 for control and 107.9 for treatment) is only 4%.

Reflective records suggest that the CCS, with 36 questions, took the longest to complete. Carers appeared to have few difficulties, though frequent carer questioning at first completion suggested some questions were difficult to understand. Some carers also appeared to answer with only agree or disagree, rejecting the optional “strongly” (see Appendix 20).

The CCS has previously been used by dementia carers for self-rating in regard to their own communication competence but not for proxy rating of their relatives (Weathers et al., 2010). Consequently, no normal values or cut off points exist for persons with dementia being communicatively competent. The scale is typically used only to compare higher and lower scoring respondents. Therefore, we cannot say whether people with dementia remained competent or not, though there seems little value in doing so as such a judgement would be relative to a number of other factors including situation, carer perception and previous ability.
Weathers et al. (2010) suggest a model whereby higher levels of communication competence influence positive health outcomes. They found that carers with higher levels of self-reported communication competence reported higher levels of satisfaction. Query and James (1989) also found that carers with higher communication competence maintained larger social networks. This raises two additional questions:

- What effect if any did the study have on the carer’s communication competence?
- What are the mechanisms of action and inter-relationships between actual and perceived carer and person with dementia communication competence?

These issues warrant comparison with semi-structured interview data in chapter 6 and present a range of opportunities for future research.

4.4.3.8 Discussion of the Therapeutic Engagement Index and Readiness scores

It is interesting that the control group appeared more ready than the treatment group after the first session. However, it is suggested this may be an indicator of different intervention expectations and goals, whereby the control group participants are left with ideas to try whilst the focus during the first session for the treatment group was on information provision.

Whilst the treatment group may have been more ready and engaged by the final session, the true value of by these measures is as a clinical indicator. As relatively simple measures, it is suggested that they enable the clinician to justify further intervention or identify areas or beliefs that needs addressing, for example with motivational interviewing (Westbrook et al., 2008), prior to goal setting. One clinical recommendation is for dementia professionals providing carer support to use the TEI and Readiness scales to monitor response and justify further interventions.
4.4.3.9 What this pilot RCT study adds

The results of this study, which are comparable to the Livingston et al. (2013) study, have tested and confirmed the potential for recruitment, delivery of the Talking Sense intervention, acceptability and significance of the outcomes used. Where limitations and weaknesses have been identified, clinical and research recommendations have been made.

The Talking Sense manual is an intervention approach which uses domains (see 1.3.1; Schulz, 2000) of knowledge, thinking, behaviour and skill modification. Comparison to the control intervention, which was primarily knowledge based, and the significant results identified provide some support to the idea that this use of multiple domains may be more effective than knowledge based interventions alone.

In comparison to the eight other studies of single component communication interventions, this pilot study has a relatively large sample size, second only to McCallion et al. (1999). Despite this, calculations for the primary outcome measures (HADS) suggest that it is likely underpowered and for this reason alone, would be rated a level 2 study under the SORT (Ebell et al., 2004) criteria (see 2.2.4). However, under the Thompson et al. (2007) quality rating system (see 2.2.4), it would score 5 points, more than any previous study.

This study has demonstrated the efficacy of some outcome measures and difficulties inherent in others (e.g. the GSES). It has successfully introduced previously untested outcomes of carer communication competence (CCS) and carer quality of life (ACQOL) suggested by previous research (Schulz, 2000). The study has also successfully incorporated the development of a new outcome measure, the CSES, which has potential for use in future clinical and research settings. This study has, to some extent, supported the idea that outcome measures which more directly measure anticipated effect (e.g. the CSES) should be considered in similar research.

The aim of the pilot study was to consider the effectiveness of the Talking Sense manual delivered in a 3 session format, compared to a single control session.
There is limited quantitative evidence to support the use of the Talking Sense manual. When comparing the control intervention to the treatment intervention, the results suggest that carers were no less anxious or depressed and had similar quality of life and general self efficacy in both groups. Whilst their overall quality of life was unchanged, those in the treatment group appeared to feel more valued by their relative. The results also suggest that the treatment group carers, at the 2 week post interventions period, noticed significantly fewer communication difficulties happening between them and their relative and were close to considering their relatives as being more competent. Whilst the primary focus of the intervention was on the carer’s beliefs and abilities, it is significant to note that these results suggest most change occurring in the relationship between the carer and the person with dementia. Where change appears to have occurred, what is not clear is whether this was change in the carer’s perceptions, carer’s behaviour or indeed behaviour and ability of the person with dementia. This study set out to ask whether carer’s skills, behaviour and self perceptions can be changed. The results have raised a new challenge; asking whether carer lone interventions can have a direct effect on their perception of, and even the behaviour of, the person with dementia.

This study has also identified a number of indicators for clinical practice, recommendations for future research and opportunities for mixed methods comparison with qualitative data which are considered in chapter 6.
5 Chapter Five: Qualitative study

This chapter details the semi-structured, interviews conducted with a purposive sample of 15 carers who received the Talking Sense intervention. It provides methods, results and discussion specifically for these interviews. Details of research governance, recruitment and interventions are given in chapter 4. This chapter contains five sections:

- Introduction to qualitative research
- Introduction to existing qualitative research in psychosocial carer communication interventions
- Methods for the semi-structured interviews
- Results of the semi-structured interviews
- Discussion of the results of the semi-structured interviews

Mixed methods analysis as well as clinical and research implications derived from these interviews are included in chapter 6.

5.1 INTRODUCTION TO QUALITATIVE RESEARCH

Qualitative research encompasses a range of techniques used in a naturalistic, interpretive way which are concerned with understanding the meanings people attach to phenomena e.g. actions, beliefs or values, within their social worlds (Ritchie & Lewis, 2012). Data collected is observational and consists of the words, artefacts and actions of those studied. Qualitative research includes a range of techniques including observation, in depth individual interviews, focus groups, biographical methods and analysis of documents and texts (Ritchie & Lewis, 2012).

Qualitative researchers have historically debated philosophical issues in ontology, what there is to know about the world, and epistemology, the nature of knowledge and how it can be acquired (Ritchie & Lewis, 2012). This programme of research has followed a pragmatic approach to qualitative research described by Ritchie and Lewis (2012) and others which encourages
selection of the most appropriate method for answering research questions rather than focusing primarily on these underlying philosophical debates.

This pragmatic approach to research methods suggests that quantitative and qualitative methods should be considered complementary strategies appropriate to different types of research question (Ritchie & Lewis, 2012). The concept of interpretivism, which is integral to the qualitative tradition, is seen to overcome some of the perceived limitations associated with positivism, the tradition associated with statistical enquiry (Ritchie & Lewis, 2014). Qualitative research allows for issues to be evaluated in depth and detail. Whilst quantitative outcome measures produce construct scores, qualitative research enables interpretation of those constructs e.g. quality of life. In addition, interview methods for example, are not necessarily limited to particular pre-determined questions and can be redirected by researchers in real time. Consequently, the direction and framework of enquiry can be revised quickly as fresh information and findings emerge.

5.2 INTRODUCTION TO QUALITATIVE RESEARCH IN PSYCHOSOCIAL INTERVENTIONS.

This section provides an overview of previously published qualitative research for dementia carer psychosocial interventions.

There has been relatively little qualitative research published looking at psychosocial interventions for dementia carers. Within the literature for multi-component psychosocial interventions for dementia carers, only one detailed qualitative study was identified: Sommerlad et al. (2014) published the results of 75 postal questionnaires completed two years after study entry to a large (n=260) UK based carer intervention study (Livingston et al., 2013). Their 5 questions concentrated on what happened as a consequence of the intervention, but did not consider why this occurred. Interestingly, their results included improved communication as the third most common consequence after increased understanding and knowledge.
In the systematic review of single component communication specific psychosocial interventions (see chapter 2) thirteen studies were identified, eight of which were controlled trials. All of the studies used quantitative measures; none employed in-depth qualitative methodology. Whilst four of these studies gathered some qualitative data (see section 2.3.7), this was limited to no more than a paragraph of text in each publication, typically obtained by including a free comment field on evaluation questionnaires. No qualitative methodology was detailed in any of these publications, limiting the credibility and reliability of reported findings. This limited qualitative research hints at potential themes e.g. the benefits of early intervention and the development of carer insight, though is far from comprehensive.

Quantitative outcomes used in these studies varied significantly though many reported changes in knowledge, a reduction in difficult communication experiences and changes in mood. This variability suggests a lack of clarity about expected and valued outcomes. Only one study, Kouri et al. (2011), suggested a process or mechanism of action, “self-efficacy”, to account for these changes. Since the studies detailed in the review also differed significantly in participant background, it is also difficult to determine which subgroups of carers are most likely to benefit from this type of intervention.

In summary, the absence of qualitative research limits our understanding of possible mechanisms of action, variability between carers and intervention effects beyond those commonly expected.

5.3 METHODS FOR THE SEMI-STRUCTURED INTERVIEW STUDY

This section explains the methods used to interview carer participants and specific detail about the approach used for data analysis.

Face to face, in-depth, semi-structured, interviews were chosen as the method of data collection to enable a balance between in depth exploration and a minimum number of prompts and probes from an interview guide (Bowling, 2009).
A series of 15 semi-structured interviews were conducted with purposively selected carers from the treatment group two weeks after they had returned their outcomes measures. This was typically between weeks 10 to 12 of their involvement in the study and is illustrated in Figure 4-2, the participants experience flowchart.

5.3.1 Aim and objectives
The aim of the interviews was to ask carers what happened to them and their relatives during and after their participation in the Talking Sense treatment. Carers were also asked to consider why this happened.

More specifically, the interviews sought to indentify:

• changes in carer reported knowledge, skill, thinking and behaviour which they attributed to the intervention process
• changes in carer reported person with dementia communication, affect and behaviour
• changes in carer perceived interaction inside and outside of the carer and person with dementia dyad
• the carers perspective on the feasibility of both the intervention and the research process
• carers understanding of how and why these processes occurred

The objectives of this qualitative study were to:

• identify outcomes not measured or identified by the quantitative measures
• consider why and how outcomes did or didn’t occur
• identify possible mechanisms of action for the intervention
• consider inter-relationships between the intervention, carers and persons with dementia and the outcomes
• enable interpretation of the quantitative results using a mixed methods approach (O’Cathain et al., 2010)
5.3.2 Participant selection

A sample of fifteen carers was chosen primarily because of funding limitations but also as an estimate of the numbers required to reach saturation (see 5.3.2.1). All of the carers consenting and randomised to the treatment arm of the pilot RCT study also consented to participate in an interview.

Selection for participation in these interviews was purposive (Silverman, 2004). The sample was chosen to ensure that all key characteristics of carers were represented (e.g. male/female, partner/child) and to ensure diversity within each key characteristic (Ritchie & Lewis, 2012). The balance of characteristics (see Table 5-1) was intended to be representative of the UK population of carers for people with dementia (Carers UK, 2013).

5.3.2.1 Saturation

O’Reilly and Parker (2012), in a review of the use of saturation in qualitative research, describe a number of controversies. One issue is transparency; for example Francis et al. (2010) identified 18 articles published in a leading journal which mentioned saturation, but without any explanation as to how it was achieved.

O’Reilly and Parker (2012) suggest that the importance of and meaning of saturation is dependent on the qualitative approach being used. Theoretical saturation is a concept which has its origins in grounded theory. O’Reilly and Parker (2012), looking at other forms of qualitative research, suggest that researchers are attempting to establish thematic or data saturation. Green and Thorogood (2004) define data saturation as the point at which nothing new is generated or no new patterns emerge from the data.

O’Reilly and Parker (2012) identify relatively few guidelines on the approach required to achieve saturation and cautiously suggest that one approach will not fit all situations.

Mason (2010), in a review of sample sizes for qualitative PhD studies, suggests a minimum of 15 and a maximum of 50 participants are required to achieve
saturation in most cases. O’Reilly and Parker (2012) point out however, that the number of participants is only one factor and that the topic of study, length of interview and depth of analysis will have an equal impact on breadth of data generated. They add that saturation is also about achieving a sample which best represents the research topic.

Mason (2010) also points out that attempts to achieve saturation are limited in research by the need to plan funding and approval prior to recruitment. This study experienced similar limitations.

However, O’Reilly and Parker (2012) add that when saturation is not achieved, this means that the phenomenon is not yet fully explored rather than that the findings are invalid.

In this study saturation (see 5.5.1) was considered by asking if:

- the selection of participants sufficiently represented the population of dementia carers
- later interviews were generating new topics which had not been explored in earlier interviews i.e. there was potential for further exploration

5.3.3 Data collection

5.3.3.1 Interview Guide

An interview guide was developed (see Appendix 29), informed by key theories of health behaviour change (Connor & Norman, 2009) (see section 3.4). These theories became seven a-priori initial codes for the analysis of carer learning, feelings, thinking, self efficacy, carer and person with dementia insight and awareness of implementation intention setting. Findings that relate to a-priori codes are highlighted in the discussion. The interview guide was modified between interviews as data saturation occurred for some topics and other areas of interest emerged.
5.3.3.2 Research interviewer

The author delivered the Talking Sense intervention. In order to minimise bias and facilitate reflexivity (Silverman, 2004), funding was secured to employ and train a separate interviewer. The interviewer was a qualified speech and language therapist. Use of a third party interviewer was included in the successful application to the IRAS research ethics committee.

Interviewer training and supervision included:

- explanation of the interview aims
- demonstration of the Talking Sense intervention
- a role play interview
- provision of a detailed interviewer procedure (Silverman, 2004)
- training on the use of digital audio recorders, the interview guide and field notes
- time to read and discuss the theory of interviewing (Ritchie & Lewis, 2012)
- training on the use of probing and widening but not leading questions (Ritchie & Lewis, 2012)
- explanation of the ethical rules for carer participation, the presence of a person with dementia and disclosure of issues of concern from the carer
- verbal and written feedback on each interview
- bi monthly meetings to discuss progress and key topics such as positionality, bracketing and reflexivity

5.3.3.3 Positionality, bracketing and reflexivity

Positionality in this context refers to the interviewer’s and this author’s ability to separate personal experience and expectations during the study (Pope & Mays, 2000).

Bracketing was used as a method of mitigating the effects of preconceptions that could have tainted the research process. Bracketing also acted as a method for protecting the researchers from the cumulative effects of examining emotionally
difficult material and facilitated the researchers to reach deeper levels of reflection across the stages of the interview process (Tufford & Newman, 2010).

Reflexivity was used as an active process that involved being aware in the moment of influences on the interviewer’s internal and external responses whilst simultaneously considering influences on their relationship to the research topic and the participants. This was both personal and epistemological (Dowling, 2006). The potential for biases to influence interviews and analysis was minimised by the use of reflexivity during interviews, post interview field note making, analysis and regular supervision between the author and interviewer during which preconceptions were identified, challenged and bracketed from the study (Ritchie & Lewis 2012).

All interviews, except the first which was conducted in a hospital clinic room, were conducted in the carer’s home.

Interviewees were reminded of the purpose of the interview which was planned to last no longer than an hour. They were shown a picture of the first author and a selection of slides from the Talking Sense programme to help them establish context.

In keeping with the ethical proposal for this study, care was taken to minimise burden for carer participants by explaining their right to withdraw or finish the interview at any stage. Verbal carer consent to participate was audio recorded at the start of each interview. Special care was also taken to ensure that relatives with dementia, who were in the same house during the interview, were safe and were happy for the interview to proceed.

An arrangement was in place to inform the link psychiatrist should any carer disclose, during the interview, information that put themselves or the person with dementia at risk of harm.

5.3.4 Data recording and handling

Interviews were simultaneously recorded on two Zoom H1 digital audio recorders. Field notes were recorded on paper by the interviewer and
summarised onto the same digital audio recorders immediately afterwards. Field notes concentrated on the circumstances of the recording situation including the presence and activity of the person with dementia, non verbal cues, off air events, carer mood indicators, the interviewer’s summary of learning from the interview and interviewer reflections including positionality and learning points about the interview process.

Audio recordings were typed verbatim by an independent typist. Audio and typed data was treated as part of the patient record and stored according to the principles of the data protection act (UK Government, 2003) and local NHS policies.

5.3.5 Data analysis

5.3.5.1 Analytical approach
The aim of the qualitative data analysis was to produce credible and trustworthy findings which would reveal meaningful descriptions of carer’s experiences and perceptions. The analysis also sought to consider the inter-relationships between these experiences, perceptions and other effects, the contextual information reported during the interview and the carer and person with dementia characteristics.

The approach used for data analysis was a pragmatic approach to thematic analysis based on the framework method (Ritchie & Lewis, 2012). The thematic framework approach classifies and organises data successively, using initial codes, concepts and themes. Once codes and themes are judged to be comprehensive, they are charted in their own matrix where every respondent is allocated a row (Ritchie & Lewis, 2012). This process allows the analyst to move back and forth between levels of abstraction e.g. case or theme based analysis without losing sight of raw data (Ritchie & Lewis, 2012).

5.3.5.2 Coding method
Once typed, transcriptions and interview notes were uploaded into NVivo 10 (QSR International, 2013) for data management and analysis of initial codes. Data
analysis occurred after each interview, allowing for emerging codes to be available as potential prompts for future interviews. Analysis beyond initial coding was conducted on paper for ease of access.

Initial coding was conducted by the author. Interpretation and naming of codes and themes was agreed by discussion between the author and academic supervisor. Codes and themes were also discussed with the research steering group. Initial codes were chosen both a-priori (Bazeley, 2011) based on the topic guide and by open coding, with emerging codes developed by a process of constant comparison within and between interviews. Purely contextual information, unrelated to the research question, was separated. As analysis progressed, new codes were iteratively applied to transcripts previously analysed.

Bowling (2009) recommends that care be taken to ensure the analysis process does not disembry the data from the people who have produced it. Funk and Stajduhar (2009) describe carer talk as both an articulation of their experience and an attempt to cope with it. The interview process itself can facilitate validation, introspection and growth, self-acknowledgement, unburdening and sense-making. Therefore, the interview data was interpreted using a combination of interpretive and critical approaches combined with the author’s experience of the carer from their contact during the intervention (Funk & Stajduhar, 2009). Consequently, the author was not blinded to the names of carers for each interview in order that they could apply their observational experience of the carer to the analysis alongside recollection of specific topics discussed and advice given during the individualised Talking Sense intervention.

During the coding process, grounded theory principles of iteration and constant comparison were used to develop relevant and credible findings. Reflexive iteration is at the heart of visiting and revisiting the data and connecting them with emerging insights, progressively leading to refined focus and understandings. This cyclic process involved action, reflection, refinement and then further action. Srivastava and Hopwood (2009) state that iteration is not a
repetitive mechanical task but a deeply reflexive process that is the key to sparking insight and developing meaning.

Throughout the analysis a detailed reflective journal was maintained alongside coding memos on Nvivo 10 (QSR International, 2013) documenting interpretations, assumptions and changes. A codebook with code definitions was also maintained (Bazeley, 2011).

Appendix 30 lists the 71 initial codes (41 of which directly related to the Talking Sense intervention) identified prior to organisation into higher order themes.

5.3.5.3 Organisation of themes and thematic charting
After initial coding was completed, related codes were grouped, by meaning, into six higher order themes. Themes were labelled using carers own words where possible (Greenwood, Habibi, Mackenzie, Drennan, & Easton, 2013), to reflect and summarise concepts. The flow and order of themes was chosen to both reflect the most significant inter-relationships between themes and the cognitive behavioural theoretical model (Laidlaw et al., 2009).

After themes were identified, descriptive and explanatory accounts were written to refine data and help to understand cause or influences (Ritchie & Lewis, 2012). This process involved consideration of inter-relationships and co-existence and the absence of themes but also sought to draw explanations from other studies.

Thematic charting (Ritchie & Lewis 2012) was used to synthesise the data in order that comparisons could be made between and across codes and participants to identify relationships, atypical comments and missing data (Ritchie & Lewis, 2012). Further analysis was made comparing initial codes with contextual information, demographic and diagnostic information. Demographic information used included carer age, sex, relationship, person with dementia age and sex. Thematic charting was conducted for more commonly used codes against severity of dementia, carer anxiety and depression score, carer engagement and readiness score. Carers were organised into higher and lower groups using M.M.S.E. (Folstein et al., 1975) and the VEMAS scale (see Appendix
2) for dementia severity, their initial score on the HADS (Zigmund & Snaith, 1983) for depression and anxiety and their final session scores for therapeutic engagement and readiness (Chee et al., 2005).

5.3.5.4 Descriptive and explanatory accounts
Within descriptive accounts, typologies were sought which aimed to describe, explain and differentiate phenomena within the carers and persons with dementia worlds (Ritchie & Lewis, 2012). In this context, two of the most important typologies to consider were which carers and carer: patient dyads benefitted most from the Talking Sense treatment, and which components of the treatment had the most effect.

The process of writing explanatory accounts involves further interrogation of the data to help understand what is causing or influencing phenomena to occur (Ritchie & Lewis, 2012). This process involved consideration of inter-relationships and co-existence as well as consideration of absence of themes but also sought to draw concepts and explanations from other empirical studies. Figure 5-1, below, summarises the process of data analysis.
5.3.6 Rigour and Validation

Internal validation was established by the use of the constant comparison method and consideration of outlier cases and coding (Ritchie & Lewis, 2012).

For external validation, investigator triangulation was used whereby three interviews were chosen at random and analysed by the academic supervisor and an independent researcher who were blind to any existing coding conducted by this author (Ritchie & Lewis, 2012). Coding and interpretation from each transcript was then compared to existing coding by the author. At the time of
this analysis 63 codes, 30 of which were context only, were in use. After discussion with the academic supervisor only one code was changed but 10 changes were made to code definitions in the codebook. At this point, these results equated to 99% validity for initial coding selection and 86% for coding definitions. Following these changes, all previous interviews were analysed to consider changes made. Patton (2002) suggested that this validation process adds to the credibility of findings, strengthening confidence in the conclusions drawn.

Respondent external validation (Ritchie & Lewis, 2012) was not attempted as the study sought to limit burden for participating carers. However, feedback relating to qualitative analysis and results, from the two carer members of the steering group was taken into consideration.
5.4 RESULTS OF THE SEMI-STRUCTURED INTERVIEWS

This section provides detailed results about the carers who participated in these interviews and the thematic analysis that was produced.

15 carers participated in interviews lasting an average of 50 minutes (see Table 5-1 below).

Table 5-1: Characteristics of semi-structured interview participants.

<table>
<thead>
<tr>
<th>Carer</th>
<th>Carer Age</th>
<th>Carer sex</th>
<th>Carer relationship</th>
<th>Person with dementia age</th>
<th>Person with dementia sex</th>
<th>Person with Dementia diagnosis</th>
<th>Last recorded MMSE score:</th>
</tr>
</thead>
<tbody>
<tr>
<td>CO1</td>
<td>73</td>
<td>Female</td>
<td>Partner</td>
<td>74</td>
<td>Male</td>
<td>Alzheimer's</td>
<td>28/30</td>
</tr>
<tr>
<td>CO2</td>
<td>88</td>
<td>Male</td>
<td>Partner</td>
<td>86</td>
<td>Female</td>
<td>Alzheimer's</td>
<td>28/30</td>
</tr>
<tr>
<td>CO3</td>
<td>52</td>
<td>Female</td>
<td>Child</td>
<td>86</td>
<td>Female</td>
<td>Alzheimer's</td>
<td>22/30</td>
</tr>
<tr>
<td>CO4</td>
<td>62</td>
<td>Female</td>
<td>Partner</td>
<td>68</td>
<td>Male</td>
<td>Mixed</td>
<td>28/30</td>
</tr>
<tr>
<td>CO5</td>
<td>54</td>
<td>Female</td>
<td>Child</td>
<td>81</td>
<td>Male</td>
<td>Alzheimer's</td>
<td>26/30</td>
</tr>
<tr>
<td>CO6</td>
<td>59</td>
<td>Male</td>
<td>Child</td>
<td>89</td>
<td>Female</td>
<td>Alzheimer's</td>
<td>23/30</td>
</tr>
<tr>
<td>CO7</td>
<td>83</td>
<td>Female</td>
<td>Partner</td>
<td>84</td>
<td>Male</td>
<td>Vascular</td>
<td>22/30</td>
</tr>
<tr>
<td>CO8</td>
<td>75</td>
<td>Female</td>
<td>Partner</td>
<td>75</td>
<td>Male</td>
<td>Mixed</td>
<td>24/30</td>
</tr>
<tr>
<td>CO9</td>
<td>87</td>
<td>Male</td>
<td>Partner</td>
<td>77</td>
<td>Female</td>
<td>Vascular</td>
<td>26/30</td>
</tr>
<tr>
<td>C10</td>
<td>65</td>
<td>Female</td>
<td>Partner</td>
<td>67</td>
<td>Male</td>
<td>Alzheimer's</td>
<td>21/30</td>
</tr>
<tr>
<td>C11</td>
<td>61</td>
<td>Male</td>
<td>Partner</td>
<td>62</td>
<td>Female</td>
<td>Alzheimer's</td>
<td>29/30</td>
</tr>
<tr>
<td>C12</td>
<td>66</td>
<td>Female</td>
<td>Partner</td>
<td>66</td>
<td>Male</td>
<td>Alzheimer's</td>
<td>27/30</td>
</tr>
<tr>
<td>C13</td>
<td>59</td>
<td>Female</td>
<td>Child</td>
<td>88</td>
<td>Female</td>
<td>Alzheimer's</td>
<td>18/30</td>
</tr>
<tr>
<td>C14</td>
<td>62</td>
<td>Female</td>
<td>Child</td>
<td>83</td>
<td>Female</td>
<td>Vascular</td>
<td>27/30</td>
</tr>
<tr>
<td>C15</td>
<td>42</td>
<td>Female</td>
<td>Niece</td>
<td>78</td>
<td>Female</td>
<td>Vascular</td>
<td>22/30</td>
</tr>
</tbody>
</table>

All and only partners were co-resident.

5.4.1 Contextual information

As well as the codes themes that related to the research question, a number of context or background information codes were generated. These included references to difficulties coping, but relatively few references to carer depression or anxiety. Carers also referred to communication strategies they already used,
though these were few in comparison to the strategies adopted and attributed to Talking Sense (TS).

Two of the most common context codes - *communication difficulties experienced* and *carer feelings* - have been used for comparison with the effects of the Talking Sense programme in the results below.

5.4.2   Themes
Excluding context codes, forty one initial codes were developed (see Appendix 30), including seven a-priori codes, and were grouped into the six themes which are described below. In the discussion section (see 5.5.2) each theme is also summarised by a series of statements.

**Theme 1: What I thought of the process**
Carers referred to the TS sessions as an individualised discussion, which included explaining, problem solving and advice-giving. A minority were surprised that TS focused on the carer.

> .. so it’s all about me looking after my dad, it’s not about dad is it? It’s all about me, caring for my dad, which is nice because everything is all about the disease isn’t it and the things you need to put in place. But, being the carer, you need to know, well you want help to know, how to handle everything and that there is somebody out there that you can actually talk to *(C05)*

Most carers thought the title “Talking Sense” referred to gained insight for the carer and easier comprehension for the person with dementia.

> If you don’t talk short sentences...they just get confused, so therefore it’s Talking Sense if you reduce the amount of information you are trying to tell them *(C07)*

Carers generally had poor recollection of the picture used for the front page of the manual. Only a small number of carers referred to the symbolism of this picture and only one carer referred to the symbolism of the wall in the picture;
I really like it because it is a brick wall sometimes and you do feel
sometimes like you’re beating your head against it (C15)

The step-by-step manual was described by the majority of carers as practical,
providing order and a source for topics. Significantly, one carer thought it
contained too much information.

A group of carers suggested the manual had to be delivered by an expert, with
experience and understanding.

Interviewer: Could somebody who didn’t have expertise have delivered
that programme?

No, because if I came up with a difficult question they may not know how
to answer it... If I delivered it ...I could only base it on what’s happened
with my mum whereas he’s (author) dealt with varying degrees of
dementia...different patients. (C06)

One carer proposed that other, less experienced, professionals could deliver
Talking Sense but it may achieve less:

I believe if they had tutoring from (author) then they could deliver it but I
think it, it really sounds like it’s his (author) baby, it’s his programme. I’m
sure that the students that work with him if they can pick up half or
quarter of the skills that he has they will be, they will be good at their job
(C11).

The majority of carers valued an approach specifically for them. Only one
suggested Talking Sense could be useful for professionals.

Well it’s the family carers that need the help isn’t it? We’re here 24/7.
(C04)
Overwhelmingly, carers said it was more practical and private to be seen alone and at home. They described this as more relaxing, easier to hear, easier to talk about private things and answer questions and more specific to their needs. Some added that it was better to be seen away from their relative for similar reasons.

*I’m in favour of coming here rather than going to hospital, I spend enough time at the hospital. (C09)*

Some cited advantages of group meetings (e.g. diversity of experience and ideas), but considerably more described disadvantages of meeting in a group such as limited time for talking, intolerance of others, feeling pressured and too much diversity.

Some carers found it hard to understand the concept of individualisation. When asked about this, most described it as a free, two way process with suggestions. When talking about the idea of individualisation, one carer commented on the disadvantages of using generic information:

*Not general rules, you get all the general rules on the internet... if you look, it’s all the same sort of thing which I already know about, so it is nice to be able to ask specific questions. (C05)*

The majority of carers had no concerns about the time taken for the programme. When carers were asked about timing, most commented that it had been offered at the right point for them as a carer and stage of their relatives’ illness, though one carer commented that it may be more relevant later in the illness. Carers comments suggested their needs varied according to the stage in their caring career or their relative’s illness. Therefore, carers within this diverse group may have benefitted differently from an intervention that was individualised to their specific needs.
**Theme 2: What I learnt and experienced**

Carers commonly found it difficult to specify factual knowledge gained from TS although there was no suggestion that this meant it didn’t help.

*He (author) confirmed a lot of the ideas I had and I think I learned a lot from what he said overall, definitely benefitted from it, but as I said the specific details, I’m not sure... (C09)*

It was often implied that knowledge was useful for driving thinking which may explain an emphasis in commenting about thinking changes rather than knowledge gained.

Only a minority of carers reported, positively, that they had gained insight into their own communication.

*Through him (the author) I’m being another me. I’ve been (name) for 70 odd years, but now I’m changing into another (name) (C01)*

*Interviewer: have you had that experience before*

*No (laughs). It is new. (C01)*

However, one carer mentioned that the TS process had made her aware of negatives in her own situation;

*It made me become more aware of my life... It made me think...my life has changed and we don’t go out with friends and do things...It’s opened my eyes up a bit more and it’s a bit more disturbing... (C04)*

Carers more commonly reported changes in insight into their relative with dementia, usually relating to communication but also with previously unrecognised abilities, behaviour, feelings and skills;
I did learn a lot ... that although she finds trouble communicating, she hasn’t lost her intellect and she does problem solve and where before we were trying to take that away from her... (C15)

I think he's feeling it as much as I'm feeling it, so I've got to try and help him as best I can... (C01)

One carer (15) was able to identify that improved insight into her relatives preserved abilities ultimately led to a sense of pride and self for the person with dementia and increased confidence for the carer.

Carers generally had difficulty explaining how their insight had changed. A small number of carers were able to attribute this change to thinking and knowledge they had gained.

Only one example was identified of a carer appearing to have difficulty understanding their relative due to limited insight:

She goes to church on Sunday, you know, she is doing different things with different people, which is good for her, so I don’t see how she could be lonely, she goes out more than I do (C13)

A change in carers’ feelings was a major theme occurring in all interviews. Some carers reported positive feelings after successfully employing communication strategies, most of which related to experiencing less confrontation.

The most common reasons given for changes in feelings were the Talking Sense programme or the effect of the individual therapist. At times, it was difficult to distinguish between these. A descriptive comparison between carers identified that, proportionally, more changes in feelings were reported by female carers than male carers.

Interestingly, one carer commented that success in employing strategies was in itself dependent on how you were feeling:
If I can make a more pleasant atmosphere for (relative) then it will be more pleasant for both of us, but it is remembering to do it. Also, it’s a bit reliant on how you’re feeling yourself (C10)

Four main types of feelings were identified:

**Reactive feelings** (toward their relative) were reported frequently in the context but appeared less influenced by the TS programme. Some carers reported reduced frustration, hate, anger and resentment. Anger appeared to be the feeling least changed.

*Interviewer: And do you hate her now?*

*No, ..I don’t because...I was feeling very against her (C13)*

*Interviewer: and what do you put that change of feeling down to?*

*I think its walking away from it (conflict) (C13)*

**Reflective feelings** (about what the carer should do) appeared to have changed the most, when comparing context themes with the effects of TS. Guilt was frequently reported in context and appeared to improve for many carers with TS.

*I am less stressed having had the experience (TS) than I was before...when I was having cross words I came away feeling so guilty of what I’d said..... Part of the learning was that it’s just life and I’m not to feel guilty for that. (C11)*

**Mood feelings** reported included feeling less burdened, less stressed and more positive. Although changes in mood and anxiety are among the most commonly reported outcomes in carer research (Braun et al., 2010), carers made relatively few comments about effects on their mood or anxiety.
I can’t tell you how much I learnt about me, about (relative) …and because of that life is a lot better than it was, but it’s (stress) not there anymore which is nice (C15)

**Ability related feelings** were mentioned more in relation to Talking Sense and rarely in the context. The most commonly reported feeling was increased confidence.

*I think he wrote it (a conversation idea) down. He said “I like that” and so if that was mine, brilliant. If it isn’t unique, it doesn’t matter, because he (author) made me feel that it was unique. Yeah, so that again was that ability of his to draw out ideas from me and he was stimulating yeah* (C11)

No carers reported any negative feelings attributed to the TS programme.

A large number of comments were interpreted as improvements in self-efficacy attributable to Talking Sense. The majority of these improvements were about capability (what they do) with the minority about confidence (what they feel and believe).

*Before it’s like you don’t know you’re doing alright, I was critical of myself.* (C06)

*It was refreshing to hear someone say that, so that gave me the credibility that what I was doing was right.* (C11)

Carers generally attributed changes in self efficacy to thinking and doing things differently, with some making associations with feeling less anxious and communicating better.
Theme 3: It made me think

Thinking is hard work, but it’s better than the arguments. (C01)

As an effect of Talking Sense, carers talked more than anything else about their thinking and beliefs. This was proportionally more prevalent in female carers. Communication situations were those that they most often thought about. Nearly all of the thinking related comments could be considered specific beliefs, many of which have been termed “permissions” i.e. things they now thought it was acceptable to do.

Some thoughts were specifically identified as self-talk and included mantras taught in Talking Sense e.g.”Say OK and walk away”.

I’m thinking different...I don’t get ruffled. As I say, I talk to myself quite a bit, I say just ignore it, just ignore it...(C01)

There were four main types of thinking expressed:

Thoughts and beliefs about the person with dementia included forgiving thoughts which may relate to insight gained into their relative’s difficulties;

He’s not deliberately ignoring me, he’s just not really processing what I’m saying I suppose. (C10)

Thoughts and beliefs about themselves as carers often related to acceptance of their own limitations, more realistic expectations and a belief that the situation was not their fault;

I know that it’s fine for me to get a little bit (cross)... I’ve learnt that it’s okay, that I will get annoyed, it’s normal, where I was thinking perhaps I shouldn’t be feeling like this.(C05).
Another popular thought was the idea that it was okay for carers to have time to themselves.

The most common thought in this category however, was that it is carers themselves who have to change;

\[ \text{We did have one very bad episode which...upset both of us, so I thought that it's me that has got to change, because he can't. (C01)} \]

**Thoughts and beliefs about carers in general** included thoughts that carers needed to be positive and not to expect problems. Permissions including “it’s okay to be angry” and “don’t expect to be perfect”, suggested carers had been able to associate themselves with carers in general.

\[ \text{I think you have this feeling that you’re the only person who is thinking them and probably loads of other people are thinking them. (C12)} \]

**Thoughts and beliefs about communication** most commonly related to avoiding confrontation. Other beliefs included the benefits of lies of omission (not telling their relatives everything) and ‘white lies’ (changing facts in their relatives’ best interests);

\[ \text{I don’t have to be right all the time...he’ll say it was that and I’m thinking it wasn’t...now I just go yeah okay, rather than no it wasn’t. It doesn’t matter} \] (C12)

\[ \text{That...helped me...I thought yeah, I am allowed to tell a little white lie. (C14)} \]
**Theme 4: I am doing things differently**

The majority of carers gave examples of successful changes in memory aid use, most commonly with notes, diaries and clocks. Carers spent time on activities such as reminiscence books and photographs, as well as enabling their relative to help with family activities and independent self care. Some of these activities were linked to more successful communication.

*I bought the clock, the date clock, it says the day and the month, year and the time and I’m gonna have that up in the kitchen near where she works so she can look* (C06)

*My daughter-in-law went in with the children yesterday. I went in Monday, so I said to mum “look in your diary and you can see who’s been to see you” so all of a sudden that diary’s become helpful and useful for us as well* (C14)

No carers reported unsuccessful activity, though some were still being planned. However, carer descriptions included almost as many reductions in activity as increases.

*If it gets too much, I’ll either go and make a cup of tea or try and do something else or I’ll just say to her “let’s not talk about it anymore then”* (C13)

Carers reduced activity primarily to avoid conflict but also to allow some time for themselves. This still made some carers feel guilty, despite recognition of reduced conflict.

Talking Sense appears to have had a lesser effect on carer pro-active or planned communication than carer communication responses.
(Author) did make some suggestions about things that were sometimes useful like photographs and memory books and certainly the memory box thing I am intending to get underway. I haven’t done it yet, I keep thinking about it (C10)

A smaller proportion of carers reported using proactive communication strategies such as reminiscence and object based conversation, using written and visual media and being selective about subject choice, including omission of information.

Although discussed in the TS programme, examples of using planned white lies were also relatively rare;

I did phone her up and say I’ve got to work late, cover for someone, which I didn’t, but I had an appointment that I wanted to go to. (C13)

The majority of proactive approaches related to simplifying the carer’s expressive language, slowing down, using certain phrases and asking questions differently, primarily to reduce conflict but also to aid comprehension.

Well it’s helped, because we can converse a bit more and he understands a bit more instead of me just rattling on. I realise I’ve got to slow down and take a phrase at a time. (C07)

A few carers reported that proactive approaches identified were unsuccessful. In contrast, response approach changes became one of the major themes reported by most carers. These included not pursuing arguments, walking away, stopping talking, telling white lies and lies of omission and letting the person with dementia do and say things.

I just thought what’s the point of arguing, I just keep quiet about it. (C09)

Carers’ rationale for responses adopted could be summarised as a set of beliefs including “there’s no point”, “the person with dementia can’t help it” and “you
can’t be perfect”. They justified these approaches by suggesting they would cause less stress and upset for their relative and, of less importance, themselves.

Thematic charts suggested that younger carers and carers who were offspring made more changes. Male carers and carers of relatives with higher MMSE (Folstein et al, 1975) scores seemed more likely to report they already knew about communication strategies. Carers with higher engagement and readiness scores were also more likely to report proactive communication changes, response changes and memory management changes.

Thematic charting also identified more reported changes for people with dementia in the non-Alzheimer’s group.

**Theme 5: The experience for the person with dementia and others**

The majority of carers reported improved communication experiences with their relative primarily linked to strategies and conflict avoidance.

Other changes described the person with dementia being empowered, more relaxed, less distressed, less negative, more competent and more orientated, usually attributed to the carer doing something differently.

*There’s no point in debating it with my mother, you could say “sorry mum, I forgot” basically like “silly me”... then she doesn’t get distressed and that’s the main thing.* (C06)

A number of carers reported specifically that they and their relative had an improved relationship following the Talking Sense programme.

*My relationship with (relative) has improved and she is much more able to understand what I’m trying to say and as a response I’m much more aware of what her needs are.* (C11)

One (15) carer reported improved family relationships following the programme.
It’s as much facilitating a better relationship for my husband and my father-in-law as well as me. My husband’s finally got it..... (C15)

The majority of carers shared specific ideas from Talking Sense with others including partners, siblings, friends and neighbours, the primary effect being others helping more practically and in communication activities.

Thematic charting suggested that younger and children carers and carers in the higher engagement group, reported more effects on others.

**Theme 6: How it worked**

For some, the change process was an active, conscious process; for others it was more subconscious;

*They (strategies) do sort of form my jigsaw... they may be only subconsciously there but if I throw a tiff while reflecting afterwards, some of those things will come into play and help me.* (C10)

When asked how it worked, carers talked about a combination of “he” (the author), “it” (the programme), “we” (the carer and author together) and “I” (the carer).

Particular attention was drawn to the author’s use of stories, recent incidents, analogies and personal information used to illustrate a point which seemed to reinforce his credibility.

*He always had an answer .....he used to sort of compare it to something that he’d been through* (C14)

When referring to “we”, carers talked mostly about the discussion and how this made them feel, emphasising that recurrent sessions fixed things in their mind. The feeling of encouragement was frequently highlighted and associated with
the motivation for carers to continue trying new things and maintaining what
they were already doing.

*Because of this conversational style, that led me to a bit of self discovery...*  
*but him (author) saying “you’re doing alright” that made such a*  
difference, I don’t get that from anyone really....to suddenly have  
someone say “actually you’re fine, you’re doing really well”, that was one  
of the best things I think I got. (C15)

When carers talked about “I”, they reported increased awareness and feeling  
enabled as well as active processes like being ready and listening, being open-  
minded and summarising for themselves. Interestingly, a number of carers  
described a positive cycle, whereby successful experiences using techniques  
reinforced belief in themselves leading to confidence and further  
experimentation.

*I remember that I went the next day (to person with dementia) or*  
something and we had a terrible time and I just walked away and sat in  
the bedroom....I felt better for it and I thought “oh that worked”. I just  
came out and....it was all forgotten and I thought “gosh that worked for  
me”. (C13)

As many carers were not aware of the process of setting implementation  
intentions as those who were aware;

*Interviewer: Did it take much planning or thought to put these strategies*  
*into action?*

*I don’t know, I’ve never thought about it that way? You just do it. (C04)*

Carers who were aware of implementation intention-setting reported thinking  
more, including ideas of self-persuasion or “making themselves do it”. Fewer  
talked about an active process of planning. Some developed ideas by talking with
others and looking at further information. Only two were aware that the changes made were driven by their beliefs;

I was sitting there knitting and I thought yeah I could do that. Yes I can, no I don’t, no, do I want to do that and I found it went over in my mind. (C01)

The few comments about aspects of the TS intervention which didn’t work related to the carers’ inabilities or limitations, commonly their own memory problems as well as limited time and other priorities;

I mean personally there’s so much my heads having to cope with and it’s never been terribly good at that. There’s just too much going on really in my head. (C10)

Interestingly, a few carers mentioned that character and previous relationships can make it harder to change the carer and the person with dementia.

5.5 DISCUSSION FOR THE SEMI-STRUCTURED INTERVIEW STUDY

This section provides a discussion for the semi-structured interview study. It starts with an overview of limitations of this specific qualitative study. This concentrates on methodological implications. Themes reported in the results are summarised in a number of key statements which are discussed for generalisability. Clinical and research recommendations are reported in chapter 6. The current section also explains what this study adds to existing understanding.

5.5.1 Limitations of this semi-structured interview study

Limitations of this study are detailed below. Strengths are incorporated into section 5.5.3.

A number of methodological issues are worth critiquing:
5.5.1.1 Saturation
The participants selected appear to be representative of and proportional to the typical population of carers (male: female and child: partner) and people with dementia. The reflective journal and codebook records suggest that analysis of later interviews (12 to 15) did not yield any codes that could not be applied to previous interviews and analysed from existing data. There were no suggestions that new areas of enquiry should be added to the interview guide at this point. Therefore, to this extent, given the original aims of this study, data saturation appears to have been achieved. However, this is not to say that many of the topics identified from these interviews could not be developed in further interview studies (see 6.8).

5.5.1.2 Carer bias in reporting
Some codes e.g. carer meaning, motivation and morality, considered important topics for analysis (Quinn, Clare, & Woods, 2013) but not referred to specifically during the interviews, yielded very few results. This suggested that carers tended to report more about the topics included in interview questions and less about those not specified. It is noticeable that many of the key findings relate to the seven a-priori codes built into the analysis and therefore it is likely that this method, whilst facilitating the interview process, may have biased the results.

5.5.1.3 Third party interviewer
The use of a third party interviewer may have reduced reporting bias as intended, although, particularly at the start of interviews, this choice may have reduced the effect of exploratory questioning due to lack of situational knowledge.

It is worth considering whether the author acting as interviewer (with a different interventionist) using a more open, e.g. grounded theory (Ritchie & Lewis, 2012), approach to interview and analysis would have yielded a less restricted set of themes (see 6.4).
5.5.1.4 Brief intervention period
This study is also limited by using a relatively brief intervention and conducting the interview at only one point in time, allowing for no consideration of longitudinal effect. Additional follow up interviews and comparative interviews with carers from the control group would have added further depth to this study.

5.5.2 Discussion for the semi-structured interview study – generalisability and implications
The research question addressed to carers during these interviews asked what happened to them and their relatives during and after their participation in the Talking Sense treatment. Carers were also asked to consider why this happened. The aims of this study were achieved through the use of a qualitative methodology which used thematic analysis to consider a purposive sample of 15 semi-structured carer interviews.

Key findings from the themes above are summarised as subheadings below and discussed in the same order as the themes. Findings that relate to one of the seven a-priori codes used are marked by “(AP)” in the summary statement. Many of the items discussed lead to clinical and research implications.

5.5.2.1 Expertise
Carers in this study emphasised the value of interventions like Talking Sense being delivered by a credible expert.

Expertise is described as a significant factor in treatment outcome (Betan & Binder, 2010; Eels, Lombart, Kendjelic, Turner, & Lucas, 2005). Betan and Binder (2010) suggest expertise can be developed by exposing novices to diverse cases, examples and explanations, teaching them to generate their own interpretations, reflecting on what they don’t know and engaging in generating their own understanding. Eells et al. (2005) found that expert cognitive behavioural psychotherapists produced more comprehensive, elaborated and systematic formulations and treatment plans than novice psychotherapists.

Comments made about the use of stories, analogies and personal information (in
theme 6) illustrate other therapist related factors such as “therapist credibility” and what Thoits (1995) calls “social comparison” theory. This is the idea that, in a crisis, people prefer to associate with others who have faced comparable situations.

One of the intentions of developing the Talking Sense treatment manual was to compensate for a lack of therapist knowledge by providing a resource of ideas linked to person with dementia difficulties (e.g. VEMAS) and carer needs (e.g. CSES). At this point, these findings could only be generalised to use of Talking Sense by other similar expert therapists. Future research may consider whether novice therapist users of Talking Sense could achieve similar or sufficiently valued outcomes. It is worth noting that Livingston et al. (2013) used novice treatment deliverers, though did not comment specifically on outcomes relating to this aspect of the design (Sommerlad et al., 2014).

5.5.2.2 Cultures of caring

Carers in this study suggested that family carers and professionals come from different cultures and have different support needs.

Levine and Murray (2004) talk about a culture clash between carers and policy makers, driven by differing values. They suggest that this culture gap is particularly noticeable in the areas of communication and especially with “truth telling”. The results of this study suggest family and professional carers should be supported and trained separately. What the results do not tell us is whether Talking Sense could be adapted and used effectively with professional carers. Dementia care professionals should be cautious in taking short cuts to adapt materials. This author would recommend that any communication intervention development and research programmes designed for professional carers should follow the same course of development as this programme, starting with a systematic literature review and incorporating a manual that contains strategies which are evidence based for the professional carer population. Therapists who become familiar with family and professional cultures could potentially help
those cultures to understand each other and in doing so maximise the effective communication that occurs between them.

5.5.2.3 Knowledge retention

**Carers in this study found it difficult to describe knowledge (AP) gained.**

Higher levels of carer knowledge have been linked with significantly lower levels of depression (Losada, Montorio, Knight, Marquez, & Izal, 2006). However, studies have shown specifically that carers of people with dementia exhibit deficits in learning, recall of episodic information and working memory (Harland & Bath, 2008; Mackenzie, Wiprzycka, Hasher, & Goldstein, 2009). Chadwick et al. (2002) found that carers were often able to carry out required strategies from procedural knowledge (actions and what to do), but found it difficult to recall and report this from semantic knowledge (how to describe it and why to do it) which is arguably more difficult to construct. It may be significant that most knowledge gained from the Talking Sense intervention would be abstract or theoretical and, for carers, may contain less familiar concepts and language. Chadwick et al. (2002) conclude that less information is easier to remember. Concrete knowledge may also be easier to describe, which may explain why carers in a similar, smaller scale, study by Barnes (1998) found it easier to report specific recommendations such as “talk about flowers” than more generic recommendations such as to “talk in shorter sentences”. Sommerlad et al. (2014) also identified that carers preferred to gain knowledge gradually. This raises a number of clinical implications about the process of information delivery and carer learning which may have broader implications for carer information provision with comparable groups of carers.

5.5.2.4 Self insight versus insight into others

**Carers in this study appeared to have more difficulty developing self insight than insight into their relative (AP).**

This result may be partly related to the focus of the Talking Sense programme which purposely addresses insight into the person with dementia as stage 3 of the manual (see chapter 3) but doesn’t address carer self insight specifically.
However, difficulties with the development of self-insight are well documented, suggesting these results may be typical for this and similar situations. In a detailed review of the research into self-insight, Dunning (2012) argues that people’s impressions of ability are not closely anchored to their actual level of skill. He suggests that people with lower levels of performance cannot be expected to recognise their inability especially in intellectual and social realms, where the skills needed to perform tasks are the same skills necessary for judging ability. In contrast, top performers are thought to have a fairly accurate view of their own ability though tend to overestimate others’ ability.

Consideration of self insight introduces a number of paradoxes. The expert, therapist and interviewer in this case may tend to over-rate the carer’s abilities. Less skilled carers may also over-rate their ability. If therapists work to increase carer skill and insight, they may reduce the carer’s ability self-rating which may potentially increase their anxiety.

One solution to carer’s difficulty in developing insight may be to provide carer training alongside objective measures such as third party ratings and feedback. However, whilst it may be beneficial, the idea of providing feedback is also fraught with problems. Dunning (2012) suggests that feedback can be incomplete, is often biased and that we have monitoring flaws in the way we interpret it. This topic raises potential clinical and research implications asking whether carer self-insight can be developed and if so, what effects this may have.

5.5.2.5 Changes in feelings

Carers in this study, especially females, experienced changes in feelings (AP).

Monin and Schulz (2009) suggest that carers experience similar emotions in response to care recipient suffering through mechanisms such as empathy, mimicry and conditioned learning. They concluded that women were more likely to experience emotional effects of care-giving because they are better at reading and mimicking non-verbal communication. Mc Donnell and Ryan (2011), in a review of male care-giving, suggest men take a less emotive approach to care-
giving which is more task orientated and focused on problem solving. They suggest that male carers experience less emotional distress and less negative outcomes as well as less burden and strain. The finding of increased changes in feelings reported by female carers appears to be supported by previous research. What is not clear is whether feelings reported were associated with the expert and/or engaging therapist or specific elements of the programme (e.g. CBT). Clinicians should be prepared to consider the importance of carer feelings in this situation and challenged to address feelings for male carers where indicated. Future research would benefit from comparing difference intervention approaches e.g. novice versus expert or knowledge alone versus CBT to consider the relative impact on carer feelings.

5.5.2.6 Guilt versus anger

Carers in this study reported that the feeling of guilt was changed most often and anger least.

In CBT formulations for older people, the presence of guilt is a key schema for depression (Laidlaw et al., 2009), whereas Marquez-Gonzalez and Romero-Moreno (2012) suggest that anger for dementia carers plays a mediating role in the relationship between the appraisal of problem behaviours and depression. One interpretation of this finding suggests that guilt relates directly to what the carer does, whilst anger is a reaction to a combination of person with dementia behaviour and carer interpretation. These interviews suggest that whilst people with dementia changed, the carers changed more in behaviour and thinking. This may partly explain the difference between changes in guilt and anger. The idea of giving “permissions” discussed below is also primarily about guilt reduction. Future research could consider whether this balance between guilt and anger would be influenced by working with the carer and person with dementia together.

5.5.2.7 Improvements in self efficacy

Carers in this study reported improvements in self-efficacy (AP), particularly in what they could do.
Semiatin and O’Connor (2012) describe a positive cycle model whereby enhanced self efficacy leads to greater positive aspects of care-giving which in turn reinforce self efficacy. However, Dunning (2004) as mentioned earlier, is critical of the accuracy of self efficacy in comparison to observer ratings. Despite possible weaknesses, higher self-efficacy has been linked to better health, more social engagement, lower anxiety and depression (Luszczynska & Schwarzer, 2009). If carers are meeting their expectations and believe they are doing well, they may have less burden and be able to care for longer. The finding from this study in combination with previous research raises research implications for measuring changes in self-efficacy over time in a longitudinal study i.e. do improvements in self-efficacy lead to greater adaptability in the future. Self efficacy is explored in more detail in the mixed methods discussion in chapter 6.

5.5.2.8 Changes in thinking

Carers in this study talked about thinking (AP) changes. Carers, especially females, reported significant changes in their beliefs, the majority of which related to communication.

Losada et al. (2006) identified that carers commonly have dysfunctional thoughts in interpretation of their relative’s behaviour, what they should do, their need for support and looking after themselves. Talking Sense appeared to address each of these areas and especially the first two in relation to communication. What these results don’t tell us is whether carers receiving a generic package, in a group setting, or without the active use of CBT, would report the same degree of belief changes.

Losada et al., (2006) also suggest that perfectionism and the need for approval mediate the relationship between stress and illness. Savundranayagam & Montgomery (2010) recommend that carers may benefit from programmes that help them to find a balance between self expectations and their appraisals of their day to day interactions with their relatives. Measuring and influencing carer expectations are also discussed in chapter 6.
5.5.2.9 Permissions

Carers in this study appeared to benefit from hearing credible permissions i.e. knowing that it is acceptable to:

- take time to themselves
- get frustrated
- not always say the right thing
- have times of quiet and inactivity
- walk away to avoid conflict
- use lies of omission and little white lies

The adoption of these beliefs appears linked to therapist credibility and carer expectation. What is not clear is whether these permissions would be so readily adopted by carers seen by novice therapists or from interventions that only developed knowledge and whether these same permissions are as effectively shared between carers e.g. in carer groups.

The Talking Sense manual (Barnes, 2011) refers to carers using lies of omission and what are commonly called little white lies. Culley, Barber, and Hope (2013) produced a set of guidelines for the use of therapeutic lies. In a survey of psychiatrists, they reported that 69% of respondents had used therapeutic lies with someone lacking capacity and 66% had sanctioned the use of lies by family carers. In contrast, Feil and Altman (2004) suggest there is no place for lies in dementia care, even for therapeutic reasons. However Day, James, Meyer, and Lee (2011), after interviewing patients with dementia, found that lying was acceptable in certain circumstances particularly to ensure safety or minimise distress.

The idea of carer permissions raises a number of clinical and research implications. A theory of permissions could be developed in its own right. Future research could consider what effect the source of the permissions has on carer beliefs. More specifically, in the area of communication difficulties, future mixed methods research could explore carer beliefs and expectations about conflict and the use of white lies. This research, which may generate norms e.g. “when
asked, most carers said...,” could be used with carers to help develop permissions. Previous clinical and research implications which have suggested involvement of the person with dementia in jointly addressing communication difficulties to introduce the potential for permissions to be given by both parties e.g. “I’m happy for you to correct me” or “Don’t tell me if it upsets me”.

5.5.2.10 Verbal conflict

Carers in this study reported high levels of verbal conflict, which appeared to be a significant stressor but, was also amenable to change.

Vaddadi, Gilleard and Fryer (2002) in a UK survey of dementia carers, identified that 42% of carers experienced verbal abuse from the care recipient in the last year. Higher rates of abuse were associated with poorer relationships between the families and care recipient. Contextual information and intervention records suggest that many of the conflicts reported in this study were arguments i.e. two-way, between carer and relative and much less often individual verbal aggression as a challenging behaviour. Carers receiving the TS programme were taught to avoid conflict, with the majority employing reactive strategies. This author would suggest that by helping carers to identify their role in the escalation of conflict (i.e. attribution) as well as potential de-escalation and avoidance strategies, carers were enabled to recognise these situations as two-way and not just “challenging behaviour” caused by their relative. This focus on attribution has clinical implications as a therapeutic approach though, more broadly, this research highlights the prevalence of conflict in dementia carer: relative dyads. Future research could aim to develop a mechanism for identifying those most at risk of conflict.

5.5.2.11 Proactive versus reactive communication changes

Carers in this study reported a number of changes in their communication approach, and in particular reactive communication.

Some of the literature for carers distinguishes between proactive and reactive communication e.g. James (2009) who talks about avoiding questions (proactive) and never contradicting (reactive). However, none of the single communication
component studies and systematic reviews detailed in chapter 3 identified a distinction between reactive and proactive communication. Hinton et al. (2007) suggest that much of dementia care is reactive rather than proactive and that this approach extends to all cultures including family carers. Despite known difficulties with proactive change, the carers in this study were encouraged to make these sort of changes. Whilst carers had difficulty explaining the lack of proactive change, one of the explanations may be difficulty with implementation intention setting (see below).

5.5.2.12 Goal and implementation intention setting  
**Carers in this study were able to describe their goal intentions (AP) i.e. what they intended to do, but not their implementation intentions i.e. when, where and how (Connor & Norman, 2009).**

Connor and Norman (2009) suggest that implementation plans benefit from cognitive rehearsal which may have been limited in this case by a relatively short intervention. Despite difficulties with implementation intention setting, this author suggests that for some interventions, especially for proactive changes, helping carers to set implementation intentions e.g. “how are you going to go about this?” will improve outcomes. The interviews also suggest that follow up sessions allow for a checking or reminding process. This has clinical implications for including implementation intention setting and progress reviews as part of therapy. Interestingly, none of the previous studies detailed in the systematic review (chapter 3) made reference to purposive implementation intention setting with carers. The role of implementation intention setting in psychosocial interventions may also benefit from further research.

5.5.2.13 Individualisation  
**Carers in this study seemed to prefer an individualised approach.**

This may account for what is interpreted as a relatively high success rate in employing memory aids, a general satisfaction with timing of delivery, satisfactory increases and decreases in activity and the ability to communicate key strategies to others in a more generic way. Harland and Bath (2008) suggest
that generic or “best information” does not exist. They describe a carer as a complex individual who actively integrates new information and constructs knowledge in unique and individual ways. Individualisation also influences achievement of what is clinically significant as this varies from carer to carer and over the course of their care-giving career (Rockwood & Gaulthier, 2006). The individualisation process appears to be more than just tailoring advice to need and circumstances. It is also about identify carer coping and learning style, the extent of seeking behaviours, related dysfunctional thoughts, relationship between knowledge and anxiety, and information needs now and in the future. Although providing individualised advice sessions may be more costly, some studies suggest it is cost effective resulting, for example, in reduced reliance on other services over the longer term (Knapp et al., 2013). Therefore, whilst this study seems to support the value of an individualised communication intervention, future research in this specific field would warrant conducting cost effectiveness comparison between individualised and generic approaches. If individualised approaches could be further supported, this may serve to protect flexibility in delivery of clinical services.

5.5.2.14 Changes in the person with dementia and others

**Carers in this study reported changes in many of their relatives. Some reported changes in relationships and others reported beneficial influence over other people.**

This study demonstrated how indirect interventions with a carer can have an effect on others. However, some authors argue that this area of research is too focused on the individual carers’ perspective and misses what the person with dementia experienced (Purves & Phinney, 2012; Ablitt, Jones, & Muers, 2009). Interestingly, Graham and Bassett (2006) found that people with dementia demonstrated they could still experience shared meanings and maintain reflexivity late into the illness. When carers were recruited to this study they were not promised any benefit, but where the potential for benefit was mentioned it was primarily focused on the carer. Future research and clinical interventions in this field may wish to consider the extent to which expectations
formed at the outset, focus on just the carer or include the person with dementia.

Care-giving for a relative with dementia has also been associated with conflict in the wider family (Etters, Goodall, & Harrison, 2008). Alm, Hellzen and Norbergh (2014) describe not only changed relationships between family members and the person with dementia, but also between parents and siblings. Balkanska (2012), in a study of communication problems in 178 families of people with dementia, suggest that communication problems within the family are directly and primarily related to communication difficulties demonstrated by the person with dementia. Both authors recommend that dementia care professionals should be supporting carer families by enabling conversations about all of the communication difficulties that are occurring. Therefore, it would seem that we should consider not just person, but relationship (O’Shaughnessy, Lee, & Lintern, 2010) and even broader, family centred care. However, this raises not only ethical research challenges but realistic clinical cost issues. Policy makers, hopefully influenced by family carers, will need to consider where time is best spent in providing support services. This highlights the importance of service providers understanding the needs of carers, people with dementia and their families as a whole and individually.

5.5.3 Interpretation - What this semi-structured interview study adds

The qualitative literature for single component communication specific psychosocial interventions with dementia carers is limited. This study represents the most in depth qualitative enquiry yet published in this field. It provides significant depth into not just the effectiveness of the Talking Sense intervention, but the mechanisms of action at play between the intervention, the therapist, the carer, the person with dementia and even their wider family. This study has also provided insight into which carers are more likely to benefit from this form of intervention and support to justify the effectiveness and use of individualised interventions in clinical settings.
Unsurprisingly, all carers involved reported difficulties with communication though what they referred to as verbal conflict was unexpectedly prevalent.

From this intervention, carers were able to identify significant changes made in thinking, feelings and behaviour which for most extended to their relative and for some, other family members. There is some indication that using an individualised approach enhanced this success. Practical changes led to more successful communication, though not necessarily more time spent talking. Changes in feelings of guilt and the use of mantras for changes in thinking were also particularly noticeable.

A number of challenges were uncovered: challenges with demonstrating change in carer knowledge, understanding the complexities of self-insight for both the carer and professional, and establishing proactive changes and conscious implementation intention-setting. Raising these issues has the potential to enhance clinical practice and future research.

For mechanisms of action, this study supports the idea that approaches using a CBT and self-efficacy framework can be effective. Far less evidence supported the process of implementation intention setting. The results indicate a complex interplay between history, context, difficulties, approach, feelings, thinking, behaviour and expectations.

There was some indication that female carers were more able to identify thoughts and feelings though perhaps this is best interpreted as an illustration of the significant differences between carers. The study also illustrates the differences between professional and family cultures of care-giving and as such emphasises the importance of not just person-centred but relationship and family centred care.
6 Chapter Six: Mixed methods analysis and final discussion

This chapter contains three main components; the mixed methods analysis, the mixed methods discussion and the discussion of this programme of research. These components are divided into eight sections. The first two sections detail the mixed methods analysis, results and key topics discussion. The third section aims to summarise the overall programme of research. Following this, two further sections consider theoretical and methodological implications from this overall programme of research. A further section then summarises the main strengths of this programme of research. The final two sections provide a detailed breakdown of clinical and research implications and recommendations based on the discussions in this and previous chapters.

6.1 Analysis of Mixed Methods Data

This section integrates and discusses the results of the two research studies (chapters 4 and 5) using a mixed methods analysis. The rationale for using mixed methods is first described in chapter 3 with mixed methods aims detailed in a mixed methods statement (see 3.2.2).

O’Cathain et al. (2010) and Lewin et al. (2009) suggest there is often a lack of integration between methods when research is reported. This programme of mixed methods research has followed recommendations for data integration described by Cresswell and Plano Clark (2011):

A concurrent data analysis was conducted which involved;

- Separate initial data analysis on quantitative and qualitative data (see chapters 4 and 5)
- Merging of the two data sets using matrices. This involved;
  - Identification of complimentary content areas represented in both data sets
  - Identification of differences between data sets including conflicting or absent data
Comparison and synthesis of results into a discussion

Some authors attempt to transform or convert data e.g. qualitative into quantitative (Creswell & Plano Clark, 2011). This approach was not considered because of differences in sample and research paradigm and subsequent effects on validity (see 6.1.1).

O’Cathain et al. (2010) talk about “following threads”, where issues identified from one method are used to inform the method or aid interpretation of the results of another. The effect of this will depend on the respective order of each approach. In this programme of research, there was a short period when quantitative results were available prior to completion of the qualitative interview study. Consequently, questions were adapted during the semi-structured interviews to take into account early quantitative findings. For example, early quantitative analysis suggested a likelihood of significant changes in carer reported person with dementia communication competence (CCS) which led to the inclusion of a question relating to communication competence in the interview schedule. The potential for developing this approach, particularly around the timing for each method, is discussed in the research recommendations below (see 6.8). Limitations to this method are discussed in section 6.5.

6.1.1 Validity, legitimation and integration

Mixed methods research may appear to be an attempt to determine concurrent validity. Concurrent validity is demonstrated when a test correlates well with a measure that has previously been validated (Bowling, 2009).

Onwuegbuzie and Johnson (2006) argue that in some instances the threats which limit validity are exacerbated when developing meta-inferences for mixed methods research. They refer to this as the problem of integration. They also propose that mixed methods researchers use the term legitimation in place of the more quantitatively orientated term validity. Included in the integration debate is the extent to which findings from different size samples can be combined and the respective weight that should be applied to each finding.
To consider the legitimacy of mixed methods conclusions, Onwuegbuzie and Johnson (2006) suggest authors consider legitimation types, four of which are detailed below:

**Sample integration** - the extent to which relationships between samples yield quality meta-inferences. In this programme of research, the smaller qualitative sample is theoretically representative of the treatment group in the pilot study, which is in turn representative of the carer population. However, it should be remembered that many of the qualitative findings are attributable to a majority and not the full sample. In respect of quantitative data, where statistically significant results have occurred because of changes in both treatment and control groups, it should also be remembered that the control group is not represented in the qualitative sample.

**Weakness minimisation** - The extent to which weaknesses from one approach are compensated by the strengths from another. When considering outcome measures, it can be argued that the broader reach of qualitative enquiry in the semi-structured interviews has compensated for the limited focus of quantitative outcome measures. In this programme of research, the use of a proportion of a-priori topics and codes in the qualitative study has also allowed for more direct comparison of results which has enabled mixed methods analysis at the potential cost of limiting the range of enquiry.

**Sequential** – the extent to which meta-inferences could be affected by reversing the sequence of data collection. This threat is least prevalent in concurrent as opposed to sequential or other mixed methods designs. In this study, early quantitative results e.g. changes in communication competence, did influence the focus of the interviews though this allowed for more direct integration of results which otherwise may not have been possible.

**Conversion** – the extent to which qualitising or quantitising has influenced meta-inferences. Direct conversion was avoided for this reason, though as already mentioned, the use of descriptive terms e.g. majority does not allow for weighting of results.
The meta-inferences made below are initially based on the assumption that results from both strands of this programme are equally weighted. This is considered to be the most likely threat to the legitimacy of these results. Therefore, the discussions that follow include consideration of the relative merit of each strand with particular emphasis on the relevance and accuracy of the questions asked/concepts measured (see 6.2.3; 6.2.4; 6.2.5).

6.2 MIXED METHODS RESULTS AND DISCUSSION

The following section describes, by discussing key topics, the results of the mixed methods analysis detailed above.

6.2.1 Depression and anxiety

The HADS baseline score did identify a higher than normal rate of anxiety and depression amongst carers in this study. However, the pilot study identified no significant mean difference in the HADS outcome score for anxiety or depression between groups. The interview study yielded few specific references to either the existence of or changes in depression or anxiety. Taken together, these findings would appear to support the finding that anxiety and depression remained unchanged for carers in the treatment group.

However, the interviews did highlight frequent reports of reduction in carer’s guilt, burden and stress alongside feelings of increased positivity which were not specifically reflected in the quantitative outcomes. Using the interview schedule (see Appendix 29), carers were asked to describe how the intervention made them feel. It is possible that carers found it harder to use words such as depression and anxiety because of the clinical or more personal nature associated with them. For example, one study, Edwards, Tinning, Brown, Boardman and Weinman (2007), found that people with mental health problems were reluctant to refer to depression when seeking help, primarily because it was perceived as a chronic condition. It may also be that carers tended to consider depression as something that required and was confirmed by treatment, which only 21% of the total sample admitted to at outset. It is also unlikely that a significant number of this relatively small sample of carers
receiving treatment for depression discontinued this, typically long term, treatment during the short period of their involvement in this study.

To consider the effect of interventions on depression and anxiety, future mixed methods research could include more specific reference to these terms in the qualitative strand, though consideration would need to be given to the order of each strand in order to minimise influence on completion of the quantitative measures. Given the higher prevalence and acceptability (Edwards et al., 2007) of anxiety (44% in the pilot study) in comparison to depression (22%), more specific discussion of anxiety may be warranted.

### 6.2.2 Quality of life

In the pilot study, the results of the ACQOL scale identified one statistically significant change, for the treatment group, in the subcategory of *value*. Overall quality of life was not significantly different. In the interviews, the majority of treatment group carers valued an approach which was designed specifically for them. Whilst the words match, with both studies suggesting that carers felt valued, examination of the ACQOL questions show that value in this context is referring to feeling valued by the person with dementia (not the therapist). Therefore, the ACQOL result may be more closely allied to the interview carers who reported that they and their relative had an improved relationship following the Talking Sense intervention. Beyond this, the interview data does not appear to be any more specific about carers feeling more valued by their relative.

Looking in more detail at the ACQOL components (support, choice, stress, money, growth, value, ability, satisfaction), the interviews would also appear to provide support for improvement in aspects of “personal growth” even though the quantitative results for this element were not significant (*p*=.571). The interviews also supported increased ability which is discussed in the self efficacy section below. The ACQOL relates personal growth specifically to tolerance, self-insight, personhood, positives of caring and being a better person. In the interviews, one carer described “changing into another (better) person” and another described a process of “self-discovery”. Alternatively, the interviews also
highlighted the difficulties that carers experienced in gaining self insight. However, one of the most significant areas of carer personal growth described in the interviews was interpreted as increased tolerance.

In other qualitative research, Elvish, Cawley and Keady (2013) identified examples of personal growth amongst carers of people with dementia engaged in psychotherapy. In particular, they identified growth occurring as a consequence of loss e.g. having to make more decisions themselves and taking on new roles leading to increased self confidence. They associated this with the idea of post traumatic growth. Barskova and Oesterreich (2009), in a review of post traumatic growth for people suffering from a serious medical condition, also identified associations between positive growth and a number of factors including reduced anxiety and increased social support. Barskova and Oesterreich (2009) also identified that the majority of studies found younger and female persons more likely to experience post traumatic growth.

One conclusion would be to suggest that, of the quality of life dimensions suggested for the ACQOL, value and growth are those most likely to have been affected by Talking Sense. Future research could measure value and growth more specifically using quantitative and qualitative enquiry. However, for comparison with other research, it would be more beneficial to continue measuring a broader construct such as quality of life.

Some mixed methods sequential designs include qualitative strands at the beginning of the research programme which are used to help develop outcome measures or theoretical mechanisms of action (Cresswell & Plano Clark, 2011). One recommendation for future research (summarised in 6.8.3) would be to first establish what carers mean by communication specific quality of life and develop a measure to identify changes in this. This may remove the diluting effect of elements such as money and other forms of support. One other aspect of this preliminary research might also be to consider differences in values and expectations between sub groups of carers (Barskova & Oesterreich, 2009).
6.2.3 Self efficacy

The “happens” results of the CSES suggest that carers in the treatment group perceived or experienced significantly fewer communication difficulties after participating in the Talking Sense intervention. This reduction in communication difficulties is supported by the majority of carers in the interviews (theme 5). Carers attributed this to changes in their own, mostly reactive, behaviour and that of their relatives. This provides a good example of results triangulating to support the idea that the Talking Sense intervention had a significant effect on the reduction of communication difficulties experienced by these dyads. This effect could have been further supported if the interview study had also included carers from the control group with the hypothetical expectation that they would have described less change in communication difficulties experienced.

The CSES “manage” score, a measure of communication self-efficacy, showed no significant difference. Similarly, there was no significant difference in the GSES score. However, the interviews suggested carers were experiencing improvements in what was interpreted as self efficacy, in particular with regard to what they could do (theme 2). These descriptions included many of the situations described in the CSES as well as a number of more general carer self efficacy issues such as planning, decision making, feeling and thinking positively, managing verbal conflict, making proactive changes, being communicatively competent and open-minded.

Moffatt, White, Mackintosh and Howel (2006) provide a framework for evaluating mixed methods research where the quantitative and qualitative results do not agree. One element of their framework suggests researchers consider whether the outcomes match i.e. if they are asking the same question. Taking this into account, there do appear to be marked differences in the way the two strands considered self efficacy. The CSES and GSES ask relatively passively how well the carer believed they would manage in specific communication situations and general life respectively. The interviews, more actively, asked if the carer was doing anything differently.
Given that self efficacy is central to the theoretical mechanisms of action for Talking Sense, it is important that it is measured most closely to its definition of “belief in one’s ability to manage in a particular situation” (Bandura, 1977). Taking this into account, the CSES would appear to be the more accurately focused outcome, with the interview data tending to mix action in with belief.

Taking this into account, these combined results do not appear adequate to support the idea that self efficacy, in its most specific sense, changed for the carers in the treatment group.

Despite the lack of a significant “manage” result, the CSES has demonstrated its usefulness as a valid tool and potential as a clinical outcome measure. It would also appear to have potential as a tool for directing individualised interventions. Future research may wish to consider whether CSES “manage” scores would yield a significant difference if the individualised interventions were more closely driven by carers’ initial reports of “manage” difficulties.

6.2.4 Communication competence

The CCS total score was close to significance in favour of the treatment intervention with a moderate effect size. Between groups visual comparison of the outcome data suggested a trend whereby carers in the control group appear to consider their relatives less competent, whilst those in the treatment group, appear to consider their relatives more competent.

The suggestion of improvement in treatment group person with dementia communication competence is supported by the interviews (theme 5) where persons with dementia were described as being empowered, more relaxed, less distressed, less negative, more competent and more orientated. It is important to remember though, that the interviews were influenced by early quantitative findings when a specific question on communication competence was added.

Comparison between methods suggests that the concept of competence in the CCS is more specifically focused on communication. Many of the interview descriptions of competence relate to communication though could equally relate
to other functions e.g. activities of daily living. It is also important to point out that the interviews did not include control group carers to determine if they were any more or less competent.

Both strands of this programme of research provide some support for changes in competence though this may require further research and definition. Like communication self efficacy, communication competence is a complex concept and perhaps easier to identify in a defined quantitative measure than a more open and subjective interview. To consider this further, future research may also wish to target the intervention towards specific difficulties with competence, interview control group carers and include more specific definition of communication competence in the interviews.

In previous research on communication competence, Rubin, Martin, Bruning and Powers (1993) suggested that self efficacy mediated the effect of experience and perceived situational difficulty on interpersonal communication competence. Koesten (2004) also identified a relationship between communication competence and family history, sex of carer and sex of relational partner suggesting that future research could also consider differences in perceived communication competence by carer and person with dementia sex.

These issues raise a number of other potential avenues for research in considering the relationship between communication competence and self efficacy. Returning to 4.4.3.7, what this mixed methods analysis does not tell us is whether carers were themselves any more communicatively competent. Future research could employ more direct methods (e.g. observation) to determine this and in doing so consider the relationship between perceived and observed competence.

6.2.5 Engagement and readiness

It is worth noting that the interviews did not yield any data that can be linked to engagement (TEI) most probably because the interviewer focused on the effect of the intervention rather than the relationship between the carer and the therapist.
However, the pilot study did identify increased readiness (to change) in the treatment group, by the final session, in comparison to the initial session and the control group. The interviews suggest that this change in readiness was less likely to be related to implementation intention setting. Future research may wish to consider the value of Talking Sense being delivered by other groups of interventionists e.g. psychology graduates (as in Livingston et al., 2013), in which case researchers may wish to consider if perceived therapist “credibility” and “expertise” are maintained and the extent to which they are related to engagement and readiness.

6.2.6 Changes in the person with dementia
The intervention in this study was delivered to carers with the expectation that they would be the principal beneficiaries. The analysis and discussion above highlights that in many ways, changes in and benefits for their relatives with dementia were equally, if not more, significant. These changes occurred primarily with a reduction in communication difficulties occurring and increase in communication competence but extended to less direct ideas like valuing the carer. This is a very encouraging result which highlights the complex inter-relationships between carer and person with dementia behaviour, thinking (beliefs) and feelings. It has already been suggested that people with dementia should be more involved in future clinical work and research e.g. with the identification of difficulties, delivery of the intervention and measurement of outcomes. This concept is expanded in the research recommendations below.

6.2.7 Additional data without comparison
Comparison of the quantitative and qualitative strands of this programme of research has identified areas where findings can be combined. All of the quantitative outcomes have been considered, leaving a wide range of qualitative findings unmatched. This mismatch appears primarily due to differences in research questions. The pilot study asked whether certain specified outcomes were significantly different, whereas the interviews asked what happened and how. Elements from the interview data lend themselves to further enquiry to consider their place in explaining the process of change. In particular,
consideration of section 5.5.2., suggests that future mixed methods research could aim to explore positive change in feeling and thinking, both of which are closely associated with the CBT component of the Talking Sense intervention.

6.2.8 What the mixed methods analysis and discussion adds

This section considers only what the mixed methods analysis has added to this programme of research.

The mixed methods analysis has yielded a number of valuable conclusions which are detailed above. It is suggested that the mixed methods analysis has supported the rationale for using mixed methods described in chapter 3, including corroboration of findings, offset of strengths and weaknesses, a greater understanding of process, greater credibility of findings, examples of context and illustration (Greene, Caracelli & Graham, 1989).

The analysis has highlighted the value of qualitative research methods by showing the depth and range of data it produces. However, attempts to compare results have also highlighted the value of quantitative outcomes in maintaining a tighter definition of complex abstract concepts such as self efficacy and communication competence. Future research may benefit from sequential methods that use qualitative enquiry to define concepts e.g. communication anxiety and depression or communication quality of life, then quantitative outcomes to determine change in these defined concepts.

The analysis has also highlighted some of the difficulties in fully integrating data from two research paradigms which used related though different research questions. It has also highlighted some of the weaknesses of each research approach and the potential for future research. The analysis has demonstrated the difficulties of working with constructs such as “quality of life” and even words such as “value”, suggesting that these need defining, ideally by participants or those closest to them, prior to the intervention evaluation phase of research. This suggestion could lead to a sequential, qualitative first, mixed methods design for future research.
6.3 SUMMARY OF THIS PROGRAMME OF RESEARCH

This programme of research set out to answer the question “Does Talking Sense work?” Each chapter and study has contributed different parts of the answer to this question. Hereafter, this chapter aims to draw together an evidence based answer.

The introductory chapter of this thesis highlighted the high prevalence of dementia and associated communication difficulties focusing on the experience of family carers. Examples of previous research illustrated what carers do, feel and think as well as the nature of communication difficulties in dementia. Data from later chapters (2, 4, 5 and 6) complimented these descriptions.

The systematic review followed established protocols and recommendations from previous reviews to identify a core of eight controlled studies that had evaluated single component psychosocial communication interventions with dementia carers. The design, intervention and results from these studies were discussed in a synopsis and synthesis. The conclusion of this discussion suggested that this form of intervention was most likely to affect carer knowledge, self-efficacy and experience of communication difficulty. A theory of change pathway was also developed which introduced the idea of levels of effect. When compared to an overview of systematic review findings for more general multi-component psychosocial research, recommendations were made for psychosocial interventions. Clinical recommendations called for interventions that were delivered one to one, individualised and manual-based, focused on self efficacy and insight development with interventions addressing a combination of knowledge, skills, thinking and behaviour. Research recommendations included a mixed methods design, the use of valid and reliable outcome measures as part of a high quality RCT and a concurrent high quality qualitative interview study.

The Talking Sense intervention was developed prior to this programme of research. This intervention met the clinical recommendations detailed in the systematic review. Theories for delivery of Talking Sense focused on self efficacy and cognitive behaviour therapy whilst theories of effect for the Talking Sense
intervention focused on engagement, threat appraisal and severity, control and implementation intention setting.

**A mixed methods design** was chosen to evaluate the benefits of the Talking Sense intervention, by bringing together the strengths of quantitative and qualitative enquiry, and identifying where data converged, contradicted, illustrated and explained findings. This approach was in keeping with recommendations for evaluating complex interventions (MRC, 2000).

**The pilot randomised controlled trial** was identified as the most rigorous quantitative research method. The trial was designed and reported in keeping with the CONSORT (Moher et al., 2010) guidelines. Outcome measures were selected from and for comparison with previous research and from recommendations in key literature. This included a primary outcome measure of depression and anxiety using the HADS (Zigmund & Snaith, 1983) selected, in part, for comparison with a contemporary UK dementia study (Livingston et al., 2013).

The RCT was considered to be a pilot study primarily because of previous experience of feasibility and limitations in sample size. After ethical approval was given, the trial recruited 55 of 60 expected carers over a period of 18 months. The recruitment rate and carer characteristics were comparable to the recruits from the Livingston et al. (2013) study.

The Talking Sense intervention was delivered by this author over three, one hour, one to one, sessions. The control group intervention involved a one hour one to one discussion with this author avoiding reference to Talking Sense and focusing primarily on knowledge.

A low attrition rate (5.5%) and high adherence to intervention rate (100%) suggested that the intervention and trial participation were feasible.

The results of the RCT (n=52) compared mean difference between groups with 95% significance. There were no statistically significant results for measures of anxiety and depression, general self efficacy, communication self efficacy, or
Overall quality of life. There was a significant difference for carer reported communication difficulties and for the value subscale from the ACQOL quality of life scale. A score close to significance (p=.052) with a moderate effect size was identified for proxy rated person with dementia communication competence. The treatment group also demonstrated a significant increase in engagement and readiness across the three contact sessions.

The clinical significance of these results is partly illustrated by comparison with the qualitative data in the mixed methods analysis, though does warrant further consideration.

Within the Pilot RCT, a newly developed measure of communication self efficacy, the CSES, was developed and shown to have evidence of internal and external reliability.

A semi-structured interview design, using a third party interviewer, was chosen to compliment the results of the pilot study and consider more specifically how the Talking Sense intervention might work. Very little qualitative research has been published in dementia carer psychosocial research. Fifteen carers were purposively selected. Data saturation was considered achieved.

A rigorous process of qualitative analysis using a framework approach identified 6 key themes. Aspects of these themes were examined to highlight difficulties carers had with verbal conflict, knowledge retention, insight development, proactive strategy use and implementation intention setting. Carers described the importance of expertise, the family carer specific caring culture, individualisation and permissions. The main effects of the intervention described were changes in carer thinking and feeling, changes in action and changes in their relative with a reduction in communication difficulties between them.

The mixed methods analysis, described above, did not support the idea that anxiety and depression and quality of life as whole constructs changed for carers in the treatment group. However, it did support that idea that these carers perceived fewer communication difficulties happening and provided some
support to the idea that their relatives had increased communication competence. Most noticeable from this analysis, was the emphasis on changes in the person with dementia (competence, communication difficulties and carer value) identified. This perceived change in communication difficulties is identified as the key outcome from this programme of research.

6.4 THEORETICAL IMPLICATIONS

Previous chapters (4 and 5) have drawn comparisons between findings from the quantitative and qualitative threads of this programme with existing literature. The following section makes a broader comparison between existing literature and this programme of research as a whole.

6.4.1 Comparison of findings to the systematic review

In the systematic review (chapter 2), the synthesis of communication specific psychosocial studies identified the most common significant outcomes as improvements in carer knowledge, carer self efficacy and carer reported communication difficulties. This programme of research found similar outcomes in reported communication difficulties but not in self efficacy.

Carer knowledge was not chosen as an outcome measure for this programme of research as previous studies (e.g. Chadwick et al., 2002) suggested it was poorly related to actual change in carer behaviour. This programme of research (chapter 5) also showed that carers experienced difficulty recalling their learning, which suggests that at least the 15 carers in the carer interviews may also have had difficulty demonstrating improved knowledge on a quantitative outcome scale. What is not known though is whether the carers in this programme of research had the same level of difficulty developing knowledge as carers involved in similar interventions or studies (e.g. FOCUSED used by Ripich et al., 1999a). For this reason, future research using the Talking Sense intervention would benefit from also measuring carer knowledge.

Revisiting the systematic review highlights that previous studies identified a higher proportion of statistically significant outcomes than the pilot randomised controlled trial in this programme of research. As a pilot study, the intention of
the RCT strand of this programme of research was to identify trends and not necessarily significant outcomes. However, the RCT in this programme (chapter 4) is comparable, in size and quality, to the majority of the studies detailed in the review (chapter 2) and therefore this difference is worth considering. Explanations for this effect could include:

- Previous interventions were more intense and or more effective
- Previous outcome measures were more sensitive to the specific effect of the intervention
- Previous studies were less reliable and more open to bias
- Previous studies used less selective methods of statistical analysis e.g. parametric test were used with non-parametric data

In most cases, it seems unlikely that this effect, in comparison to other studies, could be related to the size of the population since although this was a pilot study, it had more recruits than any other study except McCallion et al. (1999). It is possible, that previous studies have included a more suitable population (e.g. more impaired or responsive). Unfortunately, carer characteristics were rarely reported in sufficient detail in other studies to make a comparison.

Despite being of similar size to previous studies, comparison with Livingston et al. (2013) and power calculations for use of the HADS (Zigmund & Snaith, 1983), suggest that outcomes from the Talking Sense study could be better determined with a larger population (see 4.4.1.1) and a more intensive intervention.

This study is of at least equivalent quality to previous studies. Therefore, it seems likely that some of the difference between the results of this and previous studies is related to the use and interpretation of outcome measures. Comparison with Livingston et al. (2013) in this thesis has demonstrated that a good way to compare interventions is to use similar design and outcomes. Therefore, future research could compare Talking Sense with one of the interventions detailed in the systematic review e.g. Ripich et al. (1995), matching intervention intensity and outcomes, though the use of well established outcome measure tools and rigorous analysis remain essential.
6.4.2 Comparison to other mixed methods research

Few studies have been published as mixed methods research in the field of dementia care (Robinson et al., 2011; Morgan & Stewart, 2002). Robinson et al. (2011) suggest that researchers may be conducting mixed methods research, but only publishing single elements with very little if any integration of findings. One reason for this may be publication word limitations. Livingston et al. (2013) (see section 2.4) is part of a mixed methods study published in four separate articles with little integration of data. In the case of the Livingston group’s research programme, it could be said that the evaluation was weighted towards the RCT with less emphasis on the qualitative component which was a brief self-completed structured questionnaire (Sommerlad et al., 2014). This illustrates the point that where data is compared and converged, it should be of similar quality.

In another example, George, Stuckey and Whitehead (2014) applied a sequential mixed methods design, with qualitative methods used to explain quantitative findings, for a creative story telling intervention between medical students and people with dementia. Their use of qualitative data adds depth of understanding where results compliment, but makes no attempt to consider where they don’t. There is also relatively little description of the methodology and no discussion of its limitations.

Two further examples provide an interesting contrast: George (2011) provides an example of mixed methods in a study that evaluated an intergenerational (people with dementia with young children) volunteering intervention. They combined outcome measures from an RCT with structured and semi-structured interviews before, during and after the intervention as well as description from participant observation. Unsurprisingly, the study yielded rich qualitative data, though with only one significant quantitative outcome it provided limited opportunities for convergence. This combined evidence suggested that this activity could reduce psychological stress for people with dementia. Their conclusion said much about the benefits of mixed methods data analysis though highlighted the challenges, not least the cost, involved in conducting such a complex study with a relatively challenging client group.
In the only identified example of a published mixed methods dementia carer study, Greenwood and Habibi (2014) evaluated a carer mentoring service by conducting both self-completed questionnaires (anxiety, depression, quality of life and confidence in caring/self-efficacy) (n=25) as well as unstructured in-depth interviews with a purposive sample (n=11). They also used the HADS for a primary outcome measure (Zigmund & Snaith, 1983). In this case, volunteer mentors provided emotional and practical support to carers for between 6 to 24 visits. The mentors, mostly former carers, were trained and supervised regularly. However, there was no control condition. Comparison was made between baseline and completion of mentoring. In contrast to George (2011), they identified significant results (p<0.05) for all outcomes. This inevitably made integration of data easier though led to a wider range of options when attempting to explain, with the qualitative data, the possible mechanisms and facilitators of change. The use of mixed methods in this study, the qualitative data in particular, was also valuable in defining what would otherwise be a relatively unspecified intervention. The data from the study would also be invaluable in training future volunteers and establishing similar services in other locations.

6.4.3 Theory of change pathway and levels of effect
Reflecting on the theory of change pathway identified as part of the systematic review and detailed in Figure 2-3, this programme of research appears to have delivered an intervention which caused:

Difficulties with;

- knowledge recall (level one effect)
- influencing anxiety and depression (level two effect)
- influencing general self-efficacy (level two effect)
- influencing self insight (level two effect)
- influencing communication specific self-efficacy (level two effect)

Probable changes in;
Bearing in mind that this figure (2.3) was influenced by the results of the systematic review, the majority of elements it describes have been considered in this programme of research. This comparison appears to suggest that effects are perceived, can be demonstrated or achieved at the more distant levels i.e. 3 and 4. In many ways, the effects at these more distant levels appear more prevalent.

Compared to the theory of change model (Anne E. Casey Foundation, 2004), these findings would appear to suggest that distant (lower level) outcomes can be measured, but that at all levels, the most sensitive outcomes are those specifically designed to measure the expected effect. Future research would benefit from developing this model further by focusing particularly on these more distant levels to further determine whether interventions with carers can change perceived and/or actual person with dementia behaviour.

6.4.4 Mechanisms of delivery and effect
The proposed theoretical mechanisms of delivery for Talking Sense (see 3.4.1) are based on the premise that accurate knowledge development through multi-modal learning (Dale, 1969) informs all other steps.

Theme 6, how it worked, of the semi-structured interviews suggests that learning predominantly occurred through discussion and verbally presented information. Very little reference was made to the materials used in Talking Sense and none to the use of role play, which reflective records suggest was difficult to achieve. This raises a clinical and research implication to consider the development of role play (see 6.7.1) in the context of the home intervention setting and whether this can be facilitated by a more practiced interventionist. Whilst the role of the
deliverer i.e. as a credible expert is important, future research could also address this question of materials by asking “what is the most effective way of delivering Talking Sense”. In doing this, comparison to materials from similar studies e.g. Ripich et al. (1995) and other fields would be valuable.

Proctor, Martin and Hewison (2002) suggest that more knowledgeable carers can be more anxious. Bunn et al. (2012) describe studies where some carers and people with dementia are unaware of their resistance to acquiring new knowledge which acts as a subconscious coping strategy and means of preserving identity and autonomy. Whilst it may prove difficult, future research could also explore whether carers are unwilling or unable to recall information from both a cognitive ability and coping capacity perspective.

Theories for delivery also focused on the development of mindfulness, self-efficacy and the use by the therapist of encouragement (see section 3.4.1). The quantitative results provide no specific support for these theories except for the absence of significant findings for changes in self efficacy. Evidence for the development of mindfulness is seen in the interview study theme 3, *it made me think*. What is not clear is whether the control group carers were similarly prompted to think. Carers reported thinking more, though one element missing from this was development of their own self-insight (see 5.5.2.4). As for encouragement, when asked how the intervention worked (see theme 6), carers talked about the effect of the interventionist but did not emphasise the feeling of encouragement. What they did emphasise though was what was later described as permissions (see 5.5.2.9) which could be interpreted as encouragement that what they were doing or thinking of doing was acceptable and normal. This suggests that the principle of encouragement should be redefined to focus on permissions. The focus on self efficacy and mindfulness remain valuable, though an additional element of developing carer self insight would be a worthwhile addition to this theory.

One of the key elements of Talking Sense delivery is the CBT model (Wells, 2008). Clinical CBT takes a range of formats, many of which extend beyond that
provided in the three session Talking Sense intervention used in this study. Westbrook et al. (2008) include in a definition of CBT, elements such as Socratic dialogue and a focus on beliefs and assumptions which were included in step 3 of Talking Sense. They would also include the use of formulations and homework which were used in only a limited way in Talking Sense. CBT, whilst typically time limited, is generally carried out over more than 3 interventions (Wells, 2008). Rather than asking “does Talking Sense represent and support CBT”, a more useful question to consider is whether adding a focus on thinking, based on the association between thoughts and behaviour, was more effective than the alternative of a unidirectional exchange of knowledge. The results of the qualitative study in particular (see 5.5.2) would suggest that carers were thinking, feeling and doing things differently more than they were able to demonstrate a change in knowledge. Further observational research and interview data gathered from a knowledge only control group would also confirm whether this form of intervention changes carer’s perceptions, people with dementia behaviour or both.

Taking all of this into account, it is suggested that CBT should remain at the centre of the theories of delivery for Talking Sense. If future clinical and research revisions increase the intensity of the intervention, then more in depth CBT could be justified. One element that should be added to the typical expectations of CBT in Talking Sense is an emphasis on considering feelings as well as thoughts. Future users of Talking Sense would be well advised to be aware of the importance of carer feelings (see 5.5.2.5) and in particular those feelings which are more difficult to address e.g. anger.

Section 3.4 introduced a number of theoretical mechanisms of action proposed during the development of the Talking Sense Programme. These are considered below:

Talking Sense was intended to depend on therapeutic alliance and engagement (Westbrook et al., 2008). Interviewee descriptions of how it worked (see theme 6) finds carers describing a combined therapist: carer effect supporting the sense
of alliance. The results of the TEI (see 4.4.3.8) also confirm the importance of engagement with rising and higher levels of engagement seen in the Talking Sense group. Carers with higher levels of engagement also appeared to have more proactive communication changes and effects on others when engagement scores were compared with the semi-structured interview data. Therefore, the principle of therapeutic alliance was supported and should remain in the Talking Sense theoretical mechanisms of action.

Protection motivation theory (Boer & Seydel, 1995) was interpreted in this context to reflect whether carers believed themselves and their relative to be having difficulty of sufficient severity to be perceived as a threat. The results (see 4.4.1.1) would suggest that this programme recruited some carers that did not meet these criteria, with relatively low levels of communication difficulty experienced by some participants. In clinical practice, a tool like the CSES could be used to more accurately identify levels of difficulty and threat prior to offering interventions. The CSES (happens) and CCS scores suggest that carer’s perceptions of difficulty may have changed during the course of the intervention. The combination of these factors suggested that the principle of protection motivation theory was only partly supported by this programme. However, it is worth mentioning that some participants may have benefited from the intervention despite not feeling threatened by the extent of their difficulties.

The health locus of control theory (Abraham & Sheeran, 2009) was interpreted to reflect whether carers believed they had the ability to control their situation. The lack of change in communication and general self efficacy scores do not support this theory at work, though it could be argued that health locus of control is looking more specifically at belief in ability to change rather than ability to manage. This suggests that this theory would benefit from further definition, breaking down the potential for change into specific elements e.g. to change self, activities, relative, family etc.

In the carer interviews, theme 5, *the experience for the person with dementia and others* detailed a broad range of changes made, after which, *theme 6, how it*
worked attributed that change at least in part to the carers own efforts. The inclusion of the health locus of control theory suggests that clinicians may need to ask carers a combination of “what difficulties do you experience, how do you manage, and what do you think you could change?” Clinicians may benefit from creating a tool to measure this belief and using pre-intervention strategies e.g. motivational interviewing, to develop carer confidence. Lastly, the Talking Sense mechanisms of action included implementation intention setting (Abraham & Sheeran, 2009). In contrast to the other theories, there was relatively little evidence uncovered in these studies for deliberate implementation intention setting. The semi-structured interview discussion in section 5.5.2 has already suggested that this very absence may be one factor in the relative paucity of proactive strategy development. One clinical recommendation is to develop the use of implementation intention setting. Therefore, it would be valuable to retain this concept as part of the theoretical mechanism of action for Talking Sense.

In summary, the attempt to understand how the Talking Sense intervention worked has benefitted from having a theoretical or hypothetical mechanism of action. Clearly this could work differently for different carer/person with dementia dyads. There is insufficient evidence to support the removal or addition of any theories to the mechanism suggested in chapter 3. Future qualitative research, in particular looking at subgroups of dyads, could contribute to the relative importance of the theories discussed above.

6.5 METHODOLOGICAL IMPLICATIONS FOR THIS PROGRAMME OF RESEARCH

6.5.1 Limitations
The limitations of the individual strands of this programme of research are detailed in chapters 4 and 5.

Detailed below are limitations, not yet considered, which apply to both strands and more specifically to mixed methods research.
6.5.1.1 Sampling bias

Sampling bias occurs when a sample is drawn that is not fully representative of the intended population, with error due to the differences between individuals recruited and those that were not (Bowling, 2009). Consequently, the results in this programme of research can only be generalised to similar populations.

To start with, it should be pointed out that the smaller purposive sample used for the semi structured interviews was intended to be representative of carer populations as a whole and not chosen to match the larger population of the pilot RCT though visual inspection suggests they were comparable in many respects (e.g. around 25% male carers).

Comparison to Livingston et al. (2013) has suggested that this programme of research recruited a similar population to contemporary studies. However, it has already been identified that male carers and carers from ethnic minorities were under-represented in this programme of research. Taking this consideration one step further, future research should also ask whether;

- People who identify themselves as carers are typical of those actually providing care
- People who access services are typical of those who are providing care
- People who participate in research are typical of those providing care

The Princess Royal Trust for carers (2015) refers to a group of hidden carers thought likely to exist in all areas and suggests a range of approaches and resources for identifying and engaging with them.

Issues which will affect the make-up of future research include

- the awareness, understanding and attitudes of sub-groups (e.g. ethnic minorities) of dementia, their role as carer, the purpose of interventions and the value of research
- the flexibility of interventions to meet a wide range of needs (e.g. male) perspectives, translations into other cultures and languages
• the flexibility of interventions and research to meet the needs of carers who would otherwise be unable to participate

Arguably the most appropriate conclusion is to suggest that this programme of research has included a broadly representative population whilst also identifying areas for clinical inclusion and research development. With changes in population, life expectancy and historical household roles anticipated in the future, services should consider investing additional funds to reach out and address the needs of these growing minority groups of carers. Researchers could also increase their access to ethnic minorities and representativeness of the population sample by designing multicentre trials with centres that support a broad range of ethnic and socio-economic groups.

6.5.1.2 Response bias
Response bias refers to bias that influences participants’ responses away from a truthful or accurate picture (Bowling, 2009). The use of a third party interviewer and self completed questionnaires was intended to reduce this effect; however participants were aware that the interventionist was also the author of the intervention, increasing the likelihood that they would feel a desire or obligation to score positively. Whilst all materials and explanations were designed to reduce this effect, carers may have formed expectations. Given the nature of the intervention though, it seems most likely that carers would have expected change in themselves before change in their relative. Interestingly, the opposite is observed in the results of this programme.

The effect of social desirability (i.e. saying what you think is expected of you or presenting a favourable image), can also be controlled for by using a social desirability scale alongside other outcomes. Van de Mortel (2008) reviewed 14,275 questionnaire-based outcome studies and found that only 28 studies used a social desirability scale. Of these, 43% found that social desirability influenced their results with a further 10% controlling for social desirability when analysing data. Future research could consider the inclusion of a social desirability scale whilst further blinding may also reduce this effect.
Reflective records for some measures e.g. the GSES and CCS, suggest that carers may have also had difficulty understanding the relatively complex questions, potentially under-reporting their difficulties. This could also be addressed by ensuring future outcomes are more readable, which it itself could be achieved by involving carers and/or people with dementia in their development.

6.5.1.3 Limitations to using mixed methods
There are significant differences in the sampling frame for each study in this programme of research which should be taken into consideration when making comparisons. The sampling frame for the pilot study included 55 recruits randomly allocated to two arms whilst the interview participants were 15 purposively selected carers from the treatment arm only. There is potential for increasing and broadening the sample frame in each method, in particular the inclusion of the control group in the qualitative method. Continuation of the pilot study with a sufficiently powered sample would also reduce the likelihood of type one and two errors.

The use of a-priori codes in the semi-structured interview study enabled some comparison of findings, though the amount of data available for mixed methods comparison was still a relatively small proportion of the overall data available. If the interview questions and resultant analysis were limited to only focusing on topics covered by the quantitative outcomes, this could add reliability to the quantitative results but would not allow for the development of understanding that qualitative enquiry often promotes.

Mixed methods designs allow for a range of designs some of which have multiple phases of research occurring either concurrently or in sequence (Creswell & Plano Clark, 2011). Sequential research allows one strand to inform another. Influence between strands was minimal in this programme of research, but could be expanded in future research to include qualitative enquiry designed to identify, in a more systematic and population specific way, carer needs, communication difficulties occurring, the development of the intervention and the most appropriate and sensitive outcome measures.
A number of other practical limitations occur in the use of mixed methods in general (Creswell & Plano Clark, 2011):

- Studies are more complex and difficult to deliver and therefore more costly
- Data collection needs a wider range of researcher skills and flexibility
- Data integration can be difficult, particularly where discrepancies occur, though these can be informative
- One strand can influence the other in sequential studies, and therefore order needs careful consideration

Some authors are critical of the concept of mixed methods in itself (Robinson et al., 2011). In one example, Morgan and Stewart (2002) used a range of sequential mixed methods to evaluate a dementia special care unit. Their publication focuses on the issues of compatibility and convergence. They describe how some purists believe that quantitative and qualitative methods represent different incompatible paradigms. Much of the commentary in this debate centres on whether researchers are positivists (quantitative) or constructionists (qualitative) with some authors arguing that it is not possible to take both perspectives. Morgan and Stewart (2002) argue in favour of using mixed methods but maintaining a high degree of rigour and separation from the two methods before the final analysis in a similar way to this programme of research. Morgan and Stewart (2002) also avoided bias from order of data collection and sample, by using different samples for each of the methods (carers for one and people with dementia for another).

A number of recommendations for the future use of mixed methods are detailed in 6.8 below.

### 6.6 MAIN STRENGTHS OF THIS PROGRAMME OF RESEARCH

The main strengths of this programme of research are;

- It confirmed that communication difficulties for people with dementia and their carers are significant and prevalent
• It identified a need for further research into psychosocial interventions that addresses these difficulties
• The Talking Sense intervention was deliverable with high levels of adherence to the intervention
• Intervention and research methods were informed by careful consideration of findings from previous research
• The research methods used were feasible and met ethical requirements
• Sufficient carers, meeting inclusion criteria, were recruited
• The RCT used well established outcome measures and met higher quality research criteria
• The semi-structured interview study followed established protocols and added significant insight into the effects and mechanisms of action of the intervention process
• The results of this study were comparable to other studies e.g. Livingston et al. (2011)
• The mixed methods analysis complimented and added insight to the stand alone results of the studies

6.7 KEY CLINICAL RECOMMENDATIONS

This section summarises all of the clinical implications and recommendations derived from the individual strands and mixed methods of this programme of research.

6.7.1 Communication support for dementia carers

This section includes recommendations for general clinical practice providing communication support to dementia carers.

Recommendations for clinical practice were first identified in the systematic review (see Table 2-3). All of these recommendations (a to i) have been employed in and supported by this study, though as mentioned above, the use of role play (i) proved more difficult than expected. Consequently, it is unclear what effect role play would have had on the carer and the person with dementia.
6.7.1.1 Role play

The use of role play should be developed and evaluated further to determine its potential effect in dementia carer communication interventions. When considering greater use of role play, no specific examples for use of role play could be found in the dementia literature for informal carers, though Skea (2014) describes a care training system that addresses quality of interaction through role play between people with dementia and professional carers. Skea (2014) argues that role play has been shown to outperform instruction and feedback techniques in counselling and psychotherapy, suggesting that new behavioural skills are difficult to learn in a rote learning manner. Skea (2014) argues that role play allows for increased experimentation, adjustment and replaying of skills. One way to increase the use of role play in carer communication support interventions would be to make its use more explicit from the start with an expectation on both parts that, at some point during the course of the intervention, the carer and therapist may, often literally, get up from their seats and practice what they have talked about. This will require greater implementation intention setting for both parties and may require specific training for interventionists.

6.7.1.2 Detailed assessment

Clinicians should conduct more detailed assessment, ideally at the point of referral, to consider specific communication difficulties experienced, carer communication self efficacy, the potential to respond to CBT and the potential for change. Carer learning and support styles should also be considered. This will inform therapy and assist the carer in developing realist expectations. This process should help identify the most suitable carers and intervention combinations.

Czaja et al. (2009) provide an example of a risk appraisal measure (RAM) designed to identify risk areas and guide interventions for dementia carers. This measure is well designed, though has little specific communication related content. Therefore, clinicians and researchers may benefit from developing a more specific communication risk appraisal measure. One option would be to
extend the content of the CSES scale to include a third element (after “happens” and “manage”) of “risk appraisal”. The TEI and readiness scale could be added to this battery to also determine which carers are most responsive and therefore where resources should be targeted.

6.7.1.3 Including people with dementia

Clinical practice that addresses communication difficulties should include the person with dementia wherever possible and appropriate. Moon and Adams (2012), in a review of dyadic interventions (working with the person with dementia and carers together) suggested they were feasible and well accepted by participants. They described rich evidence for the development of mutual understanding and communication, with significant benefits demonstrated to both partners’ well-being and relationships. Boylstein and Hayes (2013) suggest that wives of men with dementia in particular are more likely to report a disruption in marital closeness and that support to maintain this connection is needed. Hellstrom, Nolan and Lundh (2007) identified significant benefits from including the person with dementia, alongside the carer, in interventions in the early stages of the illness, describing considerable effort and energy expended by both parties to sustain couplehood and maintain involvement. Interestingly, they found male carers as emotionally involved as their female counterparts. In another example, Whitlatch, Judge, Zarit and Femia (2006) presented an early structured intervention for carers and relatives with dementia, finding that participants successfully took the opportunity for collaboration and cooperative decision-making before the onset of significant stressors.

6.7.1.4 Relationship centred care

Clinicians need to consider the potential for extending person centred care to relationship centred care. This programme of research has highlighted the importance of relationships beyond the immediate carer: person with dementia dyad (i.e. other members of the family or friends) and more importantly, the potential to influence this. Morhardt and Spira (2013) describe a move in dementia care away from person centred toward relational or relationship centred care, which relies on recognising interactions between persons with
dementia and their carers. They believe this holds the key to giving better care and developing improved practice and policy. An example of relationship centred care is also provided by Joling et al. (2012) who describe a family meetings intervention for a group of 96 carers compared to a control group. However, their intervention of two individual and four family meetings did not demonstrate significant changes in anxiety and depression, carer burden or health related quality of life at 12 months follow up. Specific indicators of need may be required for providing this depth of support whilst future, more focused, research also appears indicated.

6.7.2 The Talking Sense Intervention

This section makes specific recommendations for modifications to the Talking Sense intervention.

Theme 1, *what I thought of the process*, of the carer interviews suggested that the carers thought the Talking Sense manual was practical, providing order and a source for topics. Interestingly, one carer thought it contained too much information. This author’s reflective diary and records of topics used also suggested that the manual contained more information than could be covered in the three intervention sessions used in this study.

Revision of the Talking Sense manual could include removal of some of the less popular topics identified from adherence records (see Appendix 27) using the contents planner. However, a manual designed for use in delivering an individualised programme in a wide range of situations, as well as development of the therapist to an expert level, will inevitably include more information than will commonly be used. The content of the manual will also be limited by any publishing requirements. Further revision of the manual may also be aided by conducting a content validity exercise in the same manner as that conducted for the first edition used in this research (see section 3.3).

In contrast to many of the single component communication studies reported in chapter 2, the Talking Sense intervention is well described and repeatable in content. What this study does not address is optimum dosage. Whilst future
research could consider more intense use of the manual content, future clinical use could include flexible doses of the intervention determined by levels of difficulty, need, engagement and outcomes.

A number of specific areas for development of the Talking Sense intervention and manual have also been identified: It is suggested that a revised Talking Sense manual and programme should include the potential for individualisation to suit male and ethnic minority carers and the participation of the person with dementia providing views, permissions and involvement in rehearsal. At the outset, Talking Sense should also include more detailed carer and person with dementia assessment, including a measure of communication competence for the carer as well as the person with dementia. This information should be available for planning and monitoring therapy. Talking Sense should also include the expectation that the carer will be sharing strategies with others and more deliberately setting implementation intentions. More specifically, Talking Sense would also benefit from the addition of an additional step intended to address and develop “carer self insight”.

Talking Sense may also benefit from including a mechanism for measuring carer knowledge. One such measure, the AD Communication Knowledge test was developed by Williams (2011), though when evaluated by this author, contained 7/16 questions considered not useful or relevant in this context. Therefore, clinicians may wish to develop simple in-house measures, potentially even individualised, and designed to reflect the knowledge taught.

Cost effectiveness has not been considered for the Talking Sense programme. Few psychosocial dementia carer studies have considered this (Jones, Edwards, & Hounsome, 2012). However, two recent studies have demonstrated cost savings from carer support programmes. Klug, Muus, Volkov and Halaas (2012) identified significant cost savings based on health service utilisation in the USA, which decreased over time, whilst Knapp et al. (2013) identified significant cost savings based on QALY’s (quality adjusted life years). Future research may be
required, but clinical services would benefit significantly by being able to
demonstrate that their carer interventions were cost effective.

6.8 KEY RESEARCH RECOMMENDATIONS

This section first describes recommendations that apply to dementia carer
studies (including multi-component studies) in general. Following this,
recommendations are made for developing this programme of research
addressing quantitative, qualitative and mixed methods. Separate
recommendations for the use of outcome measures are included. A conclusion
for future research is included in chapter 7.

6.8.1 Recommendations for general dementia carer research studies

This programme of research has identified and employed improvements in study
design in comparison to previous studies identified during the systematic review.
These are evidenced by low attrition rates, the use of more validated outcomes,
the use of a mixed methods approach and analysis, and more detailed
description of randomisation and follow up procedures.

A number of new recommendations that could equally apply to other research in
this field are detailed below:

Research design and recruitment should take into account specific reasons why
carers decline research. Relatively little has been written about non-participation
in dementia research. In related fields, Taylor, Dawson, Roberts, Sridhar and
Partridge (2007) considered non-participation for pulmonary rehabilitation trials
whilst Rogers et al. (2014) asked similar questions in a primary care physical
activity trial. Both sets of authors identified similar reasons which can be
summarised as “didn’t need to, didn’t want to, didn’t have time or didn’t want
the burden of”. Both studies also identified subgroups e.g. females in Rogers et
al., (2014), that were more likely to participate. It is important that future
researchers develop effective mechanisms for monitoring reasons for non-
participation as unpopular research studies with unrepresentative groups of
participants are less likely to lead to interventions that meet needs in an
equitable way.
Furthermore, analysis of subgroups within those recruited may identify different mechanisms of action and suggest which treatment is needed most, when and by whom.

The results of this programme of research have led to careful examination of the validity of quantitative and qualitative measures used. It is suggested that researchers in dementia care should be encouraged to consider the careful use of mixed methods enquiry as well as the influences (e.g. questions asked) that cause carers to become aware of and report their difficulties.

6.8.2 Recommendations for developing research design in this programme of research

This subsection contains a number of recommendations for developing the research design in this programme of research and the evaluation of Talking Sense.

Recommendations for changes to overall recruitment and the quantitative study component suggest;

Recruitment should be more selective i.e. participants should be experiencing significant communication difficulties, though broader reaching e.g. to incorporate younger, male and ethnic minority carers. The sample should be at least sufficient to satisfy power calculations.

A number of possible design combinations are suggested which could allow comparison of effect between novice and expert treatment delivery, knowledge only and CBT focused interventions, Talking Sense with existing programmes e.g. FOCUSED (Ripich & Wykle, 1996) and the existing programme with a more intensive programme. One possible future combined design, would allow for an increase in intensity by employing less expensive novice treatment deliverers.

A multi-centre longitudinal study may maximise recruitment, provide evidence for long term effects and potentially confirm or disprove trends and non effects seen in this pilot study. However, a longitudinal study has the potential to
increase the effect of confounding variables including changes in the person with dementia and carer outside of the influence of the study.

Future qualitative research should gather further background information before and within studies to determine the needs of male and ethnic minority carers, carer perspectives on meaningful outcomes, more structured carer communication experience data and more specific information about reasons for non-participation.

A wider range of qualitative methodologies should be considered. For example, a grounded theory approach (Ritchie & Lewis, 2012) would add depth of understanding and minimise the effect of a-priori interpretations (Orange & Colton-Hudson, 1998; Spilkin & Bethlehem, 2003). Observational approaches such as conversation analysis or dementia care mapping (Balfour, 2014; Roque et al., 2009) would also allow for comparison between perceived and actual communication difficulties and competence. Extending the range of qualitative methodologies would also provide more in-depth examples and conversation scripts which would be useful for training novice therapists.

In addition to interviewing carers in the control group, interviews and observations could also consider the mechanisms and role/relationships of implementation intention setting and the idea of permissions in more depth to determine the influence of source. It would also be valuable to conduct more in-depth enquiry into changes in carer self insight over time and the relationships between self insight, self efficacy and other outcomes as well as other topics not identified in this series of interviews e.g. meaning, motivations and relationship changes (Quinn, Clare and Woods, 2013). Understanding these relationships would enable clinicians to maximise the effectiveness of interventions by modifying delivery and selecting which and when carers are most likely to benefit.

Recommendations for the use of a mixed method approach will depend partly on the purpose of future research studies. Generally though, it is suggested that researchers should consider the benefits of alternative typologies e.g. a
sequential design (Cresswell & Plano Clark, 2011), whereby interviews or focus groups could be conducted prior to a quantitative trial to inform selection and design of the most appropriate outcomes as well as following the trial to aid interpretation of the results.

6.8.3 Recommendations for developing outcome measures in this programme of research

The following recommendations suggest future psychosocial dementia carer communication studies should:

Measures should be selected to achieve a balance between comparable outcomes from other studies, validated well established outcomes and those considered closest to the anticipated effect.

At the outset researchers should gather more accurate and up to date measures of person with dementia cognitive and communication ability. Across the study they should also use communication specific measures of anxiety and depression and quality of life. This could include outcome completion by the person with dementia in particular for emotionally significant material where their insight is thought to be more preserved (Ablitt, Jones & Muers, 2010).

Additional measures with the potential to aid understanding of the effects of these interventions include carer communication competence, time spent talking and the use of a social desirability scale to reduce threats to validity.

Priorities for future research, based on the recommendations above, are detailed in the following conclusion.
Chapter Seven: Conclusion

The purpose of this chapter is to address the aims or research questions contained within the programme of research and the implications of the programme’s findings. This chapter also includes an overview of the limitations for this programme and the primary recommendations for future research.

The aims of this programme of research are detailed below:

This programme of research introduced dementia and the people that live with it, their family carers and the communication difficulties they experience together, aiming to highlight the cause, consequence and significance of communication difficulties experienced by dementia family carers (chapter 1).

The systematic literature review aimed to identify the evidence base for dementia carer psychosocial interventions and in particular, single communication component interventions. In doing so, it aimed to identify any needs for future research as well as existing indicators for the most effective forms of intervention (chapter 2). These intervention indicators were met in the Talking Sense programme (chapter 3).

The main aim of the pilot RCT study was to determine the effectiveness of the Talking Sense intervention (chapter 4). Intended as an internal pilot study, it aimed to test whether the components of the main study could work together, focusing on processes but also testing outcomes or trends that would support the investment required for further recruitment.

The aim of the interviews was to ask carers what happened to them and their relatives, and why it happened, during and after their participation in the Talking Sense treatment (chapter 5).

The aim of collecting both quantitative and qualitative data in a mixed methods analysis was to bring together the strengths of both forms of research to determine the extent, to which both sets of data converged, contradicted,
illustrated and explained the process of the intervention and experience of carer participants in this programme of research (chapter 6).

Responses to these aims or research questions are given below:

In this programme of research the difficulties experienced by people with dementia and their carer’s are illustrated not just in the literature detailed in chapter 1, but also in the relatively high rates of referral i.e. 111 carers reporting communication difficulty, for participation in this study. In line with existing literature, quantitative baseline measures identified that these carers experienced higher than normal levels of anxiety and depression (HADS), perceived their relatives to have difficulty with communication competence (CCS) and reported experiencing communication difficulties which the carers had difficulty managing (CSES). The semi-structured interviews also contain contextual information (see 5.4.1) about the communication and other difficulties carers experienced which included a relatively high degree of what was interpreted as verbal conflict.

The systematic review identified both a need for further research and recommendations for conducting future research which were primarily related to a call for improved quality (Charlesworth & Newman, 2006). In particular, comparisons with findings from the larger base of general multi-component intervention reviews (see 2.3.8) identified the potential value of using a cognitive behavioural treatment approach, which was previously untested in single communication component interventions, and outcome measures focused on carer depression and self efficacy. The findings from the semi-structured interviews suggest significant changes in carer thinking and feelings which support the potential for using a cognitive behavioural approach. In contrast, the mixed methods research in this programme did not support the relative value of using carer anxiety and depression as a primary outcome measure. These findings also support the systematic review method of including a comparison with the larger associated evidence base of multi-component studies.
The programme of research has also provided evidence for the feasibility of the manualised approach contained within the Talking Sense intervention. Although recommendations for change to the content of the programme have been made (6.7.2), findings from the semi-structured interviews (theme 1 what I thought of the process) and the 100% attendance experienced suggest that carers found the intervention at least acceptable with some specific preferences identified e.g. being seen alone, one to one and by an expert.

In addition to this high adherence to treatment rates, the methods used to evaluate this programme were also shown to be feasible by the absence of any adverse events, close to target recruitment and low attrition rates.

The pilot randomised controlled trial has provided an objective evaluation of the effects of Talking Sense and in doing so identified two statistically significant results (ACQOL-Value and CSES-Happens) with an additional result close to significance (CCS). These significant outcomes appeared more related to changes which involved the person with dementia. The remainder of the results, primarily focused on the carers own experience, were not significantly different between groups. Consequently, the pilot RCT study alone provides only limited evidence for the effectiveness of the Talking Sense intervention which would not be sufficient to continue recruitment with the study design unchanged.

The carer interviews have added significant depth to this study and provide the largest body of evidence in support of the use of Talking Sense. The interviews identified issues relating to carer culture, therapist expertise and style that can be used to guide future users of a revised Talking Sense intervention. They also identified the difficulties carers experience with acquiring knowledge, gaining self insight and implementation intention setting especially for proactive strategies (see 5.5.2). Returning to the aim of the interviews, there is considerable evidence to suggest that what happened as a consequence of the intervention appeared to be positive changes in the carers thoughts, feelings and communication related behaviour alongside a perception of positive changes in their relative’s communication and behaviour.
The mixed methods analysis supported both the presence of some relatively unexpected significant outcomes e.g. changes in person with dementia competence and communication difficulties happening and the absence of some expected outcomes e.g. changes in anxiety and depression. In doing so, the mixed methods approach and analysis has illustrated its own value. This comparison and corroboration has in effect answered the question raised by the pilot RCT study findings, to suggest that at least part of the change in perceived person with dementia communication is attributable to actual change by that person (see 6.2.6). This remains the most significant finding from this programme of research.

This programme of research provides a wide range of contributions to the existing knowledge base for communication specific psychosocial interventions. The key contributions are discussed below:

The systematic review is the most up to date review on this topic, which has rigorously identified and evaluated more controlled studies than any previous review.

Unlike the majority of previous communication specific studies, the Talking Sense manual enables clinicians to replicate the intervention which was supported in part by the RCT pilot study and more extensively by the qualitative study and mixed methods analysis.

Results from the pilot RCT study contribute to the existing evidence base for this form of intervention though more specifically promote higher quality research methods and raise questions about the validity of some commonly used outcome measures. The absence of some outcomes within this higher quality study could also lead to questions about the validity or statistical accuracy of significant outcomes identified in previous studies. Despite recommended changes, the pilot RCT study has provided a highly feasible framework for running adapted future trials.
The qualitative study and mixed methods analysis are unique in this specific field. When taken alone or together, these studies should encourage future researchers to look beyond lone quantitative enquiry.

This programme of research has also illustrated the value of developing situation specific outcome measures such as the communication self efficacy scale (CSES) which has the potential to be used in a wider range of future research.

This programme of research has also generated new knowledge with a wide range of implications many of which are detailed in previous chapters (see 2.5, 4.4.2, 5.5.2, 6.5 and 6.7). Key implications are detailed below:

For people with dementia, this research has raised the potential that a time limited intervention like Talking Sense or similar interventions (e.g. FOCUSED Ripich & Wykle, 1996) could change their actual or perceived communication difficulties. It has also raised the potential value for involving people with dementia in interventions and outcome measurement in the future (6.7.1.3).

For family carers, this research has supported their unique needs and cultural perspective and provided an evidence based intervention which is time limited, cost effective and consequently more likely to be commissioned by policy makers in the current economic climate.

For clinicians, this programme of research, alongside the Talking Sense manual, has provided not only justification for what they do, but also the means to deliver and develop the expertise that carers value.

The most significant implication from these results was a change in communication between the carer and the person with dementia supported by each strand of the research programme.

Like all research, there are a number of limitations in this programme (see 4.4.1, 5.5.1, 6.5.1.3) not least the difference in delivery time between treatment and control, the lack of long term follow up, the relatively small sample size and the restriction of interviews to treatment group carers. Interestingly, the more
intense intervention delivered by Livingston et al. (2013), which yielded significant change in the primary (HADS) outcome, was associated with reduced treatment compliance. Therefore, it continues to be suggested that, the potential for Talking Sense to achieve a valued effect using clinical expertise over a relatively short intervention i.e. three sessions, should be preserved for future studies given the significant findings from this programme and the current economic pressures on health service provision.

Detailed clinical and research recommendations are given in sections 6.7 and 6.8. Key recommendations are given below:

The results of this programme of research support the clinical use of Talking Sense in its current form by expert interventionists. However, the overall recommendation for the Talking Sense manual is for revision, removing some of the less popular topics with the addition of the evidence base from this study including a more detailed understanding of mechanism of actions and a guide describing which carers are most likely to benefit and which require most specific adaptation.

This study has also supported the value of single component intervention research. By focusing on the effect of one component, in this case communication, it has enabled comparison with the effects of intervention research which addresses other components (e.g. anxiety in Livingston et al., 2013) though care should be taken to take into account other differences between studies (e.g. intensity of the intervention). Given that carers in this study valued the expertise of the interventionist, it is also suggested for future research, that expertise can best be developed by reporting the content and effects of single component studies in detail.

In the pilot RCT study (chapter 4), results from the CSES scale demonstrated that, on average, participating carers were experiencing (happens and manage) difficulties with communication whilst the HADS baseline results suggest that these carers had higher rates of depression and anxiety than normal. However, it was clear from the range of outcome values, that a significant proportion of
carers were not experiencing these difficulties and were therefore unlikely to demonstrate change on outcome measures selected. Therefore, the primary recommendation, for future research, from these findings is to recruit carers more selectively in order that carer difficulties and needs match the intervention, and that outcome measures are more closely associated with the intervention and its anticipated effects.

A number of recommendations for using, adapting or removing outcome measures are also included in section 6.8. The primary recommendation for outcome measure use is to develop the CSES scale alongside other communication specific measures (e.g. for quality of life and anxiety).

In particular, the carer interviews revealed a wealth of information about positive changes in carer feelings and thinking in contrast to relatively less support for changes in self efficacy. Talking Sense was designed to use a CBT approach which encourages carers to explore and develop their thinking, for example in the use of permissions and mantras. What is not clear is whether carers receiving an intervention which only uses the knowledge domain, those receiving a multi-domain generic intervention or those participating in a group would respond with similar changes to thinking. Taking into account recommendations for future research detailed in 6.8, it is suggested that these questions about the relative value of the cognitive behavioural approach should become the priority for future qualitative research. Interviewing carers in control groups (of mixed methods studies) may also aid this evaluation. These interviews should focus on exploring whether a CBT approach is promoting thinking change and whether this in turn is influencing carer and person with dementia change.

From this intervention and combination of research methods, at least part of the change in perceived person with dementia communication appeared to be attributable to actual change by that person (see 6.2.6). This remains the most significant finding from this programme of research. Pursuing and clarifying this effect is one of the primary recommendations for future research. Taking into
account recommendations in section 6.8, it is suggested that where possible, mixed methods research could also be joined by observational methods including conversational analysis (Wilkinson, 2010) to determine further the extent of behavioural change in both carer and person with dementia attributable to this form of intervention.

A further recommendation for mixed methods research suggests a change in design whereby an interview based, qualitative first, sequential design (Cresswell & Plano Clark, 2011) would allow for greater understanding of carer needs (e.g. male and ethnic) as well as carer perspectives on meaningful outcomes which in turn would inform the study design that follows.

Future research design would also do well to recruit an adequately powered sample with the primary recommendation that funding is sought to deliver a sequential (see above) mixed methods study based around a longitudinal, with multiple time points, multi-centre randomised controlled trial. After more selective recruitment, this study should continue to compare the effectiveness of a revised Talking Sense programme with a more generic and equal intensity control condition that is not CBT based. As for the participation of people with dementia, whilst taking into account carers comments about the value of individual interventions, it is suggested that their initial involvement should be in gathering outcomes prior to any future research that could potentially involve them in the intervention phase.

In summary, this programme of research has focused on a key issue for dementia carers which warranted further research. In doing so, it has indentified a valuable body of mostly qualitative evidence in support of the Talking Sense intervention. The intervention and research study delivery was feasible and as a pilot study provided a good basis, including supportive evidence, for continuing future research. The qualitative component in particular has illustrated the mechanisms of action in this form of intervention. Clear recommendations for future research have been made which can build on the findings of this programme.
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Strauss, C.L. (2001). *Talking to Alzheimer’s. Simple ways to connect when you visit with a family member or friend*. California, USA: New Harbinger.


Appendices

Appendix 1: Critical reflections on existing guides to communication for dementia carers.

<table>
<thead>
<tr>
<th>Title</th>
<th>Author</th>
<th>Year</th>
<th>Style</th>
<th>Critical Reflection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Talking to Alzheimer’s Simple ways to connect when you visit.</td>
<td>Claudia Strauss.</td>
<td>2001</td>
<td>Easy read. 8 Main chapters. A few bullet point lists. No references.</td>
<td>American. Some good advices and section on expectations. Focus on visiting ppl!. Good topic finder. Closest to what I intend to produce.</td>
</tr>
<tr>
<td>Helping communication in the person with dementia</td>
<td>Tanton</td>
<td>1993</td>
<td>Basic. Lots of simple cartoons</td>
<td>Not very personable. Hard to translate into real situations. Big things like “speak slowly.”</td>
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<tr>
<td>The Validation Breakthrough</td>
<td>Feil</td>
<td>1993</td>
<td>All text.</td>
<td>Promoting only one approach. Only useful for people who respond to validation.</td>
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<tr>
<td>Dementia</td>
<td>Bourgeois</td>
<td>2009</td>
<td>All small text</td>
<td>Excellent high level text book for SLT’s . American. 2 out of 12 chapters on communication</td>
</tr>
<tr>
<td>Title</td>
<td>Author(s)</td>
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<td>Format</td>
<td>Content Summary</td>
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<tr>
<td>Contented Dementia</td>
<td>James</td>
<td>2008</td>
<td>All text. Some good structure to ideas and good case examples</td>
<td>Not suitable for carers. Very prescriptive and overly positive. Doesn’t give readers flexibility—might make ppl feel inadequate. Some good ideas (some bad).</td>
</tr>
<tr>
<td>Windows to a damaged world</td>
<td>Clarke et al</td>
<td>1996</td>
<td>All text. Uses good summaries.</td>
<td>Outdated. Poor title. Some structure but could be better.</td>
</tr>
<tr>
<td>Hearing the voice of people with dementia</td>
<td>Innes</td>
<td>1997</td>
<td>Basic but spacious</td>
<td>Basic. Space could be used for practical ideas and notes. Structure weak. Still uses some technical terms.</td>
</tr>
<tr>
<td>Care to Communicate</td>
<td>Powell</td>
<td>2000</td>
<td>Very spacious. Lots of cartoons.</td>
<td>Bit simplistic in places. Tends to treat everyone as the same. Some good ideas though.</td>
</tr>
</tbody>
</table>
Appendix 2: The VEMAS communication and memory difficulties scale

VEMAS Communication and Memory Difficulties Scale

V: People with very early difficulties might be

- unsure whether their difficulties are a normal part of ageing
- aware of and concerned about occasional memory difficulties they are having but generally managing to remember what they need to do
- experiencing mild difficulties managing complex communication tasks such as talking to a group of people, writing a letter or reading complex material
- making efforts to manage their difficulties and maintain their skills e.g. using a range of memory aids and attempting brain exercises like crosswords or Sodoku

E: People with early difficulties might

- forget occasional things they have to do or have been told
- be able to follow a few simple reminders and memory aids
- use occasional vague words such as "thingy" or "whatsit" and have occasional word finding difficulty remembering people and place names
- have occasional difficulties with more complex daily living tasks such as managing finances, shopping, cooking etc
- have only occasional difficulties with concentration and attention
- have difficulty understanding complex instructions that are lengthy, abstract or require a number of separate actions
- have occasional pragmatic difficulties (saying the wrong thing) in unfamiliar places
- make occasional (less than daily) errors of sense making, possibly accusing or blaming others
- become frustrated and have difficulty understanding or coming to terms with what is happening to them

M: People with moderate difficulties might

- have very limited awareness of their difficulties
- repeat questions or subjects within a short space of time
- have difficulty planning and switching between activities
- produce more frequent vague or wrong words without noticing
- struggle to change their mind or beliefs
- stick to talking about one or a few more familiar topics
- have a lack of meaning (are difficult to interpret) in what they say
- often interpret things that have happened by blaming or accusing others
- be able to read aloud single words or short phrases but have difficulty writing
- struggle to understand things that are implied e.g. "Is that your paper?" (when it means "can I read it?")
- have significant difficulty following stories on the television
- be significantly dis-inhibited at times (doing or saying things that we don't usually do in that situation)

A: People with advanced difficulties might
- have no awareness of their difficulties
- spend longer periods of time being inactive and struggle to start activities alone
- struggle to understand more than single word instructions or simple actions demonstrated
- be difficult to understand, producing very few words or sentences containing little significant meaning
- respond better to more physical activities copying some simple actions
- become either over-talkative or quiet and withdrawn
- have difficulty recognising even simple verbal or visual humour
- have frequent verbal or physical challenging behaviours

S: People with Severe difficulties might
- have very limited or no verbal communication
- have a drive to maintain their basic needs (comfort, contact, safety)
- show some understanding and expression of non-verbal communication
- produce repetitive speech, sounds and physical behaviours
- respond to some stimuli such as music, pets, massage, tastes
Appendix 3: Examples slides from steps one and two of the Talking Sense manual.

How dementia affects communication

Having memory difficulties affects communication with other people by causing difficulty with:

- **Understanding.** Holding on to or recognising the words in a sentence long enough to be able to make sense of it e.g. a complex instruction.

- **Retention.** Retaining subjects, questions and instructions from one sentence to the next i.e. remembering the subject or what has already been said. Also, remembering previous instances of similar conversations and therefore being able to predict or expect what is likely to be said.

- **Words.** Thinking of suitable things to say and finding the best words to say them.

- **Beliefs.** Changing their point of view (e.g. what they think happened or is right) as this involves both understanding and remembering new information.

The experience of having dementia

- People saying things that make no sense
- People talking using simplistic communication
- People talking about you, around you and over you
- Less control over when, with whom and where to talk
- Less control of what to talk about, for how long and when to end
- People avoiding you, not sure how to treat you
- You are unable to make another person understand you
- People doing unexpected things to you
- People telling you directly or indirectly that what you know to be true isn’t right

Step one, Slide 11, from the Talking Sense manual – How dementia affects communication.

Appendix 4: Example slides from steps 4 and 6 of the Talking Sense manual.

General principles for using memory aids

- Put them somewhere prominent and reachable. It’s like you are setting a trap for yourself. Memory aids have to go somewhere that your eyes will regularly go. If you prefer to use a diary, make sure it lives in one place and won’t be easily covered up or lost.
- The bigger the better. I have worked with a few people who have used office sized white boards, which have worked well (but not everyone would want something that big in their home).
- Put most memory aids in a single place. Ideally somewhere where the user spends most of their time. This could be a desk arranged with a telephone, pens, calendar, lists and reminder notes all in one place.
- Keep memory aids regularly updated. With some aids like reminder boards, there is a tendency to get used to seeing them and after a while you take no notice of what they say.
- Keep the content simple. The more that is written on a board, the less likely you are to respond to any single item.
- For any written aids that use writing consider the person’s ability to see, write and understand and adapt what you or they write accordingly.


Content and quality

- Two types of conversation: content and quality.
- Content conversation focuses on the detail, information or facts. This is harder to remember.
- Quality conversation is more about a feeling of success and pleasure. This is more like a “good chat”.
- Content conversation become harder.
- Quality conversation can be created.
- Try to get a balance between the two.

Step 6, Slide 40, from the Talking Sense Manual – Content and quality.

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Quizzing

- As a general rule quiz questions are the most challenging for people with memory difficulties.
- They can confront them with what they don’t know.
- Typical quiz questions ask for accurate detail to what, where, when, how and why questions. Quizzing also involves correcting wrong answers.
- Bear in mind some people with mild difficulties may still enjoy quiz situations (perhaps with more flexible rules).

Starting conversation

- Plan, where possible, what to talk about.
- Focus your efforts on “making a connection”.
- Gain their attention by using their name, touch etc.
- Approach from the front, use a calm manner and slower pace to start with.
- Position yourself so they can see and hear you easily.
- Use a compliment for example “You look well”, “It’s nice to see you”
- Don’t start with a question if you can help it.
- Introduce the subject for example “I’d like talk to you about.......”
- Focus on establishing their trust i.e. don’t contradict early in the conversation
Appendix 6: Contents planner matched to VEMAS levels from the Talking Sense manual.

<table>
<thead>
<tr>
<th>Step Four – The Environment</th>
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<tr>
<td>Practical ideas to modify the environment</td>
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<tr>
<td>External Memory aids, h/o's 6+7, p29</td>
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<tr>
<td>Memory aids needs introducing, point</td>
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<td>Memory campaigns, point</td>
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<tr>
<td>Put something out to talk about, p30</td>
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<td>Conversation magnets, point</td>
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<td>Pet therapy and simulated presence therapy, point</td>
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**Step Five – The Person**

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<th>Clothes, point</th>
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<tr>
<td>Hearing and Vision, h/o 8</td>
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<tr>
<td>Equipping the person with dementia, p32</td>
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<td>Life story books, p33</td>
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<td>Memory wallets or books, p34</td>
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<td>Treasure chests and talk bags, point</td>
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<tr>
<th>Step Six – How to be The Carer</th>
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<tr>
<td>Your non-verbal communication, p37</td>
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<tr>
<td>Equip other carers with background information, point</td>
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<tr>
<td>Listening, meaning and interpretation, p38</td>
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<tr>
<td>Your style and role, Card and point</td>
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<td>Their opportunities and needs, Card and point</td>
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<tr>
<td>Communication content and quality, p39</td>
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<td>(3 topics) Communication visits and prescriptions, variety and familiarity, fatigue. Point and p40, cards</td>
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<td>Being in positions of power, Card and Point</td>
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<td>How to manage contradiction, Card and point</td>
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<td>Listening to you. How they understand your words, Point</td>
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<td>Strategies to aid understanding, h/o 9</td>
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<td>How to respond, h/o 10</td>
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<td>What to do with word finding difficulties, p41</td>
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<td>Using questions, p42</td>
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Key: O= Original, R= Results, T= Trend

Step Seven – Reminders and encouraging conversation.

- Living with very mild memory difficulties. point
- Internal memory aids with examples. p52
- Learning new tricks. p53
- Cognitive Stimulation. point
- Taking the lead. point
- Calling for help. point
- Reality orientation. p34
- Reminiscence. p55
- SPECAL including examples. p57
- Validation Therapy with example. p56
- Resolution therapy. Point
- Continuum of approaches. p58

Step Eight – Communication and Activities

- Routines and plans. p60.
- Off the shelf activities. h/o 11
- The Montessori approach. p61
- The arts. p62
- When communication is more difficult. Sensory stimulation. point
- Non-verbal activities and mirroring non-verbal communication. point
- Intensive interaction and creative communication. point
- Spirituality. point
- Family gatherings and group interaction. h/o 12
- Care tasks. h/o 13

Step Nine – Challenging Behaviours

- What is challenging behaviour. p64
- What causes challenging behaviour. p65
- What helps challenging behaviour. p66-70
- Emotions and walking away. point
- Hallucinations and delusions. point
- Repetitive vocalisations. point
Appendix 7: Definition of the control condition.

**Talking Sense - Defining the control condition**

This has to be distinct from the main treatment. It should reflect standard practice before TS was developed – a one hour discussion about their difficulties.

It contains two major elements recorded on a sheet; problems that occur and practical strategies identified. It should last up to one hour and more than 30 minutes.

It should **not** contain:

- Thinking strategies (except “what are you trying to achieve?”)
- Elements of or reference to cognitive behavioural therapy
- Skill rehearsal situations
- A series of stages such as used in the Talking Sense book
- Use of any physical resources such as books, leaflets etc
- Expectations or implementation intentions planning
Appendix 8: Approval Letter from IRAS ethics committee.

Health Research Authority

NRES Committee South Central - Southampton B
Bristol REC Centre
Level 3 Block B
Whipplesara
Lewins Mead
Bristol
BS1 2NT
Telephone: 01173 421394
Facsimile: 01173 420445

13 February 2012

Mr Colin Barnes
Speech and Language Therapy Department
St James Hospital
Lockaway Road
Portsmouth
PO4 8LD

Dear Mr Barnes

Study title:
A randomised controlled feasability study examining the effectiveness of an individualised and cognitive behavioural communication intervention for informal carers of people with dementia.

REC reference: T2SC/0015
Protocol number: N/A

Thank you for your letter of 08 February 2012, 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

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see “Conditions of the favourable opinion” below).

Conditions of the favourable opinion

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

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

Management permission (“R&D approval”) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.
Where a NHS organisation’s role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

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

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advertisement</td>
<td>TSCB18 - Referrers Leaflet v2</td>
<td>23 October 2011</td>
</tr>
<tr>
<td>Covering Letter</td>
<td></td>
<td>09 December 2011</td>
</tr>
<tr>
<td>Covering Letter</td>
<td></td>
<td>08 February 2012</td>
</tr>
<tr>
<td>Evidence of insurance or indemnity</td>
<td></td>
<td>05 August 2011</td>
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<tr>
<td>GP/Consultant Information Sheets</td>
<td>TSCB3 - Referrers Guide v4</td>
<td>22 November 2011</td>
</tr>
<tr>
<td>GP/Consultant Information Sheets</td>
<td>TSCB4 - Referral Form v2</td>
<td>01 December 2011</td>
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<tr>
<td>Interview Schedules/Topic Guides</td>
<td>TSCB11 - Interviewers Guide including schedule v2</td>
<td>01 December 2011</td>
</tr>
<tr>
<td>Investigator CV</td>
<td></td>
<td>06 December 2011</td>
</tr>
<tr>
<td>Letter from Sponsor</td>
<td></td>
<td>13 December 2011</td>
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<tr>
<td>Other: Summary CV for supervisor - Chris Markham</td>
<td></td>
<td>16 November 2011</td>
</tr>
<tr>
<td>Other: TSCB-6 Funders Letters scanned</td>
<td></td>
<td>14 September 2011</td>
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<tr>
<td>Other: TSCB19 - Interviewer Job Description</td>
<td>1</td>
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<tr>
<td>Other: TSCB20 - Interviewer Person Specification</td>
<td>1</td>
<td>01 December 2011</td>
</tr>
<tr>
<td>Other: Talking Sense Manual Summary Sheet</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other: Example Slides for Talking Sense Carer Presentation Material</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other: Talking Sense Manual</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participant Consent Form: Consent Form</td>
<td>4</td>
<td>07 February 2012</td>
</tr>
<tr>
<td>Participant Information Sheet: Participant Information Sheet</td>
<td>5</td>
<td>07 February 2012</td>
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<tr>
<td>Protocol</td>
<td></td>
<td>23 October 2011</td>
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<tr>
<td>Questionnaire: TSCB12 - Communication Competence scale</td>
<td>2</td>
<td>16 October 2011</td>
</tr>
<tr>
<td>Questionnaire: TSCB13 - The General self efficacy scale</td>
<td>2</td>
<td>16 October 2011</td>
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<tr>
<td>Questionnaire: TSCB14 - The Communication self efficacy scale</td>
<td>3</td>
<td>09 September 2011</td>
</tr>
<tr>
<td>Questionnaire: TSCB15 - The ACQOL (original pdf) scale</td>
<td></td>
<td></td>
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<tr>
<td>Questionnaire: TSCB16 - Service receipt inventory</td>
<td>2</td>
<td>16 October 2011</td>
</tr>
<tr>
<td>Questionnaire: TSCB17 - Carer background information form</td>
<td>2</td>
<td>16 October 2011</td>
</tr>
<tr>
<td>REC application</td>
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<td>15 December 2011</td>
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<tr>
<td>Referees or other scientific critique report</td>
<td>TSCB7 - Review of proposal from Carol Fogg</td>
<td>01 July 2011</td>
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<td>Response to Request for Further Information</td>
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<td>Summary/Synopsis</td>
<td>TSCB8 - Research Procedures v3</td>
<td>21 November 2011</td>
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<td>Summary/Synopsis</td>
<td>TSCB9 - Research Flowchart A v1</td>
<td>01 December 2011</td>
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<tr>
<td>Summary/Synopsis</td>
<td>TSCB10 - Research Flowchart B v1</td>
<td>01 December 2011</td>
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**Statement of compliance**

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

**After ethical review**

**Reporting requirements**

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

**Feedback**

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

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

| 12/SC/0015 | Please quote this number on all correspondence |

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

Yours sincerely

[Signature]

Professor Ron King
Chair
Email: scsha.swhrecb@nhs.net

**Enclosures:**

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

**Copy to:**

Mrs Ann Rice
Dr Sarah Williams, Research Manager Solent NHS Trust
Appendix 9: Consent form for carer participants.

Consent form version 4: 07/02/2012.

Consent Form

Title of study: The Talking Sense study: a communication programme for family carers of people with memory difficulties

Unique carer identification number: ____________

Name of researcher: Mr Colin Barnes

Please put your initials in each box if you agree and then sign on the second page.

I confirm that I have read and understand the participant information sheet (version dated 07/02/12) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily..........................

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason.......................  

I agree to audio recordings of training and interview sessions........  

I agree to the publication of anonymised direct quotations from session notes or audio recordings ......................................................  

I agree to participate in an additional interview if required.............

1
Consent Form version 4: 07/02/2012.

I agree to records of my involvement being stored securely for the duration of the study and that my relative’s overseeing psychiatrist will be informed of my participation which will also be recorded on my electronic medical record..........................

I agree to take part in the above study..........................

Name of Participant

______________________

Date

__/_

Signature

______________________

Name of Researcher

______________________

Date

__/_

Signature

______________________
Participant Information Sheet

The Talking Sense study: a communication programme for family carers of people with memory difficulties.

Invitation to the carer.
We would like to invite you to take part in our research study. This study only involves carers of people with memory difficulties. 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. The researcher will go through this information sheet with you. We suggest this should take about 15 minutes.

Part 1 tells you the purpose of this study and what will happen if you take part. Part 2 gives you more detailed information about the conduct of the study.

Please ask the researcher if there is anything that is not clear or if you would like any further information. Take time to decide whether or not you would like to take part.

Part One: About the study:
What is the purpose of this study?
This study is being carried out as part of an educational qualification for the researcher, who is a PhD student. He is also a speech and language therapist experienced in working with people with dementia.

We are interested in finding out if a new training approach for carers will help them and their relative when they experience difficulties communicating. This approach is detailed in a book called Talking Sense. A number of books have been written for carers about communication in dementia but none of them have any published research to support their potential benefit.

When we don’t know if a new form of training will be beneficial, we can compare it to the services that are already being provided. We intend to do this in this study. We will be putting carer participants into two equal groups. One group will receive the usual training approach and the other will receive the Talking Sense training as well as the usual training approach. The results will be compared to see if one is better.

To try to make the groups the same to start with, each participant will be put into a
group by chance (randomly). You will have a 50% chance of receiving the Talking Sense training in this study. Unlike some other studies, both you and the researcher will know which training you will receive.

**Why have I been invited?**

You have been invited to participate in this study by one of the clinicians in the older person’s mental health team. We understand you are involved in the care of a relative who has dementia and have reported some experience of difficulties communicating together. We are not involving people with dementia in this study. We hope to recruit up to 60 carers from the Portsmouth area.

**Do I have to take part?**

No. It is up to you to decide to join this study. We will describe the study and go through this information sheet which we will then give to you. If you wish to participate, we will 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 will not affect the standard of care you or your relative receives.

**What will happen to me if I take part?**

Whether you participate or not, you and your relative will continue to receive the older person’s mental health and speech and language therapy services that are normally available. No service will be withdrawn from you.

All participants will be given two packs of questionnaires to complete. Each pack of questionnaires includes clear instructions and should take approximately 30 minutes to fill in. These will be collected from you in the envelopes provided.

You will be involved in the study for between 10 to 12 weeks. A pack of questionnaires should be completed at the beginning and end of the study. You will be reminded by telephone if required.

Shortly after you agree to participate, you will be informed which group you will be in.

Carers receiving the Talking Sense training will be contacted to arrange a first training session within two weeks. Most carers will be seen at home but arrangements can be made to be seen at St James’ hospital if preferred. The researcher will not have access to you or your relative’s medical history unless he is already involved in their clinical care.

Carers receiving the Talking Sense training will be seen individually for 3 sessions and a maximum total time of 4.5 hours. Carers will also receive a written summary of the ideas that are discussed.
Fifteen carers that have received the Talking Sense training will also be asked to participate in an interview. This will involve another health care professional visiting their home to discuss their experience of receiving this training. The interviewer will have received training in interviewing, be familiar with people with dementia and will follow a series of standard questions. The interview questions will also ask you what changed as a result of receiving this training and how you imagine that happened. Participants that are not assigned to the Talking Sense training group will continue to receive support and services from speech and language therapy and the older person’s mental health service as normal. They will be able to discuss communication difficulties with the researcher but won’t be able to use the Talking Sense approach until this research study is completed.

All of the training sessions and the interview session will be recorded using an audio recorder. These recordings and other information collected during the study will be used and stored in accordance with the data protection act (see later section).

What will happen to my relative?
This research does not involve people with dementia directly. It may be more beneficial for the carers if the carers are seen alone. This study has not been approved for the participation of people without the capacity to consent. People with dementia can be present as observers if they have the capacity to choose to do so.

What is the training being tested?
Talking Sense has been designed as a training manual for health care professionals working with carers. The training will mostly involve you talking with the researcher. You will be able to choose what subjects you talk about within a series of nine topics. The training will explore your knowledge, beliefs, the things you do and the skills you have.

Will I have any expenses?
The main cost to carers will be their time. By providing home based therapies, it is not anticipated that carers will incur any expenses.

What will I have to do?
All participants will be asked to complete the questionnaire packs within a two week period. You can contact the researcher if you have difficulty understanding the meaning or structure of any of the questions. However, he will not be able to discuss which answers you should choose. Participants in the Talking Sense training group will also need to be available to be seen by the researcher and interviewer within the study period of up to 12 weeks.
During the training visits, participants will be asked some questions and will be encouraged to discuss communication approaches. Between training visits, participants will be encouraged to try out different ways of thinking and communicating.

**What will happen after the study?**

We hope that we can find out if offering carer communication training in this way is beneficial. After their study participation, all carers will be able to request ongoing communication advice through the older person’s mental health team or speech and language therapy service by contacting the services directly.

**What are the alternatives to this training?**

Communication difficulties are a common experience for people with dementia and their carers. Advice and support about these difficulties may be provided by mental health nurses, psychiatrists, psychologists or occupational therapists already involved in your relative’s care and your support.

More specific advice and information about communication difficulties is also currently available by speech and language therapists in carers groups and individually with carers. This can be accessed by contacting the speech and language therapy service directly.

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

We do not anticipate any risks to your health from participating in this study. You will be required to give up your time.

There is a risk that discussing these issues may cause you distress but this should be minimised by encouraging you to select the topics you wish to discuss.

You may also wish to discuss your suitability for participation if you imagine your relative will be made vulnerable by the demands and arrangements of this study. You will always be free to withdraw from the study at any time.

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

We cannot promise the study will help you but we hope the information we get from this study will help improve the support we provide for carers of people with dementia.

**Part 2: More detailed information.**

**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 for the study,
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 their best to answer your questions. He is a qualified speech and language therapist.

If you do not wish to discuss this with the researcher you can also discuss any concerns with Dr Karla Greenberg Consultant Psychiatrist or Ann Rice, Speech and Language Therapy manager who are both members of the research steering group.

If you remain unhappy and wish to complain formally you can do this through the NHS Complaints procedure.

Contact details are given at the end of this form.

In the event that something does go wrong and you or your relative are harmed during your participation in this research and this is due to someone’s negligence then you may have grounds for legal action for compensation against Solent NHS Trust, but you may have to pay your legal costs.

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

We will inform your relative’s overseeing consultant psychiatrist of your participation in this study. All information we gather about you will be kept confidential and stored on Solent NHS Trust premises. You will be given a unique code at the beginning of the study. All of the paperwork and recordings we make with you will include this code and will not include your name or other identifying details. We will also remove any personally identifiable information when we report the study.

If you join the study we will record on your electronic medical records, for Solent NHS Trust, the time and nature of any training you receive.

The researcher will be responsible for storing your data. This will be kept secure on Solent NHS trust premises and destroyed after 5 years.

We will not share any of the information we collect about you or your relative without your consent. However, if during the course of the study we identify information which indicates you or your relative are at a significant previously unknown risk we will disclose this information to your relative’s psychiatrist or your G.P. We will discuss this with you beforehand unless doing so is not in your or your relative’s best interests.

**What will happen to the results of the research study?**

We intend to report the results of this study in academic journals and also present the results at local and national conferences. It is hoped that the Talking Sense manual will
also be published. Any information we obtain from you will be confidential and we will
remove personally identifiable information before writing reports or giving
presentations. You will be able to request a copy of the research findings.

Who is organising this research?
The researcher is an employee of Solent NHS trust and a PhD student at the University
of Portsmouth.

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 interests. This study has been reviewed and
given a favourable opinion by __________ Research Ethics Committee (Reference: ).
Throughout the course of this study it will be monitored by a steering group which
includes dementia health care professionals and carer representatives.

Further information and contact details:
For any further information about the research please feel free to contact the
researcher:

Mr Colin Barnes
Speech and Language Therapy Department
St James Hospital
Locksway Road, Portsmouth
PO4 8LD
Telephone: 02392 894337 (24 hour answer phone)

Additional contact details:
Dr Karla Greenberg
Consultant in Older Persons Mental Health
St James Hospital
Telephone: 02392 682584

Ann Rice
Speech and Language Therapy Manager
Speech Therapy Department
St Mary’s Hospital
Telephone: 02392 680270

NHS Complaints
Solent NHS Trust
Patient Experience and Engagement Service.
Telephone: 0800 013 2319
Appendix 11: Marketing leaflet for referrers.

The Talking Sense study: a communication programme for relatives of people with memory difficulties.

Are you a relative of someone with memory difficulties?

Do you experience difficulty communicating together?

Most of what you do together will involve communication. Relatives of people with memory difficulties can experience difficulties:

- explaining things to them
- understanding what they are trying to say
- reminding or correcting them
- knowing how to respond when their relative is forgetful, confused, repeats themselves or says something unexpected
- making conversation and knowing what to talk about
- making plans and decisions
- having disagreements

The Talking Sense programme is a new approach for health professionals to use with relatives. We would like to explore if and how this approach might help carers by conducting a research study which is part of a PhD course.

After taking this leaflet, your name and contact details will be passed to the lead researcher, Mr Colin Barnes who will telephone you. If you are interested in participating, he will provide further information about the treatment and research study. Alternatively you can contact him directly:

Mr Colin Barnes M.A., B.Sc., MRCSLT, reg. HPC, Principal Speech and Language Therapist,
Telephone number: 02392 894337  (24 hour answer-phone)
Appendix 12: The Talking Sense study referral form.

The Talking Sense Study – Referral Form

Please use this form to refer carers who are interested in participating in this study. Carers should have been provided with a copy of the information leaflet and asked if their details can be passed to Colin Barnes. Please check criteria and other information given in the referrer’s guide.

Please post this form internally marked: Private and Confidential, Colin Barnes, Speech and Language Therapy, St James Hospital using envelopes provided.

Please write as clearly as possible:

Carers name: ____________________________

This person cares for their: ____________________ (relationship)

Carer contact telephone number: _________________________

Any special instructions regarding contacting or visiting this carer:

________________________________________________________________________

Do they meet the inclusion criteria for the study? Y/N

Have they been given a study leaflet? Y/N

Referred by: ____________________________ (Please print name)

Date: ________________________________

Thank you for making this referral.

Office use only

Date received: _________________

Unique Code: _________________

Number: _________________

Assignment: T/C
Appendix 13: Example Talking Sense intervention slide - Knowledge.

Step One: Knowledge

- What is communication?
- Human needs and survival
- Types of dementia
- More than just dementia
- Verbal and non-verbal communication
- The development of communication
- Types of memory and memory difficulties
- How dementia affects communication
- Why action memory is different
- Abstract and concrete
- Personhood

Appendix 14: Example Talking Sense intervention slide 11.

How dementia affects communication

Having memory difficulties affects communication with other people by causing difficulty with:

- **Understanding.** Holding on to or recognising the words in a sentence long enough to be able to make sense of it e.g. a complex instruction.

- **Retention.**Retaining subjects, questions and instructions from one sentence to the next i.e. remembering the subject or what has already been said. Also, remembering previous instances of similar conversations and therefore being able to predict or expect what is likely to be said.

- **Words.** Thinking of suitable things to say and finding the best words to say them.

- **Beliefs.** Changing their point of view (e.g. what they think happened or is right) as this involves both understanding and remembering new information.
Appendix 15: Carer background information questionnaire.

<table>
<thead>
<tr>
<th>Questions</th>
<th>Please circle one answer per question (in italics)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. What age group are you in?</td>
<td>Under 45</td>
</tr>
<tr>
<td>2. Are you male or female?</td>
<td>Male</td>
</tr>
<tr>
<td>3. What relation are you to your relative with dementia?</td>
<td>Spouse/partner</td>
</tr>
<tr>
<td>4. How long have you been involved in caring for your relative?</td>
<td>Less than a year</td>
</tr>
<tr>
<td>5. Do you live together?</td>
<td>Yes</td>
</tr>
<tr>
<td>6. How many days a week do you see each other?</td>
<td>1</td>
</tr>
<tr>
<td>7. How would you describe your general health?</td>
<td>very poor</td>
</tr>
<tr>
<td>8. Roughly how much time do you spend talking together each week?</td>
<td>Less than two hours</td>
</tr>
</tbody>
</table>
9. How much support towards caring do you receive from friends and other members of the family?

None a little some a lot

10. Who else is involved in caring for your relative (please describe relationships below)

11. How would you describe your education? (Circle one answer)

Early school leaver completed school college university

12. What was your last occupation? (Please describe below)

13. Apart from caring for your relative how stressful would you describe your life?

This question is asking you to consider other factors that cause stress in your life e.g. events, other people, circumstances etc (Please circle one answer)

Not at all stressful Mildly Moderately very stressful

14. Are you receiving any treatment or medication to help manage stress or depression?

Yes No

15. What ethnic group are you in? Please describe below e.g. white British, Asian, Chinese etc.

16. Do you and your relative speak any languages together other than English? Yes No

If Yes, please state which language(s)____________________
Appendix 16: Service receipt inventory (baseline version).

The Talking Sense Study - Service Inventory (Pre)

This form asks you to describe the services you have received to help you and your relative. Your answers to this form should take into account services you have received between:

When you first became aware of your relative’s difficulties and today.

Please take into account only those appointments that relate specifically to 1) your relative’s dementia 2) your role as their carer 3) any health difficulties you are having which relate to your role as carer.

During the period above, have you or your relative had any appointments (relevant to their dementia or your role as carer) in a clinic or at home with:

(Please circle one of the answers in italics)

1. Your or their GP?
   No   Yes   if Yes, approximately how many appointments______

2. The psychiatrist or consultant in older person’s mental health?
   No   Yes   if Yes, approximately how many appointments______

3. A community mental health nurse (including the memory clinic)?
   No   Yes   if Yes, approximately how many appointments______

4. A psychologist or an NHS counsellor?
   No   Yes   if Yes, approximately how many appointments______

5. An occupational therapist?
   No   Yes   if Yes, approximately how many appointments______

6. A social worker?
   No   Yes   if Yes, approximately how many appointments______

7. A speech and language therapist?
   No   Yes   if Yes, approximately how many appointments______
During this period, have you or your relative attended or received any of the following:

(Please circle one of the answers in italics)

8. A carers support group (for you - NHS or other agencies)
   No   Yes   if Yes, approximately how many times _____

9. A patients support group (for your relative)
   No   Yes   if Yes, approximately how many times _____

10. A period of respite i.e. admission to residential care for your relative
    No   Yes   if Yes, approximately for how long _____ days

11. Have you received support or advice about dementia and caring from anyone else (e.g. telephone help-lines, friends, societies and charities)? Please describe below.

12. Has anyone given you any advice about communication difficulties in dementia during this period? Please describe below.

13. Have you read any books or leaflets about managing communication difficulties in dementia? If yes, which ones?
Appendix 17: The Hospital Anxiety and Depression Scale.

<table>
<thead>
<tr>
<th>Item</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>I feel tense or ‘wound up’</td>
<td>Not at all</td>
<td>Hardly at all</td>
<td>Only a little</td>
<td>A lot of the time</td>
</tr>
<tr>
<td>I still enjoy the things I used to enjoy</td>
<td>Not at all</td>
<td>Hardly at all</td>
<td>Only a little</td>
<td>Not quite so much</td>
</tr>
<tr>
<td>I get a sort of frightened feeling as if something awful is about to happen</td>
<td>Not at all</td>
<td>Hardly at all</td>
<td>Only a little</td>
<td>Not quite so much</td>
</tr>
<tr>
<td>I can laugh and see the funny side of things</td>
<td>Not at all</td>
<td>Hardly at all</td>
<td>Only a little</td>
<td>Not quite so much</td>
</tr>
<tr>
<td>Worrying thoughts go through my mind</td>
<td>Very little</td>
<td>Not too often</td>
<td>A lot of the time</td>
<td>A great deal of the time</td>
</tr>
<tr>
<td>I feel cheerful</td>
<td>Most of the time</td>
<td>Not often</td>
<td>Sometimes</td>
<td>Not often</td>
</tr>
<tr>
<td>I can sit at ease and feel relaxed</td>
<td>Not at all</td>
<td>Not often</td>
<td>Usually</td>
<td>Definitely</td>
</tr>
<tr>
<td>I feel as if I am slowed down</td>
<td>Very often</td>
<td>Sometimes</td>
<td>Occasionally</td>
<td>Not at all</td>
</tr>
<tr>
<td>I get a sort of frightened feeling like ‘butterflies’ in the stomach</td>
<td>Very often</td>
<td>Quite often</td>
<td>Occasionally</td>
<td>Not at all</td>
</tr>
<tr>
<td>I have lost interest in my appearance</td>
<td>Very often</td>
<td>Quite often</td>
<td>Occasionally</td>
<td>Not at all</td>
</tr>
<tr>
<td>I don’t take as much care as I should</td>
<td>Very often</td>
<td>Quite often</td>
<td>Occasionally</td>
<td>Not at all</td>
</tr>
<tr>
<td>I take just as much care as ever</td>
<td>Very often</td>
<td>Quite often</td>
<td>Occasionally</td>
<td>Not at all</td>
</tr>
<tr>
<td>I feel restless as if I have to be on the move</td>
<td>Not very much</td>
<td>Quite a lot</td>
<td>Not at all</td>
<td>Occasionally</td>
</tr>
<tr>
<td>I look forward with enjoyment to things</td>
<td>Hardly at all</td>
<td>Definitely less than I used to</td>
<td>Rather less than I used to</td>
<td>As much as I ever did</td>
</tr>
<tr>
<td>I get sudden feelings of panic</td>
<td>Not at all</td>
<td>Not very often</td>
<td>Quite often</td>
<td>Very often</td>
</tr>
<tr>
<td>I can enjoy a good book or radio or television programme</td>
<td>Not often</td>
<td>Sometimes</td>
<td>Occasionally</td>
<td>Not at all</td>
</tr>
</tbody>
</table>

Total A: [ ]

Total D: [ ]
Appendix 18: The adult carers quality of life scale.
### The General Self Efficacy Scale

**Instructions**
Please describe how true the following statements are about you by circling one answer per question.

For example:

<table>
<thead>
<tr>
<th>Statement: I am good at filling out forms. Answer:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 = Not at all</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Statements:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I can always manage to solve difficult problems if I try hard enough.</td>
</tr>
<tr>
<td>1 = Not at all</td>
</tr>
</tbody>
</table>

| 2. If someone opposes me, I can find the means and ways to get what I want. |
| 1 = Not at all | 2 = Hardly true | 3 = Moderately true | 4 = Exactly true |

| 3. It is easy for me to stick to my aims and accomplish my goals. |
| 1 = Not at all | 2 = Hardly true | 3 = Moderately true | 4 = Exactly true |

| 4. I am confident that I could deal efficiently with unexpected events. |
| 1 = Not at all | 2 = Hardly true | 3 = Moderately true | 4 = Exactly true |

| 5. Thanks to my resourcefulness, I know how to handle unforeseen situations. |
| 1 = Not at all | 2 = Hardly true | 3 = Moderately true | 4 = Exactly true |

Version two: 10/10/11.
Please circle one answer per question.

6. I can solve most problems if I invest the necessary effort.
   1 = Not at all  2 = Hardly true  3 = Moderately true  4 = Exactly true

7. I can remain calm when facing difficulties because I can rely on my coping abilities.
   1 = Not at all true  2 = Hardly true  3 = Moderately true  4 = Exactly true

8. When I am confronted with a problem, I can usually find several solutions.
   1 = Not at all true  2 = Hardly true  3 = Moderately true  4 = Exactly true

9. If I am in trouble, I can usually think of a solution.
   1 = Not at all true  2 = Hardly true  3 = Moderately true  4 = Exactly true

10. I can usually handle whatever comes my way.
    1 = Not at all true  2 = Hardly true  3 = Moderately true  4 = Exactly true

Version two: 10/10/11.
Appendix 20: The communication competence scale.

The Talking Sense Study
Communication Competence Scale

This scale measures how competent you (the carer) believe your relative is in communicating.

Instructions: Please put one of the following marks (e.g. SA or ?) on the line before each statement confirming whether you:

SA = strongly agree, A = agree, ? = are undecided or neutral,

D = disagree or SD = strongly disagree.

Example:
Question 3. My Relative:

SA   3. treats people as individuals

i.e. I strongly agree that my relative treats people as individuals

Score

1. finds it easy to get along with others.
2. can adapt to changing situations.
3. treats people as individuals.
4. interrupts others too much.
5. is "rewarding" to talk to.
6. can deal with others effectively.
7. is a good listener.
8. 's personal relations (how they treat people) are cold and distant.
9. is easy to talk to.
10. won't argue with someone just to prove he/she is right.
11. conversation behaviour is not "smooth."
12. ignores other people’s feelings.
13. generally knows how others feel.
14. lets others know he/she understands them.
Scoring Key:

SA = strongly agree, A = agree, ? = are undecided or neutral,
D = disagree or SD = strongly disagree.

My relative .................

____ 15. understands other people.
____ 16. is relaxed and comfortable when speaking.
____ 17. listens to what people say to him/her.
____ 18. likes to be close and personal with people.
____ 19. generally knows what type of behaviour is appropriate in any given situation.
____ 20. usually does not make unusual demands on his/her friends.
____ 21. is an effective conversationalist.
____ 22. is supportive of others.
____ 23. does not mind meeting strangers.
____ 24. can easily put himself/herself in another person's shoes.
____ 25. pays attention to the conversation.
____ 26. is generally relaxed when conversing with a new acquaintance.
____ 27. is interested in what others have to say.
____ 28. doesn't follow the conversation very well.
____ 29. enjoys social gatherings where he/she can meet new people.
____ 30. is a likeable person.
____ 31. is flexible.
____ 32. is not afraid to speak with people in authority.
____ 33. People can go to my relative with their problems.
____ 34. generally says the right thing at the right time.
____ 35. likes to use his/her voice and body expressively.
____ 36. is sensitive to others' needs of the moment.

Appendix 21: The carers communication self efficacy scale.

The Talking Sense Study - Carers Self Efficacy Scale

This scale explores communication difficulties you and your relative may experience. You are asked firstly how often situations occur and secondly how well you believe you are able to manage them.

When you believe you are able to manage something well, it could be that you are able to resolve or avoid a difficulty, feel good about what you have done or said, have justified the situation in your mind or believe you are doing as well as anyone else would in that situation.

Please answer by circling one of the words in *italics* on each line of the shaded area, one for how often it happens and one for how well you manage it.

If something described *never* happens then try to mark it how you believe you would manage it if it did happen e.g. my relative *never* finds it difficult to start a conversation but if they did, I would manage it *very well*.

Since having dementia....................

1. My relative finds it difficult to start a conversation....
   
   This happens: *never* rarely occasionally *a lot* always
   I am able to manage this: *not at all* poorly adequately well very well

2. My relative talks much more than they used to ...
   
   This happens: *never* rarely occasionally *a lot* always
   I am able to manage this: *not at all* poorly adequately well very well

3. My relative finds it difficult to understand what I’ve said...
   
   This happens: *never* rarely occasionally *a lot* always
   I am able to manage this: *not at all* poorly adequately well very well
4. My relative finds it difficult to explain things....
This happens: never rarely occasionally a lot always
I am able to manage this: not at all poorly adequately well very well

5. My relative gets frustrated or upset in conversations....
This happens: never rarely occasionally a lot always
I am able to manage this: not at all poorly adequately well very well

6. My relative says things that are inappropriate (out of place or rude)....
This happens: never rarely occasionally a lot always
I am able to manage this: not at all poorly adequately well very well

7. My relative repeats what they have said (within a conversation)....
This happens: never rarely occasionally a lot always
I am able to manage this: not at all poorly adequately well very well

8. My relative says things that aren’t true or accurate....
This happens: never rarely occasionally a lot always
I am able to manage this: not at all poorly adequately well very well

9. My relative experiences difficulty when they talk with other people....
This happens: never rarely occasionally a lot always
I am able to manage this: not at all poorly adequately well very well

10. When communication is difficult, I get frustrated with my relative....
This happens: never rarely occasionally a lot always
I am able to manage this: not at all poorly adequately well very well
Appendix 22: The therapeutic engagement index and readiness scale.
Appendix 23: The referrers guide.

The Talking Sense Study - Guidelines for Referrers

Dear colleague

You have been asked to consider inviting people to participate in this research study. You will also have received a verbal explanation.

Talking Sense is a treatment approach for working with family carers of people with dementia on the communication difficulties they experience when they are interacting with their relative. It has been written by Colin Barnes, Speech and Language Therapist. Colin will be providing all the interventions in this study.

Before completing a brief referral form, you are asked to consider if a carer is suitable for participating in this study. You will then need to provide them with an introductory leaflet to take away. If they are interested in participating in the study you will need to ask them if Colin can be sent their contact details.

Quick check

- Are carers suitable (see next page)?
- Are they experiencing “communication difficulties”?
- Have carers received a brief explanation and leaflet?
- Are they happy for Colin to receive their contact details and telephone them?

To make a referral please send the brief referral form to Colin Barnes in the envelopes provided.

After your referral has been received, Colin will contact the carers by telephone to ask if they are still interested in participating. It is important that no-one coerces carers to participate, that carers are aware existing SLT support is available and that there are no consequences of non-participation.

This study has been approved by the NHS research and development department and local research ethics committee (reference number: ). It is being conducted as part of a PhD study. The study will be monitored by academic supervisors and a clinical steering group.
Inclusion Criteria

Carers can be included if they are:

- **Spouses, co-habiting partners or children** of the person with dementia in communication contact with their relative with dementia for more than **two hours** weekly.
- Caring for a relative with a diagnosis of **Alzheimer’s disease, vascular dementia** or **Lewy body dementia**.
- Reporting “**existing difficulties with communication**” between themselves and their relative. The leaflet should help define this.
- Demonstrating **capacity to understand and consent to participation** for the duration of the study.
- Considered mentally well enough to participate in this study (for nurse referrals, approval to participate must be sought after discussion from the team psychiatrist confirmed in writing or nhs.net e-mail).
- Only receiving support from the mental health team that could be described as “treatment as usual” i.e. **not receiving large amounts of individual support in relation to these communication difficulties**.
- Caring for a person with dementia with a recent or current likely score of between **21 and 27 out of 30 on the M.M.S.E. test** (Folstein et al, 1975).

Carers will be excluded from participation if they:

- have not been **approved for involvement** by the team psychiatrist
- are caring for someone with a **primary communication impairment** associated with fronto-temporal dementia, Parkinson’s disease or stroke as it is expected their presentation and experience will be significantly different (Nikolaou et al, 2010).
- **have already received a significant form of individualised communication therapy** e.g. with speech and language therapy.

People with dementia are not active participants in this research. Carers are expected to be seen alone though it is possible that their relatives with dementia may be present if they can consent to doing so.
After you refer someone to participate in this study, they will be contacted by Colin Barnes. He will answer any initial questions they have. He will then arrange to visit them. Prior to this he will send them a more detailed participant’s information sheet which will be explained further during the arranged visit. If carers are happy to proceed they will be asked to sign a consent form.

If you are a senior nurse referring to this study, please seek approval for the carer’s participation from your team psychiatrist and document this approval e.g. on NHS net or the Mental Health Rio system.

Participation will involve:

- Involvement in the study over a 10 - 12 week period.
- The option to withdraw at any time.
- Being randomly assigned to either an intervention or control group.
- All participants will be asked to complete questionnaires at the beginning and the end. Some may also be asked to participate in an interview.
- People in the intervention group will receive 3 visits during the first 8 weeks.
- Control group members will receive treatment as usual which is based on a single visit discussion about their communication difficulties.
- All participants can ask for further speech and language therapy support after the 12 weeks of their involvement in the study.

If you have any questions or concerns about this study please contact Colin Barnes on 02392 894337 or Ann Rice, adult speech and language therapy service manager on 02392 680270.

You can also discuss this study with Dr Karla Greenberg.
Appendix 24: Operational definitions for the therapeutic engagement index.

**Therapeutic engagement index**

What would constitute not at all (NAA) and what would constitute extremely (E).

1. **Resist the therapeutic relationship** – interpreted as reluctance to develop discussion, sharing, openness with the therapist.
   NAA would be someone who shows no uncertainties about meeting with and discussing ideas with the therapist.
   In-between may show some uncertainties but still remain active
   E would be someone who indicates strong reluctance, hesitance, blocks or avoids questions repeatedly, says it is worthless, waste of time, strong doubts about value etc.

2. **Reject suggestions** – not someone who identifies when suggestions aren’t good but someone who is not open to considering suggestions
   NAA is someone who consistently considers suggestions
   In-between could be someone who doesn’t always respond actively to suggestions or doesn’t show good consideration (overly negative)
   E would be someone who consistently doesn’t consider or is consistently negative towards suggestions

3. **Appear bored** – interpreted as not tiredness or fatigue but demonstrated disinterest
   NAA – someone who remains interested and attentive as much as they are able
   In-between may be someone who has episodes of disinterest, disengagement, yawning, clockwatching
   E - someone who cuts session short, yawns excessively, engages in other activities, belittles topics of conversation

4. **Seem reluctant to reveal information** – interpreted as someone who is guarded about what happens to them or their relatives and to a lesser extent their feelings and anything personal (take into account some people may find this harder and consider it more personal – to be protected). Not to be mistaken for difficulty understanding questions. This is more to do with their faith in your ability and need to know.
   NAA – Someone who is open to answer all questions and volunteers experiences, thoughts and feelings as well as limited personal information
   In between is someone who answers questions but doesn’t volunteer where opportunities are available or someone who may dodge occasional questions
   E – someone who frequently answers I don’t know or would rather not say where it seems likely they do have awareness – particularly where they are reluctant to engage (rather than embarrassed/shy/being protective).

5. **Indicates future contacts will be cancelled** – this is to do with lack of faith in programme and reluctance to commit / lower priority given to sessions. No negative consequences of informing you that contacts may be cancelled for genuine reasons.
   NAA – Someone who is flexible and keen to arrange future contacts
   In between may be someone who is vague in arranging future contacts and willing to prioritise other activities e.g. clubs, hairdressers above therapy sessions. May also mention the possibility that they may cancel even though they take an arrangement on.
   E may be someone who is strongly reluctant to commit to future sessions or mentions that it is unlikely they
will complete the course, will probably not commit to a session – may offer to call therapist to arrange but seem unlikely to do so.

6. **Make interventionist feel welcomed.** This is about the extent to which you are warmly greeted and allowed to stay. This could involve how prepared they are for you, whether they offer refreshments (as expected or not), seating offered and flexibility in creating seating or table space, mentions of time limits etc and how they end.

   E = positive action on all the above

   In between some negative action on the above

   NAA = Someone who acts negatively on the majority on above and acts in such as way as to make the interventionist leave or feel unable to complete tasks.

7. **Involve the interventionist in family activity.** This may be harder to rate. This could include whether they volunteer family information, introduce you to others in the home (e.g. pwd, children, visitors etc) or gives the impression that they would introduce you to others, ask you to liaise with other family members (where relevant). This is partly related to how “ashamed/embarrassed” they are of you and how likely they are to share you ideas with others.

   NAA = someone who maybe is not only not welcoming but also isolates the therapist from family members, information and activities

   In between some reluctance to introduce you to others for no good reason

   E- someone who makes a point of introducing you to others, seems keen on their association with you and perhaps asks if you would talk with other family members (where possible).

8. **Do most of the talking.** Not clear if this is a positive or negative aspect. To take as a negative aspect. It could be positive in that they answer questions, engage where required and don’t leave therapist having to take the lead or negative in that they dominate conversation making it hard to get ideas across. Overall to interpret this as a comment on engagement in talking, control of self and conversation skills (pragmatics).

   E (scoring 0). Someone who talks to excess, doesn’t answer questions, dominates topic choice etc

   In between may be someone who either talks too much or to little perhaps habitually but still engages as much as they are able

   NAA (scoring 4). Someone who listens well, gives detailed but succinct answers, discussed, volunteers ideas, listens well etc

9. **Disclose relevant information.** Distinction from question 4 is that this is less about guardedness and more about ability to understand and identify relevant answers. Could also include an element of asking relevant questions (so not just answering).

   NAA = someone who doesn’t ask questions and often generates answers to my questions that are unrelated, weak in content or show poor understanding

   In between might be someone who make occasional errors answering questions

   E- someone who shows high levels of awareness and insight into their situation and feelings (to the limit of their ability) and who consistently understands topics and questions and discloses information about them.

10. **Share knowledge with the interventionist.** This is about knowledge and could include skills. Carers volunteer what they know (which may not need to be accurate) and demonstrate skills they have.

    NAA = could include someone who has knowledge but doesn’t share it and someone who has no knowledge.

    In between - someone demonstrates some knowledge by volunteering what they have read, thought about,
recognised, learnt from life etc with phrase including “I know”, “I’ve tried that”, “I worked out” etc
E- Someone who regularly volunteers information, seeks additional information outside of sessions including thoughts and experiences recounted, someone who debates ideas adding in their own thoughts and ideas.

11. **Ask questions.** See also do most of the talking. This is purely about asking of relevant questions that follow topics being talked about (as opposed to someone who detracts from topics by asking unrelated questions).

NAA – someone who never asks any questions or indicates that they are questioning what they are learning (could e.g. be reflecting inside their head)
In between – someone who asks only occasional questions e.g. one per session or poor quality questions that show limited understanding
E – someone who asks frequent detailed and relevant questions that add to their understanding and maintain the balance of conversation (i.e. not talking too much);

12. **Offer feedback.** Feedback could include positive and negative comments made constructively about the arrangements of the session, how topic and materials are delivered (with the aim of helping themselves or others) and comments intended to aid their development about specific issues. Helpfulness of feedback is also included.

NAA – Someone who may still answer questions but doesn’t make any comments about ideas, arrangements future use of approach, research study and doesn’t take an active role in trying to make the approach work. Could also include someone who only makes feedback that isn’t at all helpful.
In between could include someone who offers occasional feedback but isn’t fully or enthusiastically engaged.
E- someone who is fully and enthusiastically engaged in making this work reflecting on ideas for their own benefit as well as future users and the therapist.

13. **Express a need for more information**

NAA - Linked in with asking questions but focuses specifically on information. This could include information questions, requests for other resources, a desire to learn information and skills, facts etc.
In between could be someone who makes occasional requests for information but appears to still have areas of knowledge they are not addressing.
E- someone who regularly shows a desire to learn, identifies areas of knowledge and skill that are lacking and generally communicates a consistent desire to know and understand more.

14. **Indicate the contact was useful.** This could be made directly e.g. “that was really helpful”, implied “this will help me do x” or indirectly “thank you for coming to see me” unless it is clear they appreciated the social aspect of the visit only.

NAA – Someone who never acknowledges the value of the visit. Some allowance may be needed to take into account differences in personality – one test is how likely are they to express this in other circumstances.
In between may be someone who thanks you for the contact occasionally or does so non-specifically.
E – Someone who expresses the value of the contact with reasons given and ideally more than just once at the end of the contact.
Appendix 25: The development of the carer communication self efficacy scale.

The development of the Carer Communication Self Efficacy scale (CCSES).

August 2011

A wide range of outcome measures were considered to qualitatively evaluate the effect of the talking sense programme. A selection of measures was chosen to consider the effect of the programme on both the carer and (indirectly) the person with dementia in keeping with 1) the theoretical basis of effect of the programme 2) contemporary thinking on carer outcome measures and 3) comparable recent or key studies.

One key influence in this process was Shulz (2000).

Measures already selected would consider a) the psychological effect (HADS) on the carer 2) the carer’s quality of life (ACQOL scale) and the carer’s perception of their relatives competence (communication competence scale).

Kouri et al (2011) the most recent and best quality study in this field used the idea of carers self–efficacy in both their theoretical process of treatment and outcome measure. They proposed that their intervention would affect the carer’s perception of their ability to manage situations and communicate with their relative. They measured this using an adapted version of the RBMPC (Teri et al 1992) and the caregiver self efficacy scale (Bandura 2001).

The RBMPC had already been considered as a measure. It has a very useful design looking at frequency of event and resultant burden but this is not the same as efficacy. The scale also uses a complex 1-9 point rating scale with uneven points which may be difficult for older carer self completion.

Kouri et al (2011) refer to using the caregiver self efficacy scale quoting Bandura’s book on the subject. However no such scale is included in this book. A revised version of the same scale is quoted in Steffen et al (2002) called the revised scale for care–giving self efficacy (Bandura is one of the authors). This was ruled out as 1/3 of the questions were specific to obtaining respite and again most questions focused on very specific scenarios. Very little of this relates specifically to communication.

The decision was made to evaluate carers specific beliefs about their communication efficacy as this is the issue being addressed.

A search was conducted for similar communication specific self efficacy scales. Farran et al (2011) had developed the caregiver assessment of behavioural skill (CABS-SR). This was ruled out as too specific and less than 50% of the (17) question relevant to communication scenarios. It also did not seem to focus on efficacy as specifically as recommended by Bandura.

The decision was made to develop a self-efficacy scale based around the steps of the talking sense programme and “issues that occur” identified from carer completed questionnaires (n=30) during the development of talking sense. This would also capture whether specific situations
occurred as well as whether the carer believed they were able to manage them.

A guide for constructing self-efficacy scales (Bandura 2006) was consulted which recommended that self efficacy should be distinguished from self-esteem, locus of control and outcome expectancies. They define self efficacy as the judgement of capability to execute given types of performance.

(Bandura 2006) also recommend using a 0-100 linear scale where the completer is encouraged to mark a point on a line. This approach was rejected as not in keeping with other outcome measures used and potentially too complex for self-completion.

A layout similar to the RBMPC (Teri et al 1992) was chosen and originally a 4 point scale was added with descriptions similar to the RMBPC. This was later changed to a 5 point (unidirectional) scale after reviewer feedback and consideration of the literature on scale design (Gill, 2009).

Face Validity Exercise
A first version of the scale was developed and presented to a group of 3 other SLT’s to consider face validity. The concept of self efficacy was explained and the purpose of the scale was discussed as well as each specific question. Changes were agreed to wording though all 11 original questions were kept to develop version two.

Utility exercise
Version two of the form was used in an outcome measures utility exercise. Five personal contacts of the researcher were asked to trial completing the full set of outcome measures. A purposive sample was chosen to represent age, sex and education more typical of dementia carers in previous research studies.

This study suggested the form would take 4 minutes (n=5, range 3-5 minutes) to complete. After trial completing the form, participants were asked to re-read the form and add any comments on design, readability, ease of use and content.

Content Validity Exercise
The Lawshe method (1975) of measuring content validity was used. Version two of the form was sent to 24 health professionals including SLT’s, mental health nurses and a psychologist all of whom had experience of working with carers. A small incentive (kit-kat) was offered for completion. 14 forms were returned (58% response rate).

After reading and explanation of self-efficacy and the purpose of the form, participants were asked to firstly grade the questions for e=essential, u=useful and n=not necessary. They were then asked to write any comments on design and readability on the form.
**Version 3**
A third version of the CCSES form was produced taking into account comments on design and readability (that didn’t change the meaning of any questions).
One question, question 6 that considered arguments between carers and their relatives was removed as this achieved only 36% scoring as essential. All other questions achieved at least 58% essential (a score of 51% was required to achieve a greater than chance score for 14 respondents).

**Establishing Reliability**
Given that this is being used in a larger feasibility study it was decided to establish reliability of this measure within the study by making comparison to other outcome measures. For this purpose a general self efficacy scale (ref) with supporting psychometric data was identified. Full permissions for using this scale and detailed data were obtained. The utility exercise identified that this scale would take approximately 2 additional minutes (n=5, range 2-3 minutes) to complete.
Appendix 26: Individual carer summary scores template.

<table>
<thead>
<tr>
<th>Description</th>
<th>Pre</th>
<th>Tx1/Ctr</th>
<th>Tx2</th>
<th>Tx3</th>
<th>Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of contact</td>
<td>Wk</td>
<td>Wk</td>
<td>Wk</td>
<td>Wk</td>
<td>Wk</td>
</tr>
<tr>
<td>Duration</td>
<td>mins</td>
<td>mins</td>
<td>mins</td>
<td>mins</td>
<td>mins</td>
</tr>
<tr>
<td>Carers age at onset</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Referrer Dr, Nurse, Case load, Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Person with dementia age at onset</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dementia type (or more complex)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Last MMSE score</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>VEMAS score</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Person with dementia: Male/Female</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carer: Male/Female</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length of caring</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Co-habit</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Days a week together</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General health</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time spent talking</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Support towards caring</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Who else is involved (record no of people)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occupation (full, judgement, professional or not)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>How stressful is your life</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment for depression</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Ethnic Group (white british or not)</td>
<td></td>
<td></td>
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<td>Speak other languages</td>
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<td>Contact with GP</td>
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<td>Contact with psychiatrist</td>
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<td>Contact with CMHN</td>
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<td>Contact with psychologist or counsellor</td>
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<td>Contact with OT</td>
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<td>Contact with social worker</td>
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<td>Carers support group</td>
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<td>Other support</td>
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<td>Communication advice received</td>
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<td>Books or leaflets</td>
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<td>ACQOL – Support for caring</td>
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<td>ACQOL – Caring Choice</td>
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<td>ACQOL – Caring Stress</td>
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<td>ACQOL – Money Matters</td>
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<td>ACQOL – Personal Growth</td>
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<td>ACQOL – Sense of value</td>
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<td>Test</td>
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<td>ACQOL – Ability to care</td>
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<td>ACQOL – Carer satisfaction</td>
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<td>ACQOL – Total Score</td>
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<td>General Self Efficacy Scale – Total Score</td>
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<td>Carers Comm’ n SE scale – Happens score</td>
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<td>Communication Competence score</td>
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<td>TEL Score – openness</td>
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<td>TEL Score – connectedness</td>
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<td>TEL Score – Involvement</td>
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<td>TEL Score – combined open and connect</td>
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<td>TEL Score – Total</td>
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<td>TEL - Readiness score</td>
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<td>Expectations achieved</td>
<td>Yes/No</td>
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</table>

**Talking Sense Adherence check:** Pages covered:

1   2   3   4   5   6   7   8   9   10  
11   12  13  14  15  16  17  18  19  20  
21   22  23  24  25  26  27  28  29  30  
31   32  33  34  35  36  37  38  39  40  
41   42  43  44  45  46  47  48  49  50  
51   52  53  54  55  56  57  58  59  60  
61   62  63  64  65  66  67  68  69  70  

Any additional topics mentioned:

**Scoring Procedures:**

**ACQOL:** Score for items is between 0 and 4 - use laminate overlay to score. Different questions score in different directions dependant on whether it is a positive or negative question – see instructions.

**GSES** – add all points below questions up to achieve a score between 10 and 40. Low score = low self efficacy.

**CSES** – to score from 5 to 1 for each question. Low score = high incidence of difficulties and low self efficacy. All questions are negative (question two is ambiguous as talkativeness could be both a problem and something desired - may need to be interpreted as to whether carers saw it as a –ve or +ve). "This happens e.g. never = 5 ..., always = 1". Reverse use of 1-5 for second row where "I manage this e.g. not at all = 1 ... very well = 5".

**HADS** – see score sheet copy (in file). Is divided into anxiety and depression sub-scores, plus a total score.

**Communication competence** – Items are scored 5 – 1. Higher score = greater competence. Items 4, 8, 11, 12, and 28 are reverse coded so watch out.
Appendix 27: Topics selected by carers and therapist during the delivery of the Talking Sense programme.

Key: The Number in brackets indicates how many carers from the treatment group (n=27) selected that topic. Topics are displayed and grouped by order of popularity (>20, >10 and <10).

- Managing decision making (27)
- Put something out to talk about (26)
- Avoiding quizzing (26)
- What is communication? (25)
- How dementia affects communication (25)
- What are our human needs (24)
- Understanding the development of communication (24)
- The importance of non verbal communication (24)
- Communication visits, variety or familiarity and managing fatigue (24)
- Managing contradiction (24)
- The need to communicate, make sense, choose, control, be right and be truthful (23)
- The experience of having dementia – developing insight into the person (22)
- General principles for using external memory aids (22)
- Memory campaigns (22)
- Using questions appropriately (22)
- What is being right and what is being truthful (21)
- Using life story books and aids (21)
- Using reminiscence (21)
- Different types of Dementia (20)
- The thought behaviour cycle (19)
- Memory aids need introducing (19)
- Talking about dementia together (19)
- Learning new tricks (19)
- Understanding thoughts, beliefs and assumptions (18)
- Using the telephone (18)
- Real Life examples of carer communication difficulties (17)
- What people with dementia might feel (16)
- Ask yourself- what am I trying to achieve? (16)
- Conversation magnets - objects that attract conversation (16)
- Your communication style and role (16)
- Using humour (15)
- Even clothes make a difference (14)
- Making the most of hearing and vision (14)
- The Steps to developing a Talking Sense (13)
- Family gatherings (13)
- Different types of memory (12)
- Equipping others with information and aids to communication
• Reality orientation (12)
• Action memory and establishing habits (10)
• Keeping a balance between communication content and quality (10)

• Strategies to aid understanding (9)
• Positive thoughts, vicious and virtuous circles (8)
• Practical ideas to modify the environment (8)
• Treasure chests and talk bags (8)
• Listening, understanding meaning and interpretation (8)
• How they listen to you (8)
• What to do with word finding difficulties (8)
• Reading and writing difficulties (8)
• Validation therapy (8)
• Human Tendencies - the way we interpret the world (7)
• How to challenge thoughts, beliefs and assumptions (7)
• Considering positions of power (7)
• Calling for help (7)
• Forming realistic expectations (6)
• Using memory wallets to aid orientation (6)
• The SPECAL approach (6)
• Off the shelf activities (6)
• What causes challenging behaviour (6)
• Using pets for interaction (5)
• Equipping the person with information for memory and conversation (5)
• Using internal memory aids (5)
• Cognitive stimulation (5)
• Establishing new beliefs (4)
• Care tasks (4)
• What is challenging behaviour (3)
Appendix 28: Further demographic results comparing carer groups.
Appendix 29: Interview guide (version 4).

Interview Guide for Talking Sense interviews Version 4

- Check both microphones are recording and near to the carer. Say date.
- Show picture of book and Colin.

1. What happened when Colin came to see you?
2. What did you learn?
3. How did it affect you (both)?
4. What changed (for you both)?

Points to consider:

- **Knowledge** – what people learn.
- **Insight** (Competence) – what they learn to understand about their relative. *One of the questionnaires you completed asks about your relatives communicative competence/ability – what do you think of their competence now.*
- **Thoughts and feelings** (CBT model) – any ways of thinking adopted or identified. *Do they remember CBT slides. Have they used the thought behaviour cycle. Can they tell you more about that?*
- **Permissions** – Did carrying out this programme/meeting with Colin give you any sense of approval (it’s OK) for doing or thinking things differently?
- **Self efficacy** – *has it affected your belief in your ability to communicate with/respond to/ care for your relative*
- Any change in **use (and remembering) of strategies** (did you do anything differently) inc objects, activities, aids, approaches etc. *Some people find these hard to remember – why do you think this is?*
- **Intentions** – how did you *go about making a change in what you do*
- **Examples** – can you give me an example of what you did
- **Anything else going on** that made it easier or harder.
- **What was the experience** like for them – encouraging, tiring, stressful, reassuring etc.

**Thoughts re context/field notes – you can record your thoughts on a separate file on the Sony recorder**

Where did interview take place?

How comfortable did they seem?

How comfortable were you?

Was it quiet, noisy?

Did anything else happen during the interview?

Were there any points when they reacted differently?

How would you summarise what they said – what was your lasting impression?

What would you do differently if you could do it again?
Appendix 30: Initial codes from semi-structured interview analysis.

- **ADVICE FROM OTHERS** outside of Talking Sense
- **BELIEFS ABOUT SERVICES AND PROGRAMMES OF LEARNING**
- **CHANGES BEFORE OR NOT PART OF** Talking Sense
- **COMMUNICATION DIFFICULTIES** we experience
  - COMMUNICATION STRATEGIES we already use
  - Communication STRENGTHS
- **CONTEXT**
  - FAMILY AND FRIENDS
  - LIFE EXPERIENCES
  - NEGATIVE context
  - Depression and anxiety
  - POSITIVE context
  - RELATIONSHIP with person with dementia and how communication used to be
  - WHAT I (the carer) AM LIKE
- **EXISTING OR NON Talking Sense THINKING** including things not known
  - BELIEFS ABOUT WHAT OTHER PEOPLE might think or do
  - EXPERIENCE OF DEMENTIA (not communication)
  - BEING A CARER - what it feels like etc
  - CONCERNS about the future
  - CURRENT activities and approaches
  - EVENTS - things that have happened
  - EXPERIENCE FOR OTHERS
  - INSIGHT into the person with dementia
  - PATTERNS OF CHANGE in activity
  - Person with Dementia WAS AND IS LIKE ..... 
  - SUPPORT from professionals
  - WHAT Person with Dementia DOES now (not comm’n)
- **GENERAL COMMENTS ABOUT CHANGE PROCESS**
- OTHER WAYS I HAVE LEARNT AND COPED
  - NOT COPING

- TALKING SENSE
  - ADVANCED talking sense - developing something new or giving something back
  - Changes in MOOD and Anxiety
  - CHANGES MADE BY OR TO OTHERS
  - CHANGING OR KNEW ANYWAY (that were covered in Talking Sense)
  - The THERAPIST OR PROFESSIONALS LIKE HIM
  - COMMITMENT changes
  - DEVELOPING A TALKING SENSE (live adaptation)
  - EASIER OR HARDER THINGS
  - EFFECT ON OTHERS from Talking Sense
  - ELEMENTS
  - EXAMPLES OF ACTUAL SPEECH
  - FEELINGS (including encouragement) And Coping and negatives
  - GENERAL COMMENTS
  - HOW IT WORKED (minor themes - not intentions, feelings, self efficacy etc)
  - INSIGHT CHANGES about the pwd
  - INTENTION SETTING
  - KNOWLEDGE and UNDERSTANDING (not beliefs)
  - LOOKING AFTER MYSELF
  - MATERIALS AND PROCESS
    - DELIVERY
    - TIMING in point of illness
  - MEANING changes
  - MORAL changes and changes in attitude
  - MOTIVATION changes
  - NOT REMEMBERED OR DIDNT WORK and WHY
  - NOTICEABLE PWD CHANGES OR EFFECTS inc communication competence
  - PERCEPTIONS OR MISPERCEPTIONS about the programme
- RELATEDSHIP changes
- RICH COMMENTS to include in write up (positive and negative)
- SELF DISCOVERY and gained insight into self
- SELF EFFICACY and less self criticism
- SPECIFIC STRATEGIES
  - ACTIVITY changes
  - ACTUAL SPEECH examples
  - MEMORY MANAGEMENT strategies
  - PROACTIVE communication
  - RESPONSE changes
- Things I REMEMBER from Talking Sense S (not in other codes)
- THINKING and BELIEF CHANGES (including reinforcement) and permissions
- WHAT NEXT - THE FUTURE
Appendix 31: UPR 16 Research ethics checklist.

---

**FORM UPR16**  
Research Ethics Review Checklist

Please include this completed form as an appendix to your thesis (see the Postgraduate Research Student Handbook for more information)

<table>
<thead>
<tr>
<th>Postgraduate Research Student (PGRS) Information</th>
<th>Student ID: 32030 01</th>
</tr>
</thead>
<tbody>
<tr>
<td>PGRS Name: Colin Barnes</td>
<td></td>
</tr>
<tr>
<td>Department: School of Health Sciences and Social Work</td>
<td></td>
</tr>
<tr>
<td>First Supervisor: Dr Chris Markham</td>
<td></td>
</tr>
<tr>
<td>Start Date: October 2010 (or progression date for Prof Doc students)</td>
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<tr>
<td>Study Mode and Route:</td>
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<td>Part-time [ ]</td>
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<td>Professional Doctorate [ ]</td>
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</table>

| Title of Thesis: A pilot study to evaluate the effectiveness of an individualised and cognitive behavioural communication intervention for informal carers of people with dementia. |
| Thesis Word Count: 67,115 (excluding ancillary data) |

If you are unsure about any of the following, please contact the local representative on your Faculty Ethics Committee for advice. Please note that it is your responsibility to follow the University’s Ethics Policy and any relevant University, academic or professional guidelines in the conduct of your study.

Although the Ethics Committee may have given your study a favourable opinion, the final responsibility for the ethical conduct of this work lies with the researcher(s).

**UKRIO Finished Research Checklist:**
(If you would like to know more about the checklist, please see your Faculty or Departmental Ethics Committee rap or see the online version of the full checklist at: [http://www.ukrio.org.uk/what-we-do/code-of-practice-for-research/](http://www.ukrio.org.uk/what-we-do/code-of-practice-for-research/))

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<td>YES</td>
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<tr>
<td>a) Have all of your research and findings been reported accurately, honestly and within a reasonable time frame?</td>
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<tr>
<td>b) Have all contributions to knowledge been acknowledged?</td>
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<tr>
<td>c) Have you complied with all agreements relating to intellectual property, publication and authorship?</td>
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<tr>
<td>d) Has your research data been retained in a secure and accessible form and will it remain so for the required duration?</td>
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<tr>
<td>e) Does your research comply with all legal, ethical, and contractual requirements?</td>
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**Candidate Statement:**
I have considered the ethical dimensions of the above named research project, and have successfully obtained the necessary ethical approval(s)

**Ethical review number(s) from Faculty Ethics Committee (or from NRES/SCREC):** NRES 12/SC/0015

If you have not submitted your work for ethical review, and/or you have answered ‘No’ to one or more of questions a) to e), please explain below why this is so:

UPR16 – August 2015

---
Appendix 32: Ethical declaration of the end of a study.

---

Health Research Authority

DECLARATION OF THE END OF A STUDY
(For all studies except clinical trials of investigational medicinal products)

To be completed in typescript by the Chief Investigator and submitted to the Research Ethics Committee that gave a favourable opinion of the research (the main REC) within 90 days of the conclusion of the study or within 15 days of early termination. For questions with Yes/No options please indicate answer in bold type.

1. Details of Chief Investigator

<table>
<thead>
<tr>
<th>Name</th>
<th>Mr Colin Barnes</th>
</tr>
</thead>
</table>
| Address:      | Speech and Language Therapy Department  
                St James Hospital  
                Locksway Road, Portsmouth  
                Hampshire, PO4 8LD |
| Telephone:    | 02392 894337    |
| Email:        | colin.barnes@solent.nhs.uk |
| Fax:          | n/a             |

2. Details of study

<table>
<thead>
<tr>
<th>Full title of study:</th>
<th>A randomised controlled feasibility study examining the effectiveness of an individualised and cognitive behavioural communication intervention for informal carers of people with dementia.</th>
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<tr>
<td>Research sponsor:</td>
<td>The University of Portsmouth</td>
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<tr>
<td>Name of main REC:</td>
<td>Southampton-B</td>
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<tr>
<td>Main REC reference number:</td>
<td>12/SC/0015</td>
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3. Study duration

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<th>Date study commenced:</th>
<th>1st April 2012</th>
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<tbody>
<tr>
<td>Date study ended:</td>
<td>End December 2013. As a mixed methods study, analysis was extensive and completed in June 2014.</td>
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</table>
| Did this study terminate prematurely? | No  
If yes please complete sections 4, 5 & 6, if no please go direct to section 7. |
4. Recruitment

<table>
<thead>
<tr>
<th>Number of participants recruited</th>
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<tr>
<td>Proposed number of participants to be recruited at the start of the study</td>
<td>60 by December 2013.</td>
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<tr>
<td>If different, please state the reason or this</td>
<td>Recruitment was more difficult than expected. 111 carers were referred of which 55 were suitable or willing to participate. This is comparable with contemporary studies. All recruits participated though three failed to complete post measures. The sample recruited met the study aims as a pilot/feasibility study. Further recruitment was not required or indicated.</td>
</tr>
</tbody>
</table>

5. Circumstances of early termination

| What is the justification for this early termination? | N/A |

6. Temporary halt

| Is this a temporary halt to the study? | No |
| If yes, what is the justification for temporarily halting the study? When do you expect the study to re-start? | |

7. Potential implications for research participants

| Are there any potential implications for research participants as a result of terminating/halting the study prematurely? Please describe the steps taken to address them. | N/A |

8. Final report on the research

| Is a summary of the final report on the research enclosed with this form? | No |
| To be forwarded within 12 months after completion of PhD thesis. | |

*Declaration of end of study (non-CTIMP), version 1.2, December 2013*
9. Declaration

| Signature of Chief Investigator: | [Signature]
|---------------------------------|-----------------
| Print name:                     | Mr Colin Barnes
| Date of submission:             | 11th August 2014.

Declaration of end of study (non-CTIMP), version 1.2, December 2013