

# **A pilot study to evaluate the effectiveness of an individualized and cognitive behavioural communication intervention for informal carers of people with dementia: The Talking Sense programme**

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## **Abstract**

**Background:** People with dementia and family carers often experience difficulties communicating together. These difficulties are considered to contribute significantly to the depression, anxiety and negative feelings such as guilt often reported by dementia family carers.

**Aims:** To develop and contribute to the theory and evidence base for single-component, psychosocial interventions that address these difficulties by evaluating the effectiveness of the Talking Sense programme which was designed to reflect existing best evidence.

**Methods & Procedures:** Talking Sense was delivered as an individualized, one to one, cognitive behavioural approach for developing knowledge, skills, thinking and behaviour of dementia family carers in managing communication difficulties. In this study, a randomized controlled trial compared 27 carers who completed three one-to-one individualized sessions using Talking Sense with 25 carers who received a single, knowledge-only, control discussion.

**Outcomes & Results:** There were no significant differences for the primary outcome measure of carer anxiety and depression as well as carer quality of life and general self-efficacy. Statistically significant results suggested carers receiving the Talking Sense intervention had fewer communication difficulties happening ( $p = 0.046$ ) and felt more valued by their relatives ( $p = 0.046$ ). A score close to significance ( $p = 0.052$ ) suggested they perceived the irrelatives to be more communicatively competent.

**Conclusions & Implications:** The intervention and research design were shown to be effective with low attrition and high adherence to treatment. A non-significant finding for the primary outcome measure does not support the potential for this intervention to effect carer anxiety and depression. The potential for perceived change in the person with dementia, with statistically fewer communication difficulties happening and the carer feeling more valued by their relative, was the most significant finding from this programme of research. Recommendations for further research are made.

## Introduction

There are an estimated 670,000 people in the UK acting as primary family carers (hereafter referred to as 'carers') for people with dementia (Alzheimer's Society 2014). Levine and Murray (2004) argue that the culture of caregiving for family carers is distinctly different from that of professionals. Between 18% and 47% of dementia carers report feelings of anxiety and related depression (Akkerman and Ostwold 2004). This appears to be influenced by factors such as increased isolation, outside pressures, feelings of disappointment and poorer health of the carer (Andren and Elmstahl 2008).

Communication difficulty is one of the earliest presenting features for most people with dementia. The most common early language symptoms of a typical presentation are word-finding, naming and verbal-description difficulties. The ability to interpret meaning from facial expression, tone of voice and touch remain relatively intact until the later stages of most dementia presentations (Bourgeois and Hickey 2009).

Communication difficulty is one of the most frequent and hardest-to-cope-with experiences for carers (Egan et al. 2010). Carers suffering from depressive symptoms have also been found to use less positive communication themselves (Braun et al. 2010). How long an informal carer of a person with dementia (PWD) provides care has been strongly correlated with their experience of challenging behaviours and communication difficulties (Searson et al. 2008). The most common way of addressing communication difficulties with carers is to provide a list of generic guidelines aimed at supporting successful communication, such as 'slow your speech' or 'use yes/no questions' (Small et al. 2003) and recommended approaches such as validation therapy (Feil 1995).

Psychosocial interventions in dementia care are defined by the INTERDEM group as 'interventions that involve interactions between people to improve psychological or social functioning' (Moniz-Cook et al. 2011).

Schulz (2000) describes psychosocial interventions as constructed from a unique combination of single or multiple components (e.g., components could include communication strategies, anxiety management, use of services, managing finances etc.), domains targeted (e.g., thinking, knowledge, skills, behaviour), delivery methods (e.g., one to one or group, generic or individualized) and theoretical methods of action.

This research programme was preceded by a systematic review of dementia carer multi-component and communication-specific single-component psychosocial interventions studies (Barnes 2016). The best-quality evidence for multi-component interventions appeared to support the use of individualized behaviour management therapy, such as cognitive behaviour or reframing therapy (Vernooij-Dassen et al.

2011). The most likely outcome from this form of intervention appeared to be a reduction in carer-reported depression (Thompson et al. 2007). The Barnes (2016) review also concluded that the research evidence from multi-component intervention studies best supported individualized interventions (Schulz 2000).

In the systematic review, Barnes (2016) identified eight controlled studies that had previously evaluated single-component psychosocial communication interventions with dementia carers (Bourgeois et al. 1997, Done and Thomas 2001, Haberstroh et al. 2011, Kouri et al. 2011, Liddle et al. 2012, McCallion et al. 1999, Ripich et al. 1998, 1999). He concluded that although evidence for this form of intervention remained limited, it was most likely to affect carer knowledge, self-efficacy and experience of communication difficulty. When comparing these eight studies with the evidence for multi-component interventions, it was significant that none of the single-component communication studies had specifically addressed the domain of carer thinking (e.g., using cognitive behaviour therapy—CBT) in their intervention.

## **Materials and methods**

This study is described below using the CONSORT guidelines (Moher et al. 2010).

The objectives of this pilot study were:

- to apply best evidence from a systematic review to the design of both the intervention and the research study;
- to identify a significant clinical potential by recruiting appropriate carers, achieving low rates of attrition, minimal burden and no harm identified;
- to test the acceptability of the intervention and outcome measures; and
- to measure outcomes for significance or trends that reject the null hypothesis that the Talking Sense intervention will be no more effective than a control intervention.

## **Design and setting**

Decisions regarding design were overseen by a steering group that included carers. A randomized controlled trial design was chosen in keeping with recommendations made by Carroll and Nuro (2002) and the Medical Research Council (MRC) (2000) for researching manualized and complex interventions.

The trial was conducted amongst carers of people known to a city-based older person's mental health service in the south of England. A network of 20 dementia care professionals referred carers for participation in this study.

Relatively few dementia carer psychosocial intervention studies have been conducted in the UK. Consideration was also given during design of this study to allow for comparison with a large (n = 260) UK-based multi-component study reported by Livingston et al. (2013).

## **Recruitment and consent**

All referred carers were contacted by the first author to explain the nature of participation and to screen for inclusion and exclusion criteria. Eligible carers indicating a desire to participate were sent a participant information sheet and consent form by post. A home visit was then arranged with the carers to discuss participation. The participant information sheet and consent form were explained verbally to the carers.

## **Eligibility criteria**

Carers were included in this study if they were:

- spouses, co-habiting partners or children of the PWD, in contact for more than 2 h 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 consent and considered suitable for participation in this study by the approving or referring psychiatrist; and
- caring for a PWD with a recent score or functional ability judged by the referrer to be typical of between 21 and 27 out of 30 on the Mini Mental State Examination (MMSE) test (Folstein et al. 1975).

Carers were excluded from participation if they:

- were caring for someone with a primary communication impairment which was either associated with fronto-temporal dementia, Parkinson's disease or a stroke; and
- had already received individualized communication therapy.

## **Randomization and blinding**

The randomization sequence was generated by a third party colleague who produced a list of 30 randomly generated numbers between 1 and 60 using the website random.org. The remaining numbers formed the control group. The third-party colleague also produced a set of 60 cards that were labelled 'control' or 'treatment' and folded such that the randomization could not be seen. The cards were then labelled 1–60 to match the random allocation sequence. Once carers had consented and completed baseline measures, they observed the first author opening the next sealed card in sequence.

In this study, blinding of participants was not possible due to the nature of the information and intervention provided. Blinding of the authors during quantitative analysis was also not possible due to familiarity with the research participants.

## The Talking Sense intervention

Talking Sense (Barnes 2011) is a manual-based treatment programme designed for dementia care professionals to use, working in a one-to-one and individualized way with carers of people with dementia to address communication difficulties. The content of Talking Sense was developed following an extensive literature review, a consultation exercise with dementia carers and a content validity exercise conducted with dementia care professionals. Theoretical mechanisms of action for the Talking Sense intervention focus on developing self-efficacy by using a CBT framework. Self-efficacy is defined as 'an individual's belief in their ability to perform a specific behaviour or task' (Bandura 1997, 37). Cognitive behavioural therapy is an approach designed to challenge thoughts driven by an individual's beliefs, e.g., 'I am useless', and assumptions, e.g., 'If I do x then y will happen' (Wells 2008). A simplified interpretation of the cognitive behavioural model suggests that events lead to thoughts (driven by beliefs), thoughts lead to feelings and physiological changes, which then result in actions or responses.

As an intervention, Talking Sense targets domains (Schulz 2000) of thinking, knowledge, skills (e.g., with role play) and behaviour by exploring nine steps (see figure 1 and Appendix A). The nine steps of Talking Sense are interdependent, i.e., step 1 is explored before step 2 and so forth.

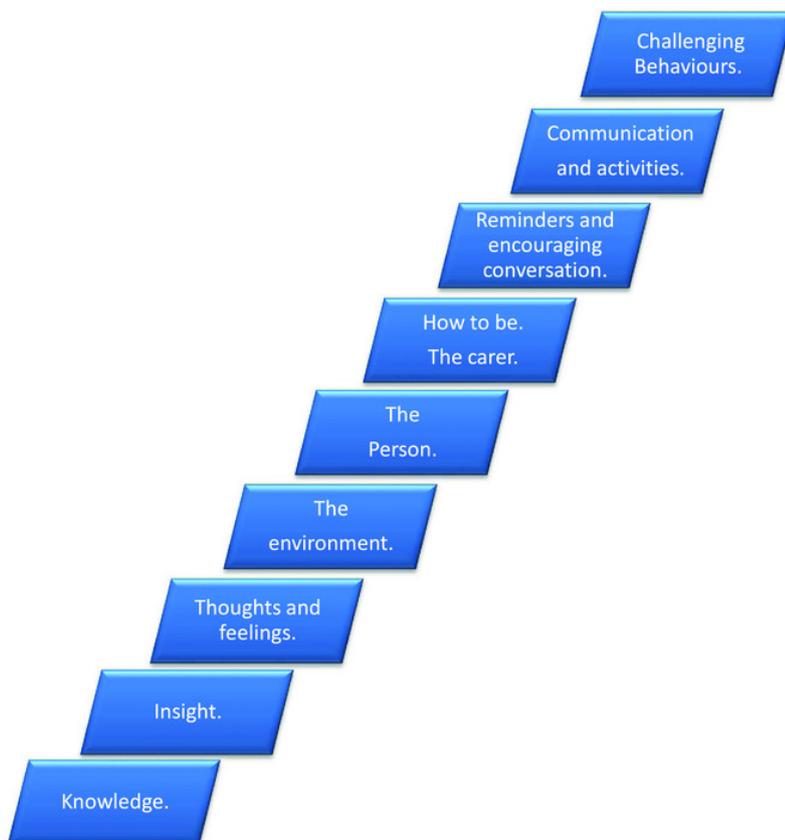


Figure 1: The nine steps of the Talking Sense programme.

This intervention was selected for this study to meet the clinical and research recommendations detailed in Barnes's (2016) systematic review, in particular the use of an individualized cognitive behavioural approach.

The Taking Sense intervention was delivered by the first author, a UK-registered speech and language therapist. After the recruitment visit, the carer was seen at home on three separate occasions, each lasting 1 h, all delivered within 8 weeks. This commitment was judged by the research steering group to be realistic for both therapist and carer. Time between sessions was flexible to minimize carer burden, though no more frequent than once a week.

The intervention was based around a discussion between the first author and carer using a series of 70 A4-laminated colour slides adapted from the original Talking Sense manual (Barnes 2011). Each of the nine steps was detailed in a summary slide and a variable number of more specific topic slides. Examples of summary slides for steps 1–4 are included as Appendix A.

The intervention sessions systematically followed each step of the Talking Sense programme (figure 1), though specific topics within steps were selected jointly after discussion by the carer and the first author. The first author also used a contents planner, carer difficulties descriptions and levels of communication difficulties scale detailed in the Talking Sense manual to plan for and guide the carer in selecting topics.

Typically, the initial intervention session covered the first two steps of Talking Sense. The first step 'Knowledge' is designed to develop the carer's understanding of dementia, types and potential causes of communication difficulties. The second step 'Insight' builds on this understanding to aid development of the carer's insight into their relative's experience of communication situations.

The second session typically covered steps 3–5, with session 3 covering any remaining topics. Step 3, 'Thoughts and feelings', introduces the carer to the basic principles of CBT and the idea that the discussion and any recommendations may be about how you think as well as what you do. Typically, the carer would be challenged to consider 'What are you thinking when that happens?' or 'What beliefs do you have that influence your thinking?' Between sessions carers were often encouraged to trial adopting different thoughts.

The remaining steps provide an explanation and strategies for developing communication skills, thinking and behaviour starting with the communication environment in step 4, how to equip the PWD for communication in step 5 and more specific situations and approaches in the later steps (figure 1).

After the third session, carers in the treatment group were sent a letter summarizing ideas, individualized recommendations and strategies identified.

### **Control condition**

It was agreed with the study steering group that the most suitable control condition would be providing a single 1 h-long discussion with the first author where issues identified by carers at the point of referral were discussed using individualized and generic information. The primary distinguishing feature of the control condition was that the therapist did not use a manual and did not refer to, or address, carer thinking. Unlike the treatment group, the single control session did not provide for the opportunity to review behaviour change or practise skill development through role play.

### **Outcome measures**

Previous outcome measures used in dementia carer psychosocial research were evaluated during the associated systematic review (Barnes 2016). Six outcome measures were identified as best supported by previous studies and contemporary theory. With the exception of a newly developed communication self-efficacy scale, all measures used were established with evidence of validity and reliability and suitable for self-completion by dementia carers.

### **The Hospital Anxiety and Depression Scale (HADS)**

The primary outcome was carer anxiety and depression measured using the HADS (Snaith 2003). It is well established with detailed validity records and established use amongst elderly and psychiatric case groups in a range of settings including hospital, home and clinic in over 750 published papers (Bjelland et al. 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 = 0.40–0.90). They describe sensitivity and specificity scores of approximately 0.80 and correlations with other commonly used questionnaires ranging between 0.49 and 0.83.

The HADS is self-administered over a relatively short period, minimizing the burden to the carer and reducing the risk of incomplete data. The HADS scale contains 14 questions for self-completion. Seven questions are designed to identify anxiety, e.g., by asking about tension, fear and worry, and seven to identify depression, e.g., by asking about enjoyment, interest in appearance and activities. Despite the name, the questions are not specific to hospital care. Each question scores between 0 and 3, making a total score range of between 0 and 42. The scale identifies single scores for anxiety and depression as well as a total score.

Crawford et al. (2001) conducted a study (n = 1792) to identify normal scores for the HADS that 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.

### **Adult Carers Quality of Life scale (ACQOL)**

The ACQOL scale (Joseph et al. 2012) measures the carer's quality of life with extensive data supporting face and construct validity, internal consistency reliability, utility and convergent validity. The scale contains 40 questions in eight domains. The domains are: support, choice, stress, money, growth, value, ability and satisfaction. 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 score range of between 0 and 120.

### **The Communication Self Efficacy Scale (CSES)**

Talking Sense was designed specifically to address carer self-efficacy in relation to communication. No suitable communication self-efficacy scales were identified and, therefore, a new scale, the CSES (see Appendix B), was developed, based on the steps of the Talking Sense programme and common communication issues reported in carer consultations undertaken during the development of Talking Sense. Face validity was established from a discussion with a group of three specialist dementia therapists. Utility was established from a trial by five non-professional/non-carer volunteers. Content validity followed the Lawshe (1975) method with responses from 14 dementia care professionals.

In the present study, the examination of baseline and outcome scores from the CSES generated a Cronbach's alpha of 0.868 for 'happens' and 0.941 for 'manages', suggesting a high level of internal reliability.

For external reliability, correlations were conducted with the most similar baseline scores collected during the study that follows. At 95% significance ( $n = 52$ ), the CSES 'manage' total appeared to be significantly correlated to the HADS total score ( $r = -.351, p = .011$ ), the General Self Efficacy Scale (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 ( $r = .283, n = 51, p = .044$ ) 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 and lower communication competence scores.

The CSES presents carers with nine difficult communication scenarios which are scored for how often they happen and how well the carer believes they manage in that situation. Subtotal scores for 'happens' and 'manage' are reported separately. Higher scores (range = 9–45) indicates that the scenario happens less and the carer manages better.

### **The General Self Efficacy Scale (GSES)**

The GSES (Schwarzer and Jerusalem 1995) was chosen to enable correlation of results with the CSES in an attempt to establish its validity. Detailed psychometric properties of the GSES are published by 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. The GSES asks 10 questions with answers scoring between 1 and 4, giving a total score range of 10–40. Questions, for example, ask about the carer's ability to problem solve, stick with aims and goals, and their confidence in dealing with the unexpected. A higher score indicates greater general self-efficacy.

### **The Communication Competence Scale (CCS)**

The Communicative Competence Scale (CCS) (Query and James 2009) was identified as most suitable for completion by carers to consider a change in experience and/or belief in their relative's communication competence. For reliability of the CCS, Jones and Brunner (1984) report coefficient alpha scores of between 0.96 and 0.86. The CCS scale contains 36 questions and results in a single summary score. For example, positive and negatively orientated questions ask how their relative gets on with others, interrupts, is a good listener and ignores others' feelings. It has a total score range of 36–180. A higher score equates to greater competence.

### **The Therapeutic Engagement Index (TEI) and readiness**

In order to monitor engagement in therapy and allow a comparison with other outcomes, this study measured engagement, scored by the first author at the end of each treatment or control session, using the TEI and a 4-point measure of readiness (Chee et al. 2005). The TEI consists of three components: openness, connectedness and involvement. Higher scores (range = 0–56) suggest higher engagement.

Readiness for change in carer thinking and carer behaviour was scored using the following four levels:

- 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.

### **Study visit schedule**

After consent to participate and prior to randomization, carer participants were asked to complete demographic and characteristics information, e.g., age, sex, relationship, cohabitation (table 1) and baseline outcome measures unaided, except for limited explanation where required.

Table 1. Carer and person with dementia (PWD) characteristics

Description	Treatment group (N= 28)	Control group (N = 27)	Total recruits (N = 55)
<i>Carer characteristics</i>			
Mean carer age, years (SD)	67 (11.8)	68 (14.3)	67 (12.9)
Range of carers ages (years)	42–88	30–89	30–89
Male carers (n)	30% (8)	16% (4)	23% (12)
Carers who were partners (n)	63% (17)	72% (18)	67% (35)
Carers who were children of PWD (n)	33% (9)	24% (6)	29% (15)
White British carers	100%	92%	96%
Carers attending carer support groups	68% (19)	70% (19)	69% (38)
<i>Carer and relative with dementia interaction</i>			
Cohabiting carers and PWD (n)	59% (16)	72% (18)	65% (34)
Mean number of days spent together	6	6	6
Range of days spent together	2–7	3–7	2–7
<i>Carer mental health</i>			
Carers receiving treatment for depression (n)	19% (5)	24% (6)	21% (11)
Baseline HADS caseness for anxiety ( $\geq 9$ ) (n)	44% (12)	44% (11)	44% (23)
Baseline HADS caseness for depression ( $\geq 9$ ) (n)	18.5% (5)	24% (6)	21% (11)
<i>PWD characteristics</i>			
Range (SD) of PWD ages, years	62–89 (7.5)	55–91 (9.1)	55–91 (8.2)
PWD with Alzheimer' disease	48% (13)	32% (8)	40% (21)
PWD with vascular dementia	19% (5)	16% (4)	17% (9)
PWD with mixed dementia	30% (8)	40% (10)	35% (18)
Average PWD MMSE scores (SD)	24/30 (3.9)	24/30 (4.5)	24/30 (4.2)
Range of PWD MMSE scores	15–29/30	12–29/30	12–29/30

Note: HADS, Hospital Anxiety and Depression Scale; MMSE, Mini Mental State Examination; SD, standard deviation.

All measures and interventions were completed within a 12-week period following consent. The TEI and readiness scales were completed by the researcher after each intervention session. The remaining outcome measures were sent to carers by post to be completed alone 2 weeks after their last intervention session.

### Safety reporting

Recruitment to this study, participant experience, adverse events and reasons for non-participation were monitored by the research steering group, the local National Health Service (NHS) research and

development service, and a named psychiatrist. Processes for registering concerns and complaints as well as carer disclosure were established.

### **Sample size**

Cooper et al. (2006) identified a mean HADS anxiety score of 7.2 (standard deviation (SD) = 4) in a pilot study with dementia carers. They also suggested a decrease of 2 points in the mean to be a clinically significant improvement in mental well-being. They calculated that in order to achieve this reduction, with 90% power, at a 5% level of significance, 75 participants per group were needed.

For this pilot study, 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.

### **Statistical analysis**

In each of the only two cases of missing data, one item (from 40) was missing from the ACQOL scale. An average score for other four items within the respective domain for that individual was calculated and added to the data set.

The mean difference from baseline scores was analysed between groups. Distribution of the 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  $-1.96$  and  $1.96$ ). Levene's test for the homogeneity of variance ( $p > 0.05$ ) verified the equality of variance in the parametric samples.

For normally distributed parametric data, independent t-tests were used. For non-parametric data, the Mann–Whitney U-test was used. No adjustments were applied to the data.

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 2014). In this pilot study, the sample size was likely to be underpowered. For these reasons, statistical significance is reported at 95%, though results are reported that are close to significance, operationally defined as  $p < 0.10$ .

### **Ethics**

People with dementia were not active participants in this research study or the Talking Sense intervention. This research was approved by the UK Integrated Research Application System.

The interventions were judged likely to be of benefit to carers and their relatives with dementia, in proportion to the burden. The models of intervention were based around contemporary methods of good practice.

## **Results**

The primary outcome (HADS) was not significantly different between groups.

### **Recruitment**

From 111 referrals received over an 18-month period, 55 carers participated in the study. The carers recruited were randomly allocated: 28 to the treatment arm and 27 to the control arm. Referral suitability was determined as 89%. Fifteen per cent of referrals declined to participate. Despite accounting for only 31% of referrals, male carers made up 53% of the 'didn't want to participate' responses.

### **Intervention and outcome completion**

All treatment and control carers completed all interventions in contrast to Livingston et al. (2013), where 28% of carers failed to attend at least one of eight treatment sessions. 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%. No adverse events were reported.

Participant flow is illustrated in figure 2.

### Participant flow diagram (adapted from Moher et al., 2010).

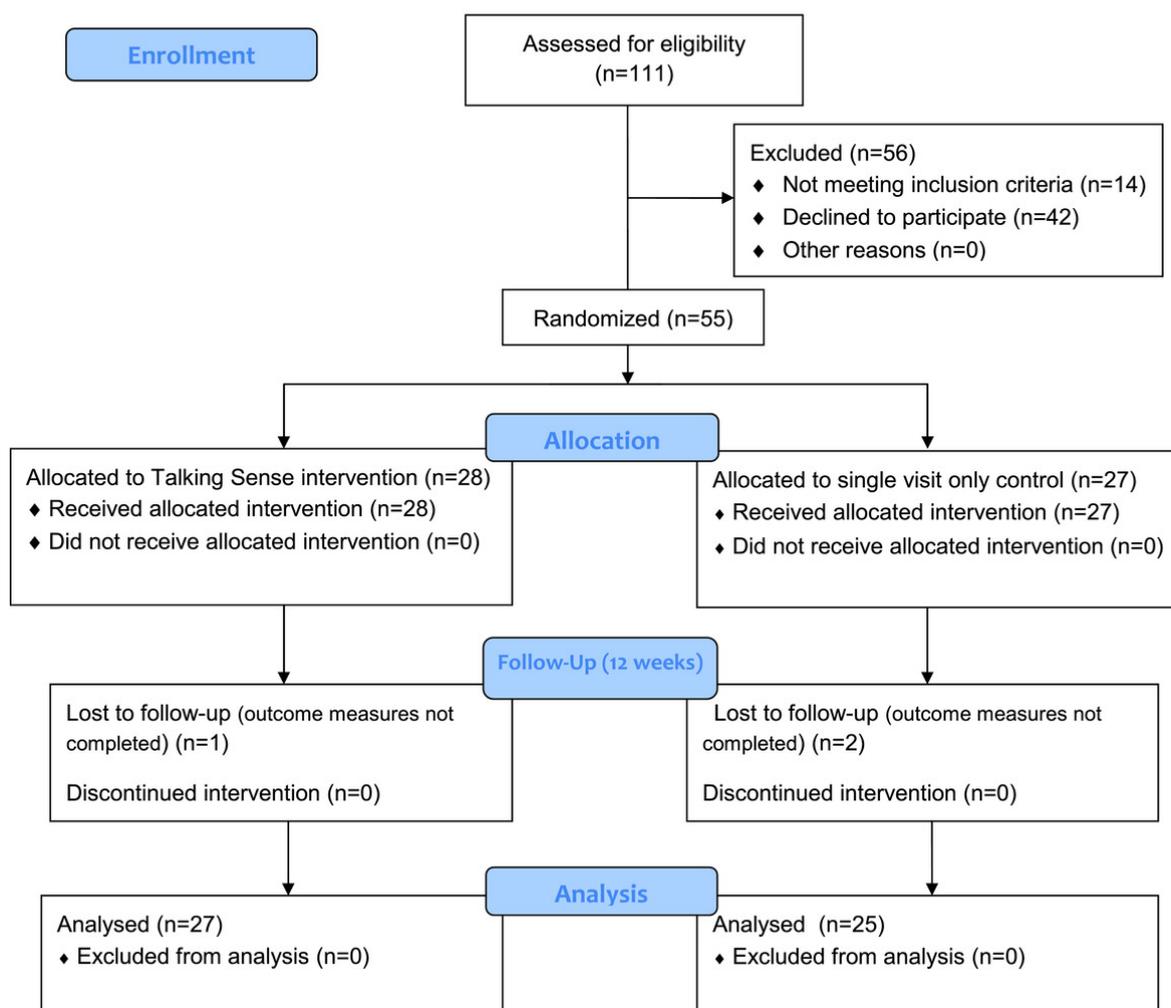


Figure 2: Participant flow diagram (adapted from Moher et al. 2010).

### **Carer and person-with-dementia characteristics**

Carer and PWD characteristics are illustrated in table 1.

Visual comparison of carer and PWD characteristics suggests the groups were similar, with the treatment group containing more males, and slightly more cohabiters and males with dementia.

### **Outcomes**

The results of baseline and outcome measures are given in Table 2. The majority of outcomes including the primary outcome (HADS) were not significantly different between groups. However, two outcomes were significantly different between groups: the CSSES happens and the ACQOL sub-score, as well as the CCS total score which was close to significance ( $p = 0.052$ ).

Table 2. Results of baseline and outcome measures

Outcome	Difference means between ...			
	Treatment mean difference (actual means)	Control mean difference (actual means)	Confidence intervals (low to high)	Test (*) result and $p$ -value
<i>HADS total score</i>	-0.2	1.3	-0.5 to 3.58	* Not significant, $p = .133$
	(13.9–13.7)	(13.3–14.6)		
Anxiety sub-score	-0.3	0.5		† Not significant, $p = .100$
	(8.1–7.8)	(7.9–8.4)		
Depression sub-score	0.1	0.8		† Not significant, $p = .122$
	(5.8–5.9)	(5.4–6.2)		
<i>ACQOL total score</i>	4.3	-0.2	-10.6 to 1.5	* Not significant, $p = .138$
	(69.6–73.9)	(69.4–69.2)		
Support sub-score	-0.1	-0.3		† Not significant, $p = .912$
	(8.6–8.5)	(7.7–7.4)		
Choice sub-score	0.9	0.6		† Not significant, $p = .933$
	(7.6–8.5)	(7.2–7.8)		
Stress sub-score	-0.1	0.1		† Not significant, $p = .978$
	(10.1–10.0)	(10.2–10.3)		
Money sub-score	0.3	-0.2		† Not significant, $p = .219$
	(10.6–10.9)	(10.4–10.2)		
Growth sub-score	1.1	0.5		† Not significant, $p = .571$
	(6.9–8.0)	(6.4–6.9)		
Value sub-score	0.6	-0.6	-2.3 to -0.02	* Significant difference, $p = 0.046$ , $\eta^2 = 0.09$
	(7.8–8.4)	(8.8–8.2)		
Ability sub-score	0.7	-0.1		† Not significant, $p = .155$
	(9.4–10.1)	(9.5–9.4)		
Satisfaction sub-score	0.3	-0.3	-1.9 to 0.7	* Not significant, $p = .357$
	(9.0–9.3)	(9.2–8.9)		
CSES total score happens	1.3	-0.7	-3.5 to -0.3	* Significant difference, $p = 0.046$ , $\eta^2 = 0.09$

	(25.7–26.9)	(25.7–25.0)		
CSES total score manage	2.1	0.7	-3.6 to 0.6	* Not significant, $p = .152$
	(29.7–31.8)	(29.0–29.7)		
GSES total score	-0.4	0.1	-1.2 to 1.8	* Not significant, $p = .702$
	(31.9–31.5)	(31.4–31.3)		
CCS total score	4.0	-2.1	-12.2 to 0.6	* Close to significance, $p = 0.052$ , $\eta^2 = 0.09$
	(107.9–111.9)	(112.5–110.4)		

Note: Confidence intervals are reported for parametric data only. Tests used are independent t-test (\*) and Mann–Whitney U-test (†).

### Therapeutic engagement and readiness

There was no statistically significant difference between groups for therapeutic engagement ( $p = .530$ ). However, the control group appeared significantly more ready ( $p = .012$ ) than the treatment group with a moderate effect size (Cohen 1988). Comparisons were made between groups after session 1. A Friedman test was used to consider ‘within group differences’ for the treatment group between the first, second and third treatment sessions. There was a statistically significant increase in both engagement  $\chi^2 (2, n = 27) = 8.68$ , ( $p = 0.13$ ) 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 1 with treatment group results at session 3 was conducted showing no significant differences in engagement ( $p = .156$ ) but a significant difference in readiness in favour of the treatment group ( $p = .011$ ). These results should be interpreted cautiously due to the subjective nature of the measure and the potential for bias introduced by researcher completion.

## Discussion

### Generalizability

There were no significant differences in anxiety and depression from the primary outcome measure (HADS). The results from using the HADS in this pilot study were in a similar range to the results achieved by Livingston et al. (2013). The Livingston et al. intervention targeted carers with anxiety. They also reported a small but significant difference in HADS scores between groups. When considering why this pilot study did not achieve similar results, four factors appear likely: it was underpowered, 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.

The HADS measures general depression and anxiety including questions on topics such as appearance and restlessness; it does not focus specifically on communication. Pederson et al. (2008) highlight the value of measuring communication specific anxiety and depression, i.e., features of communication and associated behaviour which are indicators of depression and anxiety. Research conducted by Ornstein et al. (2013) also recommends that depression for the PWD should be measured. They suggest this is more strongly correlated to carer depression than PWD behaviour. Therefore, future research may benefit from the development of associated scales specifically designed to measure communication-related depression and anxiety for dementia carers and for, potentially by, people with dementia.

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 and Newman 2006). When considering the subsections of the ACQOL, it is less likely that a communication intervention would influence practical topics such as money and future caring choice. Again, future research may benefit from using a communication specific quality-of-life scale.

For CSES, there was a significant difference with a moderate effect size ( $\eta^2 = 0.09$ ), suggesting that carers in the treatment group reported fewer difficulties happening. There was no significant difference in their managing scores. This is a promising outcome, which may be measuring more directly the intended aim of the intervention (to reduce communication difficulties). It is suggested that the CSES has not only potential for use in future research, but also as a clinical assessment and outcome measure.

The results of the GSES identified no significant differences or trends in this study. The GSES 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.

The CCS total score was close to significance in favour of the treatment intervention with a moderate effect size ( $\eta^2 = 0.09$ ). 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 also associated with a perceived improvement in PWD competence.

The results of this study suggest from recruitment rates that carer communication difficulties are prevalent. Significant differences in engagement and readiness and 100% adherence to treatment suggest that Talking Sense, delivered in this way, was acceptable as an intervention by carers. Low attrition (5.5%) also suggests that this research design was not overly burdensome to carers.

The Princess Royal Trust for Carers (2014) estimates the average age of a dementia family between 60 and 65 years. The carers in this study (mean age of 67) were older than those in the Livingston et al. (2013) study (mean age of 52). This may have been influenced by provision of a weekday daytime intervention making access more difficult for working-age carers. Future research may seek to include a wider range of carers.

The caseness rates of 21% for depression and 44% for anxiety suggests this study attracted carers who were more anxious and depressed than typical, possibly as a consequence of communication difficulties. Though, as with many of the outcomes measured, this condition was not absolute, i.e., the majority of carers were not clinically anxious and therefore the potential for change was limited.

Male carers were underrepresented in the recruitment to this study, creating an element of selection bias. Gant et al. (2007) found that male carers preferred informational and skill development interventions over emotional focused interventions. It appears likely that the emotion and thinking-focused nature of this intervention may have influenced participation in which case future adaptations for male carers may be required.

### **Limitations**

A number of limitations in research design may have influenced the results of this pilot study.

The eligibility inclusion criteria did not sufficiently identify the target population. The mean CSES baseline scores for happens and manage of between 25 and 29/45 suggest recruited carers had only occasional communication difficulties happening which were managed adequately. Likewise, the inclusion of some people with lower engagement and readiness scores suggests that some carers would not have met typical clinical criteria for ongoing therapy. Future research would benefit from more selectively identifying the target population.

The results of this study were limited to the carer's perspective. The views expressed are only those of the carer. Given that the results indicate perceived or actual changes in the PWD, this raises the importance of including people with dementia in future research. Should this happen, it is also suggested that a more contemporaneous measure of dementia and communication skills is used than referrer reported MMSE scores (Folstein et al. 1975).

Confounding variables may have influenced outcomes. Access to the literature, carers groups, and support from the health- and social care services also had the potential to have a positive effect on outcomes from this study. In 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 (three sessions in comparison with one) between the treatment and control groups. Future research should aim to minimize these influences and differences.

The period of follow-up was relatively short. Sommerlad et al. (2014) found that two-thirds of carers reported continued use of strategies at 2-year follow up. Future extension of this randomised controlled trial (RCT) could evaluate any long-term effect.

Limited blinding may also have introduced bias. Blinding of the outcome assessor and more objective measurement could also be introduced in future research design.

The intervention was relatively brief. As well as reducing burden for the client, this form of therapy, assuming it yields outcomes, is more cost-effective for deliverers. Future research may also consider a more intensive intervention and/or most cost-effective mechanism of delivery.

Clinically, the link between assessment, the nature of difficulties and intervention was limited by the use of outcome measures only as measures of effect and not to inform the intervention topics or goals. Greater access to the detail held in the TEI and CSES measures in particular may have potential to aid clinicians in planning and delivering this form of intervention.

## **Conclusions**

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 originally on the carer's beliefs and abilities about themselves as carer communicator, it is significant to note that these results suggest most change occurring in the relationship between the carer and the PWD. Where change appears to have occurred, what is not clear is whether this was a change in the carer's perceptions, the carer's behaviour or indeed the behaviour and ability of the PWD.

Recommendations for future research have been made above. A larger longitudinal and more selective multicentre trial incorporating mixed methods will be pursued by these authors.

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## Appendix A: Example step summary slides from the Talking Sense programme

### 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

### Step Two: Insight

- Real life examples
- Some of the difficulties you experience
- Levels of difficulty (VEMAS) scales
- What people with dementia do
- The experience of having dementia
- Your relative's needs

### Step Three: Thoughts and feelings

- Thoughts and thinking and CBT
- Beliefs, assumptions and automatic thoughts
- Positive thoughts
- Vicious and virtuous circles
- Human tendencies
- CBT Strategies
- Thoughts worth thinking
- What am I trying to achieve?
- What is right?
- What is truth?
- Establishing new beliefs.
- Developing realistic expectations.

### Step Four: The environment

- Practical ideas to modify the environment
- External memory aids
- Memory aids need introducing
- Memory campaigns
- Put something out to talk about
- Conversation magnets
- Pets and simulated presence

## Appendix B: The Communication Self Efficacy Scale

Since having dementia ...

1 My relative finds it difficult to start a conversation ...

This happens:	<i>never</i>	<i>rarely</i>	<i>occasionally</i>	<i>a lot</i>	<i>always</i>
I am able to manage this:	<i>not at all</i>	<i>poorly</i>	<i>adequately</i>	<i>well</i>	<i>very well</i>

2 My relative finds it difficult to understand what I've said ...

This happens:	<i>never</i>	<i>rarely</i>	<i>occasionally</i>	<i>a lot</i>	<i>always</i>
I am able to manage this:	<i>not at all</i>	<i>poorly</i>	<i>adequately</i>	<i>well</i>	<i>very well</i>

3 My relative finds it difficult to explain things ...

This happens:	<i>never</i>	<i>rarely</i>	<i>occasionally</i>	<i>a lot</i>	<i>always</i>
I am able to manage this:	<i>not at all</i>	<i>poorly</i>	<i>adequately</i>	<i>well</i>	<i>very well</i>

4 My relative gets frustrated or upset in conversations ...

This happens:	<i>never</i>	<i>rarely</i>	<i>occasionally</i>	<i>a lot</i>	<i>always</i>
I am able to manage this:	<i>not at all</i>	<i>poorly</i>	<i>adequately</i>	<i>well</i>	<i>very well</i>

5 My relative says things that are inappropriate (out of place or rude) ...

This happens:	<i>never</i>	<i>rarely</i>	<i>occasionally</i>	<i>a lot</i>	<i>always</i>
I am able to manage this:	<i>not at all</i>	<i>poorly</i>	<i>adequately</i>	<i>well</i>	<i>very well</i>

6 My relative repeats what they have said (within a conversation) ...

This happens:	<i>never</i>	<i>rarely</i>	<i>occasionally</i>	<i>a lot</i>	<i>always</i>
I am able to manage this:	<i>not at all</i>	<i>poorly</i>	<i>adequately</i>	<i>well</i>	<i>very well</i>

7 My relative says things that aren't true or accurate ...

This happens:	<i>never</i>	<i>rarely</i>	<i>occasionally</i>	<i>a lot</i>	<i>always</i>
I am able to manage this:	<i>not at all</i>	<i>poorly</i>	<i>adequately</i>	<i>well</i>	<i>very well</i>

8 My relative experiences difficulty when they talk with other people ...

This happens:	<i>never</i>	<i>rarely</i>	<i>occasionally</i>	<i>a lot</i>	<i>always</i>
I am able to manage this:	<i>not at all</i>	<i>poorly</i>	<i>adequately</i>	<i>well</i>	<i>very well</i>

9 When communication is difficult, *I get frustrated* with my relative ...

This happens:	<i>never</i>	<i>rarely</i>	<i>occasionally</i>	<i>a lot</i>	<i>always</i>
I am able to manage this:	<i>not at all</i>	<i>poorly</i>	<i>adequately</i>	<i>well</i>	<i>very well</i>

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