Effectiveness of Weekly Cognitive Stimulation Therapy (CST) for People with Dementia and the Additional Impact of Enhancing CST with a Carer Training Programme

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Thesis declaration form

I confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

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Overview

This thesis focuses on interventions for people with dementia and their carers. Part 1 of the thesis is a literature review examining the effectiveness of combined intervention programmes for people with dementia and their carers. A previous review examined literature published before 2005 and current review sought to update this review. The 18 papers retrieved from the review are presented according to the type of intervention they describe. The effectiveness of each type intervention was discussed followed by a consideration of the effectiveness of interventions for people with dementia and their carers according to different outcomes.

Part 2 is an empirical study using a randomized controlled trial to assess the effectiveness of weekly Cognitive Stimulation Therapy (CST) and the additional effects of enhancing CST with a carer training program. Quantitative outcomes for people with dementia are reported. This paper forms part of a joint research study conducted with Jacobi (2013; Counselling Doctorate Trainee, City University) who will report quantitative outcomes for carers and evaluate the carer training program using a qualitative approach.

Part 3 is a critical appraisal and discusses the factors that should be taken into account when interpreting non-significant research findings. A discussion of the ethical obligations of publishing non-significant research findings is also presented. Finally, the quality of the research study described in Part 2 is assessed. Consideration is given to the strengths and weaknesses of the research and a quality rating, using a formal assessment scale, is undertaken.

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Part 1: Literature Review

The Effectiveness of Combined Interventions for People with Dementia and their Carers

Abstract

Background: Receiving a diagnosis of dementia can have a profound effect on both the person with dementia and their carers. Developing interventions to support both groups are therefore essential. This review aims to determine the effectiveness of combined intervention programmes for people with dementia and their informal carers.

Method: A systematic review was conducted to identify studies published between February 2005 and March 2013 which included combined intervention programmes for people with dementia and their carers. 18 studies were found to meet inclusion criteria and included in the final review. Scoring criteria were used to rate the quality of each study.

Results: The 18 papers were categorised according to the type of intervention offered. These were: psychotherapeutic, psychosocial, support group, rehabilitation or case management interventions. Functional rehabilitation and case management interventions appear to be most effective, whilst less conclusive evidence for other categories of interventions was found. No consistent pattern between type of intervention and outcomes observed was noted.

Discussion: Combined interventions for people with dementia and their carers may have positive outcomes for both but interventions are not consistently effective. The mixed outcomes reported and variability in the quality of the studies means that definitive conclusions are difficult to draw and further research is required.

Dementia is a progressive, chronic neurodegenerative disorder characterised by widespread decline in cognitive functioning. Specific impairments include memory loss, in particular problems with short-term memory, language impairment, changes in personality and mood, disorientation, difficulty concentrating, impaired reasoning abilities, difficulties with activities of daily living and self-neglect. People with dementia have high levels of care needs, particularly as their condition deteriorates and a high proportion of these needs are met by informal or family carers. In 2010 the number of people living with dementia worldwide was estimated at 35.6 million. It is estimated that this will double by 2030 and more than triple to 115.4 million by 2050 (World Alzheimer's Report, 2010). As such dementia is now a major public health priority, with particular emphasis being placed on increasing knowledge and awareness of dementia, early detection and diagnosis and development of suitable interventions for people with dementia and their families (Department of Health, 2009).

With these priorities in mind, much research has been focused on the development and evaluation of treatments for dementia, which has included both pharmacological and non-pharmacological interventions. Although pharmacological treatments can slow the progress of dementia for some people, they are limited in their effectiveness, can cause unpleasant and intolerable side effects and are not suitable for everyone. As such the need for non-pharmacological interventions, which offer greater choice, can be accessed by a wide range of people with dementia, are cost-effective and can also include carers, is increasingly important. Olazaran et al. (2010) define non-pharmacological interventions as *"any theoretically based, nonchemical, focused and replicable intervention, conducted with the patient or the caregiver (CG), which potentially provides some relevant benefit" (p.162).*

Non-Pharmacological Interventions for People with Dementia

Non-pharmacological interventions for people with dementia include treatments for cognitive, behavioural and emotional symptoms. A wide variety of interventions have been developed, including cognitive stimulation (Breuil et al., 1994; Spector et al., 2003), reality orientation (Onder et al., 2005), music therapy (Guetin et al., 2009), multisensory stimulation (Milev et al., 2008) and multicomponent treatments (Teri, Gibbons, McCurry & Logsdon et al., 2003). Interventions have aimed to improve or slow the rate of deterioration of cognition, mood, behaviour, physical activity, quality of life, activities of daily living or a combination of these. It is important to note that positive outcomes following an intervention for people with a progressively deteriorating disorder such as dementia may include changes in outcome measures from baseline but also a slower rate of deterioration in outcomes than would be expected.

Olazaran et al. (2010) conducted a systematic literature review and meta-analysis of all available randomised controlled trials to determine the efficacy of non-pharmacological interventions for people with dementia. Cognitive stimulation groups, cognitive training, behavioural interventions and activities of daily living training all resulted in positive outcomes for people with dementia. Multicomponent interventions demonstrated the most diverse benefits including improvements in the cognition, behaviour (general behaviour and withdrawal), mood, orientation and performance of activities of daily living. No recommendations were found for electrical stimulation, physical exercise, use of music, reminiscence, massage and touch, recreation therapy, use of light, multisensory stimulation, support and psychotherapy, validation therapy, case management or respite care. However, lack of evidence may reflect a paucity of studies, lack of adequate outcome measures and

poor study designs. When included as part of multicomponent interventions reminiscence, physical exercise, support and relaxation were found to result in positive outcomes for people with dementia.

It appears that despite the wide range of non-pharmacological interventions available for people with dementia, there is a lack of evidence to support the efficacy of many of these at present. However, as stated, some interventions do result in positive outcomes. Olazaran et al. (2010) conclude that such therapies "*can make both a realistic and affordable contribution to the improvement and provision of care for people with Alzheimer's disease and related dementias*" *(p.172).*

Impact of Caregiving

Caregiving is described by Shultz and Martire (2004) as:

> *... the provision of extraordinary care, exceeding the bounds of what is normative or usual in family relationships. Caregiving typically involves a significant expenditure of time, energy, and money over potentially long periods of time; it involves tasks that may be unpleasant and uncomfortable and are psychologically stressful and physically exhausting (p.240).*

As a long term and often unpredictable condition, dementia not only imposes a significant impact on the life of the person with dementia but also on those involved in their care. Informal carers (most frequently family members), defined by Brodaty, Green and Koschera, (2003) as *"persons providing unpaid care, at home or in a non-institutional environment" (p.657)*, commit time, energy, money and effort to caring. However, caregiving is associated with higher levels of depression, anxiety and psychotropic drug use. Up to half of dementia carers report experiencing high levels of depression and over 80% report that they frequently feel stressed (Alzheimer's

Association, 2006). Caregiving is also associated with decreased quality of life, diminished self-efficacy, lower life satisfaction and poorer health outcomes, such as obesity (Vitaliano et al. 2005) and compromised immune systems (Kiecolt-Glaser, Dura, Speicher, Trask & Glaser, 1991). Brodaty and Dunkin (2009) report that carers are also at increased risk of experiencing social isolation due to lack of social contact and a concurrent reduction in social support and of experiencing financial strain due to cutting back on working hours. Kasuya, Polgar-Bailey and Takeuchi (2000) define these negative consequences of caregiving as 'caregiver burden'.

Given the huge impact caregiving can have it is essential that the needs of carers are met as well as the needs of the person they are caring for. In addition to the impact on the carer, high levels of caregiver burden can also result in poorer outcomes for people with dementia, including decreased quality of life and early admission to institutional settings (Etters, Goodall & Harrison, 2008). This evidence serves to strengthen the need to provide suitable and effective interventions for carers of people with dementia.

Non-Pharmacological Interventions for Carers

A number of interventions to support the carers of people with dementia have been evaluated, including individual or group psychoeducation, peer support groups, psychotherapy and multicomponent interventions. Outcomes of research into the effectiveness of such interventions are mixed. Broadaty et al. (2003) found no evidence to support the efficacy of short education programmes, support groups, single interviews or brief interventions, whilst evidence for the effectiveness of cognitive behavioural therapy is mixed. However, Olazaran et al. (2010) reported that carer education, use of electronic devices and multicomponent interventions, such as long term counselling and support, led to positive outcomes. In addition,

Etters et al. (2008) reported that both multicomponent interventions and psychoeducation plus role-play training led to a reduction in carer burden. These authors state that offering tailored interventions which respond to individual carer needs, can improve outcomes for both carers and people with dementia, including delayed admission to nursing or care homes. Despite the mixed outcome of research studies, a number of interventions for carers of people with dementia do have demonstrable positive outcomes for both carers and the people they care for.

Combined Interventions

Given that the effects of dementia on both people with dementia and their carers can be great and can interact with each other, providing effective interventions may result in improved outcomes for both. Alongside individual interventions, the value of designing combined interventions has also been recognised (Brodaty et al., 2003). These authors note that a key feature of successful carer interventions was the involvement of people with dementia alongside their carers in structured programmes. Dröes, Meiland, Schmitz and van Tilburg (2006) point out that given the complex and diverse range of problems experienced by people with dementia and their carers, single interventions simply do not met their needs. Interventions which include both can have a greater impact than interventions which target each alone.

Combined interventions are designed to meet the needs of both the person with dementia and their carer, either by including both in the same intervention or by offering separate interventions to run concurrently and complement each other. Such interventions can be more cost-effective and more convenient for families. They take a holistic approach to treatment and provide scope for tailoring treatment to individual family needs. Interventions which include both the person with dementia and their carer include family counselling, occupational therapy, case management,

and support group programmes. Combined programmes in which people with dementia and their carers receive separate interventions are varied, but include drug treatment and cognitive stimulation for people with dementia and support groups for carers and memory training plus music therapy for people with dementia and support groups for carers.

Existing Review of Combined Interventions

One previous systematic review has examined the effects of combined intervention programmes for people with dementia and their carers. Smits et al. (2007) reviewed 22 interventions in 25 reports published between January 1992 and February 2005. Outcomes for people with dementia reported in the review were: mental health, cognitive functioning, behavioural problems, physical functioning, delayed admission to long-stay care and mortality. Depressive symptoms were found to improve in people with dementia following participation in combined interventions and time to admission to long-stay care units was delayed. Evidence for the remaining outcomes was mixed. The authors classified outcomes for carers into three groups: mental health, burden and competence. Only carer general mental health was found to be significantly improved following combined intervention programmes. Results for carer burden and other areas of mental health were inconclusive, whilst competence appeared to improve in some carers but not others.

Only 18 of the 22 studies reported outcomes for both people with dementia and their carers and of these 10 reported at least some positive results for both, suggesting that some types of combined interventions are effective for both people with dementia and their carers. However, no discussion of the types of interventions which may be most effective was included. The authors also point out that the review was limited by the lack of sufficient power of many of the included studies, the

varying degree of quality of the studies and the limited number of studies available, although it should be noted that only three databases were searched.

Although combined interventions appear to delay time until admission to institutional care and improve aspects of both people with dementia and carer mental health, Smits et al. (2007) were unable to make specific recommendations for the development and implementation of intervention programmes because of the inconclusive nature of the results for the remaining outcomes reported.

The Current Review

This review aims to update the previous review conducted by Smits et al. (2007) by examining literature published since February 2005 in order to examine the most recent literature. The review will seek to determine whether clear positive effects of combined intervention programmes for people with dementia and their carers can be established. A more detailed evaluation of the effectiveness of specific types of combined interventions will be included.

Literature Review Questions

The following questions will be addressed in this literature review:

1. What effects do combined intervention programmes for people with dementia and their carers a) have on people with dementia, and b) have on their carers?
2. Can combined intervention programmes result in positive outcomes for both the people with dementia and their carers who participate?

Method

The review followed the recommendations made by Petticrew and Gilbody (2004) for planning and conducting systematic literature reviews. In order to include

only studies published since Smits et al.'s (2007) systematic review the search was limited to studies published between February 2005 and March 2013.

Inclusion Criteria

- Randomised controlled trials (RCTs) and quasi-experimental designs
- Studies which evaluate the effectiveness of one or more combined, non-drug intervention programme for people with dementia and their carers
- Studies which report one or more quantitative, psychological outcome for people with dementia and/or their carers
- Studies which include only informal carers providing care at home or in non-institutional environments
- Studies published in English in peer reviewed journals

Exclusion Criteria

- Interventions for either people with dementia or carers alone
- Studies which include pharmacological interventions
- Studies which include herbal remedy/vitamin supplement interventions
- Studies investigating carer-led interventions in which carers receive no intervention themselves
- Thesis dissertations, policy guidelines, case study designs and qualitative studies

Search Strategy

Systematic searches of the PsycInfo, PubMed, Medline, Embase and CINAHL electronic databases were conducted separately, with all searches limited to results in English, including human subjects and published between February 2005

and March 2013. Keywords entered were identical for each database and were chosen to identify results involving combined (combined, joint, integrated) intervention programmes (intervention*, therap*, treatment*, *psychotherapy**, counsel?ing, *support*, programme*, *training*) for people with dementia (dementia, Alzheimer's disease) and their carers (caregive*. Carer*, *family member*). The terms 'combined', 'intervention', 'dementia' and 'carer' were entered into subject heading or thesaurus searches to include any related synonyms not already identified. Terms in italics were added to the list of search terms after consulting the search terms used by Smits et al. (2007) in their review of the same subject area. The wildcard symbol was used where there were variations in spellings, such as counselling or counseling and search terms were truncated where plural or other forms of the word were relevant, for example therapy and therapies; carer and carers.

The titles and abstract of all papers were screened for relevance, with further examination of papers conducted wherever necessary to determine whether they met inclusion criteria. For those articles which met the inclusion criteria, a reference list search was conducted to identify further articles.

Evaluating the Quality of Studies

Oxman and Guyatt (1988) cite assessment of the quality, or validity, of studies as a key component of systematic reviews of the literature. In order to provide a structured assessment of the quality of each study included in this review, several assessment tools were employed. To assess the methodological quality of randomised controlled trials (RCTs) the scoring criteria developed by Jadad et al. (1996) was used (see Appendix A). Petticrew and Gilbody (2004) highlight these criteria as one of the most widely used for RCTs. The Jadad Scale is both valid and reliable and allows the quality of different studies to be compared. These criteria

provide a rating of studies according to the quality of the randomisation and double-blinding procedures used and the description of withdrawals and dropouts. A rating of between 0 and 5 is given to each study. However, in psychological research only single blinding is possible meaning that the Jadad Scale is limited when used with such research because to achieve a maximum score of five a study will need to have employed a double-blind strategy. Therefore, the maximum score studies in this review could achieve was four.

For RCTs using cluster randomisation (cluster randomised controlled trials, CRCTs) CONSORT guidelines were consulted to assess the quality of these studies (Campbell, Elbourne and Altman, 2004). CRCTs do not randomise participants individually but in groups and the CONSORT guidelines allow the specific procedural requirements of CRCTs to be reviewed.

In order to assess the quality of non-randomised designs the York Centre for Systematic Reviews criteria was used (University of York, 2009). Studies are rated on eight criteria (see appendix B) including: adequacy of the description of participants and interventions, reliability, validity and suitability of outcome measures, dropout rates, follow-up procedures, matching or statistical control of groups and blinding of outcome assessors. Studies which met all criteria were rated as good, those which met more than half were rated as adequate and those which met less than half were rated as poor.

Results

Overview of Results

The search strategy yielded 329 results, of which 14 studies met inclusion criteria and were included in the final review. Of the remaining papers 185 were excluded because they were not relevant to the current review, 43 did not include an

intervention, 28 included carers only, 25 included people with dementia only, 12 were either conducted in residential settings or involved formal carers, 11 used pharmacological or herbal remedy/vitamin supplement interventions, 6 were conference abstracts, 4 were research protocols and 1 was a qualitative study. An additional four papers were included following the reference list search.

Eighteen papers describing 17 interventions were included in the final review, as two papers described different outcomes from the same study. The 18 papers were categorised according to the type of intervention offered. The following groups were identified: psychotherapeutic interventions (N=4); psychosocial interventions (N=3); support group programmes (N=2); rehabilitation including cognitive rehabilitation (N=2) and functional rehabilitation (N=3) and case management (N=4). Seven studies offered fully individualised interventions, whereby each dyad received interventions based on individual need and assessment. Six studies utilised a manual-based or fixed programme intervention whereby all dyads received the same treatment. The remaining four studies were only partially individualised, either because they offered a combination of fixed and flexible components, or because the selections of modules from a manualised intervention were individualised. Details of the studies included in the review are summarised in Table 1.

Table 1

Summary of studies examining the effectiveness of combined interventions

Psychotherapeutic Interventions

Authors	Design, intervention, duration of intervention & level of individualisation	N	Intervention received	Outcome measures and assessment points	Results	Quality Rating
Bakker et al. (2011)	RCT Psychotherapeutic nursing home programme vs. usual care *Duration*: 13 weeks Fully individualised	168 dyads	**PWD** :Individualised package of integrative psychotherapeutic interventions including counselling, life review, CBT, IPT, BRT, rehabilitation, pyschoeduction, family therapy **CG**: Family therapy	**PWD**: NPI, MMSE, BI, MOS Short-Form General Health Survey-20, EQ-5D, subjective health, Global Deterioration Scale **CG**: N-EMD, CB, Caregiver Competence List *Baseline, 3 and 6 months*	**PWD**: • Sig. decrease in behavioural disturbance (NPI) as rated by carers but not staff at 3 and 6months in intervention group. • Sig. improvement in cognition (MMSE) between baseline and 3 months but not maintained at 6 months. • Sig. decrease in self-care (BI) in intervention group • No sig. change in quality of life(EQ-5) **CG**: • Sig. greater reduction in CG burden (N-EMD, CB) • sig. greater increase in competence (Caregiver Competence List) at 3 and 6 months in intervention group	*Jadad*: 3/4 ***Strengths***: 6 month follow-up, adequate N, use of intention-to-treat principle in analysis ***Weaknesses***: assessors not blind, inclusion of participants with DSM-IV diagnosis of dementia or amnesiac disorder or other cognitive impairment, low recruitment uptake numbers

Paukert et al. (2010)	One group time series design CBT for Anxiety *Duration*: 6 months Partially individualised (treatment manualised but selection of modules individualised)	9 dyads	**PWD**: no individual intervention (see both) **CG**: psychoeducation, information re: communication skills and increasing self-care **Both**: 12 weekly CBT home-based session, between session telephone check in, 8 telephone booster sessions	**PWD**: NPI-Anxiety subscale, RAID, PSWQA, GAI, GDS, RMBCP, CSQ **CG**: RMBCP, NPI-Anxiety (distress question), CSQ *Baseline, 3 and 6 months*	PWD**:** • Improvements (20% or more reduction from baseline score) in anxiety (86% and 66% showed reduction in NPI-A at 3 and 6 months respectively, 25% and 57% showed improvements according to RAID at 3 and 6 months, 50% and 43% showed improvements according to PSWQA at 3 and 6 months, 38% and 43% showed improvements according to GAI at 3 and 6 months respectively) • 75% and 57% showed a decrease in depressive symptoms (GDS) at 3 and 6 months respectively • 1 participant showed improvement in behaviour (RMBCP) at each time point • Average satisfaction at 6 months was 28.8/34 **CG**: • 71% and 50% reported decrease in distress over PWD anxiety (NPI=Anxiety) at 3 and 6 months respectively, • 38% and 57% reported decreased distress over PWD problem behaviours (RMBCP) at 3 and 6 months • Average satisfaction at 6 months was 29.7/34	*York*= Poor **Strengths**: use of relevant outcome measures **Weaknesses** lacks internal validity due to lack of control group, small N, no power to detect sig. changes therefore only improvement (defined as 20% reduction in scores from baseline) reported, no follow-up
Weber et al. (2009)	One group time series design Psychotherapeutic day hospital programme *Duration*: mean = 9 months (SD=7) Fixed programme	76 dyads	**PWD**: day hospital programme including group: music therapy, movement therapy, psychodynamic therapy and sociotherapy. Individual reviews **CG**: Family intervention including assessment of communication patterns, discussion of carer needs and relief from caregiver burnout	**PWD**: CAS, SAS, GES, NPI **CG**: none recorded *Baseline, 3, 6 and 12 months, discharge*	**PWD**: • No sig. self-reported (CAS) improvement in progress in therapeutic community treatment (inc. behaviour, attitude and cognitive change) but sig. increase in staff-reported ratings of progress (SAS) at all time points • Sig. progress made in groups (GES) across time • Sig. decrease in behavioural disturbance (NPI) at all time points **CG**: none recorded	*York*=Poor **Strengths**: analysis controlled for stressful life events and medication **Weaknesses**: lacks internal validity due to lack of control group, assessors not blind, no follow-up, variation in treatment duration across participants, no description of drop out, no description of CG participants

Woods et al. (2012)	RCT Reminiscence groups vs. care as usual *Duration*: 10 months Manualised intervention	487 dyads	**Both**: 12 weekly reminiscence groups followed by 7 monthly maintenance sessions	**PWD**: QoL-AD (PWD & CG rated), AMI(E), QCPR, CSD, RAID, EQ-5D, Bristol Activities of Daily Living Scale, CSRI, use of day services **CG**: GHQ-28, QCPR, HADS, RSS, EQ-5D, CSRI *Baseline, 3 and 10 months*	**PWD**: • no sig. difference between the two groups on any primary or secondary measure: quality of life (QoL-AD, EQ-5D), autobiographical memory (AMI(E), depression (CSD), anxiety (RAID), activities of daily living (Bristol ADL Scale), quality of PWD-CG relationship (QCPR) at any time point • Sig. greater use of day care services in the intervention group. **CG**: • No sig. difference between the two groups in overall psychological distress (GHQ-28), stress (RSS), anxiety and depression (HADS), quality of the PWD-CG relationship (QCPR), quality of life (EQ-5D) at any time point. • Sig. higher anxiety in the intervention group compared to control group at 10 months as assessed by the anxiety subscale of the GHQ-28	*Jadad*=4/4 **Strengths**: assessors blind, good description of randomisation process, ITT analysis, description of drop-outs **Weaknesses**: different retention rates across study sites, low compliance to treatment rates, no follow-up

CG-=Caregiver, PwD= Person with Dementia
AMI(E)= Autobiographical Memory Interview (extended), BI= Barthel Index, CAS= Client Assessment summary, CB= Caregiver Burden, CSD= Cornell Scale for Depression, CSQ= Client Satisfaction Questionnaire, CSRI=Client Services Receipt Inventory, EQ-5D=European Quality of Life- 5 Dimensions, GAI= Geriatric Anxiety Inventory, GDS= Geriatric depression Scale, GES= Group Evaluation Scale, GHQ= General Health Questionnaire, HADS=Hospital Anxiety and Depression Scale, MMSE= Mini Mental State Examination, N-EMD=Neuropsychiatric Inventory-Emotional Distress Scale, NPI= Neuropsychiatric Inventory, PSWQA= Penn State Worry Questionnaire, QCPR=Quality of Carer-Patient relationship, QoL-AD= Quality of Life in Alzheimer's Disease Evaluation Scale, RAID= Rating Anxiety in Dementia Scale, RMBPC= Revised Memory and Behavioural Problems Checklist, RSS= Relative's Stress Scale, SAS= Staff Assessment summary

Psychosocial interventions

Authors	Design, intervention, duration of intervention & level of individualisation	N	Intervention received	Outcome measures and assessment points	Results	Quality Rating
Dias et al. (2008)	RCT Home Care Programme vs. waiting list control Home based, flexible stepped-care Programme *Duration*: 6 months Fully individualised	81 dyads	**PWD**: referrals for behaviour management as appropriate **CG**: support in activities of daily living **Both:** psycho-education re: dementia, behavioural problems and their management; family networking, signposting.	**PWD**: EASI, NPI (severity) **CG**: Zarit Burden Scale, NPI (burden), GHQ-12 *Baseline, 3 and 6 months*	**PWD**: • Non-sig. reduction in behavioural disturbances (NPI) and functional ability (EASI). **CG**: • Sig. improvement in mental health (GHQ-12) and burden as measured by the NPI but not the Zarit Burden Scale	*Jadad*: 4/4 **Strengths**: attempted to use blind assessors (although success of blinding was limited), drop outs adequately dealt with **Weaknesses**: no follow-up, small N therefore inadequate power to detect significant changes in behaviour and functioning, attrition due to death high , otherwise low
Dröes et al. (2006)	Quasi-experimental pre-test post-test matched control group design Meeting Centre Support Programme vs. regular day centre care *Duration*: 7 months Partially individualised (fixed programme but some optional components)	128 dyads	**PWD**: Social club (inc. recreation/social activities, reality orientation, reminiscence, validation, psychomotor therapy, music therapy)	**PWD**: ASEP (inactivity and aggressive behaviour subscales), CDS, Behaviour Observation Scale (non-social behaviour subscale), Philadelphia Geriatric Centre morale Scale, NPI (severity), time to admission to nursing home	**PWD**: • Sig. longer delay in time to admission to nursing home • Sig. less chance of being admitted for intervention group. • Near sig. increase in behavioural disturbances (NPI) in intervention group (effects on remaining outcomes not reported as reported in previous article)	*York= adequate* **Strengths**: description of drop outs, successful group matching confirmed statistically, outcome measures delivered according to balanced incomplete block design to avoid systematic effects

			CG: Informative meetings, long term discussion group **Both**: Consulting hour, social festivities, excursion, case management	**CG**: GHQ-28, Sense of Competence Scale, Jalowiec Coping Scale, Social Support List, adapted Use of Services checklist, Loneliness Scale, NPI (burden), satisfaction with service questionnaire *Baseline and 7 months*	**CG**: • sig. greater reduction in psychological and psychosomatic symptoms (GHQ-28) following intervention for carers who felt lonely at start of programme • Sig. decrease in expressed feelings of burden between at 7 months in intervention group on a single 'burden question' on satisfaction questionnaire • No sig. difference between groups for sense of competence (Sense of Competence Scale), coping behaviour (Jaloweic Coping Scale), loneliness (Loneliness Scale), experienced social support (Social Support List), experienced support from services (Use of Services Checklist), impact of behavioural disturbances (NPI)	**Weaknesses**: control group data taken from previous study, assessors not blind, no adjustment of alpha level to account for multiple analyses, under powered, unbalanced group sample size (94 vs. 34), no follow up, groups not randomly assigned
Waldorff et al. (2012)	RCT Routine follow-up plus psychosocial support programme vs. routine follow-up only (following dementia diagnosis *Duration*: 8-12 months Fully individualised	330 dyads	**PWD**: 5 week course inc. info on key issues of dementia and its consequences and handouts on different topics **CG**: 5 week course inc. formal education re: dementia and handouts on different topics **Both**: Routine follow up plus counselling sessions, comprehensive written info., telephone support	**PWD**: MMSE, CDS, EQ-VAS (PWD & CG rated), QoL-AD, NPI, ADSC-ADL **CG**: GDS, EQ-VAS *Baseline, 6 and 12 months*	**PWD**: • No sig. effect of treatment at either 6 or 12 months for all measures: cognition (MMSE), depression (CDS), health-related quality of life (EQ-VAS), quality of life (QoL-AD), behavioural disturbances (NPI), functional ability (ADSC-ADL) **CG**: • No sig. effect of treatment at either 6 or 12 months for all measures: depression (GDS), health related quality of life (EQ-VAS)	*Jaded*=4/4 **Strengths**: assessors blind, ITT analysis, description of drop outs and analysis controlled for drop out, a priori power calculation **Weaknesses**: variable inclusion period, no follow-up

CG-=Caregiver, PwD= Person with Dementia
ADSC-ADL= Alzheimer's Disease Cooperative Study Activities of Daily Life Scale, ASEP= Assessment Scale for Elderly Patients, CSD= Cornell Scale for Depression, EASI= Everyday Abilities Scale for India, EQ-VAS= European Quality of Life Visual Analogue Scale, GDS= Geriatric depression Scale, GHQ= General Health Questionnaire, IADL= Instrumental Activities of Daily Living, MMSE= Mini Mental State Examination, NPI= Neuropsychiatric Inventory, QoL-AD= Quality of Life in Alzheimer's Disease Evaluation Scale.

Support Group Interventions

Authors	Design, intervention, duration of intervention & level of individualisation	N	Intervention received	Outcome measures and assessment points	Results	Quality Rating
Gaugler et al. (2011)	Single group, pre-test, post-test design Memory Club *Duration*: 10-13 weeks Fixed programme	PWD: 63 CG: 61	**Both**: weekly 90 minute sessions involving a) joint support groups, b) separate group sessions for PWDs and CGs, c) joint wrapping up session. Weekly sessions cover different topics including: information about dementia, communication, relationships, confidence, future planning, increasing support.	**PWD**: Ratings of effectiveness in completing activities, GDS, satisfaction survey, IADL dependence **CG**: Care Partner Stress measure, Care Partner Effectiveness measure, GDS, Preparation Checklist, Anticipation of Care (3 subscales), satisfaction with service questionnaire *Baseline and 10-13 weeks*	**PWD**: • Sig. increase in IADL dependency • No sig. change in depression (GDS) or ratings of effectiveness but high pre-test MMSE score sig. positively correlated with increased activity effectiveness • Moderate levels of satisfaction with service **CG**: • Sig. increase in perceived effectiveness, number of preparation activities undertaken & reports of preparation for care needs. • No sig. change in depression (GDS) or stress (care partner stress measure) • High levels of satisfaction with service	*York*= Poor **Strengths**: Intervention delivered across multiple sites, peer supervision to ensure consistency of objectives across sites **Weaknesses**: lacks internal validity due to lack of control group, assessments conducted by intervention facilitators, non-standardised conduct of intervention across the 3 research sites, no follow-up

Logsdon et al. (2010)	CRCT Early-stage memory loss vs. wait list control *Duration*: 9 weeks Manualised intervention	142 dyads	**Both**: weekly manual-based structured support programme. Sessions include PWD & CG who meet together for part of the session and separately for the rest.	**PWD**: QoL-AD, SF-36, GDS, RMBPC	**PWD**: • Sig. effect of group and time on quality of life (QoL-AD) and depression (GDS) favouring the intervention group. • No sig. difference in health-related quality of life (SF-36) or memory-related behaviour problems (RMBPC)	*Jadad*=2/4 **Strengths**: low attrition rate (although no description of drop outs), ITT analysis, adjustment of alpha level, analyses adjusted for clustering effects **Weaknesses**: group allocation done on 2:1 ratio, unclear if assessors were blind, no follow-up, no report of sample size calculation
				CG: GDS, FAM (communication, affective expression & involvement subscales), PSS, Self-Efficacy Scale *Baseline and post-treatment*	**CG**: • No sig. differences in depression (GDS), communication (FAM), stress (PSS), self-efficacy (Self-Efficacy Scale)	

CG-=Caregiver, PwD= Person with Dementia
FAM= Family Assessment Measure, GDS= Geriatric depression Scale, PSS= Perceived Stress Scale, QoL-AD= Quality of Life in Alzheimer's Disease Evaluation Scale, RMBPC= Revised Memory and Behavioural Problems Checklist, SF-36= Short Form Health Survey.

Rehabilitation Interventions

Authors	Design, intervention, duration of intervention & level of individualisation	N	Intervention received	Outcome measures and assessment points	Results	Quality Rating
Gitlin et al. (2008)	RCT Tailored Activity Programme vs. wait list control *Duration*: 4 months Fully individualised	60 dyads	**PWD**: no individual intervention (see both) **CG**: stress reducing techniques **Both**: OT led individualised activity prescription and planning	**PWD**: Agitated Behaviours in Dementia Scale, RMBCP, CSD, 5 item activity engagement measure, QoL-AD **CG**: 5-item mastery scale, subjective burden rating scale, Zarit Burden Scale, objective burden measure, CES-D, 5-item measure of confidence using activities, Task Management Strategy Index *Baseline and 4 months*	**PWD**: • Sig. main effect of treatment for frequency of behavioural occurrences (shadowing and repetitive questioning), agitated and augmentative behaviours, activity engagement and ability to keep busy, with intervention group doing sig. better on each. • Trend towards improved quality of life (QoL-AD) • no sig. impact on depression (CSD) **CG**: • Sig. fewer hours spent 'on duty' and doing things for PWD in intervention group compared to controls. • Sig. greater mastery (mastery scale), self-efficacy using tasks (confidence using activities) and use of simplification techniques (task management strategy index) in intervention group at 4 months compared to controls. • No sig. impact of intervention on burden on any measure	*Jadad*=4/4 **Strengths**: assessors blind, appropriate randomisation, low attrition, high average session participation **Weaknesses**: no follow-up, no adjustment of alpha level, pilot study with no a priori sample size calculation

Graff et al. (2006)	RCT Community OT vs. care as usual *Duration*: 5 weeks Fully individualised	135 Dyads	**PWD**: no individual intervention (see both) **CG**: cognitive and behavioural interventions to support use of effective supervision, problem solving and coping strategies **Both**: home-based twice weekly sessions– goal setting, development of meaningful activities, home adaptations, ADL training	**PWD**: Assessment of Motor and Process Skills (process scale), Interview of Deterioration in Daily Activities in Dementia (performance scale) CG: Sense of Competence questionnaire *Baseline, 6 and 12 weeks*	**PWD**: • Sig. improvement in daily functioning (Assessment of Motor and Process Skills, Interview of Deterioration in Daily Activities in Dementia) across time and group **CG**: • Sig. increase in competence (Sense of Competence questionnaire) across time and group	*Jadad*= 4/4 **Strengths**: assessors blind, appropriate randomisation, low attrition rate, ITT analysis, adjustment of alpha level, follow-up **Weaknesses**: recruitment limited to one institution therefore results may not generalise
Graff et al. (2007)			**PWD**: no individual intervention (see both) **CG**: cognitive and behavioural interventions to support use of effective supervision, problem solving and coping strategies **Both**: Occupational Therapy – development of meaningful activities, home adaptations, ADL training	**PWD**: Dqol, GHQ-12, CSD **CG**: Dqol, CES-D, GHQ-12, Mastery Scale *Baseline, 6 and 12 weeks*	**PWD**: • Sig. greater increase in quality of life (Dqol), health status (GHQ) and mood (CSD) in intervention group at 6 and 12 weeks **CG**: • Sig. greater improvement in health status (GHQ), mood (CES-D) and sense of control (Mastery scale) in intervention group at 6 and 12 weeks • Sig. better quality of life (Dqol) at 6 weeks on 2 out of 4 subscales (aesthetics and self-esteem) and on all subscales at 12 weeks	

Kurz et al. (2012)	RCT Cognitive Rehab and Psychotherapy vs. standard medical management *Duration*: 12 weeks Manualised intervention	201 dyads	**PWD**: cognitive rehabilitation and CBT programme delivered in 4 modules – introduction, neuro-rehabilitation (use of external memory aids, introduction of daily routines), psychotherapy strategies (day structuring, activity planning, reminiscence), closing module **CG**: Attendance at half PWD sessions, written information on all modules	**PWD**: B-ADL, AFIB, DEMQOL, GDS, NPI, WMS-R, Trail Making test, Regensburg Word Fluency test, Satisfaction Questionnaire ZUF-8 **CG**: BDI, Zarit Burden Interview, Satisfaction Questionnaire-ZUF-8 *Baseline, 3 and 9 months*	**PWD**: • No sig. impact of intervention on activities of daily living (B-ADL, AFIB), quality of life (DEMQOL), behaviour disturbance (NPI), cognitive ability (WMS-R, Trail Making Test, Word Fluency test) at 3 and 9 months • Sig decrease in depression (GDS) for females but not males at 3 and 9 months in intervention group compared to control group • No sig. difference between groups in treatment satisfaction **CG**: • Sig. increase in burden (Zarit Burden Interview) in intervention group but not control group at three months but no effect of group at 9 months • No sig. difference between groups in changes to depression or treatment satisfaction	*Jadad*=4/4 **Strengths**: assessors blind, ITT analysis, treatment standardised, control of treatment fidelity, low attrition, good participant adherence to treatment, follow-up **Weaknesses**: low sensitivity of B-ADL and AFIB, short duration of treatment
Viola et al. (2011)	Single blind, non-randomised controlled trial Multidisciplinary Cognitive rehabilitation vs. wait list control *Duration*: 12 weeks Fixed programme	41 dyads	**PWD**: multidisciplinary cognitive rehabilitation including cognitive rehabilitation and training, speech, art, physio and occupational therapy, cognitive stimulation and physical training **CG**: psychoeducation and psychological counselling	**PWD**: MMSE, SKT, NPI, GDS, QoL-AD **CG:** GDS, QoL-AD (carer protocol), NPI-distress *Baseline and 12 weeks*	**PWD**: • No change in cognition (MMSE, SKT) in intervention group, sig. decline shown in cognition on SKT but not MMSE in control group. • Sig. reduction in depression (GDS) and sig. improvement in quality of life (QoL-AD) in intervention but not control group. • No change in behavioural disturbances (NPI) for either group **CG:** • Sig. reduction in depression (GDS) and distress (NPI) and sig. improvement in quality of life (QoL-AD) in intervention but not control group.	*York*= Adequate **Strengths**: assessors blind, good description of intervention, groups well matched, standardised treatment **Weaknesses**: participants not randomised, small sample size, no follow-up

CG-=Caregiver, PwD= Person with Dementia
AFIB=Aachen Functional Item Inventory, B-ADL= Bayer Activities of Daily Living, BDI= Beck Depression Inventory, CES-D= Centre of Epidemiological Studies Depression Scale, CSD= Cornell Scale for Depression, DEMQOL=Quality of Life in dementia, Dqol= Dementia Quality of Life Instrument, GDS= Geriatric depression Scale, GHQ= General Health Questionnaire, MMSE= Mini Mental State Examination, NPI= Neuropsychiatric Inventory, QoL-AD= Quality of Life in Alzheimer's Disease Evaluation Scale, RMBPC= Revised Memory and Behavioural Problems Checklist, SKT= Short Cognitive Test, WMS-R= Wechsler Memory Scale-Revised.

Case Management Interventions

Authors	Design, intervention, duration of intervention & level of individualisation	N	Intervention received	Outcome measures and assessment points	Results	Quality Rating
Callahan et a. (2006)	CRCT Care Management vs. usual care *Duration*: 12 months Partially individualised (some standardised and some individualised elements)	153 dyads	**PWD**: Support group **CG**: Support Group, coping skills, caregiver guide form Alzheimer's Association **Both**: Care manager, education on communication skills, legal and financial advice, behavioural interventions (based on individual need)	**PWD**: NPI (severity), Activities of Daily Living, Health Care Resource Use, CSD, Telephone Interview for Cognitive Status (telephone version of MMSE), rate of nursing home placement **CG**: NPI (burden), PHQ-9, satisfaction with PWD's care (assessed with single question) *Baseline, 6, 12 and 18 months*	**PWD**: • Sig. greater improvement in behavioural disturbances (NPI) at 12 and 18 months in intervention group compared to control • No sig. impact of intervention on depression (CSD), cognition (MMSE), activities of daily living or rates of nursing home placement. • Sig. increase in health care use by intervention group compared to controls at 12 and 18 months **CG**: • Sig. improvement in distress (NPI) at 12 months but not 18 months • Sig. improvement in mood at 18 months. • Sig. greater number of CGs report being satisfied with PWD care at 12 months but no difference at 18 months	*Jadad*=4/4 **Strengths**: assessors blind, low chance of Type I error on primary outcome measures, ITT analysis, good handling of drop outs, follow-up, sites randomised before recruitment but recruitment team blind to randomisation clusters, analyses adjusted for clustering effects **Weaknesses**: underpowered to detect changes on secondary measures, baseline differences in two groups, PwD in intervention group more likely to be taking medication, control participants received a substantial intervention

Jansen et al. (2011)	RCT Nurse-led case management vs. care as usual *Duration*: 12 months Partially individualised (some standardised and some individualised elements)	99 dyads	**PWD**: development of individualised care plan, on-going monitoring as required, **CG**: formulation of individualised care plan **Both**: Assessment, sign posting, information and advice, referrals to relevant services, family meetings for other relatives to increase social support and provide psychoeducation	**PWD**: Dqol, health care utilisation **CG**: SCQ, consequences of caring, satisfaction with own performance, satisfaction with PWD, SF-36, CES-D, SPPIC, health care utilisation *Baseline, 6 and 12 months*	**PWD**: • No sig. impact of intervention on quality of life (Dqol) or health care utilisation **CG**: • No sig. impact of intervention on sense of competence (SCQ), quality of life (SF-36), depression (CES-D), burden (SPPIC) • Sig. decline over time for both groups in satisfaction with PWD and consequences of caring (SCQ). • No effect of time on other measures	*Jadad*=4/4 **Strengths**: assessors blind, a priori sample size calculation, suitable N, drop out adequately addressed, ITT analysis, low attrition **Weaknesses**: included participants with no formal diagnosis of dementia, insufficient power to detect small effects, no follow-up, poor treatment fidelity
Specht et al. (2009)	CRCT Nurse Care Manager vs. traditional case management *Duration*: not stated Fully individualised	**PWD**: 249 **CG**: 168	**PWD**: no individual intervention (see both) **CG**: optional CG support group **Both**: Nurse care manager, including delivery of direct services using traditional and non-traditional methods, as well as traditional case management	**PWD**: MMSE, Global Deterioration Scale, Activities of Daily Living index, Functional Assessment II, Behaviour Rating Checklist (13 items) **CG**: NOC (measuring wellbeing, endurance and stressors). *Baseline, 3-9monts, 9-15 months*	**PWD**: • Sig. increase in functional ability (ADL index) in intervention group across all time points (no change in control group). • No sig. difference between the two groups in functional ability in either follow-up period • No sig. effect of time or group on cognition (MMSE) , stage of dementia (Global Deterioration Scale), behaviours (Behaviour Rating Checklist) **CG**: • No sig. increase in stress (NOC) in intervention group, increase in control group at 3-9months but not 9-12 months. At 3-9months control group sig, more likely to have extensive stress than intervention group • No change in wellbeing (NOC) for intervention group, sig. decrease in wellbeing in control group at both follow-up periods. Control group sig. more likely to have extremely compromised wellbeing at 9-15 months. • Sig. increase in endurance potential (NOC) at 3-9 months in intervention group only	*Jadad*= 1/4 **Strengths**: alpha level adjusted for some analyses, differences between completers & drop outs explored **Weaknesses**: sites randomised before recruitment, recruitment team not blind, assessors not blind, data collection points variable, no ITT analysis, attrition high, inclusion of PWDs without formal dementia diagnosis, no sample size calculation reported,

Vickery et al. (2006)	CRCT Care management vs. care as usual *Duration*: 12 months Fully individualised	408 dyads	**Both**: guideline-based individualised care management, including assessment, individualised treatment plan, referral to appropriate services, education and support.	**PWD**: HUI-3, health state classification, overall health care quality (care-rated) **CG**: Carer Survey (knowledge of dementia, confidence & mastery, health related QoL, social support, unmet need for assistance managing problem behaviours) *Baseline, 12 and 18 months*	**PWD**: • Sig. smaller decline in health related quality of life (HUI-3) at 18 months in intervention group, • Sig. better health care quality (carer rated) at 12 and 18 months for intervention group **CG**: • No sig. main effect of time or group on knowledge or use of services. • Intervention group sig. higher confidence and mastery, social support and sig. fewer unmet needs (carer survey) at 18 months than control group. • No between group difference in health-related Qol at 18 months **Both**: • Sig. more dyads received community services, respite care, health services and professional caregiving services in intervention group. • At follow-up sig. more dyads enrolled on Alzheimer's Association programme for wandering in intervention group.	*Jadad*= 3/4 **Strengths**: ITT analysis, power analysis and data analysis adjusted to account for clustering effects, follow-up **Weaknesses**: no between group comparison of drop outs

CG-=Caregiver, PwD= Person with Dementia
CES-D= Centre of Epidemiological Studies Depression Scale, CSD= Cornell Scale for Depression, Dqol= Dementia Quality of Life Instrument, HUI-3= Health Utilities Index-3, MMSE= Mini Mental State Examination, NPI= Neuropsychiatric Inventory, NOC= Nursing Outcomes Classification, PHQ-9= Patient Health Questionnaire-9, SCQ= Sense of Competence Questionnaire, SF-36= Short Form Health Survey, SPPIC= Self-Perceived Pressure by Informal Care

Study Characteristics

Of the 18 studies included in the review, 13 were RCTs. Of these four were CRCTs, although none of these studies identified themselves as such in the title or abstract. The remaining five studies were non-randomised trials and of these two used a quasi-experimental design and three used a single group design.

All but three studies specified that research participants had a formal diagnosis of dementia. Ten studies used formal diagnostic criteria such as the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (4th ed.; DSM–IV*;* American Psychiatric Association, 1994) to confirm diagnoses and three studies stated that diagnosis was confirmed through screening medical records. Two studies by Dröes, Meiland, Schmitz and Tilburg (2006) and Vickery et al., (2006) specified that participants had a diagnosis of dementia but did not state how this was made or confirmed. Bakker et al. (2011) included people with a DSM-IV diagnosis of dementia or an amnesic disorder or other cognitive impairment, Specht, Bossen, Hall, Zimmerman and Russell (2009) included participants with memory impairments and Jansen et al. (2011) required participants to have an MMSE score of below 24 and a risk of dementia of 50% or more according to the 7 Minute Screen (7MS).

Description and Evaluation of Interventions

Psychotherapeutic Interventions

Description: Psychotherapeutic interventions offer theory-based psychological therapies. Four studies investigated the impact of psychotherapeutic interventions. Bakker et al. (2011) evaluated a nursing- home based integrative psychotherapeutic programme and although the intervention was delivered in a nursing home setting all participants were community dwelling. Meanwhile, Woods

et al. (2012) examined the effectiveness of joint reminiscence groups, which were manual based and covered a number of themes including childhood, schooldays, working life, marriage, and holidays. Two further studies utilised single group time series designs. Paukert et al. (2010) investigated the effectiveness of a home-based, manualised cognitive-behavioural therapy (CBT) progamme for anxiety, whilst Weber et al. (2009) evaluated a psychotherapeutically oriented day hospital programme.

Effectiveness: Bakker et al. (2011) reported that their nursing home programme resulted in significant reductions in the neuropsychiatric symptoms of people with memory impairments (as rated by carers but not staff) and in carer burden, as well as significant increases in carer competence, when compared to usual care. Initial improvements in the cognition of people with memory impairments were not maintained at 6 month follow-up and self-care was significantly poorer in the intervention group. The generalisability of the results is limited because only 50% of eligible dyads consented to participate. Furthermore, only 65% of participants had a DSM-IV diagnosis of dementia. The RCT by Woods et al. (2012) revealed no significant effect for people with dementia following participation in reminiscence groups except an increase in use of day care services. For carers, anxiety was observed to increase on one measure but not another and no other significant effects were observed. This study was rated as good quality and adhered to all criteria on the Jadad Scale. In contrast, the study by Paukert et al. (2010) was rated as poor quality. Improvements for in people with dementia following CBT for anxiety were demonstrated across all measures of anxiety and on a measure of depression and carers displayed reductions in distress. However, results across different measures of anxiety were not consistent between or within participants, the sample size was only

nine meaning results could not be generalised and the study did not have power to detect any statistically significant effects. The study by Weber et al. (2009) was also rated as poor quality. A significant decrease in behavioural disturbance for people with dementia was observed. However, although staff reports of progress indicated a significant positive effect of treatment, self-ratings of progress did not improve indicating that people with dementia did not experience any change themselves. This was the only study found which collected but did not report carer outcomes.

Psychosocial Interventions

Description: Psychosocial interventions focus on the interaction between psychological and social or environmental factors .Three studies investigating psychosocial interventions were found in the review. Using an RCT, Waldorff et al. (2012) compared routine follow-up plus a semi-tailored psychosocial intervention (Danish Alzheimer Study Intervention, DAISY) with routine follow-up only for newly diagnosed people with dementia and their carers. In a second RCT, Dias et al. (2008) investigated the effectiveness of a home-based, flexible stepped-care outreach intervention for people with dementia and their carers living in Goa. A third psychosocial intervention was evaluated by Dröes et al. (2006), who employed a quasi-experimental two group design to explore the impact of the Meeting Centre Support Programme (MCSP).

Effectiveness: Waldorff et al. (2012) found no significant effects for either people with dementia or carers. This study was rated as high quality and despite the lack of any significant findings the authors recommend further research as this was an exploratory study. The study may have been under powered because sample size calculations did not adjust for multiple primary outcomes and assessment time points. Dias et al. (2008) observed a significant reduction in carer distress and general

mental health. No significant effects for people with dementia were observed. The quality of this trial was high although it may also have been underpowered to detect smaller changes. The final psychosocial intervention evaluated by Dröes et al (2006) resulted in significantly longer delay in time to admission to nursing home for people with dementia. However, no significant treatment effect was found for carers on any of the primary outcome measures. Secondary analysis revealed a significant reduction in psychological and psychosomatic symptoms only for carers who were rated as lonely at baseline. A significant reduction in burden was observed but this was based on a single item on a carer satisfaction questionnaire. Caution is needed when interpreting these results as no adjustment was made to the alpha level to account for multiple analyses therefore increasing the chance of finding significant group differences. At the same time the study was under powered meaning that significant effects may have gone undetected.

Support Group Interventions

Description: Two support group programmes offering a combination of psychoeducation and peer support for people with early stage dementia and their carers were identified. Logsdon et al. (2010) randomised dyads at a ratio of 2:1 to either the Early Stage Memory Loss (ESML) intervention or a wait list control group. Gaugler et al. (2011) evaluated the effect for dyads of participating in a joint Memory Club support group programme whose aim was to increase knowledge, improve communication and confidence, enhance feelings of support, reduce isolation, increase self-efficacy and improve awareness of wider support services.

Effectiveness: The results of these two studies were mixed. Logsdon et al. (2010) demonstrated that their intervention resulted in significant improvements in the quality of life and significant reductions in depression of people with dementia in

comparison to the control group, but found no effect on health-related quality of life or memory-related behaviour problems. No benefits for carers were found. The quality of this study was average and benefited from low attrition rates. However, it is unclear whether assessors were blind and whether a priori sample size calculations had been conducted. Gaugler et al. (2011) reported a significant increase in the functional dependency of people with dementia and no effect on their mood or perceived effectiveness. However, the intervention did significantly improve carers' preparedness for the future and perceived effectiveness, although had no effect on their mood or stress. This study was rated as poor quality and as the intervention was not standardised across research sites it is difficult to draw conclusions about the source of the positive outcomes observed.

Rehabilitation-Focused Interventions

Description: Rehabilitation interventions aim to optimise the capabilities of people with dementia. Two forms of rehabilitation interventions were found, those that focused on cognitive rehabilitation and those that focused on functional rehabilitation, the latter of which centred predominantly on activities of daily living. Two studies investigating cognitive rehabilitation interventions were found. Kurz et al. (2012) investigated the impact of cognitive rehabilitation combined with cognitive-behavioural treatment. This study has been included in this section as it focuses more strongly on rehabilitation than psychotherapy. Viola et al. (2011) investigated the effectiveness of a multidisciplinary cognitive rehabilitation programme. Some participants originally in the control condition subsequently went on to complete the intervention condition.

Two RCTs exploring interventions designed to improve functional ability were found, one of which was described in two papers (Graff et al., 2006, 2007).

These authors examined the effects of a community occupational therapy programme aiming to support people with dementia to improve their functional abilities by maximising existing compensatory and environmental strategies. Gitlin et al. (2008) investigated the impact of an occupational therapist led Tailored Activity Program (TAP). This programme aimed to reduce the vulnerability of people with dementia to their environment and increase their threshold for tolerating stress by devising individualised activity programmes designed to enhance preserved abilities.

Effectiveness: Kurz et al. (2012) found no change in the functional ability, quality of life, behavioural disturbance or cognition of people with dementia. A significant decrease in depression was observed in females but not males. Although carer burden had increased at the end of treatment this effect disappeared at follow-up. This trial was high quality but it should be noted that psychological interventions were included alongside cognitive rehabilitation strategies meaning results are representative of a joint intervention. The intervention evaluated by Viola et al. (2011) resulted in a significant reduction in depression and a significant increase in quality of life for both people with dementia and carers, as well as significant reductions in carer distress. No change in the cognition or behaviour of people with dementia was observed in the intervention group, whereas a small but significant decrease in cognition was observed in the control group. This study included well matched treatment groups and was rated as adequate.

Gitlin et al. (2008) demonstrated that their intervention resulted in a reduction in behavioural disturbance and an increase in engagement and ability to keep busy for people with dementia. For carers a significant increase in competence was observed, alongside a reduction in time spent caring. Similarly positive results were reported by Graff et al. (2006, 2007) whose intervention significantly improved the

functional ability, quality of life, health status and mood of people with dementia and the competence, health status, mood and sense of control of carers. Both studies investigating functional rehabilitation were rated as high quality, although the generalisability of Graff et al.'s (2006, 2007) results may be limited as recruitment was confined to one institution.

Case Management Interventions

Description: Case management interventions focus on the co-ordination of services and the rehabilitation, support and care of participants by utilising a range of strategies, including psychoeducation, sign-posting, skills training, behavioural management and care co-ordination, based on individual assessments of need. Four studies investigated the impact of case management. Callahan et al. (2006) developed an individualised collaborative care management programme to supplement usual treatment. A similar programme was evaluated by Vickery et al. (2006) who compared a multi-component, guideline based care management programme with care as usual. Care managers used algorithm software to develop and initiate individualised treatment action plans based on assessment information. Specht et al. (2009) described the effectiveness of enhanced case management delivered by dementia nurse care managers. Finally, Jansen et al. (2011) explored a more traditional case management programme whereby the case managers' role was predominantly one of individualised co-ordination.

Effectiveness: Jansen et al. (2011) found no benefits of case management for either people with memory impairments or their carers. Although this study was high quality it included people with dementia symptoms but not a formal diagnosis and the authors concluded that this intervention may not be effective if offered too early. Other studies did find benefits of case management. Callahan et al. (2006) observed

significant improvements in the behavioural and psychological symptoms of people with dementia and an increase in their health care use, as well as significant improvements in carer mood. Other improvements were observed but not maintained at follow-up. This study may have been underpowered to detect changes on secondary outcome measures and the impact of the intervention may have been underestimated because the control group received substantial input. Meanwhile, Vickery et al. (2006) reported a significantly smaller decline in the health related quality of life of people with dementia compared to usual care. The intervention had no effect on carer knowledge or health related quality of life but did result in significantly improved carer confidence, mastery, social support and fewer unmet needs. A fourth study (Specht et al., 2009) was of poorer quality. No significant changes for people with memory impairments were observed. However, carer stress and wellbeing was maintained in the intervention group but declined in the control group and endurance potential was greater in the intervention group. This study not only included people without a formal diagnosis of dementia, it also included people with no carer, although analyses controlled for this.

Discussion

Summary of the Effectiveness of Interventions

This review of the literature revealed that combined interventions for people with dementia and their carers are not consistently effective. The mixed outcomes reported and variability in the quality of the studies means that definitive conclusions are difficult to draw. This is in line with the conclusions reached in the previous review by Smits et al. (2007). The effectiveness of psychotherapeutic interventions appears to be limited. Reminiscence therapy was largely ineffective, a therapeutic day hospital programme displayed very limited effectiveness and conclusions as to

the effectiveness of CBT for anxiety are limited by the poor quality nature of the study. A psychotherapeutic nursing-home based programme was more promising, although only resulted in consistent benefits for carers. No consistent positive outcomes from psychosocial interventions were reported across the three studies included in the review. Support group programmes appear to facilitate positive outcomes for people with dementia, although conclusions as to the effectiveness of such interventions for carers are mixed. Furthermore, both the studies described were of poor quality meaning that it is not possible to be confident in the results observed. Cognitive rehabilitation programmes appear to have no impact on the cognitive abilities of people with dementia. In contrast, functional rehabilitation interventions appear to be effective for both people with dementia and carers. Finally, case management appears to be an effective intervention for both people with dementia and carers if offered to those with a formal diagnosis of dementia.

Methodological Limitations

There were a number of common methodological issues identified in the included studies. Firstly, over half did not include a follow-up assessment, thus conclusions as to their long-term effectiveness cannot be drawn. Secondly, in one third of the studies assessments were completed by assessors not blind to participants' group allocation, introducing the possibility of bias (Schulz & Grimes, 2002). Furthermore, the generalisability of some studies was limited, for example because they only included participants from single institutions, thus limiting the extent to which results can be applied beyond the sample studied. Another weakness of several studies was a lack of power. Without an adequate sample size studies risk making type II errors, that is, reporting false negative results through being unable to detect significant effects where they exist. Additional limitations included high levels

of attrition, lack of description of drop-outs and failure to adjust alpha-levels to account for multiple analyses.

Effectiveness of Interventions for People with Dementia by Outcome

Outcomes for people with dementia were classified as following: behavioural problems; cognitive functioning, mental health, functional ability, admission to an institution and quality of life. It appears that combined interventions programmes do not have a consistent effect on behavioural problems, or quality of life although do not result in any decline in either outcome. Interventions are more likely to report no change in depression than to report an improvement and no evidence was found of an improvement in anxiety following any of the interventions. Similarly no improvements in cognition were observed, including in the two studies designed specifically to target cognition, suggesting that cognition is not a promising target for interventions. Functional ability improved in the two studies specifically targeting this outcome. However, although several other studies observed no change, declines in functioning were observed in three studies. This suggests that careful monitoring of functioning should be included in interventions which do not specifically target functional ability as decline is possible. An inadequate number of studies reported outcomes for admission to institutions.

Apart from interventions targeting functional ability which consistently resulted in improvements, no other consistent patterns between category of intervention and outcome observed emerged. Not all outcomes were assessed in each study meaning broader conclusions are further limited. Finally, the level of individualisation of intervention programmes does not appear to be related consistently to any specific type of outcome.

Effectiveness of Interventions for Carers by Outcome

Outcomes for carers were classified into four categories: burden, mental health, competence and quality of life. Combined interventions appear to have no negative consequences for carers. Competence appears to improve most consistently and presents a promising target for interventions, with the impact on burden being more mixed. Mental health is more likely to remain stable than improve, with general mental health the most promising target for interventions. Depression and stress appear almost exclusively resistant to change. Only five studies reported outcomes for quality of life making it difficult to draw conclusions, although as with all other outcomes no negative effects were observed.

No consistent pattern emerged between category of intervention and outcomes observed and the level of individualisation of intervention programmes does not appear to be related consistently to any specific outcomes. Again, not all outcomes were assessed in each study meaning broader conclusions are further limited.

Effectiveness for both People with Dementia and Carers

All but one study, that of Weber et al. (2009), reported outcomes for both people with dementia and carers. Only two studies (Graff et al., 2006, 2007; Paukert et al., 2010) reported consistently positive outcomes for both, whilst six studies found partially positive outcomes for both (Bakker et al., 2011; Callahan et al., 2006; Gitlin et al., 2008; Vickery et al., 2006; Viola et al, 2011 & Woods et al., 2012). Six studies found positive results for either people with dementia or carers, but not both (Dias et al., 2008; Dröes et al., 2006; Gaugler et al., 2011; Kurz et al., 2012; Logsdon et al., 2010 & Specht et al., 2009). Jansen et al. (2011) and Waldorff et al. (2012) found no positive outcomes for either people with dementia or their carers. No

consistent link between type of intervention and presence or absence of positive outcomes for people with dementia and their carers was found. Similarly, no consistent link between the level of individualisation of interventions and presence of absence of positive outcomes was found.

Implications for Practice

The lack of consistent positive results within each category of interventions and the small number of studies in each group makes any wider recommendations for practice as to the most effective combined interventions for people with dementia and their carers limited. However, case management appears to be an effective combined intervention when delivered to people with a formal diagnosis of dementia and may therefore represent a promising mode of intervention in practice. Similarly, although this review found only two studies offering functional rehabilitation interventions, both resulted in positive outcomes for people with dementia and their carers, providing initial, albeit limited, evidence to recommend the use of functional rehabilitation in practice. On the other hand, cognitive rehabilitation interventions appear not to impact the cognition of people with dementia making their use as a means of enhancing cognition in practice questionable. However, given the secondary benefits demonstrated they should not be abandoned, although realistic expectations of outcomes should be held in mind. Whilst support group interventions appear to offer promising results, in particular for people with dementia, caution should be exercised before considering the use of such interventions in practice given the poor quality of both studies described. Combined psychotherapeutic interventions appear to result in limited outcomes and as such should be considered carefully before being implemented in practice and the mixed

outcomes from psychosocial interventions again warrants caution before use in practice.

Implications for Research

The limited number of studies in each category highlights the need for further research to allow more robust and definitive conclusions to be drawn. Larger scale studies are recommended to replicate those studies that were underpowered and future research should strive to ensure adequate power is achieved. The poor quality of some studies renders their conclusions less reliable and the limitations of these studies should be addressed in future research so as to provide more meaningful results. Interventions which do not result in positive outcomes for both people with dementia and their carers should consider modifications to target both members of the dyad more effectively and research to determine the active elements of each intervention would facilitate the development of efficient programmes. Finally, research studies should strive to use a homogeneous range of outcome measures to allow outcomes across studies to be more readily compared.

More specifically, given the heterogeneous nature of psychotherapeutic interventions direct comparisons between studies is less reliable. Replication of studies using similar interventions would allow for greater reliability of results. In order to strengthen the conclusions as to the effectiveness of case management interventions, those interventions which included people without a formal diagnosis of dementia should be replicated with people with a formal diagnosis.

Conclusions

There is evidence that combined interventions for people with dementia and their carers can be effective, although definitive conclusions as to the best types of interventions are limited. Functional rehabilitation offers consistently positive

outcomes but requires further research to make this conclusion more reliable and case management appears to offer promising outcomes when offered to people with a formal dementia diagnosis. More high quality research is needed across all types of interventions to allow for reliable recommendations to be made. No recommendations as to the level of individualisation of programmes can be made as outcomes of studies at each level were mixed. Furthermore, no one type of outcome emerged as a consistently promising target for interventions, with different interventions resulting in different outcomes. Nevertheless, use of some combined interventions in practice may have positive outcomes for both people with dementia and their carers if chosen carefully. Monitoring of outcome in practice is recommended in order to adapt interventions to ensure their effectiveness.

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Part 2: Empirical Paper

Effectiveness of Weekly Cognitive Stimulation Therapy (CST) for People with Dementia and the Additional Impact of Enhancing CST with a Carer Training Programme

Abstract

Background: Cognitive Stimulation Therapy (CST) is a widely used, evidence based intervention for people with dementia. Although designed as a 14 session, twice weekly intervention, anecdotal evidence suggests that CST is routinely delivered once a week for 14 weeks. However, this method of delivery has yet to be evaluated. In addition, CST does not, at present, include any formal carer training. The aim of the current study was firstly to evaluate the effectiveness of once weekly CST and secondly to determine any additional impact when enhancing CST with a carer training programme.

Design: A single blind, randomised control trial was used. 68 people with dementia and their carers were recruited through three community Memory Assessment Services. Dyads were randomised to one of three conditions: CST plus carer training, CST only or a wait list control. People with dementia were administered standardised measures of cognition, quality of life and relationship with carer at baseline and again after 15 weeks.

Results: 21 dyads were randomised to CST plus carer training, 24 to CST only and 23 to the control group. There were no baseline differences between people with dementia across the three groups. At follow-up there were no significant differences between people with dementia in the three groups on any of the outcome measures.

Conclusions: Weekly CST with or without carer training may not be an effective form of delivery. However, there are several possible explanations for the outcomes observed and further research is needed to determine the reliability of the results. Services currently offering weekly CST should collect routine outcome data from participants to support its use and provide practice-based evidence.

Currently in the UK there are an estimated 800,000 people living with dementia (Dementia 2012). Five percent of the population aged over 65 have dementia, with this figure rising to 20 percent in those aged over 80 and to 30 percent in those aged over 90 (National Service Framework for Older People, NSF-OP, 2007). As the population continues to age the number of people diagnosed with dementia is also set to increase. Indeed, estimated figures predict that by 2021 there will be over one million people in the UK with dementia (Dementia 2012). Dementia is a progressive mental health disorder characterised by pervasive impairment of mental function. Symptoms include a gradual loss of memory and cognitive disturbances that cause significant impairment.

Given the progressive and chronic nature of dementia and the large number of people currently (and predicted to be) diagnosed with the condition, the need for effective and accessible treatments is paramount. Pharmacological treatments are available but these are not appropriate for everyone and can result in intolerable side effects for some. Much attention has therefore been focused on the development of non-pharmacological interventions for the treatment of cognitive, behavioural and/or emotional symptoms. The literature review of Cove (2013) provides a description of non-pharmacological interventions for people with dementia.

Cognitive Interventions in Dementia

Cognitive symptoms frequently predominate in those suffering from dementia. These symptoms, highlighted in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (4th ed.; DSM–IV*;* American Psychiatric Association, 1994) include memory loss, deficits in executive function, visuo-spatial skills and attention, as well as impaired language, problem solving and reasoning ability These impairments can also impact on the quality of life, self-efficacy,

functional ability and mental health of people with dementia. There has been a wealth of research exploring the efficacy of cognitive-based interventions in the treatment of dementia, which focus on improving or stabilising cognitive symptoms. Such interventions are of value because despite wide-spread cognitive decline, some aspects of cognitive functioning, including some memory functioning can remain relatively stable and interventions which aim to maximise preserved functions have demonstrated successful outcomes. Whilst cognitive rehabilitation and training typically focus on improvement or maintenance of specific cognitive modalities, often at an individual level, cognitive stimulation is typically delivered in groups and adopts a more global approach, seeking to enhance general cognitive functioning, as well as social functioning (Clare & Woods, 2004). In his 1992 paper, Backman concluded that the use of well-designed cognitive stimulation interventions may have the potential to slow down the progression of dementia. Furthermore, a recent systematic review (Aguirre, Woods, Spector & Orrell, 2013) reported that cognitive stimulation interventions consistently result in positive outcomes for people with dementia with respect to their cognitive functioning, social interaction, communication and quality of life. Indeed, current NICE guidelines (NICE, 2007) recommend that:

> *"People with mild/moderate dementia of all types should be given the opportunity to participate in a structured group cognitive stimulation programme. This should be commissioned and provided by a range of health and social care workers with training and supervision. This should be delivered irrespective of any anti-dementia drug received by the person with dementia." (p.216).*

Involving Carers in Cognitive Stimulation

Receiving a diagnosis of dementia can have an impact both on the person with dementia but also on their family members, especially those directly involved in caregiving. The impact of caring for a person with dementia is multifaceted, with negative consequences on physical and mental health, quality of life, self-efficacy, social support and financial stability frequently reported. These effects, referred to collectively as caregiver burden (Kasuya, Polgar-Bailey and Takeuchi, 2000), are described in more detail in the literature review of Cove (2013). High levels of caregiver burden can also result in poorer outcomes for the person with dementia, including decreased quality of life and early admission to nursing homes (Etters, Goodall & Harrison, 2008).

Research has shown that involving carers in cognitive stimulation interventions for the person they care for can have positive benefits for both (Onder et al., 2005; Quayhagen and Quayhagen, 2001). Although not designed to offer direct intervention to carers, these studies aimed to involve carers in the delivery of cognitive stimulation. Benefits for people with dementia included improved memory, problem solving and verbal fluency, whilst carers experienced enhanced communication and interaction with the person they care for as well as maintenance of their quality of life and psychological well-being.

Cognitive Stimulation Therapy

Cognitive Stimulation Therapy (CST) is one version of cognitive stimulation (Spector et al, 2003). It is a brief, evidenced-based group therapy for people with mild to moderate dementia. The CST programme involves 14 sessions, lasting approximately 45 minutes, held twice weekly over seven weeks. The sessions cover a range of themes, with an emphasis on cognitive stimulation. CST is underpinned by

a set of eighteen key principles which guide all CST activity and aim to maximise the potential of people with dementia and build on their existing strengths. There is a focus on implicit rather than explicit learning and opinions not facts (a more detailed description is presented later in this paper).

Development of CST

CST was developed based on the findings of two Cochrane reviews of the research into psychological treatments for people with dementia, in particular Reality Orientation and Reminiscence (Spector, Orrell, Davies & Woods, 1998a; Spector, Orrell, Davies & Woods, 1998b). The CST programme was developed based largely on two concepts – Reality Orientation (RO) and Cognitive Stimulation, the therapeutic approaches found to have the best outcomes by the reviews. RO, described by Folsom (1968), was designed to improve memory and reduce confusion in people diagnosed with dementia. RO involves presenting orientation information to people with dementia about time, place or person in order to increase their understanding and recognition of their surroundings and thus also improve their self-esteem and confidence. Cognitive Stimulation, described by Breuil et al. (1994), aims to stimulate encoding, consolidation and retrieval of information through global stimulation of cognitive functions.

Evidence Base for CST

An initial pilot study by Spector, Orrell, Davies & Woods (2001) demonstrated positive outcomes for people with dementia following participation in CST and resulted in some modifications to the original intervention. Based on these outcomes Spector et al. (2003) conducted a single blind, multi-centre randomised controlled trial to evaluate the modified CST programme. Two hundred and one people with dementia, from across 23 sites (residential homes and day centres) were

randomised to either the CST or control group (control groups continued with their usual daily activities whilst the CST groups took place). Results of this study demonstrated that those people with dementia receiving CST had a significantly better outcome in terms of both cognitive functioning and quality of life, although no benefits in communication, behaviour, global functioning, mood or anxiety were observed. In addition, the authors demonstrated that CST produced effects comparable to those achieved by acetyl cholinesterase inhibitor drugs.

Further research has supported the findings of Spector et al. (2003), including studies by Knapp et al. (2006) who demonstrated that CST is cost-effective and Aguirre et al. (2013), who found that as well improvements to cognition and quality of life, CST had positive effects on the behaviour of people with dementia and was effective regardless of whether participants were taking acetyl cholinesterase inhibitor drugs. Hall, Orrell, Stott and Spector (2013) determined that the cognitive domains most influenced by CST were memory, comprehension of syntax and orientation, although their study used a small sample, one group pretest-posttest design. Finally, in a qualitative study exploring the impact of CST (Spector, Gardner & Orrell, 2011), people with dementia reported feeling more positive, relaxed and confident following CST. They thought that sharing views broadened their outlook on life which they experienced as an achievement. Furthermore, they enjoyed the groups, found them fun and expressed the wish that the groups could have continued for longer.

Carer Involvement in CST

At present, CST does not include any formal carer involvement. However, qualitative data reveals that carers often feel frustrated at not knowing what happens in CST groups, often because the person they care for cannot recall much from the

group (Spector et al., 2011). Involving carers more formally would allow them to develop a greater understanding of CST and may potentially encourage them to apply some of the principles and activities of CST in their day-to-day interactions. Furthermore, it may allow people with dementia to receive a higher 'dose' of CST if carers do apply its principles and use CST activities between sessions. This might produce additional benefits for people with dementia in line with previous research.

The Current Study

Despite the demonstrable efficacy of CST, very little phase IV implementation work is currently being conducted to evaluate the effectiveness of CST in the 'real world' i.e. in naturalistic settings. Phase IV trials (Medical Research Council, 2008) are conducted after an intervention has been developed and its efficacy has been demonstrated. Typically in the form of an RCT, they aim to evaluate interventions that have been introduced into clinical practice. The only implementation work the author is aware of is that which forms part of Orrell et al.'s Support at Home – Interventions to Enhance Life in Dementia (SHIELD, 2013) programme which, in part, is evaluating the use of CST in the community. However, this project does not include any carer involvement and no results are currently available. Although CST was designed and evaluated as a seven week, 14 session programme, in practice many NHS services deliver the programme once a week over 14 weeks, due to both time constraints and resource limitations. In addition, at present CST does not formally include any carer involvement and no previous study exploring the impact of including carer involvement in the programme has been found, making this a second important area for exploration.

Aims

CST delivered once a week for 14 weeks appears to be common in practice but is yet to be evaluated. Therefore, the first aim of the current study was to establish its effectiveness using a Phase IV trial. In addition, a carer training programme was developed to provide carers with an overview of CST to a) educate them and b) give them the opportunity to apply its principles at home, should they wish to. The second aim of the current study was to evaluate whether additional carer training led to any benefits above and beyond weekly CST.

Hypotheses

1. Weekly CST will result in improved cognition, quality of life and quality of the caregiving relationship for people with dementia, compared to those receiving no treatment.
2. Carer training in addition to CST will result in further improvements in cognition and quality of life as well as improved quality of the caregiving relationship for people with dementia, over and above those achieved following CST alone

Method

Joint project

A joint study was conducted with Nicola Jacobi, Trainee Counselling Psychologist (City University). The current study examined the impact of once weekly CST and the additional impact of enhancing CST with a carer training programme, looking solely at outcomes for the participants with dementia. Jacobi (2013) investigated the impact on carers of participating in the carer training programme. She assessed carer burden, psychological well-being, perceived level of competence and the quality of the carer-patient relationship. She also evaluated the

carer training programme using qualitative focus groups in order to evaluate and develop the programme (see appendix C for an outline of the contribution of each trainee to the research process).

Design

A single blind, randomised control design was used, with three independent conditions – two treatment conditions and a control condition. In treatment condition one, people with dementia received 14 sessions of weekly CST and their carers received CST training (CST plus carer training). In treatment condition two, people with dementia received 14 sessions of weekly CST (CST only). The control condition was a waiting list group, people with dementia did not receive CST and their carers received no training. People with dementia were placed on the waiting list for CST and continued with their usual activities. Although participants in the control group were not asked to withhold from participating in any other interventions whilst on the waiting list the research team were not aware of any participant who did participate in another psychological intervention during this time. At the end of the study people with dementia in the control group were offered CST and carers of people with dementia in the CST and control group were offered session 1 of the carer training programme. The trial was single blind: assessors were blinded to treatment allocation. In an attempt to maximise blindness, participants were reminded not to reveal the group they were in before each assessment. It was not possible to conduct a double blind trial because, as in any psychosocial trial, participants could not be blind to the condition they were in.

Randomisation

Participants were randomised using the block method (Schulz & Grimes, 2002) to achieve equal group sizes and using Random Allocation Software version 1

(Saghaei, 2004). Randomisation was done separately for each site to ensure participants did not have to travel further than necessary. Randomisation was conducted by the clinician who would be running the CST groups at a particular site. This clinician then informed participating dyads of their group allocation, arranged a date for the initial assessment and gave them details of CST group dates and carer training session dates where necessary.

Setting

Data collection took place across three sites within South Essex Partnership Trust (SEPT). At one site CST groups were already routinely offered to people with dementia and at the other two sites CST groups were set up for the purpose of this study. All CST groups were conducted in community settings with transport available for those who needed it. Carer training sessions were similarly conducted in community settings and care for the person with dementia was provided when needed, to facilitate their attendance. Although the same procedures were followed in each site (see below) the research did not run concurrently across sites and separate CST groups and carer training sessions were held for participants at each site.

Participants

People with dementia were recruited from three Memory Assessment Clinics. All people with dementia who had a) been through one of the Memory Assessment Clinics during the previous two years (or who were on the waiting list for CST), b) met the inclusion criteria and c) had a carer who met the inclusion criteria, were invited to take part in the study, along with their carer.

Inclusion Criteria

Eligibility criteria were adapted from Spector et al. (2003) whose study helped to determine which people CST is most suitable for. People with dementia were eligible for participation if they:

1. Met the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV; APA, 1994) criteria for dementia of any type;
2. Scored 18-30 on the Mini-Mental State Examination (MMSE; Folstein, Folstein & McHugh, 1975) indicating mild to moderate dementia. See section on outcome measures for a fuller description;
3. Could speak English and had some ability to communicate and understand communication – a score of 1 or 0 on questions 12 and 13 of the Clifton Assessment Procedures for the Elderly – Behaviour Rating Scale (CAPE–BRS; Pattie & Gilleard, 1979);
4. Lived in the community (i.e. not in a residential setting);
5. Were able to see and hear well enough to participate in the group and make use of most of the material in the programme;
6. Could engage in group activity for at least 45 minutes;
7. Did not have major physical illness or disability which could affect participation;
8. Did not have a diagnosis of a learning disability;
9. Had a carer who was willing to take part in the study (and met inclusion criteria – see below).

Point 2 was adapted to include those with an MMSE score of 18-30 as this fitted with the current inclusion criteria for CST used in the services where data collection took place. Point 9 was added to account for the inclusion of carers in this study.

The research team, which consisted of the author and Nicola Jacobi (Trainee Counselling Psychologist), Dr Aimee Spector (Senior Lecturer in Clinical Psychology) and Dr Helen Donovan (Consultant Clinical Psychologist) developed a set of inclusion criteria for carers to ensure that they could participate fully in the research. Carers were considered eligible for participation if they:

1. Had a minimum of three contacts per week with the person they cared for and were able to continue this for the period of the research study;
2. Were aged 18 or above;
3. Could speak English;
4. Did not have major physical illness or disability which could affect participation.

Power analysis

As no previous research was found examining the effect of once weekly CST or carer involvement, it was not possible to calculate an a priori sample size. However, using G*Power 3.1 (Faul, Erdfelder, Lang, & Buchner, 2007) it was determined that a sample size of 144 participants (72 dyads), with power set at 0.80 and using a 5% significance, would be adequate to detect an effect size of 0.34 or above.

Procedure

Recruitment

For each of the three research sites, people with dementia and their carers (dyads) who met inclusion criteria were contacted to discuss the study. An information sheet for people with dementia and carers (appendix D) were sent to those who expressed an interest in participating. Dyads were given time to review this information (on average one week) before being contacted to determine if they

wished to participate. For those who agreed to participate, written informed consent was obtained, in accordance with the provisions of the Mental Capacity Act (2005), from both people with dementia and carers (see appendix E for consent forms) at the first assessment meeting. The General Practitioner of people with dementia was informed of their participation in the research (appendix F).

Intervention: CST

The study followed the standardised CST manual (Spector et al, 2005) used by health care professionals to deliver CST to people with dementia. Groups were held weekly for fourteen weeks, with sessions lasting approximately 45 minutes. One site already had an established CST programme. People were welcomed into the group, which was run by two facilitators. To enhance orientation a Reality Orientation (RO) board displayed orientation and group information such as the day, date, time, month and the group name (collectively chosen by the group during session 1). Sessions opened with the group song, again chosen collectively by the group in session 1, which was followed by a warm up exercise. Following this a news article was discussed by the group. The main activity then followed, based on that weeks' theme. Themes included: physical games, childhood, using money, word association and food (see appendix G for full list of themes). Sessions were designed to be as inclusive as possible and activities were tailored to the groups' abilities. Sessions closed with the group song.

Intervention: Carer CST Training Programme

Development of the Programme: The training programme was adapted from the current CST training programme and training manual (Making a Difference 2, Aguirre et al., 2011). Adaptations were made based on the specific needs of this research project, drawing on the knowledge of the research team. An initial version

of session 1 of the training programme was piloted prior to the start of the research with a group of nine carers who had a family member with dementia who had recently attend a CST group. Feedback indicated that carers found the content of the training relevant. However, they thought the background information on dementia and the development of CST was too long and reduced the time they could spend learning about the content of CST sessions and how to apply its principles at home with the person they care for. Modifications were made based on the feedback from this pilot. The initial background information was condensed and links to websites providing more detailed information were provided in order to allow greater focus on the latter parts of the presentation. Further adaptations to the timing of the session were made following the delivery of the training at the first research site.

Aims of the Programme: The aim of the CST carer training programme was not to train carers to deliver CST, but to provide them with training about the nature and rationale of CST, introduce essential skills around interacting with the person they care for and on implementing activities at home using the guiding principles of CST. The objective was to enhance the interactions between the carer and the person they care for in their home environment in such a way that carers felt empowered and could support the experience of the CST group for the person cared for.

Overview of the Programme: Carers allocated to the CST plus carer training conditions were asked to attend two training sessions, with an optional workshop offered between these two sessions. The training was delivered in conjunction with the CST programme. Session 1 was a half-day session (three hours) and was delivered to coincide with people with dementia beginning CST. During this session carers were given an overview of dementia and of the development of and rationale for CST. The CST programme was outlined and details of individual session

presented. DVD clips from CST sessions taken from the Making a Difference 2 manual (Aguirre et al., 2011) were also presented. Following this each of the 18 guiding principles of CST (Table 1) was described and ways of engaging the person at home according to these principles were suggested. Carers were given a work book which outlined a selection of activities that related to each theme undertaken in the CST programme, which they could select to try with the person between CST sessions. Space was provided for carers to write down their own ideas for relevant activities and they were also encouraged to share their ideas with the group. The workbook also contained a diary and carers were asked to record any activities tried at home with the person they care for, along with ratings of the success of these activities. The workbook and diary were developed by the team based on previous experience of training programmes. Carers were given a copy of the training presentation and a copy of the Making a Difference 2 manual (Aguirre et al., 2011) to take away.

Session 2 was delivered during the final week of the CST programme and lasted approximately 1 hour. The focus of this session was on maintenance of skills acquired into the future. A brief presentation was given to remind carers of the basic content of CST sessions and the underlying principles of CST. Time was given for answering questions and addressing concerns and to share ideas of successful activities used at home. An optional workshop was offered at week seven. This was a one hour question and answer session to give carers the opportunity to discuss any problems they were experiencing and to receive support if they would like, but was not compulsory.

Table 1

The 18 key principles underlying CST

	Key Principles
1	Mental stimulation
2	New ideas, thoughts and associations
3	Using orientation, both sensitively and implicitly
4	Opinions rather than facts
5	Using reminiscence as an aid to the here-and-now
6	Providing triggers to aid recall
7	Continuity and consistency between sessions
8	Implicit (rather than explicit) learning
9	Stimulating language
10	Stimulating executive functioning
11	Person-centredness
12	Respect
13	Involvement
14	Inclusion
15	Choice
16	Fun
17	Maximising potential
18	Building / strengthening relationships

Assessments

All participants were assessed at baseline (the two week period before the intervention) and at follow-up (the two week period after the intervention ended). Although participants were offered the choice of meeting with researchers at their home or at their local memory clinic, all participants elected to complete assessments at home. Wherever possible two researchers visited each dyad to conduct assessments so that assessments could run concurrently, therefore minimising the time commitment for dyads and ensuring people with dementia were not alone whilst carers completed assessments. Cares were asked to provide demographic details for themselves and for the person they care for at the first assessment.

Outcome measures

The outcome measures for cognition and quality of life which showed sensitivity to change in previous CST research were selected (Spector et al., 2003). In addition, the quality of the person with dementia-carer relationship was assessed. This has not been previously assessed in CST trials as they have not included carer input.

Cognition

Two outcome measures were used to assess cognition – the Mini Mental State Examination (MMSE; Folstein et al., 1975) and the Alzheimer's Disease Assessment Scale – Cognition (ADAS-Cog; Rosen, Mohs & Davis, 1984). The MMSE is a brief, 30 item test with good reliability and validity, assessing a range of cognitive functions including orientation, registration, attention and calculation, recall, language, repetition and complex commands. People with dementia score 1 point for each correct response up to a total of 30, with a score of 0-10 indicating severe dementia, a score of 11-20 indicating moderate dementia and a score of 21 and above indicating mild dementia (Folstein et al., 1975). The ADAS-Cog is a more comprehensive and extensive measure of cognitive function than the MMSE and one of the most commonly used assessments of cognition in clinical trials with people with dementia. Items cover word recall, naming, commands, constructional praxis, ideational praxis, orientation, word recognition, spoken language, comprehension, word-finding and remembering instructions. Scores range from 0-70 with higher scores indicating greater impairment. The ADAS-Cog has high reliability and validity (Rosen et al, 1984).

Quality of Life

Quality of life for people with dementia was assessed using the Quality of Life – Alzheimer's Disease scale (QoL-AD; Logsdon, Gibbons, McCurry & Teri, 1999). The QoL-AD is a brief, 13-item questionnaire delivered in interview format. Response options, and where needed questions, were displayed for people with dementia to follow. People with dementia rate the quality of different aspects of their life. Questions cover the following domains: physical health, energy, mood, living situation, memory, family, marriage, friends, chores, fun, money, self and life as a whole. People with dementia rate each item on a four point scale whereby a rating of 1= poor, 2=fair, 3=good and 4=excellent. Scores are in the range of 13-52, with higher scores indicating better quality of life. The QoL-AD has good internal consistency, validity and reliability (Thorgrimsen et al., 2003).

Quality of the caregiving relationship

The quality of the relationship between the person with dementia and their carer was assessed using the Scale for the Quality of the Current Relationship in Caregiving (QCRC; Spruytte, Van-Audenhove, Lammertyn & Storms, 2002). This scale is a 14 item measure assessing relationship quality, including level of criticism and level of warmth. The scale is delivered in interview format with response options and where needed questions, displayed for people with dementia to follow. Each item is in the form of a statement e.g. *'I blame my relative for the cause of my problems'; 'I feel very good if I am with my relative'.* People with dementia rate the degree to which they agree or disagree which each statement on a five point scale (totally agree, agree, not sure, disagree, totally disagree). The maximum score is 70 with high scores indicating good relationship quality. Good reliability and validity have been demonstrated (Spruytte et al., 2002).

Ethics

Ethical approval for this study was granted by London South East National Research Ethics Service (NRES) Committee (appendix H). This committee is designated to review research involving adults who may lack capacity under The Mental Capacity Act (2005). The British Psychological Society (BPS; Dobson, 2008) sets out procedures for determining the capacity to consent for research participants. In this context, consent has to be regarded as a continuing process rather than a one-off decision. An assessment of the capacity to consent to participate in the research of each person with dementia was undertaken at the start of the research and willingness to continue participating in the study was checked through discussion with the person with dementia and their carer during subsequent assessments. Participating carers were also asked to consent to the participation of the person they were caring for. The following procedures, based on the BPS criteria, were in place to manage any case where the capacity of a person with dementia was in doubt:

1. Where the researcher has any doubts regarding the capacity of the person with dementia to provide informed consent, advice from an appropriate clinician will be sought.
2. Where the person with dementia has previously given informed consent to participate, this will provide a good indication of their views regarding the research.
3. All people with dementia participating will be doing so with the full involvement and assent of a family carer; the family carer will be able to withdraw the person with dementia from the study at any time.

4. A personal consultee (not a carer taking part in the research) will be invited to consider what they think the views of the person with dementia would have been, if they had capacity.
5. Any person with dementia showing verbal or non-verbal indications of refusal or reluctance to participate in group sessions or assessment interviews will be withdrawn from the study.
6. Informed consent from the carer will be sought separately and they are not considered to be a vulnerable group.

Data analysis

The Statistical Package for Social Sciences (SPSS) version 17 was used to analyse data. Intention to treat analysis was applied using the last observation carried forward method for data missing at follow-up. Scores on the MMSE were found to be normally distributed. However, for the CST group baseline scores on the QoL-AD and QCRC showed significant skewness and kurtosis. For the control group, scores on the ADAS-Cog showed significant skewness and kurtosis at both time points. Z-scores were calculated to check for outliers and subsequently 4 scores considered as extreme (a z-score of 3 or above) were replaced with the next highest or lowest score. Removal of these extreme scores rendered all outcome measure normally distributed and this was confirmed by calculations of residual scores and Cook's Distance scores for each measure, all of which were within the accepted level needed to assume normality.

One-way ANOVAs and χ^2tests were used to check for differences in demographic characteristics between participants in three conditions at baseline. Outcome measures were analysed using mixed method ANCOVAs to evaluate the changes in scores over time and across conditions. Use of ANCOVA allows for

variability in baseline characteristics (covariates) to be controlled for. The age and gender of the people with dementia were entered as covariates. Effect sizes were calculated using Partial Eta^2 (η_p^2).

Results

Recruitment and Attrition

One hundred and sixty six dyads were identified as suitable for inclusion. Of these 122 consented to receive information packs and of these 72 consented to participate and were randomised into one of the three treatment conditions. Four dyads dropped out before the first assessment, therefore no data was available for these participants and they were not included in the final analyses. Nine dyads dropped out between the first assessment and follow-up. Figure 1 displays details of the flow of participants through the research. There were no significant differences in the proportion of completers and non-completers across the three conditions $\chi^2(2)=1.042$, p=0.594. Comparison of baseline characteristics of those who dropped out and those who did not revealed no significant differences. Baseline characteristics explored were age t(66)=-0.53, p=0.60, gender $\chi^2(1)=0.03$, p=0.87, diagnosis $\chi^2(6)=4.92$, p=0.56, carer age t(66)=-1.36, p=0.18, carer gender $\chi^2(1)=0.52$, p=0.47 and the scores of people with dementia on the four outcome measures: MMSE t(66)=0.73, p=0.47; ADAS-Cog t(64)=-1.47, p=0.14; QoL-AD t(66)=0.78, p=0.44; QCRC t(65)=-0.29, p=0.77.

Participant Characteristics

A description of the characteristics of people with dementia across the three conditions can be found in Table 2. Details of education were not consistently collected and are therefore not included. Across the whole sample approximately one

quarter of participants had moderate dementia (26.5%) and three quarters had mild dementia (73.5%). Two thirds of participants (67.6%) had a diagnosis of Alzheimer's disease (early onset, late onset or mixed/atypical). The majority of participants were White British (86.8%) and lived in their own home (92.6%). It was most common for participants to be cared for by their spouse (75%) and the majority of participants had not previously attended any intervention related to their dementia (89.7%). Of the seven who had done so, three attended a music for memory group, two attended a Parkinson's disease group, one attended an Alzheimer's Society group and one participant specified only that they attended a non-therapy group. There were no significant differences across the three conditions in any of the participant characteristics. 77.8% of people with dementia assigned to receive CST attended more than half of the group sessions. There were no differences in the mean number of sessions attended by participants in the CST plus carer training and the CST conditions.

Figure 1

Participant flow through the study

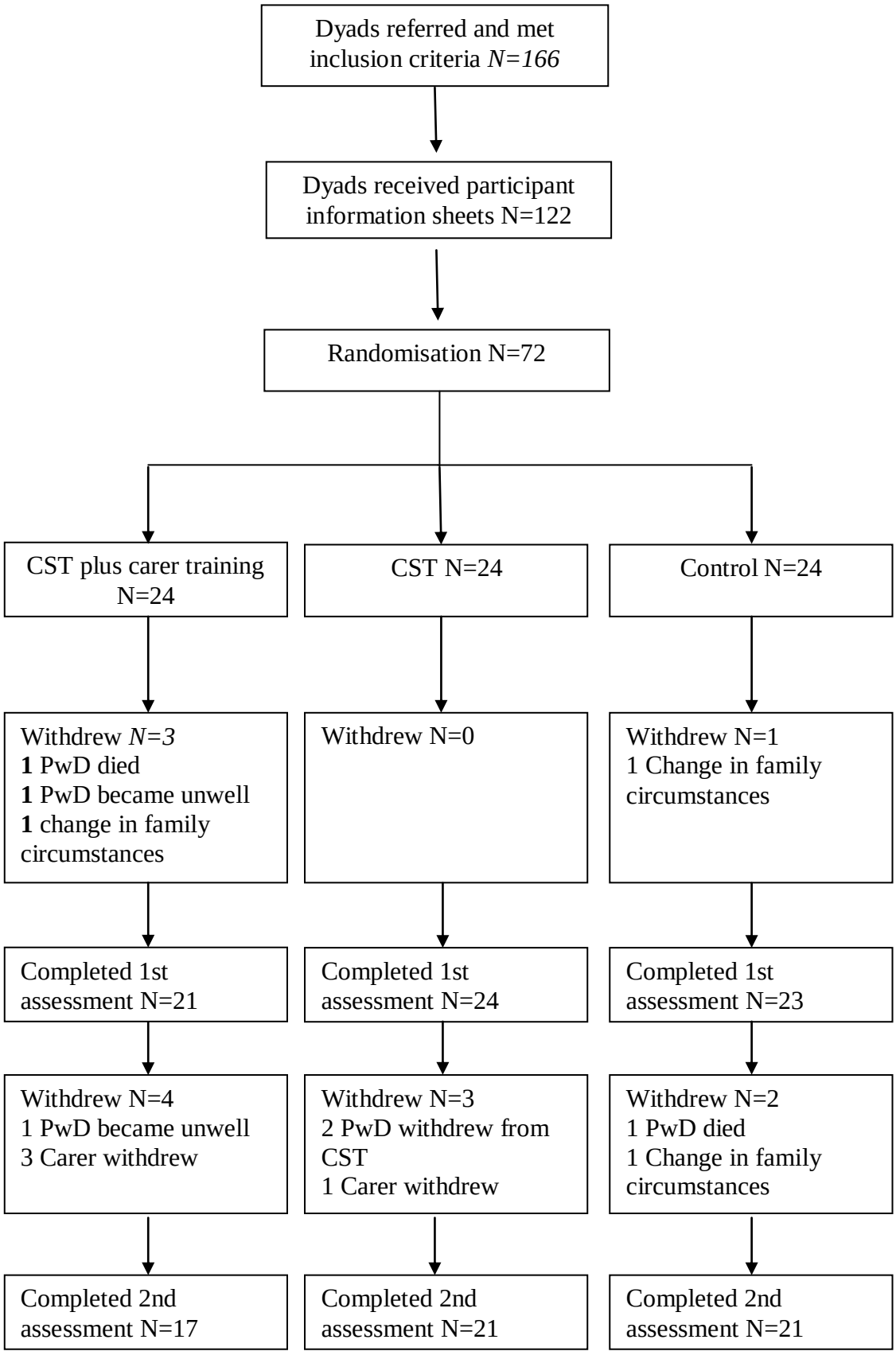

Table 2

Baseline characteristics of participants with dementia

	CST plus carer training	**CST**	**Control**	**F/t/χ^2 value, *p-value***
Age, mean (sd)	75.4 (5.56)	76.8 (6.62)	77.8 (7.47)	F=0.73 ***p=0.49***
Gender				
Male (%)	11 (52.4)	15 (62.5)	10 (43.5)	χ^2=1.71 ***p=0.43***
Female (%)	10 (47.6)	9 (37.5)	13 (56.5)	
Ethnicity				
White British (%)	17 (81.0)	23 (95.8)	19 (82.6)	
White Irish (%)	0 (0)	0 (0)	2 (8.7)	χ^2=12.78 ***p=0.12***
White Other (%)	2 (9.5)	0 (0)	0 (0)	
Black Caribbean (%)	2 (9.5)	0 (0)	2 (8.7)	
Indian (%)	0 (0)	1 (4.2)	0 (0)	
Living Situation				
Private Accommodation (%)	20 (95.2)	20 (83.3)	23 (100)	χ^2=5.39 ***p=0.25***
Sheltered Housing (%)	0 (0)	1 (4.2)	0 (0)	
Supported Living (%)	1 (4.8)	3 (12.5)	0 (0)	
Dementia Diagnosis Sub-Type				
Alzheimer's disease (early onset) (%)	0 (0)	0 (0)	1 (4.3)	
Alzheimer's disease (late onset) (%)	15 (71.4)	11 (47.8)	10 (43.5)	
Alzheimer's disease (atypical/mixed) (%)	1 (4.8)	2 (8.7)	6 (26.1)	χ^2=17.12 ***p=0.15***
Vascular dementia (%)	0 (0)	3 (13.0)	1 (4.3)	
Sub-cortical Vascular dementia (%)	2 (9.5)	1 (4.3)	2 (8.7)	
Dementia in Parkinson's disease (%)	0 (0)	4 (17.4)	1 (4.3)	
Unspecified dementia (%)	3 (14.3)	2 (8.7)	2 (8.7)	
Dementia Severity				
Mild (%)	15 (71.4)	18 (75.0)	17 (73.9)	χ^2=0.08 ***p=0.96***
Moderate (%)	6 (28.6)	6 (25.0)	6 (26.1)	
Living with Carer				
Yes (%)	18 (85.7)	19 (79.2)	19 (82.6)	χ^2=1.67 ***p=0.85***
No (%)	3 (14.3)	5 (20.8)	4 (17.4)	
Relationship to Carer				
Spouse (%)	17 (81.0)	17 (70.8)	17 (73.9)	
Partner (%)	0 (0)	0 (0)	1 (4.3)	χ^2=7.81 ***p=0.45***
Mother/Father (%)	4 (19.0)	5 (20.8)	4 (17.4)	
Mother/Father-in-law (%)	0 (0)	2 (8.3)	0 (0)	
Aunt/Uncle (%)	0 (0)	0 (0)	1 (4.3)	
Age of Carer, mean (sd)	68.81 (10.39)	67.13 (11.26)	70.43 (11.12)	F=0.54 ***p=0.59***
No. of medications, mean (sd)	5.19 (4.14)	3.88 (2.62)	5.70 (4.16)	F=1.53 ***p=0.22***
Dementia Medication				
Yes (%)	10 (47.6)	16 (66.7)	13 (56.5)	χ^2=1.67 ***p=0.43***
No (%)	11 (52.4)	8 (33.3)	10 (43.5)	

Attended previous dementia intervention				χ^2=1.01
Yes (%)	1 (4.8)	3 (12.5)	3 (13.0)	***p=0.60***
No (%)	20 (95.2)	21 (87.5)	20 (87.0)	
No. of CST sessions attended, mean (sd)	10.95 (3.64)	10.50 (4.53)	N/A	t=0.37 ***p=0.72***

Carer Attendance at the Training Programme

Although carer outcomes will be reported in full by Jacobi (2013) the level of attendance at the carer training programme is reported here. Of the 21 carers in the CST plus carer training condition, 14 (66.7%) attended all sessions (sessions 1, 2 and the optional workshop). Two (9.5%) attended sessions 1 and 2 but not the optional workshop, four (19%) attended session 1 only. In total 20 carers attended the first (and main) training session and one (4.8%) did not attend any sessions. Although carers were asked to record all CST activity they used at home, the majority of carers did not, meaning hardly any data about level of use of CST activities or principles were available.

Analysis of Outcomes

There were no significant baseline differences across the three conditions on any of the outcome measures: MMSE, F(2,67)=0.16, p=0.85; ADAS-Cog, F(2,65)=0.05, p=0.96; QoL-AD, F(2,67)=0.69, p=0.51; QCRC, F(2,66)=0.22, p=0.81. Mean scores at baseline and follow-up for each outcome measure for each condition are displayed in Table 3, which also displays between-group effects and effect sizes from the ANCOVA analysis.

There were no changes in cognition as assessed by the MMSE over time, F(1,63)=0.81, p=0.37 (η_p^2 =0.01) and no significant differences between the three groups at follow-up, F(1,63)=0.84, p=0.92 (η_p^2=0.003). Although there was a significant decline in cognition between baseline and follow-up across the whole

group as assessed by the ADAS-Cog, F(1,61)=4.38, p=0.04, this effect was very small (η_p^2=0.07) and there were no between group differences on this measure at follow-up, F(1,61)=0.02, p=0.98 (η_p^2=0.001). There were no between group differences on any of the 12 subscales of the ADAS-Cog. There were no changes in quality of life (QoL-AD) over time, F(1,61)=0.003, p=0.96 (η_p^2=0.0001) and no differences between the three groups at follow-up, F(1,63)=0.82, p=0.44 (η_p^2=0.03). Similarly, there were no changes in the QCRC over time, F(1,62)=1.68, p=0.20 (η_p^2=0.03) and no between group differences at follow-up, F(1,62)=0.97, p=0.39 (η_p^2 =0.03).

Table 3

Mean Scores at baseline and follow-up for each outcome measure

	Baseline			Follow-Up			ANCOVA between group difference	η_p^2
	CST plus carer training	CST	Control	CST plus carer training	CST	Control		
Mini-Mental State Examination	22.33 (3.54)	22.71 (3.76)	22.91 (3.01)	22.19 (4.48)	22.38 (4.75)	22.13 (3.40)	F=0.84 p=0.92	0.003
Alzheimer's Disease Assessment scale – Cognition	18.35 (7.1)	18.13 (8.24)	17.68 (6.51)	20.10	19.04	20.09	F=0.02 p=0.98	0.001
Quality of Life – Alzheimer's Disease scale	36.43 (6.06)	36.42 (5.44)	34.78 (5.43)	36.45	35.65	35.32	F=0.82 p=0.44	0.03
Scale for the Quality of the Current Relationship in Caregiving	57.38 (6.49)	57.09 (6.91)	56.13 (6.53)	57.90	55.65	56.41	F=0.97 p=0.39	0.03

Discussion

Summary of Findings

The current study aimed to determine the effects for people with dementia of delivering CST once a week for 14 weeks and to establish any additional benefits of enhancing weekly CST with a carer training programme. However no improvements for people with dementia in their cognition, quality of life or the quality of the relationship with their carer were observed in groups who received either CST or CST plus carer training, when compared to the no treatment control group.

Interpretation of Results

The results demonstrate that delivering CST once a week for 14 weeks may not be an effective format. There is strong evidence for the efficacy of twice weekly CST and this format is recommended in the NICE guidelines (NICE, 2007). The current study does not provide any evidence that delivering a once weekly programme of CST is effective and as such leads to the conclusion that this format should not be utilised in practice. There is no indication that NICE guidelines should be amended to include a once weekly programme and as such services should offer twice weekly programmes. Twice weekly CST provides a more intensive treatment 'dose' and this may be a necessary ingredient to ensure effective outcomes. Although the structure and content of the once weekly CST programme was the same as that utilised in the twice weekly paradigm, simply delivering the same programme with the same session content may not be sufficient to achieve change without the intensity of the session delivery. New learning or maintenance of existing capacities may require a more frequent level practice or repetition to be successful than once weekly CST is able to achieve. Twice weekly CST may provide the required dose to

achieve the learning that cognitive stimulation aims to achieve. Therefore, CST may simply not achieve its aims if delivered too infrequently.

The results of the current study indicate that once weekly CST and a carer training programme do not have positive outcomes for people with dementia,. However, it is important to consider several other possible explanations of the result observed.

Participants' Level of Cognitive Functioning

One explanation for the lack of positive outcomes observed is that people with dementia in the current study were already functioning at their optimum level, particularly in terms of their cognitive abilities. Cognitive functioning as assessed by the MMSE and the ADAS-Cog was higher in the present study than in previous trials. Mean MMSE scores in both the study by Spector et al. (2003) and that by Aguirre et al. (2013) were lower (14.4 and 16.7 respectively) than that observed in the current study (22.66). Similarly, on the ADAS-Cog people with dementia in the current study scored, on average, 18.05, compared with 27 and 34.4 in Spector et al. (2003) and Aguirre et al. (2013) respectively. According to the criteria set out by Folstein et al. (1975), using MMSE scores reveals that participants in the two previous studies were on average in the moderate range of dementia, whilst people with dementia in the current study were, on average, in the mild range. Previous studies may have observed improvements in cognition because people with dementia had already deteriorated to a level that gave scope for improvements.

This conclusion is supported by Hall et al. (2013) who observed no change from baseline in cognition as assessed by the MMSE. The average baseline MMSE score in this study (20.3) was closer to that of the current study and supports the possibility that initial higher levels of cognitive functioning may not leave scope for

any improvements to be achieved. However, it is possible that the impact of CST continues to take effect, particularly for those people with dementia whose carers received CST training and who could effectively be receiving a longer term 'dose' of CST. As the current study did not include a long term follow-up assessment it is not possible to determine if such effects occur.

Sensitivity of Outcome Measures

A second possibility is that there were differences between the groups in the current study which were not adequately assessed. Although Hall et al. (2013) did not observe any improvement in cognition as assessed by the MMSE, they did observe some improvements in cognition on other measures. However, these were more comprehensive, domain specific measures than either the MMSE or the ADAS-Cog. It could therefore be that ceiling effects on the MMSE and ADAS-Cog were observed in the current study, whilst more sensitive measures would have allowed differences to be detected. Furthermore, of the two previous studies which have measured quality of life, only one (Spector et al., 2003) found improvements following CST on the QoL-AD (the measure of quality of life used in the current study). Aguirre et al. (2013) found improvements in quality of life as assessed by the Dementia Quality of Life measure (DEMQOL; Smith et al., 2005) but not as assessed by the QoL-AD. The two measures may, the authors argue, be measuring two different aspects of quality of life. The current study therefore, may not have assessed all aspects of quality of life and could have missed improvements due to a limited assessment of this outcome.

Range of Outcomes Assessed

It is also possible that people with dementia experienced benefits following CST that were not measured in this study. The outcome measures used were selected

based on those for which Spector et al. (2003) found improvements in their study, meaning that no measures of communication, behaviour, global functioning, mood or anxiety were included. However, as stated there were differences in participants' cognitive functioning between the current study and that of Spector et al. (2003) and the majority of participants in their study lived in residential settings whilst all participants in the current study were community based. It is therefore possible that people with dementia in the current study could have experienced positive outcomes in these domains, or other domains not assessed. For example, the qualitative study by Spector et al. (2011) revealed that people with dementia experienced a range of benefits following CST not assessed in the quantitative studies of Spector et al. (2003), Aguirre et al. (2013) and Hall et al. (2013), including increased confidence and sense of achievement.

Validity of the Carer Training Programme

One possibility as to why the carer training programme appears to have been ineffective is that it was not substantial enough and failed to achieve its aims of providing people with dementia with a higher 'dose' of CST. The training programme was developed by the research team and modified based on limited feedback from a small pilot study and as such may not have been a good enough programme to achieve its aims. The maximum number of hours training received by carers was five and this may simply not have been enough to ensure any differences occurred in their interactions or activities undertaken with the person they care for. No data as to whether the training had successfully changed carers' knowledge or behaviour were collected so it is not possible to determine whether the training programme was valid.

Changes in Carers' Interactions with the Person they Care for

A final possibility is that, even if the training programme was a valid and useful one, carers may not have implemented any changes in their interactions with the person they care for following the training. Almost no data was available as to the extent to which carers used any of the recommended activities or adapted their interactions according to the CST principles because the majority of carers did not fill in the weekly diary given to them to record such activity. One possibility then is that carers were not using the CST at home and therefore people with dementia in this group did not receive a higher 'dose' of the intervention than those in the CST group as planned. This does not explain why no positive outcomes from receiving CST were observed but may explain why involving carers in the intervention appears to have had no more impact for people with dementia than receiving CST alone. Even if carers did interact differently with the person they care for having learnt about dementia and the key principles of CST, it is possible that the outcome measures chosen were not appropriate to detect the impact of such changes for the person with dementia as the constructs assessed may not have been influenced by changes in carer behaviour.

Methodological Limitations

There were several limitations to the current study. Although attempts to ensure that all assessors were blind to participants' group allocation were made, no formal measure of the integrity of the blinding process was included. One way to measure the integrity of blinding is to ask assessors to indicate which group they think a participant is in and how confident they are in this perception. As this was not done, it was not possible to determine the extent to which observer biases were introduced to assessments in the current study.

Secondly, no monitoring of treatment fidelity was undertaken, hence the extent to which CST sessions were implemented as planned and the consistency with which they were implemented is unknown. Adherence checks, for example the completion by facilitators of a checklist to measure adherence to the intervention at the end of each session, would have allowed for an estimation of the level of adherence to the CST programme to be made and thus increase confidence that the intervention received by people with dementia was the intended intervention.

Thirdly, although it was originally planned that the same assessor would complete baseline and follow up assessments for the same participants, in practice this was not possible. This was due to the availability of assessors and the loss of blinding of one assessor in particular meaning she was unable to complete the majority of follow up assessments. This introduces the possibility that systematic differences in the way assessors delivered assessments may have resulted in biases across participants' pre and post assessments. However, given the proven inter-rater reliability of both the MMSE and ADAS-Cog the difference in assessors is unlikely to have resulted in significant bias in assessment outcomes.

Finally, although the study was powered to detect large effect sizes, the relatively small sample size may have meant it was under powered to detect smaller effects that exist.

Clinical Implications

The evidence from this study suggests that weekly CST and enhancement of CST with the carer training programme should not be recommended in practice. There is clear evidence from past research that CST is an effective intervention for people with dementia when offered on a twice weekly basis and as such should continue to be offered by services in line with the NICE guidelines (NICE, 2007).

Many services currently offer CST on a once weekly basis, whereas the findings of this study would not support such a mode of delivery at present. However, within South Essex Partnership Trust (SEPT) one service (included in the current study) that routinely offers CST on a weekly basis has noted, through routine monitoring of outcomes, improvements in the quality of life of people with dementia who attend weekly CST. Although no formal evidence is available this anecdotal evidence offers some support for the use of once weekly CST. Furthermore, participants in the current study frequently reported how much they had enjoyed going to the groups and expressed the wish that the groups could continue. Groups appear to offer a lifeline to many participants by providing a chance to make connections with others and an opportunity to share experiences and feel less isolated. The low attrition rate from CST groups also points towards participants experiencing some benefits of attending and CST groups may be more cost effective than other available services. Thus, it should not simply be concluded that CST delivered once a week with or without carer training is ineffective.

Nevertheless, at present services setting up new CST groups should consider carefully whether to run them once or twice weekly. This should involve a consideration of both the above evidence and NICE guidelines alongside the practical issues, such as time, resources and participant availability, of running groups on a twice weekly basis. Services currently delivering weekly CST should consider changing their programme to a twice weekly format. If this is not feasible services should undertake service level monitoring of outcomes to ensure that those who participate are benefiting, to provide justification for delivering CST in this format given the evidence from the present study and to provide service-level data that can be used to further explore the effectiveness, or not, of weekly CST. The

impact for people with dementia of including carer training should similarly be monitored and assessed.

Implications for Research

The findings of the current study were in contrast to those of previous research indicating the effectiveness of CST and of service level observations of the effectiveness of once weekly CST. It is therefore recommended that the current study be replicated using a wider range of outcome measures to capture possible benefits missed in the current study, for example mood, communication and behaviour. At the same time, a qualitative study with people with dementia to explore the impact of once weekly CST, for example the impact on participants' daily lives, confidence, self-efficacy and sense of achievement, could be considered. This would allow a more subjective exploration of the benefits of once weekly CST and weekly CST enhanced with carer training. Including a cost-effective analysis in future research would facilitate a comparison with other services to determine whether CST offers a lower cost alternative to such services.

Further development of the carer training programme will also be of benefit. We developed the carer training programme to be a brief, low intensity intervention and to see if this would provide an increased 'dose' of CST for people with dementia. As this appears not to have been the case a more intensive programme may be necessary to achieve the desired effects. The development and evaluation of such a programme should form a focus of future research efforts. As part of the wider research project that the current study formed a part of, a qualitative analysis of carers' experiences of the CST training programme was undertaken. The outcomes of this evaluation alongside a review of relevant literature, a consensus conference and consultation with service users should be combined to enable the development of

the programme to take place. As well as evaluating this alongside weekly CST, this could be evaluated alongside twice weekly CST to determine whether carers can maintain the observed benefits of twice weekly CST in the longer term. The validity of the programme should be explored, for example through the use of measures of carers' knowledge of dementia.

Conclusion

There is no evidence from this study to suggest that weekly CST is effective or that enhancing CST with carer training offers additional benefits to people with dementia. Whilst services should exercise caution if offering CST in a weekly programme and consider changing to offer a twice weekly programme, continued collection of outcome data will allow for ongoing monitoring of the progress of participants to ensure benefits are being achieved and would also contribute to the further evaluation of weekly CST. Further research should explore other outcomes and include a qualitative exploration of the benefits for people with dementia of weekly CST and weekly CST enhanced with a carer training programme.

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Part 3: Critical Appraisal

Overview

This review will reflect on two aspects of the research process. Firstly, given that the results described in Part 2 (Cove, 2013a) were all non-significant, I will discuss factors that must be considered when interpreting non-significant findings and the ethical obligations of disseminating non-significant results. Secondly, I will evaluate the methodological quality of the RCT described in Part 2 (Cove, 2013a), based on knowledge I have developed through conducting this RCT and assessing the quality of RCTs included in the literature review (Cove, 2013b). The evaluation will consider aspects of the study that contribute and detract from its overall validity and provide a quality rating according to The Jadad Scale (Jadad et al., 1996).

Non-Significant Research Findings

The results found in the RCT described in Part 2 (Cove, 2013a) were, to a certain extent surprising. Twice weekly CST has proved to be effective and service-level evidence suggests that people with dementia experience at least some positive effects following once weekly CST. It was therefore hypothesised that weekly CST would be effective and that enhancing CST with carer training would provide an even greater 'dose' of CST, thus resulting in increased benefit above that achieved by CST alone. The fact that all findings were non-significant was therefore unexpected. This raised two important questions in my mind. Firstly, how should non-significant findings in research be interpreted? Secondly, what are the implications of publishing or not publishing these findings?

Interpreting Non-Significant Research Findings

Failure to Reject the Null Hypothesis

My immediate thought when considering the outcomes of my research was to conclude that the non-significant results meant that weekly CST, with or without

training for carers, is not an effective intervention for people with dementia. Therefore, in relation to my hypotheses I should reject the alternative hypothesis and accept the null hypothesis that no group differences would be observed. However, I considered the fact that in any research, failure to reject the null hypothesis (as in my study) is not the same as accepting the null hypothesis. Inferential statistics tell us the probability that our results occurred by chance. When a study finds a non-significant result all we can say with confidence is that the results of that particular study provide no evidence for the effectiveness of the intervention tested. We cannot say for certain that it does not work. This an important distinction and reflects the reason why, although I could not conclude that weekly CST for people with dementia and CST enhanced with carer training are effective interventions, I did not then simply conclude that they are ineffective. The results of my research told me only that, on the basis of the results, the probability of weekly CST with or without carer training being an effective intervention for people with dementia is low at present.

In order to confirm (of refute) research findings and ensure they have not occurred by chance, research must be replicated to allow conclusions to be confidently accepted (Flay et al., 2005). This is why I included this as a recommendation in Part 2. Replication is an essential aspect of scientific research and is necessary in order to ensure that observed outcomes did not occur by chance. My confidence in the results I observed was limited by the fact that it was the first study of this nature and without replication it is not possible to conclude that the intervention is ineffective with confidence.

Considering Competing Explanations for Observed Outcomes

As well as being cautious when declaring an intervention ineffective on the basis of a non-significant and non-replicated result, it is also important to consider

alternative explanations as to why a non-significant result was observed. For the most part these considerations relate to methodological issues such as poor study design, inadequate sample size (and the resultant lack of power) and the effect of confounding variables. However, as Hewitt and Mitchell (2008) have highlighted, it is tempting when discovering a non-significant result to succumb to interpretive bias. This occurs when results are underemphasised by, for example, highlighting the limitations of a study as the reason for the lack of significant findings. Simply listing any reason any study may have found a non-significant result without proper consideration of the specific factors pertinent to a specific study is misleading to the reader. However, failure to consider competing explanations for observed effects may also be misleading. A careful consideration of both the evidence from the study, what is already known about the field and the limitations of the study is needed when drawing conclusions.

These principles were applied in my own discussion. Only reasonable explanations for the observed findings were discussed, although it was tempting to list all possible sources of bias in an attempt to show that it was these that produced the non-significant finding. For example, discussion about possible confounding variables between groups was not included because use of randomisation should eliminate such bias and analysis of baseline variables confirmed the success of the randomisation. I attempted to present a balanced and realistic consideration of the results based on comparisons with previous research and identified methodological issues directly relevant to the study.

Disseminating Non-Significant Findings

Publication Bias

A common reaction to research yielding non-significant results is that of disappointment, the implication being that such results are less important than significant results. One reaction I noticed to my own non-significant results was "that is a shame". This led to me to consider further the implications of disseminating non-significant research outcomes because my own reaction had been more along the lines of 'that's unexpected" given what we had been predicting but I did not think the results were unimportant. On the contrary, lack of support for once weekly CST may have important implications for how services deliver CST programmes, particularly if the findings are replicated in future research. However, it appears that there is a bias towards proclaiming statistically significant results important and statistically non-significant results unimportant. Scargle (2000) has stated that *"The literature of social sciences contains horror stories of journal editors and others who consider a study worthwhile only if it reaches a statistically significant, positive conclusion; that is, an equally significant rejection of a hypothesis is not considered worthwhile" (p.93)*. This attitude is reflected in what has been referred to as publication bias, defined by Abaid, Grimes and Schulz (2007) as the *"selective publishing of research that yields favourable or statistically significant results" (p.339).* Several review studies (Easterbrook, Berlin, Gopalan & Matthews, 1991; Hopewell, Loudon, Clarke, Oxman & Dickersin, 2009) retrospectively following up all research approved by a chosen Research Ethics Committee within a particular time period found that research yielding statistically significant results was more likely to be published.

Implications of Publishing or not Publishing Non-Significant Results

I considered the reasons I may have for not publishing my own research. My primary concern was that the findings may be interpreted to mean that once weekly CST categorically does not work. As already stated there are important considerations to make when interpreting any research findings. Whilst I have attempted to present these in Part 2 of this thesis I was concerned that if the results were taken in isolation, negative conclusions about weekly CST which are not confirmed at this stage could influence decisions about service delivery. Similarly, given the current NHS focus on evidence-based practice whereby commissioning of services is often based on proven effectiveness, these non-significant findings could potentially jeopardise current service provision. If commissioners are looking to the research for evidence of the effectiveness of weekly CST, the non-significant findings of this study may contribute to the decision making on the continuation of existing services. As stated, any judgements based on these findings would be premature given that they are yet to be replicated.

However, it is clear that the non-publication of research which yields results that are not statistically significant means that literature which is published is a biased sample. As such, scientific conclusions, service development and direction of future research based on this literature are also likely to be biased. I considered the specific implications of failing to disseminate my own research findings. Firstly, the results of my study may provide valuable information about the psychological treatment of dementia. Failure to publish these findings means that knowledge as to the most effective interventions for this group will be limited. Secondly, given the emphasis within psychology practice for service provision to be evidence-based, failure to share my results places limits on the evidence from which those planning

services can draw. If weekly CST is indeed ineffective, this evidence must be made available. Clinical decision making may be unreliable and invalid if non-significant findings are not reported. Thirdly, from a research perspective, published research can help shape the direction of future research. Given that I have recommended that my study be replicated to provide greater confidence in the results, if I do not disseminate my research this recommendation will go undetected. It is also important to note that if future studies confirm the findings of my study, these should also be published to ensure that studies do not continue to repeat research which consistently shows no significant outcomes.

My conclusion has been that all research, including my own, regardless of the outcome is important, whether it be to add to the scientific knowledge base, provide information for service-level decisions or guide the direction of future research. The key is for research to be reported honestly and without bias and for non-significant results not simply to be declared in-significant and thus ignored.

Consideration of the Quality of the Research

Assessment of the methodological quality of any research is essential to allow a judgement as to the validity of the research findings. Jadad et al. (1996) define quality in relation to a research study as *"the likelihood of the trial design to generate unbiased results" (p.2).* Poorly conducted research is more likely to yield biased results whilst high quality research yields results in which the reader can be more confident. Although I have already presented a consideration of the limitations of the research I conducted in Part 2 (Cove, 2013a), these are summarised below. I will now also consider the strengths of the research in more detail so as to provide an overall conclusion as to the quality of this study.

Strengths

Randomisation

A randomised controlled trial was chosen as this is accepted to be the 'gold standard' i.e. the most scientifically rigorous design for assessing the effectiveness of an intervention. By randomly assigning participants to the research conditions I was able to reduce the chance of selection bias and the occurrence of confounding variables. This is because influences on participants in the different groups should be equal and not differ across groups following randomisation. This increases the internal validity of the study. Furthermore, inclusion of a control group meant that any effects on participant outcomes other than the intervention, e.g. natural improvements, the Hawthorne effect etc., were controlled for.

I consider the method of randomisation chosen to be the most suitable given the resources available, as it was both replicable, unpredictable and not open to control by the researchers. Ideally randomisation should be conducted by trial units completely unconnected to a research study in order to ensure complete impartiality; however, this was outside the scope of my research. Success of the randomisation process was confirmed through statistical analysis. There were no baseline differences in either the demographic or clinical characteristics of people with dementia at baseline so I could be confident that sampling error had been minimised. However, I still elected to use Analysis of Covariance (ANCOVA) to control for the age and gender of people with dementia so that chance variations between treatment conditions were controlled for.

Description of Participants and Recruitment Process

I included a description of participant characteristics and of the recruitment process which I consider to be suitably detailed. Both these factors increase the

quality of my research because they allow generalisation of the findings. Without a detailed description of participants and where they have been drawn from, it is not possible to determine to whom we may generalise the findings. It should be noted that although a detailed description of carer characteristics was not included, these are described in detail by Jacobi (2013).

Blinding of Assessors

The quality of the research trial was strengthened through the use of assessors blind to participant group allocation, which reduces the chance of bias in the assessment of outcomes, specifically measurement bias. It is ideal to also ensure that participants are masked with respect to treatment allocation. However, in trials investigating psychological interventions this is rarely possible and there was no way to achieve this in my trial.

Rate of Attrition and Description of Dropouts

A further factor that improved the overall quality of the study was the low attrition (dropout) rate observed. High levels of participant dropout can result in threats to the internal validity of a study, particularly if reasons for dropout are non-random or if the rate of dropout differs across conditions. A review of reasons for why participants in my research dropped out revealed no systematic reasons for attrition related to the design or outcomes of the study. Furthermore, there were no differences in the characteristics of those who dropped out across all three conditions. In addition, the rate of attrition was low overall, suggesting a high level of acceptability of the intervention. This is further confirmed by the high level of compliance to the CST groups by those who were allocated to attend, with no differences in compliance between the CST and CST plus carer training groups. By

reporting compliance rates I allow the reader to make judgements as to the acceptability of CST.

Intention to Treat Analysis

I elected to use Intention to Treat (ITT) analysis in order to strengthen the quality of my research. ITT holds that all participants entered into a trial should be included in the final analysis. This is in order to avoid biases in the statistical analysis caused as a result of different attrition rates across groups, which leads to biases in estimates of the impact of an intervention (Flay et al., 2005). These authors report that biases in statistical tests can still occur even if rates of attrition across treatment conditions do not differ significantly. For this reason I still applied the principles of ITT to my data analysis. I believe that use of the last measurement carried forward technique to provide data for those who dropped out was suitable as the low rate of attrition meant I would not be including a high number of unverifiable measurements yet would still maintain a complete data set.

Weaknesses

The weaknesses of the research have mostly been described in Cove (2013a). In summary, no monitoring of treatment fidelity was undertaken; the study may have lacked power to detect smaller effects; pre and post assessments were not always completed by the same assessor and the degree to which assessors remained unbiased is unknown as this was not assessed. From my own experience I did find that despite being asked not to tell me which group they were in, participants did sometimes inadvertently do so by, for example, saying ‘I really enjoyed going to the groups’ or ‘I haven’t had anything yet’. However, it is my judgement that the majority of participants did not reveal their group allocation. No long-term follow-up

assessments were included, meaning that any longer term effects could not be monitored.

Quality Rating

Using the Jadad Scale (Jadad, 1996) I was further able to rate the quality of my research study by obtaining a quantitative estimate of quality. The Jadad Scale rates the quality of RCTs based on three criteria: randomisation, blinding and dropouts. These criteria are described in Appendix A. As psychological research is not able to include participants blind to treatment allocation, my study was rated out of 4 rather than 5.

Randomisation

I consider my method of randomisation to be appropriate because each participant had the same chance of being allocated to each condition and investigators had no way of predicting which participant would be allocated to which condition as a computerised method of randomisation was used. I therefore suggest a score of 2/2.

Blinding

The criterion for single blinding was met as the method I used was appropriate and described in the paper. I considered it appropriate because assessors did not know which condition participants had been allocated to and could not identify this. I suggest a score of 1/1 for this criterion, although this could be refuted as no confirmation of the success of the blinding is available.

Dropouts

In order to achieve the maximum score of 1 for this criterion, the research must state the number of dropouts from each treatment condition and report the

reasons for these, both of which I did and I therefore believe a score of 1/1 is appropriate for this criterion.

According to the Jadad Scale I rated my research study with a score of 4/4 suggesting that it is of high quality. I have adopted the same strategy to rate my own research as I used to rate the RCTs in my literature review (Cove, 2013b). Although there are several weaknesses in the methodology of my study there are also many strengths and I therefore consider the research I have conducted to be of high quality, with minimal biases and therefore a high chance that the results produced were also unbiased.

Conclusions

The process of conducting both a literature review and an RCT has allowed me to gain a broader understanding of all the elements that are necessary to produce good quality research. Furthermore, the process of conducting a literature review has allowed me to recognise the limitations placed on the validity of outcomes of poor quality research. The need for good quality research in order to provide unbiased results is paramount. My knowledge of the factors to consider when designing, conducting and reporting an RCT to ensure it is of the highest possible quality has been greatly enhanced through first-hand experience. The importance of carefully interpreting and publishing all results, regardless of whether they are significant or not has been highlighted and the effects of not doing so have given me greater confidence in the need to publish my own findings, despite their lack of statistical significance. I consider my research findings to be non-significant not in-significant.

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Appendices

Appendix A
The Jadad Scale - Scoring Criteria for Randomised Controlled Trials

The Jadad Scale is a three-item, five-point questionnaire used to rate the quality of randomised controlled trials. Each question must be answered with a yes or no. Each yes scores one point and each no scores zero points.

The questions are as follows:

1. *Was the study described as randomized?*
2. *Was the study described as double blind?*
3. *Was there a description of withdrawals and dropouts?*

To receive the corresponding point, an article should describe the number of withdrawals and dropouts, in each of the study groups, and the underlying reasons.

Additional points were given if:

- *The method of randomisation was described in the paper, and that method was appropriate.*
- *The method of blinding was described, and it was appropriate.*

Points would however be *deducted* if

- *The method of randomisation was described, but was inappropriate.*
- *The method of blinding was described, but was inappropriate.*

Appendix B
York Centre for Systematic Reviews criteria for reviewing non-randomised trials

Non-randomised research studies were rated on an eight-item scale based on criteria from the York Centre for Systematic Reviews:

1. Was there adequate description of participants?
2. Was there adequate description of an intervention and who received it?
3. Is measurement likely to be reliable and valid?
4. Are the measures used the most relevant ones for answering the research question?
5. What was the drop-out rate and has this introduced bias?
6. Is the length of time long enough to identify changes in the outcome of interest?
7. In studies where two groups are compared are the groups similar? Were they treated similarly? And if not were there attempts to control for those differences
   (matching or statistical control)?
8. Was outcome assessment blind to exposure status?

In this review studies that met all of the criteria were rated as good. Those that met more than half the criteria were rated as adequate and those that met less than half the criteria were rated as poor.

Appendix C

Trainees' Contribution to the Joint Research Project

The design of the research study, ethics application and development of project materials was conducted jointly by both trainees. Nicola Jacobi identified participants who met inclusion criteria and recruitment was then conducted jointly. Baseline assessments were carried out jointly by both trainees with support from assistant psychologist working within South Essex Partnership Trust. Follow-up assessments were predominantly conducted by Jenny Cove (again with support from assistant psychologists) as Nicola Jacobi was no longer blind to participants' group allocation. Nicola Jacobi conducted focus groups with carers who had attended the carer training programme. Scoring of assessment was evenly divided. Each trainee analysed the data related to their own thesis separately and independently wrote up their own thesis.

Appendix D
Information Sheets:

1. People with Dementia
2. Carers

PARTICIPANT INFORMATION SHEET

Pilot study examining the effectiveness of weekly Cognitive Stimulation Therapy (CST) and the additional impact for people with dementia and their carers of including carer training in CST

Invitation to participate in a research study
You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this information sheet.

What is the purpose of the study?
In recent years, cognitive stimulation therapy (CST) groups have shown to be an enjoyable and beneficial therapy for people with memory problems. This project will show whether once weekly CST is effective.

Often the carers of those taking part in CST groups request to have more involvement in the treatment so that they can understand the therapy being given and provide support to their relative/friend over the course of the group. This project also aims to show how inclusion of a carer training programme affects the impact of CST for both the person attending CST and their carer.

What happens in a cognitive stimulation therapy (CST) group?
Traditionally CST groups are held as a 14 session programme, twice a week for seven weeks. However, in practice NHS services tend to deliver CST once weekly for 14 weeks due to resource limitations. The activities include for example multi-sensory stimulation, word categorisation and discussion of current affairs. The idea is to keep the mind active through enjoyable activities, undertaken as a structured programme facilitated by experienced and trained staff that will look after the group. The sessions include physical games, current affairs discussions, sounds, food, word games, and numbers games.

Why have I been chosen?
You have been invited to take part because you have at some point had a memory assessment. We need a large number of people with memory problems to help us evaluate the once weekly CST groups – 72 in total. Each CST group may include up to 8 people.

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?
This study is a randomised trial. We need to have three groups so we can compare the outcomes for each group – a group in which people with dementia receive CST and their carers attend a carer training programme; a group in which people with dementia receive CST but their carers do no attend the carer training programme and a group in which people with dementia do not receive CST and their carers do not attend the carer training programme.

Firstly we need to establish the effectiveness of weekly CST groups, and so we need to compare any changes experienced by people with dementia in CST groups with changes in people with dementia who have not received any treatment.

Secondly we are exploring the impact on both people with dementia and their carers of adding a carer training programme to CST. So we need to compare any changes experienced by people with dementia and their carer if the carer receives training with changes experienced by people with dementia and their carer if the carer does not receive training. The fairest way of doing this is to select people for each group by chance. The decision is made by an independent computer, which will not have any identifying information about you or your carer.

If you decide to take part, your participation in the study will last for a time period of about four and a half months. Following discussion of any questions you may have with a researcher, and signing the consent form, **all participants** will be asked to:

1. Meet with a researcher for between an hour and an hour and a half to complete some questionnaires covering quality of life, cognition and your relationship with your carer. The time stated to complete the interviews and questionnaires is an estimate; you may take as many breaks as you want or feel necessary, and even complete the process over two sessions if preferred.

2. To repeat these questionnaires with the researcher, after 15 weeks.

Usually, the researcher will come to your home or the home of your relative/friend, but will be happy to meet you elsewhere if you would prefer. Usually, the researcher will meet with and interview your relative/friend at the same time as you are completing the questionnaires. <u>Your answers to all the questions will be kept confidential and will not be disclosed to your relative/friend.</u>

Two thirds of participants entering the trial will be asked to attend CST once a week for fourteen weeks. The CST groups will include up to eight people and each session will last for about an hour. They will be held in a suitable venue within your area and refreshments and transport will be arranged if needed. Those allocated to CST

groups will be assessed in the two week period prior to the CST group starting and in the two week period following the end of the CST group.

Those people allocated to the group with no CST (one third of participants) will be asked to complete the assessment immediately on entering the project. They will complete a further assessment approximately 15 weeks later, and will then be offered the opportunity to attend the groups. Therefore everyone who takes part in the research will receive the treatment.

Expenses
Any travel expenses incurred by yourself or your carer will be reimbursed.

What do I have to do?
Taking part in the study does not involve any lifestyle restrictions or changes. You can carry on your everyday activities as normal while participating in the study. All we ask is that you keep your appointments with us during the time that you are taking part.

What are the possible disadvantages and risks of taking part?
CST involves participating in a group programme that aims to be stimulating and enjoyable. Sessions involve discussing themes such as food, childhood and current affairs and the level of risk in taking part is therefore minimal. If the participant feels uncomfortable or distressed while taking part in a group, facilitators will be able to give additional one to one support if this is needed.

What are the possible benefits of taking part?
If you decide to take part, and are involved in the CST Groups we hope that this may be of some help to you, and previous group members have indeed reported that they have enjoyed the experience greatly. For all participants, the information we get from this study may help us to treat people with memory problems better in the future.

Will my taking part in the study be kept confidential?
We will ask for your permission to send your GP a letter explaining that you have agreed to take part in the study. All information which is collected about you during the course of the study will be kept strictly confidential. All data is stored without any identifying details under secure conditions.

What will happen if I don't want to carry on with the study?
You will be free to withdraw from the study at any time, without giving a reason. Withdrawing from the study will not affect the standard of care you receive.

What if something goes wrong?
If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for your legal costs.

Regardless of this, if you wish to make a complaint about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints procedures should be available to you. If you are unhappy or dissatisfied about any aspect of your participation, we would ask you to tell us

about this in the first instance, so that we can try to resolve any concerns and find a solution.

What will happen to the results of the research?
The research is being carried out by two trainee psychologists as part of their Doctorate Training. Nicola Jacobi is at City University London and undertaking a Doctorate in Counselling Psychology. Jennifer Cove is at University College London (UCL) and undertaking a Doctorate in Clinical Psychology.

Both will produce a research dissertation which forms as part of their final course assessment. It will not be possible to identify individual results specifically, though a summary of the findings will be available if you are interested.

Results will also be published in relevant journals. No participants will be identified in any publication arising from the study without their written consent.

We will make arrangements for participants to be informed of the progress of the research and the results will be summarized in a document following the completion of the project. Please let us know if you would like to receive a copy.

Who has reviewed the study?
All NHS research is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity. This study has been reviewed and been given a favourable opinion by the London South East National Research Ethics Committee.

Who can I contact for further information?
For more information about this research, please contact:

Dr Helen Donovan
Consultant Clinical Psychologist
Clinical Psychology Service, Gilbert Hitchcock House
21 Kimbolton Road
Bedford MK40 2AW

Phone:
Mobile:
Email:

Or if you have any complaints about this study please contact:
Ruth Burrell, R&D Administrator
R& D Department, Disability Resource Centre
Poynters House, Poynters Road,
Dunstable
Bedfordshire, LU5 4TP

Phone:
Email:

Thank you for considering taking part in this research study!

INFORMATION SHEET FOR CARERS

Pilot study examining the effectiveness of weekly Cognitive Stimulation Therapy (CST) and the additional impact for people with dementia and their carers of including carer training in CST

Invitation to participate in a research study
You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this information sheet.

What is the purpose of the study?
In recent years, cognitive stimulation therapy (CST) groups have shown to be an enjoyable and beneficial therapy for people with memory problems. This project will show whether once weekly CST is effective.

Often the carers of those taking part in CST groups request to have more involvement in the treatment so that they can understand the therapy being given and provide support to their relative/friend over the course of the group. This project also aims to show how inclusion of a carer training programme affects the impact of CST for both the person attending CST and their carer.

What happens in a cognitive stimulation group?
Traditionally CST groups are held as a 14 session programme, twice a week for seven weeks. However, in practice NHS services tend to deliver CST once weekly for 14 weeks due to resource limitations. The activities include for example multi-sensory stimulation, word categorisation and discussion of current affairs. The idea is to keep the mind active through enjoyable activities, undertaken as a structured programme facilitated by experienced and trained staff that will look after the group. The sessions include physical games, current affairs discussions, sounds, food, word games, and numbers games.

Why have I been chosen?
You have been invited to take part because of your support for a person who at some point had a memory assessment. We need a large number of people with memory problems to help us evaluate the weekly CST groups – 72 in total. Each CST group may include up to 8 people. In addition, we need each of them to have a carer who

has regular contact with them to evaluate impact of adding a carer training programme to CST for both the individual in the CST group and for their carer.

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care your relative / friend receives.

What will happen to me if I take part?
This study is a randomised trial. We need to have three groups so we can compare the outcomes for each group – a group in which people with dementia receive CST and their carers attend a carer training programme; a group in which people with dementia receive CST but their carers do no attend the carer training programme and a group in which people with dementia do not receive CST and their carers do not attend the carer training programme.

Firstly we need to establish the effectiveness of weekly CST groups, and so we need to compare any changes experienced by people with dementia in CST groups with changes in people with dementia who have not received any treatment.

Secondly we are exploring the impact on both people with dementia and their carers of adding a carer training programme to CST. So we need to compare any changes experienced by carers and people with dementia if the carer receives training with changes experienced by carers and people with dementia if the carer does not receive training. The fairest way of doing this is to select people (the person with dementia and their carer) for each group by chance. The decision is made by an independent computer, which will not have any identifying information about you or your relative/friend.

Those people allocated to the group for which the person with dementia does not receive CST and their carer does not receive training will be asked to complete the interviews described below immediately on entering the project and then after 15 weeks. <u>Your friend/relative will be invited to attend a CST group following their involvement in the research project.</u>

Those allocated to a group in which the person with dementia will receive CST will be interviewed in the two week period prior to the CST group starting and in the two week period following the end of the CST group.

If you decide to take part, your participation in the study will last for a time period of approximately four and half months. Following discussion of any questions you may have with a researcher, and signing the consent form, **all participants** will be asked to:

1. Meet with a researcher for between an hour and an hour and a half to complete some questionnaires. Your relative/friend's questionnaires will cover their cognitive abilities, and their perception about the quality of their life. The questionnaires you will be asked to complete will be about your

general health, your feelings of self-efficacy, satisfaction and burden. Both of you will be asked to complete a questionnaire about the quality of your relationship. The time stated to complete the interviews and questionnaires is an estimate; you and your friend/relative may take as many breaks as you want or feel necessary, and even complete the process over two sessions if preferred.

2. To repeat these questionnaires with the researcher, after 15 weeks

3. Usually, the researcher will come to your home or the home of your relative/friend if you live separately, but will be happy to meet you elsewhere if you would prefer. Usually, the researcher will meet with and interview your relative/friend at the same time as you are completing the questionnaires. Your answers to all the questions will be kept confidential and will not be disclosed to your relative/friend.

Carers allocated to receive carer training (one third of carers) will be also be asked to:

1. Attend two training sessions

    a. The first session will be held at the time the person you care for begins their CST group. This session will last for half a day and introduce you to the key principles of CST and explore ways for you to engage in activities at home based on these principles.

    b. The second session will be held around the time the person you care for finishes their CST group. This session will last for approximately an hour with a focus on maintaining the ideas from the first session into the future.

    c. An optional third session will be offered mid-way through the CST sessions. This session will be one hour long and offer you the opportunity to come and discuss any difficulties you are having and get advice if you need it.

2. To complete a weekly diary reflecting on your thoughts and the activities undertaken. You will be asked to undertake activities as directed in the first training session at least three times a week

3. Participate in either a *focus group or an individual interview* in order to explore in more depth your experience of undertaking the carer training programme. *Focus groups/individual interviews* will last approximately an hour, during which time you will be asked to reflect on your experiences of the carer training programme. An experienced researcher will lead the *focus groups or interviews*.

    The focus groups will be audio recorded in a digital recording format. You will not be identified in the recording. The recordings will be encrypted and password protected and kept on a secure server of the Sponsor organisation

(SEPT NHS Trust). They will be retained as research data for a period of 7 years after which time they will be permanently deleted.

4. Refreshments will be provided and transport arranged as needed. Suitable breaks will be scheduled into all groups. Carer training sessions will be led by skilled and trained members of staff who receive regular support and supervision.

5. Those carers who do not get allocated to the carer training programme as part of the research will have an opportunity to undertake some training in CST principles and activities after their involvement in the research has finished. This will be completely voluntary.

Expenses
Any travel expenses incurred by you or your relative/friend will be reimbursed.

What do I have to do?
Taking part in the study does not involve any lifestyle restrictions or changes either for you or your friend, relative. You can carry on your everyday activities as normal while participating in the study.

What if my relative/friend is unable to consent to take part, or loses the ability to consent?
All participants in research are invited to complete a consent form before the research commences. Sometimes people with memory problems are unable to make a decision to consent to a research project because they have difficulty in understanding or retaining the information provided about the project. Sometimes people with memory problems are able to do this at the beginning of the project, but later may not be able to provide their consent. In either of these circumstances, the research team is required to consult with someone who is involved in the person's care, such as a family member, regarding whether the person should participate, or continue to participate, in the project. If concerns do arise regarding the your relatives'/friends' ability to consent, we would seek your advice regarding whether the person with memory problems should participate and what you think the person's feelings and wishes would be regarding taking part. If the person has previously made an advance statement or advanced decision that is relevant, we would not do anything to go against this.

What are the possible disadvantages and risks of taking part?
You may feel that the requirements of your participation appear onerous and time consuming. However, the CST carer training programme has been designed with input from other carers whose family member have been through CST and is based around what they feel they would have liked to receive. Meetings and training sessions will be organized as far as possible to fit around your own commitments.

For your relative/friend CST involves participating in a group programme that aims to be stimulating and enjoyable. Sessions involve discussing themes such as food, childhood and current affairs and it the level of risk in taking part is therefore minimal. If while taking part the participant feels uncomfortable or distressed while

taking part in a group, facilitators will be able to give additional one to one support if this is needed

What are the possible benefits of taking part?
If you decide to take part you will receive training which will provide you with a greater understanding of the treatment your relative/friend is involved in, peer support and new communication skills.

We hope that your relative/friend being involved in the CST groups will be of some help to them, and previous group members have indeed reported that they have enjoyed the experience greatly. For all participants, the information we get from this study may help us to treat people with memory problems better in the future.

Will my taking part in the study be kept confidential?
We will request permission to send the person with memory problem's GP a letter explaining that you have both agreed to take part in the study. Otherwise, all information collected about you during the course of the study will be kept strictly confidential. All data is stored without any identifying details under secure conditions.

What will happen if I don't want to carry on with the study?
You and your relative/friend will be free to withdraw from the study at any time, without giving a reason. Withdrawing from the study will not affect the standard of care your relative/friend receives. We will need to use any data collected in the study up to the point of withdrawal.

What if something goes wrong?
If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for your legal costs. Regardless of this, if you wish to make a complaint about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints procedures should be available to you. If you are unhappy or dissatisfied about any aspect of your participation, we would ask you to tell us about this in the first instance, so that we can try to resolve any concerns and find a solution.

What will happen to the results of the research?
The research is being carried out by two trainee psychologists as part of their Doctorate Training. Nicola Jacobi is at City University London and undertaking a Doctorate in Counselling Psychology. Jennifer Cove is at University College London (UCL) and undertaking a Doctorate in Clinical Psychology. Both will produce a research dissertation which forms as part of their final course assessment. It will not be possible to identify individual results specifically, though a summary of the findings will be available if you are interested.

Results will also be published in relevant journals. No participants will be identified in any publication arising from the study without their written consent.

We will make arrangements for participants to be informed of the progress of the research and the results will be summarized in a document following the completion of the project. Please let us know if you would like to receive a copy.

Who has reviewed the study?
All NHS research is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity. This study has been reviewed and been given a favourable opinion by the London South East National Research Ethics Committee.

Who can I contact for further information?
For more information about this research, please contact the Chief Investigator:

Dr Helen Donovan
Clinical Psychology Service, Gilbert Hitchcock House
21 Kimbolton Road
Bedford MK40 2AW

Phone:
Mobile:
Email:

Or if you have any complaints about this study please contact:

Ruth Burrell, R&D Administrator
R& D Department, Disability Resource Centre
Poynters House, Poynters Road,
Dunstable
Bedfordshire, LU5 4TP

Phone:
Email:

Thank you for considering taking part in this research study!

Appendix E
Consent Forms:

1. People with Dementia
2. Carers

Providing Partnership Services in Bedfordshire, Essex and Luton

SEPT

CITY UNIVERSITY LONDON

UCL

Participant Consent Form

Participant Identification Number for this trial _____

Pilot study examining the effectiveness of weekly Cognitive Stimulation Therapy (CST) and the additional impact for people with dementia and their carers of including carer training in CST

Name of Researcher:…….. **Please Initial Boxes**

1. I confirm that I have read and understand the participant information sheet (Version 2 - 09.05.2012) for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care or legal rights of myself or my relative being affected. ☐

3. I give permission for my GP to be informed of my participation in the study. ☐

4. I understand that all information given by me or about me will be treated as confidential by the research team. ☐

5. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent (if different from the researcher)	Date	Signature
_____	_____	_____
Researcher	Date	Signature
_____	_____	_____
Name of Carer	Date	Signature
_____	_____	_____

Providing Partnership Services in Bedfordshire, Essex and Luton

SEPT

CITY UNIVERSITY LONDON

UCL

Carer Participant Consent Form

Participant Identification Number for this trial _____

Pilot study examining the effectiveness of weekly Cognitive Stimulation Therapy (CST) and the additional impact for people with dementia and their carers of including carer training in CST

Name of Researcher:…….. **Please Initial Boxes**

1. I confirm that I have read and understand the information sheet for carers (Version 2 - 09.05.2012) for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care or legal rights of myself or my relative being affected. ☐

3. I give permission for my relative's GP to be informed of our participation in the study. ☐

4. I have been consulted regarding the participation of my relative, as required by the Mental Capacity Act, and I believe they would wish to take part / continue to take part in the study. ☐

5. I understand that all information given by me or about me or my relative will be treated as confidential by the research team. ☐

6. I agree to take part in the above study with my relative. ☐

Name of Participant Date Signature

_____ _____ _____

Name of relative

_____

Name of Person taking consent (if different from the researcher) Date Signature

_____ _____ _____

Researcher Date Signature

_____ _____ _____

Appendix F
Letter for General Practitioner

Providing Partnership Services in Bedfordshire, Essex and Luton

SEPT

CITY UNIVERSITY LONDON

UCL

Clinical Psychology Service
Gilbert Hitchcock House
21 Kimbolton Road
MK40 2AW
Tel:
Fax:

[GP Address]
[DATE]

GENERAL PRACTITIONER INFORMATION SHEET

Title: Pilot study examining the effectiveness of weekly Cognitive Stimulation Therapy (CST) and the additional impact for people with dementia and their carers of including carer training in CST

…….. (Dob)…….. has been invited and consented to take part in a research study. Please let us know if there is anything that is not clear, or if you would like more information.

Dr Gary Kupshik is the sponsor for this project from South Essex Partnership University NHS Foundation Trust (SEPT). The project is being run across a number of sites, including Bedfordshire and Camden and Islington. Dr Helen Donovan is co-ordinating the trial in the Bedfordshire area and Dr Joshua Stott is co-ordinating the trial in the Camden and Islington area.

Cognitive Stimulation Therapy (CST) groups are an enjoyable and beneficial therapy for people with memory problems. The idea is to keep the mind active through enjoyable activities, which are undertaken as a structured programme facilitated by experienced and trained staff. The activities include multi-sensory stimulation, for example: physical games, discussion of current affairs, sounds, food, word and number games. Traditionally CST groups are held as a 14 session programme twice a week for seven weeks.

This study aims to show whether weekly CST (14 sessions once weekly for 14 weeks) is effective and whether adding a carer training programme to CST has an impact on the well-being of people with dementia and their carers..

We are interested in including people with any type of dementia. We will interview them and their carer who has also agreed to take part in the study at the start of their involvement with the project and after 15 weeks.

The interviews will use outcome measure which will evaluate:

- Quality-of-life

- Cognition
- Quality of patient-carer relationship

Interviews will also collect information about:

- Personal details (age, relationship, educational level, etc.)

The study will **not** affect your patient's current or future treatment.

The results of this study are expected to be published in relevant journals and at conferences. All interviews are confidential and will not be disclosed to anyone else. The information collected in the study will be anonymous and patients will not be identified in any report/publication.

All proposals for research using human subjects are reviewed by the local Ethics Committee before they can proceed and the appropriate permission.

Thank you for reading this information sheet. Please do not hesitate to contact Dr Helen Donovan if you need any further information.

Kind regards,

[name of member of research team]

Appendix G
List of Themes of CST Groups

CST sessions followed one of 14 general themes:

1. Physical games
2. Sound
3. Childhood
4. Food
5. Current affairs
6. Faces / scenes
7. Word association
8. Being creative
9. Categorising objects
10. Orientation
11. Using money
12. Number games
13. Word games
14. Team quiz

Appendix H

Approval Letter from Research Ethics Committee

NHS
Health Research Authority
NRES Committee London - South East
Room 4W/10
4th Floor West
Charing Cross Hospital
Fulham Palace Road
London
W6 8RF

23 May 2012

Dr Helen Donovan
Consultant Clinical Psychologist
South Essex Partnership NHS Trust
Gilbert Hitchcock House
21 Kimbolton Road
Bedford
MK40 2AW

Dear Dr Donovan

Study title: **Pilot study examining the effectiveness of weekly Cognitive Stimulation Therapy (CST) and the additional impact for people with dementia and their carers of including carer training in CST**

REC reference: **12/LO/0539**

Thank you for your letter of 09 May 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.

Mental Capacity Act 2005

I confirm that the committee has approved this research project for the purposes of the Mental Capacity Act 2005. The committee is satisfied that the requirements of section 31 of the Act will be met in relation to research carried out as part of this project on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

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

Conditions of the favourable opinion

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

Document	*Version*	*Date*
Advertisement		
Covering Letter	1	12 March 2012
GP/Consultant Information Sheets	1	07 March 2012
Interview Schedules/Topic Guides		09 May 2012
Investigator CV	1	03 March 2012
Letter from Sponsor		05 March 2012
Other: Summary CV for Nicola Jacobi		05 March 2012
Other: Don Rawson		07 March 2012
Other: Summary CV for Aimee Spector		07 March 2012
Other: Summary Cv for Jenny Cove		07 March 2012
Other: Revised scale for caregiving self-efficacy		
Other: carers assesment of satisfaction index		
Other: patient demographics form		

Other: Carer demographics form		
Participant Consent Form	1	07 March 2012
Participant Consent Form: Carer participant consent form	1	07 March 2012
Participant Consent Form: Carer participant consent form(interview focus group)	1	07 March 2012
Participant Information Sheet: Participants	2	09 May 2012
Participant Information Sheet: Carers	2	09 May 2012
Protocol	1	07 March 2012
Questionnaire: Mini mental state exam		18 October 2011
Questionnaire: Alzheimer's Disease Assessment Scale		
Questionnaire: Quality of life		
Questionnaire: Quality of the care-giver patient relationship		
Questionnaire: General health questionnaire-28		
REC application	1	16 March 2012
Referees or other scientific critique report		18 October 2011
Response to Request for Further Information		09 May 2012

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/LO/0539	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

Professor David Caplin
Chair

Email:

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Cherie Morgan, South Essex NHS Partnership Trust (SEPT)*