DEVELOPMENT OF AN EVIDENCE-BASED EXTENDED PROGRAMME OF MAINTENANCE COGNITIVE STIMULATION THERAPY (CST) FOR PEOPLE WITH DEMENTIA

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ABSTRACT

Psychosocial interventions for dementia have often been developed without a sound theoretical, empirical and clinical basis, and most evaluations of these interventions have had serious methodological limitations. This highlights the need to link intervention development with evaluation and design issues during the early stages of phase 1 or development of an intervention. Best practice is to develop interventions systematically, using the best available evidence and appropriate theory. This study focuses on the developmental stage of the Medical Research Council (MRC) guidelines (2008) to develop an evidence-based Maintenance Cognitive Stimulation Therapy (MCST) programme for dementia.

The intervention was developed based on a mixed methods approach, using evidence obtained from the Cochrane review of Cognitive Stimulation for dementia followed by a Delphi consultation process with key stake-holders. Four techniques were used: (1) Cochrane review of cognitive stimulation for dementia, (2) a consultation with key stake holders using a Delphi Consensus Process (including an expert consensus conference), (3) focus groups with the target population and (4) a Delphi survey. These techniques were used to complete the theoretical preclinical and phase I modelling of the MRC framework for developing the MCST intervention for dementia.

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It was feasible and effective to use a systematic development process to produce successive modifications of the draft manual for an evidence based maintenance CST programme for dementia. Close involvement of users and carers ensured that the manual was well targeted on the preferences and abilities of people with dementia.

The final Maintenance CST programme and manual is currently being tested as part of a large multicentre, randomised controlled trial.

Keywords: Cognitive Stimulation Therapy (CST), Complex intervention, Medical Research Council (MRC) guidelines, psychosocial intervention, dementia.

INTRODUCTION

Psychosocial interventions for dementia have often been developed without a sound theoretical, empirical and clinical basis, and most evaluations of these interventions have had serious methodological limitations (Woods et al., 2005). In our earlier work, the Cochrane Review on Reality Orientation (RO) was used to develop an evidence based Cognitive Stimulation Therapy (CST) programme for dementia (Spector et al., 2000; 2001; 2003). The results of a randomised controlled trial (RCT) of CST compared favourably with trials of cholinesterase inhibitors for Alzheimer's disease, in terms of the size of the effects on cognition (Spector et al, 2003) and the economic analysis showed that CST was likely to be cost-effective (Knapp et al, 2006). The NICE guidelines (NICE-SCIE, 2006) recommended that people with mild/moderate dementia should be 'given the opportunity to participate in a structured group cognitive stimulation programme'. Cognitive stimulation approaches may have long-term effects (Zanetti et al., 1995; Metitieri et al., 2001) and a 16 week pilot study of maintenance CST (Orrell et al., 2005) following the initial 7 weeks of CST, found a significant improvement in cognitive function (MMSE) and identified the need for a large-scale, multi-centre RCT. Best practice is to develop interventions systematically, using the best available evidence and appropriate theory (Craig at al., 2008). This highlights the need to link intervention development with evaluation and design issues during the early stages of phase 1 or development of an intervention. This study focuses on the developmental stage of the Medical Research Council guidelines (2008) for the development and evaluation of complex interventions (Figure 1). Modelling a complex intervention prior to a full-scale evaluation can provide important information about the design of both the intervention and the evaluation (Clancy et al., 2002; Wortman, 1995; Nazaret et al., 2002). The aim was to develop a programme of Maintenance CST for dementia, as a complex long-term intervention in preparation for its evaluation in a large RCT. The three main steps for the development of the programme (MRC, 2008) were: identifying the evidence; identifying and developing theory and modelling process and outcomes.
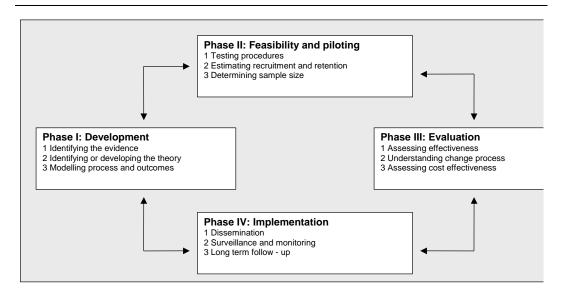
Figure 1. Key elements of the development and evaluation process (MRC framework 2008).

Methods

Identifying the Evidence Base

An updated Cochrane Systematic Review on the effectiveness of cognitive stimulation programmes for people with dementia was conducted. Searches were based on the Cochrane Dementia and Cognitive Improvement Group (CDCIG) methods guidelines. The therapeutic content of each study and subsequent outcomes were tabulated (Table 1). Priority was given to studies with stronger methodology, such as RCTs. Studies, which did not match the inclusion criteria for the Cochrane Review, but were classified as high quality studies were also included in our analyses (Table 1). The criteria for classification as high quality studies were: 1) extensive description of the intervention classified as being cognitive stimulation, 2) positive outcome and 3) strong methodological design (although not a RCT). Studies with positive outcomes were drawn out from the tables, and the contents of the intervention examined. Through this process, potentially beneficial elements of each type of therapy were identified, and were incorporated into the design of the new maintenance CST programme on the basis of consensus agreement amongst the expert group (EA, BW, AS, MO). In Table 1, the studies and elements, which contributed to the design of this programme, are highlighted in italic type.

Table 1. Included studies for the development of the draft Version 1 of the manual

Authors	Description	Outcome
Studies in the Cochrane Review Woods et al., 2010 (Also included in Spector et al., 2000) C /B*		
Baines 1987	RO Board, old and current newspapers, personal and local photos, materials to stimulate all senses (e.g. cinnamon, silk, honey)	+ B*
Baldelli, 1993	No info given	
Breuil 1994	Copying pictures, associated words, naming and categorising objects.	+C
Ferrario, 1991	No info given	
Gerber 1991	Simple exercises, self-care, food preparation, orientation room with RO board, large clock, coloured illustrations.	+C
Hanley 1981	RO Board, clocks, calendars, maps, posters, and room overlooked garden area to enable discussion.	+C
Wallis 1983	Repetition of orientation information (e.g., time, place, weather), charts, pictures, touching objects and material.	-C
Woods 1979	Daily personal diary, group activities (dominoes, spelling, bingo) naming objects, reading RO board.	+C
New studies included in the Cochrane Review Woods et al., 2010		
Baldelli 2002	No info given	+C
Bottino 2005	Temporal and spatial orientation, discussion of interesting themes, reminiscence activities, naming people, daily activities, *planning use of calendars and clocks*	+C
Chapman, 2004	Current events; discussion of hobbies and activities; education regarding Alzheimer's disease; life story work; links with daily life encouraged.	+C
Onder 2005	Current information, topics of general interest, historical events and famous people, attention, memory and visuo-spatial exercises; *use of clocks, calendars and notes*	+C
Requena 2007	Orientation, Body awareness, family and society, *caring for oneself*, reminiscing, *household tips*, animals, people and objects	+C
High quality studies used in the development of the manual but not included in the Cochrane Review		
Olazaran 2004	Reminiscing parents home, significant event, sounds, favourite sports, word game, visual clues to make a trajectory, similarities, *what to do in case of fire*, verbal calculations, serial additions, current affairs, write a letter, orientation, make a cake, make budget from shopping.	+C
Farina, 2002	Searching for words in a text, naming pictures, ranging words in alphabetical order, identifying specific visuospatial stimuli, matching figures, drawing figures, puzzles.	+C
Farina 2006	Conversation, singing, comments on pictures, collage, and poster creation.	+C, +B
Zanetti 2001	Procedural memory training stimulation. Basic and instrumental activities of daily living train, washing face, closing door, writing a letter, locking door.	+C

*C: Cognition
 B: Behaviour

Identifying and Developing Appropriate Theory: The Theoretical Basis for CST in Dementia

A theoretical understanding of the likely process of change in the primary outcomes (cognition and quality of life) was developed by drawing on existing evidence and theory.

Global Stimulation of Cognitive Abilities: Changes in Cognition

Dementia is characterised by declining cognition but nevertheless, people with dementia often have reserve capacity for cognitive information processing (Katzman et al., 1988, 1993). Implicit memory in people with Alzheimer's is preserved for a longer period than episodic memory, and also responds to regular stimulation (Fleischman et al., 2005) and beneficial effects on cognition may not only be based on implicit memory, but may enhance facilitation of residual explicit memory (Hunkin et al., 1998; Tailby and Haslam, 2003). Offering people with dementia a set of mental activities that takes this remaining reserve capacity into account, allows them to maintain, for a certain period, a relatively enhanced level of cognitive performance. CST provides global stimulation of cognition: memory, concentration, language, executive functioning, spatio-temporal orientation and visuo-constructive abilities. Strategies such as including multi-sensory stimulation, mental imagery, categorical classification, and semantic association, have the aim of maximising episodic and semantic memory functions as well as consolidating implicit memory. The CST activities are adapted to the interests and activities of the participants. Each theme contains exercises of different types including categorical classifications, old /new comparisons of objects, numerical and musical exercises designed to enrich the general cognitive stock as well as the use of implicit strategies for recalling words or concepts. The latter is particularly important in that lack of confidence due to cognitive problems and the consequent anxiety of forgetting words in the middle of a conversation constitutes a risk factor for social withdrawal (Rubin, 1982; Rubin, LeMare, & Lollis, 1990).An important element is stimulation of orientation and each session includes an orientation board with information about the day, time, place and current news so participants can discuss current information and news. CST uses reminiscence as an aid to orientation; this may contribute to the psychological health of people with dementia given that the progressive deteriorating nature of the disease erodes the ability to succeed at a range of previous activities and makes individuals increasingly dependent on past accomplishments for a sense of competency (Kiernat, 1979). People with dementia may retain the capacity to recall and integrate the past because remote memory is spared through most of the disease process (Woods, 1992). Another element of the programme is the use of physical activity in the sessions, including 10 minutes of warm up activity at the beginning of each session, and a session theme called 'physical games'. This constitutes an important element of the intervention as some studies have shown that physical activity delays the onset of dementia in healthy older adults and slows down cognitive decline to prevent the onset of cognitive disability (Forbes et al., 2008). Studies

using animal models suggest that physical activity has the potential to attenuate the pathophysiology of dementia. (Cotman et al., 2007).

Stimulation of Social Abilities and Person Centred Care: Changes in Quality of Life

Cognitive and affective functions influence the social roles of people with dementia, such as family activities, maintenance of social relationships and participation in social activities. CST also targets the effects of the intervention on the person's well-being and quality of life (QoL). Cognitive based approaches in dementia care have been criticised suggesting that cognitive gains after the intervention may be achieved at the expense of reduced wellbeing and adverse effects (American Psychiatric Association, 1997). In view of these concerns, person centred care has been included as the basis of the development of the CST programme (Spector et al., 2001) and it has been suggested that improvements in QoL have not arisen simply from non-specific factors, such as the enjoyment of a group activity and social interaction except insofar as these factors also contributed to cognitive change (Woods et al., 2006). CST appeared to have a single mechanism for its effects, with improvements in cognition and QoL going hand in hand. Participants in CST groups reported improved quality of life specifically in relation to memory, as well as energy, relationships and managing chores (Woods et al., 2006).

The structural framework of the CST sessions (groups of 5 to 8 people) permits the participant to meet others in similar situations, which in turn serves to reduce anxiety with respect to one's individual situation. The basis for delivering CST in groups as a psychosocial intervention is the assumption that when individuals gather together to share their concerns, they can cope with the stress better than on their own. The group supplies: (a) emotional bonding that creates closeness and reduces feelings of isolation; (b) enhanced self-esteem in having information to share about current coping strategies; and (c) information exchange that creates a sense of hope and efficacy (Toseland, 1997). Offering CST in a group might increase the performance of the cognitive tasks presented in sessions (such as problem-solving, decision-making, inference and idea generation), as it has been argued that groups can be conceptualized as information processors (Hinsz, Tindale, & Vollrath, 1997). Information processing in groups involves activities that occur at the individual as well as the group level which involves the sharing of solutions, preferences and ideas during discussion (Tindale & Kameda, 2003).

A possible mechanism for QoL change is that the CST approach is grounded in a strong value base of respecting individuality and personhood (Woods, 2001). Kitwood (1997) conceptualised person-centred dementia care in response to a reductionist biomedical view of dementia that downgraded the person to a carrier of an incurable disease ignoring personal experiences of well-being, dignity, and worth (Kitwood, 1997). Kitwood, described the characteristics that define the concept of person-centred care in his seminal work on the subject: the acknowledgment that the individual is a person that can experience life and relationships, despite the progressive disease; offering and respecting choices; the inclusion of the person's past life and history in their care; and the

focus on what the person can do, rather than the abilities that have been lost owing to the disease (Kitwood 1997). Person-centred care has been defined as supporting the rights, values, and beliefs of the individual; involving them and providing unconditional positive regard; entering their world and assuming that there is meaning in all behaviour, even if it is difficult to interpret; maximising each person's potential; and sharing decision making.

The different CST principles serve as strategies to meet and fulfil the psychological needs expressed by Kitwood (1997): Identity, attachment, comfort, inclusion, occupation and love. The CST approach to deliver person-centred care incorporates:

(a) Biographical knowledge of the person that helps facilitators to adapt the different sessions according to the individual's needs and interest. Accounts of a person's previous life, routines, and occupation providing interpretative cues for their present behaviour, needs, and wishes.

(b) Reminiscence is used to promote person-centredness as an aid to the here and now. It is thought to affirm the experiences and views of the world of people with dementia and foster social interaction through sharing of autobiographical memories using multisensory stimuli such as pictures, music, and scrapbooks.

(c) Focusing on opinion rather than facts promotes the use of validation to acknowledge the person's interpretation of reality through validation of their individual experiences. This unconditional positive regard may promote confidence and well being (Overshott & Burns 2006; Neal & Wright 2003). CST sessions offer freedom of expression and a release from previous constraints and concerns to present new sources of pleasure and satisfaction for the person with dementia.

(d) Giving consistency between sessions using the same place and session structure providing home-like surroundings. This has been associated with positive effects on the behaviour and mood of people with dementia (Cohen-Mansfield & Werner 1998), and smaller-sized groups show increased social interaction and community formation (McAllister & Silverman 1999; Moore, 1999).

(e) Valuing every person in the group and helping them feel content; offering dignity and striving to preserve a sense of self; accepting everyone's ways of being and opinions; sharing everyday life with a sense of togetherness (15 minutes included before the session with refreshments for extra social interaction); encouraging a sense of belonging to the group (selecting their group name and song in the first session of the programme); offering a secure environment; providing opportunities for occupation through the different proposed activities; and promoting a sense of power and control (including encouraging different roles within the group).

Using Consensus Methods Drawing on Evidence and Theory to Develop the Programme

In the absence of a large body of good quality evidence regarding the effectiveness of long-term CST programmes for dementia and theory behind this, a consensus conference was convened. This brought together the knowledge and expertise of local and external professionals, researchers and family caregivers involved in cognitive programmes in the dementia care field. Maintenance CST programme Version 1 was presented at an international consensus conference in London compromising key academics, research staff, clinical staff and family caregivers. A consensus method provides a means of synthesising the available information (Jones and Hunter, 1995). The aim of the consensus conference was to develop indicators for the successfulness of CST activities by considering the research evidence for the effectiveness of this therapy, and to use the feedback from participants to validate and review the draft Version 1. Participants reviewed the different presented themes in the programme and considered which activities they felt would be successful or unsuccessful for a long term intervention. The conference began with a presentation of the evidence from the Cochrane review (Woods et al., 2010), a presentation about the evidence from the CST trial (Spector et al., 2003) and a presentation about the development of the Maintenance CST programme Version 1. The participants worked in small multidisciplinary groups that facilitated the discussion about the presented themes (old and new) in the maintenance programme. Each group included clinical and research professionals plus family caregivers. Each group was asked to appoint a chairman whose role was to ensure that the group worked to the brief and to report back to the other groups. The groups worked on their brief for one and a half hours and drew up a list of the themes that they were reviewing. The groups were asked to split the themes into pros and cons for each of the activities. Subsequently, the groups came together and presented their opinions about the themes to the whole group. After the consensus conference, the different discussed points were typed and circulated to the Maintenance CST panel and consensus attendees, in the first phase Delphi survey, to encourage comments on the points. The changes from the consensus conference were included and integrated into the programme, leading to the maintenance CST programme draft Version 2. A list of the key principles of CST underlying the relevant theory behind the success of this therapy was also established among the CST panel (AS, BW, MO, JH, EA).

Modelling Process

To improve the therapy programme in terms of clarity, appropriateness and effectiveness asoutlined in Phase I (modelling) of the MRC guidelines (2008), we included qualitative testing of the intervention through focus groups. Focus groups were undertaken separately with the three main groups of users who constituted key stakeholders in the project; people with dementia, family carers and staff, in order to identify strengths and weaknesses in the programme and refinement of the therapy. Focus groups were the

natural choice since the aim was to gain as comprehensive a picture as possible of the views of the key stakeholders with regards to the Maintenance CST programme. Two members of the research team conducted nine (one-hour each) focus groups (3 with people with dementia, 3 with family caregivers and 3 with care staff). The groups focused on the 19 themes developed for the Maintenance CST programme and cognitive stimulation as defined by Clare et al (2003). Clare & Woods (2003) has made headway in categorising cognitive interventions by attempting to draw together the different ideas into three main types: 'Cognitive Stimulation', 'Cognitive Training' and 'Cognitive Rehabilitation'. Accordingly 'Cognitive Stimulation' is applied to interventions which involve the engagement in a range of activities and discussions aimed at general enhancement of cognitive and social.

The focus group interviews were tape-recorded and subsequently transcribed. The authors used an inductive thematic analysis approach (Boyatzis, 1998) to code and analyze the data. Using the final codebook, all transcripts were coded independently by both raters and then compared to reach 100% consensus (Aguirre et al, 2010).

Establishing Consensus

In order to establish the extent of agreement and consensus among the consensus conference participants with regards to the therapy programme Version 3, a final step was taken. A Delphi survey was sent to the consensus conference attendees that consisted of a covering letter introducing and explaining the steps followed for the development of the manual Version 3, plus a survey questionnaire that aimed to clarify points of the development of the programme and reach consensus about its development and key features.

Results

The different stages that were undertaken for the development of the intervention resulted in different therapy programme manual versions (Figure 2). These are detailed below:

Draft Manual Version 1

The systematic review found 5 new studies published from 2002 to 2007 meeting the inclusion criteria since the last Cochrane review (Spector et al., 2000). Combining the results from 15 RCTs (8 included in the previous review, 5 new and 2 from our team; Spector et al., 2001; Spector et al., 2003) (Table 1), the meta-analyses showed that people receiving cognitive stimulation improved significantly more than controls in cognition and quality of life (Woods et al., 2010). In addition to Spector et al., 2003 two other studies were the most influential studies in the design of this Maintenance programme: Requena et al., 2004 and Onder et al., 2005. Requena et al., 2004 was a single blind RCT demonstrating improvements in cognition and memory over a two-year period. They

included a new technique using 'visual clips' that was included in the draft Version 1 of our programme. Onder et al, 2005 was a single blind RCT that demonstrated improvements in cognition over 25 weeks of therapy, delivered individually by family care-givers for 30 minutes three times a week. They included a session about the use of calendars, notes and clocks that was adapted and included in the draft Version 1 of the manual as a new theme called "useful tips - caring for oneself".
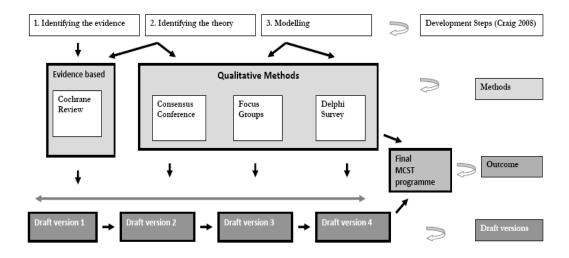

Figure 2. Development of the Maintenance CST programme manual

As a result of the process of identifying and developing appropriate theory for the programme, a table identifying themes and properties of the manuals was developed. A database was also created including the different elements, guiding principles and session themes that were found in the Cochrane review included studies. The key themes from the initial CST manual (Spector et al., 2006) guiding principles and sessions were organised in the database including the 16 sessions developed for the Maintenance CST pilot project (Orrell et al., 2005). From the analysed interventions of the Cochrane review studies, a 24 weekly session of Maintenance CST programme Version 1 was developed (Table 2). The MCST programme was based on the structural model of CST (Spector et al., 2003) and had similar criteria set out for it before development was started, as its aim was to complement it. This criterion was that the programme sessions had to be flexible, with stimulating exercises grouped by theme (e.g. food, childhood, sounds, physical exercises, famous faces, word game, and number games). Each theme had to contain exercises of different types, focusing on memory, concentration, linguistic, and executive abilities and each session had to follow the following structure: beginning with introductions and a warm-up activity (such as ball game), followed by a main activity and finishing with a closing to the session.

Table 2. CST and Maintenance CST programme themes

Programme	Pilot MCST	Version 1	Version 2	Version 3	Final Version
1	Childhood	Childhood	My life / Childhood	My life / Childhood	My life / Childhood
2	Current affairs	Current affairs	Current affairs	Current affairs	Current affairs
3	Current affairs	Food	Food	Food	Food
4	Using objects	Being creative	Being creative	Being creative	Being creative
5	Number Games	Number Games	Number Games	Number Games	Number Games
6	Team Games, Quiz	Team Games, Quiz	Team Games, Quiz	Team Games, Quiz	Team Games, Quiz
7	Sound	Sound	Sound	Sound	Sound
8	Physical Games	Physical Games	Physical Games	Physical Games	Physical Games
9	Categorising objects	Categorising Objects	Categorising Objects	Categorising Objects	Categorising Objects
10	Using objects	Using objects *P	Household treasures	Household treasures	Household treasures
11	Useful tips	Useful tips (Household) *P	Useful tips (Household)	Useful tips (Household)	Useful tips (Household)
12	Golden Expression cards	Golden Expression cards *P	Thinking cards	Thinking cards	Thinking cards
13	Golden Expression cards	Visual Clips *C	Visual Clips	Visual Clips	Visual Clips
14	Art Discussion	Art Discussion *P	Art Discussion	Art Discussion	Art Discussion
15	Famous faces/Scenes	Famous faces/Scenes	Famous faces/Scenes	Famous faces/Scenes	Famous faces/Scenes
16	Word Games	Word Games	Word Games	Word Games	Word Games
17		Food	Food	Food	Food
18		Associated words	Associated words	Associated words	Associated words
19		Orientation	Orientation	Orientation	Orientation
20		Using money	Using money	Using money	Using money
21		Current affairs	Current affairs	Word Games	Word Games

Table 2. (Continued)

Programme	Pilot MCST	Version 1	Version 2	Version 3	Final Version
22		Golden Expression cards *P	Thinking cards	Household treasures	Household treasures
23		Childhood	My life / Occupations	My life / Occupations	My life / Occupations
24		Useful tips (Health/Memory) *C	Useful tips (Health/Memory)	Useful tips (Health/Memory)	Useful tips (Health/Memory)

*C: Themes developed from the systematic review
*P: Themes from the pilot maintenance CST
 # Themes included from the original CST programme

Draft Manual Version 2

The maintenance programme themes in the draft Manual Version 1 were validated and reviewed through the application of a Delphi consensus process. The consensus conference took place at University College London (UCL) over one afternoon and was attended by 34 participants comprising key academics, research staff, clinical staff and family caregivers. As a result the activities included in the different presented themes were extended and adapted to be more suitable for the target population. Some theme titles were also modified, 'using objects' was replaced by 'household treasures', 'golden expression cards' was replaced by 'thinking cards' and 'childhood' by 'my life'. 'My life' theme was incorporated twice in the programme, about the first one focussing on childhood and the second one focusing on occupations. The overall format of the programme Version 1 was preserved, although it was suggested that the programme should incorporate activities that could be drawn on by different cultural communities. At the consensus conference, it was fed back that the way that CST was defined and how this differed to other cognitive therapies or other occupational activities normally run in day centres and care homes was not entirely clear. In the response to this, '18 key principles' were developed. These were subsequently included in the manual and used as an additional measure of adherence and continuous training for group facilitators and co-facilitators.

Draft Manual Version 3

The programme Version 2 was presented in nine focus groups. In total 17 people with dementia, 13 staff and 18 family carers participated (Aguirre et al., 2010). Thematic analysis revealed themes relating to perceptions and opinions of 'mental stimulation/use it or lose it'; 'examples of mental stimulating activities of daily life '; 'factors influencing successfulness and unsuccessfulness of a mental stimulation activity' and 'opinions and perceptions of specific themes of the presented Maintenance CST programme'. Patterns of themes were found among the different groups (people with dementia, family caregivers, staff). Positive agreement was found among the presented 14 CST session themes and suggestions were made for the 5 remaining new session themes. The feedback from the analyses of the focus groups involved the organisation of the different session themes in a different order and reclassification of the session themes that were planned to run twice during the 24 weeks of intervention. Two session themes (current affairs and thinking cards) that were originally planned to run twice on the Version 2 of the programme were reduced to once, and replaced by two session themes that were rated very highly in the focus groups with people with dementia: word games and household treasures. Detailed information about the modification of the programme themes from Version 1 to Version 3 is shown in Table 2. These results were used to produce the manual for the Maintenance CST programme Version 3 of the programme.

Final Maintenance CST Programme

As the final round of the Delphi process, 23 questionnaires were sent to the consensus conference participants. Six were returned and considering the multiple feedback processes inherent in the Delphi process, the potential exists for low response rates. Striving to maintain robust feedback can be a challenge as poor response rate is magnified fourfold as a maximum of four surveys may be sent to the same panellists (Witkin & Altschuld, 1995). All participants who replied to the survey felt that the draft Version 3 included all the elements discussed at the consensus conference and felt that would be a beneficial programme for people with dementia, as well as a useful tool for professionals working in the field. Although a low response rate was achieved in this survey, consensus in the long-term maintenance programme was expressed by the number of professionals that replied.

The feedback from the surveys resulted in some minor editorial changes and survey participants expressed their concerns about preparation time in order to run the sessions. They suggested that in order to make the manual more user friendly for staff, the appendixes of the manual could be extended. Appendixes were added with: resources for each session, and guidance for co-facilitators of CST, recommending steps to help prepare for the sessions, and procedures to follow when co facilitating a group. Following the feedback from these questionnaires the final Version of the Maintenance programme was prepared. Table 2 shows how each theme within the programme has evolved through the different developmental stages from Version 1 to final version.

Discussion

This study shows that it is feasible to develop a psychological therapy as a complex intervention following the Medical Research Council (2008) guidelines using the three stages of: identifying the evidence, developing the theory and modelling. The original MRC framework 2000 identified designing, describing, and implementing a well defined intervention as: "the most challenging part of evaluating a complex intervention and the most frequent weakness in such trials." By developing a programme following the framework we have ensured that the intervention has been developed to the point where it can reasonably be expected to have a worthwhile effect. Although several studies have described using the MRC framework for the development of their intervention, the interpretation of the content and purpose of phases seems to differ between the studies (Rowlands et al., 2005; Robinson et al., 2005; Haw et al., 2007). It appears that carefully developing complex interventions is regarded as a good thing, but details of how to achieve phase 1 (review of theory and evidence) and modelling of the framework are lacking.

The specific model (Figure 2) shows the use of mixed methods along phase I: the use of a systematic review; qualitative methods including the involvement of service users through consensus conference and focus groups; and a final Delphi survey. The involvement of service users as well as being ethically preferable represents practical

advantages for the future phases of the evaluation of the intervention. Recruitment and retention are likely to be better if the intervention is valued by potential participants, concerns about fairness are addressed and the knowledge that community leaders support the evaluation in the case of community-based interventions (MRC framework 2008). The use of focus groups as a modelling exercise to prepare for the trial, also allowed us to think about implementation at an early stage (before embarking on a lengthy and expensive evaluation process) as recommended by some studies (Glasgow et al., 2003; Tunis et al., 2002). Although there is growing awareness of the role that qualitative research can play in the design and evaluation of interventions, a recent methodological study about the use of qualitative methods alongside randomized controlled trials of complex interventions (Lewin et al., 2009) identified that less than one third of recently completed trials of complex interventions in the Cochrane Effective Practice and Organisation of Care register included some form of qualitative research. Of these, only about two thirds were published studies. This may contribute to the view that earlier phases of research, such as efficacy trials, do not need to incorporate qualitative studies to explore the effects of contextual and other moderating factors. Such methods are seen as important only in the later phases of evaluation (Glasgow et al., 2003).

Some limitations included in the development of this programme included the number of questions we sought to answer in relation to developing the theory step from our literature review and the limited resources we found from the included studies, meant relying predominantly on expert knowledge. The generalisability of our qualitative results may also have been limited as our consensus conference steering group relied on individuals participating, and the small number of participants in the focus groups. Definitive evidence of effectiveness of our intervention requires an evaluation in a randomized trial. We now have an intervention worthy of further evaluation although comprehensive development of intervention is not synonymous with efficacy. Harderman et al., (2005) developed an intervention to encourage people at risk of diabetes to be more physically active and followed the MRC framework but the intervention was subsequently shown to be ineffective in the RCT. Therefore, the results of the maintenance CST RCT (Phase III) are needed before drawing conclusions about its effectiveness.

In order to better understand the effectiveness of the developed intervention and as recommended by the MRC guidelines (2008) that suggests a more circular approach to their understanding, a process evaluation, phase IV study will be carry out following the evaluation through the RCT (Aguirre et al., 2010). The purpose of the final phase will be to examine the implementation of the intervention into practice, paying particular attention to the rate of uptake, the stability of the intervention, any broadening of subject groups, and the possible existence of adverse effects. Furthermore, this phase study will provide valuable insight into why the intervention fails or has unexpected consequences, or why the intervention results successful and works and how it can be optimised.

Conclusions

This study demonstrates that an evidence-based approach, tempered with the input of experienced professionals and input from service users, is feasible and productive. The involvement of people with dementia ensured that the maintenance CST sessions included in the programme were appropriate to their preferences and abilities. The detailed manual to accompany the Maintenance programme is also being prepared (available from the authors). A large, multi-centre RCT is now under way, representing phase III of the development of a complex intervention (Aguirre et al., 2010), which uses the final version of the Maintenance CST programme.

Competing Interests

AS runs the CST training course on a commercial basis.

AS, BW and MO have co-authored a CST manual, the royalties from which are received by the Dementia Services Development Centre Wales.

Authors' Contributions

Contributions: MO, RTW, ITR developed the original concept of the trial, and EA and MO drafted the original protocol; AS, ASt and JH co authored the treatment manual; all authors reviewed and commented on drafts of the protocol and paper.

Acknowledgements

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