An exploratory study of the "active ingredients" that lead to positive outcomes following cognitive stimulation therapy in dementia care and Clinical Research Portfolio

Ashley Gibson, BA (Hons), MSc.

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Institute of Health and Wellbeing
College of Medical, Veterinary and Life Sciences
University of Glasgow

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In loving memory of my Nana

CHAPTER ONE: SYSTEMATIC REVIEW

Loneliness and cognitive function among older adults: a systematic review

Ashley Gibson*

*Address for correspondence
Mental Health and Wellbeing
University of Glasgow
1st Floor, Administrative Building,
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XY
E-mail: a.gibson.2@research.gla.ac.uk

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Abstract

Background

As populations age, societies are becoming challenged with age-related diseases such as dementia. There is a need to identify determinants of cognitive disabilities, so that policy and preventative programs can be further developed. A previous review has highlighted an association between loneliness and cognitive function (Boss, Kang & Branson, 2015). However, this review did not formally consider the quality of studies included in relation to study outcomes and only included research from January 2000-July 2013, limiting the strength of interpretations.

Objective

The aim of this review was to examine, considering study quality, whether there is evidence for an association between loneliness and cognitive function.

Method

Primary quantitative research assessing the relationship between loneliness and cognitive function among older adults was systematically searched across six databases on 31st January 2018. Data were extracted, synthesised and summarised: describing the characteristics of research participants, assessment tools, and results. The AXIS methodological quality rating tool was used to assess the quality and risk of biases of studies.

Results

Fifteen studies were identified. Quality and risk of bias among studies varied. Many did not use a robust psychometric measure to measure loneliness. Despite variation in study

design, most studies reported similar findings of a significant and negative association between loneliness and cognitive function.

Conclusions

Increased loneliness is associated with reduced cognitive function. Loneliness may therefore be an indicator of those at increased risk of cognitive decline. More longitudinal research is required to explore the causal relationship association between loneliness and cognitive function.

Key words: older adults, dementia, loneliness, cognitive function

Introduction

As populations age, societies are becoming challenged with age-related diseases such as dementia. Currently, there are around 50 million people with dementia worldwide, and this is projected to increase to 82 million by 2030 (WHO, 2017). As such, there is a need to identify determinants of cognitive disabilities, so that policy and preventative programs can be further developed. Biological, psychological and social factors are all recognised to be important determinants of health, wellbeing and the development of age-related conditions. One such psychosocial factor is loneliness. Loneliness has been defined as "a distressing feeling that accompanies the perception that one's social needs are not being met by the quantity, or especially the quality of one's social relationships" (Hawkley & Cacioppo, 2010, pp.218). Loneliness is therefore a multifaceted concept reflecting one's subjective experience of relationships and social network.

It has been argued that individuals who are lonely have increased risk of developing dementia (Holwerda, Deeg, Beekman et al., 2014), including Alzheimer's disease (Wilson, Krueger, Schneider et al., 2007) and generally experience more rapid cognitive decline than individuals who are not lonely (Conroy, Golden, Jeffares et al., 2010). Several mechanisms have been proposed for the effect of loneliness upon cognition, potentially leading to dementia. It has been hypothesised that loneliness may affect pathways of cognitive and memory domains by reducing cognitive stimulation (Wilson et al., 2007). In one study, boredom-proneness (an inability to engage and maintain attention on any object) was linked with loneliness (Conroy et al., 2010). Loneliness may therefore share a common underlying executive cognitive process with impaired effortful attention, whether on social relationships in the case of loneliness or other objects or activities in the case of boredom-proneness (Conroy et al., 2010). Longitudinal research has also implicated a

bidirectional loneliness-cognition relationship over time (Zhong, Chen, Tu et al., 2017). Less engagement in social activities and reduced social network size due to diminished cognition are alternative explanations proposed for this reverse relationship (Zhong et al., 2017). However, these explanations are tentative and further research is required to explain the association between loneliness and cognitive function.

The literature on loneliness and cognition was reviewed by Boss, Kang & Branson (2015), who concluded that greater loneliness is associated with lower cognitive function, though some initial correlations were not significant after controlling for a range of demographic and psychosocial risk factors thought to influence loneliness. However, this review did not formally consider the quality of studies included in relation to study outcomes, and only research from January 2000-July 2013 was reviewed, limiting the conclusions that can be drawn from this.

Looking at indicators of the relationship between loneliness and cognitive function in older people prior to the development of a cognitive age-related condition is important as this period potentially provides the best opportunity for psychosocial intervention.

Aims and Objectives

The aim of this review was to examine, taking into account study quality, whether there is evidence for an association between loneliness and cognitive function.

Methods

Studies selected for this systematic review included primary quantitative research assessing the relationship between loneliness and cognitive functioning among older adults (without an existing diagnosed cognitive age-related condition).

Search Strategy

A search of EMBASE, Medline, Psychinfo, Ebsco, Cochrane, and CINAHL databases was conducted on 31st January 2018. Subject headings were searched for Loneliness, Social Isolation, Cognition, Memory, Aged and Ageing. Search terms (shown below) were applied to the title, abstract and key words using the Boolean operators "AND" and "OR". Truncation, indicated by the asterisk, was used to ensure any word endings following the truncation would be identified.

Lonel* OR Isolation

AND

Cogniti* OR Memory

AND

Aged OR Ageing OR Geriatric* OR Older Adult* OR Older People OR Older Person OR Elderly

No limits were placed on dates. Titles and abstracts were screened against eligibility criteria. This process was repeated by assessing the full article of the remaining selection of records. The reference lists of included articles were then reviewed. Only peer reviewed published articles that met criteria were included. Data extraction (i.e. of study population,

outcome measure type for loneliness and cognition, results) was completed for final eligible articles. Evaluation using the AXIS methodological quality rating tool (Downes, Brennan, Williams et al., 2016) was also conducted on the final articles.

Inclusion and Exclusion Criteria

Studies were included if:

- They were primary quantitative research
- They assessed the association between loneliness and cognitive function among older adults

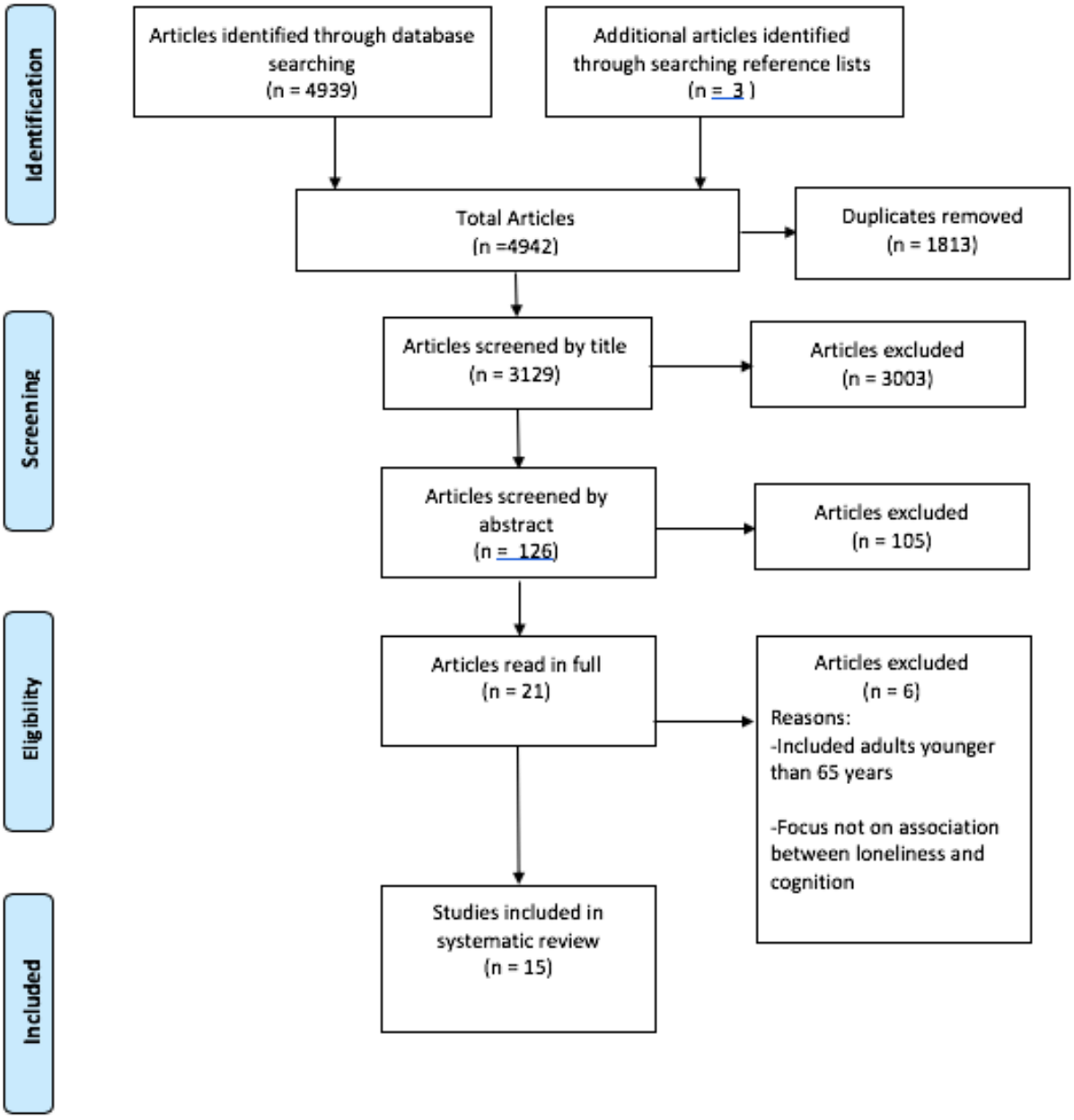
Studies were excluded if

- They were not written in English
- They did not focus on loneliness or include a measure of loneliness
- They included participants with a diagnosed cognitive age related condition at baseline
- They included participants who were under the age of 65 years old.

Search Outcome

Figure 1 provides an overview of the outcome of searches and screening process followed within this review. A total of 3129 studies were identified from database searches excluding duplicates, and 15 studies were eligible for inclusion.

Figure 1. Flow Diagram of Selection of Papers for Inclusion in the Systematic Review



Quality Appraisal

The AXIS (Downes et al., 2016) was developed to assess the quality and risk of bias in observational cross-sectional studies. It comprises 20 questions, relating to quality of reporting, study design, and the possible introduction of biases. All questions can also be

applied to longitudinal study designs. As such, this tool was used to assess all eligible articles. To evaluate inter-rater reliability, a sample (60%) of the included articles was independently rated by a second rater. There was 85-100% agreement between raters across papers by assigning ‘yes’, ‘no’ or ‘do not know/comment’ across all 20 components. Following discussion, 100% agreement was reached.

Results

Study Characteristics

15 journal articles met inclusion criteria. Table 1 summarises the characteristics of included studies. Seven were cross sectional and eight were longitudinal with follow-up periods ranging from one year to 68 years. Two studies (Gow, Corley, Starr et al., 2013; Gow, Pattie, Whiteman et al., 2007) used the same cohort of participants, The Lothian Birth Cohort, 1921, although analysis of the data differed with different research questions. Nine studies were conducted in Europe, and the remaining studies in Canada, USA, and China. Number of participants per study ranged from 189 to 14,199, with a total of 45,914 participants across all studies. All authors provided a description of sampling methods and sample size, although specific details varied among studies. Thirteen studies included male and female samples, and two studies included male only samples (Tijhuis et al., 1999; Tzang, Yang, Yeh et al., 2015). Samples were mostly community dwelling and independently living older adults. One study included a small number of participants in nursing homes, accounting for 4% of the total sample (Wilson et al., 2007). Another study included participants recruited from a veteran's home (Tzang, et al., 2015). The health status varied among participants, however, all were free from a dementia diagnosis at baseline.

Table 1: Characteristics of Included studies

Cross sectional Studies			
Author and Year	**Aims**	**Characteristics of sample and setting**	**Results**
Conroy et al. (2010)	To examine the relationship of cognitive impairment, with loneliness, boredom-proneness, social relations, and depression.	N = 802 (423, 53% women) Age = 65-102 (M= 74.2 years) Participants were part of a population survey of persons aged 65> living in the Irish Republic Community dwelling Irish population	Loneliness is associated with reduced cognitive function in older age (p=0.003), and clusters with other factors associated with cognitive reserve (p=0.001)
Gilmour (2011)	To examine correlates of low performance on four cognitive tasks among older adults without Alzheimer disease or dementia	N=13,176 Males and females Age > 65 years Community dwelling Canada	Loneliness was negatively correlated with worse performance in immediate recall, executive function, semantic fluency, and processing speed (all p<0.01)
Gow et al. (2013)	To examine associations of diverse measures of social contact and support with cognitive ability	N= 1091 males and females (M=70 years) Participants were part of the Lothian Birth Cohort, 1936 Community dwelling Scotland	Loneliness was negatively correlated with general cognitive ability (Spearman's rho = -0.14, p<0.0001), processing speed (Spearman's rho = -0.12, p<0.001) and memory (Spearman's rho = -0.08, p<0.01) When all variables were examined in separate ANCOVAs, lower loneliness was significantly better correlated with better general cognitive abilities at age 70 (p<0.05)
Holmen et al. (1992)	To investigate experienced loneliness among the elderly	N= 1725 males and females Age ≥75 Participants were part of the Kungsholmen project Community Dwelling Stockholm	High frequency of loneliness was found among participants with reduced cognitive function. MMSE scores explained loneliness in a stepwise regression analysis (p<0.05).
O'Luanaigh et al. (2012)	To explore associations between loneliness and	N= 466 males and females M age= 75.5 years	Loneliness was negatively correlated with global cognitive function (p = 0.047), category fluency (p < 0.05),

	cognition and to determine whether specific cognitive domains are associated with loneliness	Participants were part of The Dublin Healthy Ageing Study Community dwelling Ireland	psychomotor processing speed ($p = 0.036$), immediate visual memory ($p = 0.003$), visual memory ($p = 0.003$), pre-morbid IQ ($p < 0.001$), and visual memory savings ($p = 0.003$).
Stessman et al. (1996)	To find the determinants of feelings of loneliness in 70 year olds living in Jerusalem.	N= 605 (Mean age 69.95 ±0.3 years) Community Dwelling Jerusalem	Impaired cognitive function was not found to be associated with loneliness
Tzang et al. 2015	To investigate the effect of loneliness and depression on total as well as specific cognitive domains in cognitively normal male subjects	N= 189 non-demented male participants Age 65-98 years (M=80.2) Veteran's home Taiwan	Depression and loneliness are negatively correlated with global cognitive function as evaluated with CASI (r=–0.227, p=0.002; r=–0.214, p=0.003, respectively). The domains of Attention, Orientation, Abstraction and judgment, and List-generating fluency of cognitive function were specifically associated with loneliness.
Longitudinal Studies			
Author and Year	**Aims and Follow-up periods**	**Characteristics of sample and setting**	**Results**
Donovan et al. (2016)	To examine the reciprocal relations of loneliness and cognitive function in older adults, adjusting for social network, depression and other demographic and health related-factors 12 year follow up	N= 8382 Males and females Age ≥65 Non-Hispanic white and black Participants part of the US Health and Retirement Study from 1998 to 2010 Community Dwelling United States	Baseline loneliness predicted accelerated cognitive decline over 12 years independent of baseline socio-demographic factors, social network, health conditions and depression (β=0.2, p=0.002). Reciprocally, poorer baseline cognition was associated with greater odds of loneliness over time in adjusted analysis (OR 1.3, 95% CI (1.1-1.5) p=0.005), but not when controlling for baseline depression.
Gow et al. (2007)	To examine associations between early cognitive ability and later social networks and social support, and to examine associations between social	N= 497 males (42%) and females (M=79) years Participants were part of the Lothian Birth Cohort, 1936	Loneliness was negatively correlated with significant negative change in cognition ($r = -0.22$, $p = < 0.001$)

	networks, social support and cognitive change between age 11 and 79 68 year follow up	Community Dwelling Scotland	
Gow & Mortensen 2016	To examine associations between social resources and cognitive ageing 30 year follow up, at 10 year intervals	N=802 (436 men; 366 female) Age 50 – 80 years Participants were part of The Glostrup Cohort – longitudinal study of health and ageing. Community Dwelling Copenhagen	When the social resources showing significant associations were considered together (accounting for sex, education and social class), loneliness at age 70 was associated with lower cognitive ability level and greater cognitive decline at age 80, while married individuals experienced less decline
Holwerda et al. (2014)	To examine associations between social isolation, feelings of loneliness, and incident dementia in a cohort of older people without dementia 3-year follow-up	N= 2173 males and females. Age = 65-86 years Participants were part of the Amsterdam Study of the Elderly (AMSTEL) Community dwelling Netherlands	The decrease in global cognitive function score from baseline to follow-up was more pronounced in those with greater loneliness (baseline: *M* = 27.52, *SD* = 2.12, follow-up: *M* = 25.84, *SD* = 4.11) when compared to those with less loneliness (baseline: *M* = 28.05, *SD* = 1.84, follow-up: *M* = 27.06, *SD* = 2.71). Feeling lonely rather than being alone is associated with an increased risk of dementia (OR = 2.56, 95% CI = 1.82–3.61).
Tijhuis et al. 1999	To investigate (i) whether loneliness increased in old age, and if so, whether it relates to ageing itself, to time trends or to cohort effects and (ii) the relationship between changes in institutionalisation, partner status and health and loneliness 5, 10 year follow up	N= 939 males Age 65> Participants were part of the Zutphen Elderly Study Community Dwelling Netherlands	Changes in cognitive function were not related to loneliness

Tilvis et al. (2004)	To identify preventable and treatable risk factors of cognitive decline. 1, 5, and 10-year follow-up	*N* = 650 males and females, Age= 75 > Participants were obtained from The Helsinki Aging Study Community dwelling Finland	At 10-year follow-up only, baseline loneliness scores were significantly correlated with a decline in MMSE scores (RR = 3.0, 95% CI = 1.4–6.8).
Wilson et al. (2007)	To test the hypothesis that loneliness is associated with increased risk of Alzheimer disease (AD). 4 years of annual follow-up	*N* = 823 males and females (*M* age = 81 years) Participants were obtained from the Rush Memory and Aging project Community dwelling, nursing homes United States	Greater loneliness at baseline was associated with the presence of dementia at follow up ($p < 0.01$). Participants with higher loneliness were 2.1 times more likely to develop AD compared to those with low loneliness (RR = 1.51, 95% CI = 1.063–2.14). Loneliness was negatively correlated with all cognitive domains at baseline, as well as with more rapid decline over time (all $p < 0.01$).
Zhong et al. (2017)	To examine the relationship between loneliness and cognitive function and to explore the mediating role of physical health on the loneliness–cognition relationship in Chinese older adults 2, 4, 7, 10, 13 year follow up	Data came from a nationally representative sample of 14,199 Chinese OAs (aged 65+) from 2002, 2005, 2008, and 2011 waves of the Chinese Longitudinal Healthy Longevity Survey Community Dwelling China	Severe loneliness at prior assessment points was significantly associated with poorer cognitive function at subsequent assessments, and vice versa.

Measurements of Loneliness

Most studies utilised one or two Likert-style or yes/no question(s) to measure loneliness. Two studies measured loneliness with the De-Jong Gierveld Scale for Loneliness (Tijhuis et al., 1999; Wilson et al., 2007), although one of these studies (Wilson et al., 2007) used a modified version of the scale. In one study, loneliness was measured with the Loneliness Scale (University of California, Los Angeles, UCLA version 3) (Tzang et al., 2015). Gilmour (2011) also appears to use this scale, although this is not explicitly stated but the description of how loneliness was measured fits the description for this tool. For further information regarding these tools, please refer to Appendix 1.3.

Loneliness and Global Cognitive Function/General Cognitive Ability

Eleven studies explored the association between loneliness and general or global cognition. Five were longitudinal studies follow up periods between one and 30 years (Donovan, Rentz, Sperling et al., 2016; Gow & Mortensen, 2016; Tilvis et al., 2004; Tijhuis et al., 1999; Zhong et al., 2017). The majority of these studies found a significant association between these two variables.

Tilvis et al. (2004) found that loneliness significantly predicts cognitive decline with a 10 year follow-up period. Similarly, Gow & Mortensen (2016) found that loneliness at age 70 was associated with greater cognitive decline at age 80 (-0.582, p=0.011). Contrary to this, Tijhuis et al. (1999) found no significant association between loneliness and cognition over 10 years. Of note, a male only sample was utilised within this latter sample.

Two studies investigated the reciprocal relationship of loneliness and cognitive function and found similar results. Donovan et al. (2016) reported that loneliness at baseline predicted accelerated cognitive decline over 12 years independent of socio-demographic factors, social network, health conditions and depression (β = -0.2, p=0.002). Reciprocally, poorer cognition at baseline was associated with greater odds of loneliness over time in adjusted analysis (OR 1.3, 95% CI (1.1-1.5) p=0.005), but this association did not persist when controlling for baseline depression. Zhong et al (2017) found that more severe loneliness at prior assessment points was significantly associated with poorer cognitive function at subsequent assessments and vice versa ($p<0.001$); indicating loneliness has an adverse impact upon cognitive functioning, but also that cognitive dysfunction may exacerbate loneliness. This association persisted after controlling for a range of socio-demographic, social network and health factors. Of note, they did not control for depression.

Six cross-sectional studies explored the association between loneliness and global cognitive function and found mixed results. Five of these studies (Conroy et al., 2010; Holmen et al.,1992; Gow et al., 2013; O'Luanaigh et al., 2012; Tzang et al., 2015) found loneliness to be significantly and negatively associated with cognitive function. Additionally, O'Luanaigh et al. (2012) found this association persisted after controlling for depression and social networks. However, Gow et al. (2013) found this relationship did not persist when depression symptoms were considered.

One cross-sectional study (Stessman, Ginsberg, Klein et al., 1999) found no association between cognitive status and loneliness. Of note, this study failed to report what cognitive assessment was utilised to measure cognitive function.

Loneliness and Dementia/Alzheimer's Disease

Two longitudinal studies explored the association between loneliness and incidence of dementia (Holwerda et al., 2012) and risk of Alzheimer's disease (Wilson et al., 2007). Both studies found that baseline loneliness significantly increased the risk of dementia after a three year follow-up (Holwerda et al., 2012) and Alzheimer's disease after a four year follow-up (Wilson et al., 2007). These associations persisted after controlling for social isolation (Wilson et al., 2007) and demographic, somatic and psychiatric risk factors (Holwerda et al., 2012).

Loneliness and Memory

Six studies explored the association between loneliness and various domains of memory, including immediate and delayed recall, visual and general memory, episodic, semantic and working memory (Donovan et al., 2016; Gilmour, 2011; Gow et al., 2013; O'Luanaigh et al., 2012; Tzang et al., 2015; Wilson et al., 2007). Findings were mixed with only some studies reporting significant associations.

Gilmour (2011) explored immediate and delayed recall and found significant and negative correlations of loneliness with immediate recall only ($p<0.01$). Whereas, O'Luanaigh et al. (2012) explored delayed recall only and found greater loneliness was associated with worse performance on delayed recall ($p<0.05$). In contrast to this, Tzang et al. (2015) assessed for short term, long term and working memory and found no significant associations with loneliness.

In their longitudinal study, Wilson et al. (2007) measured episodic, semantic and working memory, and reported significant and negative associations with loneliness at baseline, but only semantic memory remained significant at the fourth year follow-up period ($p=0.01$) when controlling for demographic factors.

O'Luanaigh et al. (2012) found that loneliness was significantly associated with reduced visual memory. These associations persisted when controlling for a wide range of demographic and social network factors.

Gow et al. (2013) explored general memory and found that loneliness was significantly and negatively associated with memory in bivariate correlations ($p<0.01$), however this association was no longer significant when considering demographic factors and childhood IQ.

Loneliness and Executive Function/Attention

Two studies explored loneliness and executive function/attention. These studies were similar in design, but varied considerably in sample size from 189 (Tzang et al., 2015) to 13,176 participants (Gilmour, 2011). Tzang et al. (2015) found attention, orientation, abstraction and judgement were specifically associated with loneliness. In their larger study, Gilmour (2011) found a significant and negative association between loneliness and executive function ($p<0.01$). However, when social interaction (frequent participation in community events) was considered, the negative association between these two variables no longer continued.

Loneliness and Intelligence

Two population based studies measured cognitive domains related to intelligence (Gow et al., 2007 & O'Luanaigh et al., 2012). Whilst these studies differed in design, they reported similar findings. Gow et al. (2007) assessed the association between early cognitive ability and loneliness later in life using the Lothian Birth Cohort, 1921 with a 68 year follow up. Cognitive function was assessed between the ages of 11 and 79 years, and loneliness was assessed at the age of 79 years only. Results revealed that individuals reporting greater loneliness had poorer cognitive function at age of 79, and this association persisted after controlling for demographic factors and age-11 IQ (Gow et al., 2007). O'Luanaigh et al. (2012) used a cross-sectional approach with participants in The Dublin Healthy Ageing Study and measured loneliness with IQ. Results revealed that increased loneliness was significantly correlated with worse estimated pre-morbid IQ ($p<0.05$).

Loneliness and Processing Speed

Two cross-sectional studies found significant and negative associations between loneliness and processing speed (O'Luanaigh et al., 2012; Gow et al. 2013). Sample size ranged from 466 (O'Luanaigh et al., 2012) to 1091 (Gow et al., 2013). Whilst O'Luanaigh et al (2012) found this significant association to persist after controlling for depression, pre-morbid IQ, global cognition and other demographic factors, Gow et al. (2013) found that the association between loneliness and processing speed was no longer significant after considering depression scores. As such, this research reflects conflicting findings with regard to the influence loneliness has upon mood.

Loneliness and Verbal Fluency

O'Luanaigh et al. (2012) reported no significant associations between verbal fluency and loneliness when controlling for depression, social networks, and a range of demographic factors (O'Luanaigh et al., 2012). Whereas, Tzang et al. (2015) found that list-generating fluency was associated with loneliness (p=0.005).

Critical Appraisal

The design quality and risk of bias varied among studies. A breakdown of how studies were appraised using the AXIS, as well as details of covariates controlled for within studies, is presented in Appendix 1.2. No studies justified sample size. One study's (Tzang et al., 2015) sample frame was not taken from an appropriate population that closely represented the target population being investigated, and another study (Zhong et al., 2017) had funding sources conflicts of interest that may have affected the authors' interpretation of the results. Only three studies used a validated measure for assessing loneliness among participants (Tijhuis et al., 1999; Tzang et al., 2015; Wilson et al., 2007), which may have affected the validity of results among the other 12 studies. Seven studies raised concerns about potential non-response bias (Conroy et al., 2010; Donovan et al., 2016; Gow et al., 2013; Holmen et al., 1992; O'Luanaigh et al., 2012; Tilvis et al., 2004; Zhong et al., 2017), which may have affected validity of results. In terms of the quality of reporting among studies, five failed to discuss limitations (Conroy et al., 2010; Gilmour, 2011; Holmen et al., 1992; Stessman et al., 1996; Tijhuis et al., 1999), three did not adequately describe the methods (Gilmour, 2011; Holmen et al., 1992; Stessman et al., 1996), and six did not

adequately describe basic data (Gilmour, 2011; Gow & Mortensen, 2016; Gow et al., 2007; Holmen et al., 1992; O'Luanaigh et al., 2012; Stessman et al., 1996).

Only two studies found no association between loneliness and cognitive function (Stessman et al., 1996; Tijhuis et al., 1999). Tijhuis et al. (1999) used a male only sample and did not adequately describe basic data, limiting conclusions that could be made. Stessman et al. (1999) did not use a validated psychometric measure to assess loneliness and also failed to state the tool used to measure cognitive function, indicating potential risk of bias. As such, these two studies were considered low quality. Of note, quality and risk of bias varied among studies that did find an association between loneliness and cognitive function, with some having low risk of bias (e.g.Wilson et al., 2007) and others having potential high risk (e.g. Conroy et al., 2010). Therefore, the quality and risk of bias among studies did not appear to affect the outcome of results.

Discussion

This systematic review examined the evidence relating to the association between loneliness and cognitive function among older adults. Results largely indicate that increased loneliness is associated with lower cognitive function. This association was most significant when loneliness was explored in relation to global cognitive function, with a large number of studies providing evidence for this (Conroy et al., 2010; Donovan et al., 2016; Gow & Mortensen, 2016; Gow et al., 2013; Holmen et al., 1992; O'Luanaigh et al., 2012; Tilvis et al., 2004; Tzang et al., 2015; Zhong et al., 2017). Of these studies, some found this association to persist after controlling for demographic and psychosocial risk factors thought to influence loneliness (Donovan et al., 2016; Gow & Mortenson 2016; O'Luanaigh et al., 2012). This review also produced some evidence that there is a direct effect of cognition on loneliness, with two studies reporting that poorer cognition at baseline was associated with increased loneliness over time (Donovan et al., 2016; Zhong et al., 2017). However, this association did not persist when controlling for depression (Donovan et al., 2016). It could be that depression is a consequence of loneliness, making them highly correlated, contributing to this finding. Nevertheless, there was less evidence for the effect of cognition on loneliness.

Whilst there was variation in the way in which loneliness was measured, results were largely consistent with many studies finding a negative association between loneliness and cognitive function. Of the two studies that found no association between loneliness and cognitive function, one used a validated tool to measure loneliness (Tijhuis et al., 1999), whereas the other study used one Likert scale style question to measure loneliness (Stessman et al., 1996).

Whilst an association was found for loneliness and cognitive function among studies that did not use a more extensive psychometric tool, there is still a risk that measuring loneliness in a more simplistic way (e.g. using one or two binary or Likert style questions) will not capture the multifaceted nature of this concept. The De-Jong Gierveld Scale for Loneliness was utilised in two studies (Tijhuis et al., 1999; Wilson et al., 2007) and includes both positive and negative questions about emotional loneliness (missing an intimate relationship) and social loneliness (missing a wider social network). This scale was designed for use with older adults. The UCLA Loneliness Scale was utilised in one study (Tzang et al., 2015). It was developed to assess subjective feelings of loneliness or social isolation. Questions are worded in a negative and positive direction. The third version of the scale was simplified to facilitate administration of the measure to less educated populations, such as older adults. A focus on different aspects of loneliness will better capture the multifaceted nature of this construct. As such, these measures may allow for a more comprehensive assessment of loneliness among older adults.

When studies controlled for demographic and risk factors thought to influence loneliness, the relationship between greater loneliness and decreased cognitive function persisted for global cognitive function (Tilvis et al., 2004; Wilson et al., 2007; Zhong et al., 2017; Donovan et al., 2016; Tzang et al., 2015; Gow et al., 2007; Gow and Mortensen, 2016; Conroy et al., 2010), risk of dementia (Holwerda et al., 2014) semantic memory, processing speed (Gilmour, 2011) and visual memory (O'Luanaigh et al., 2012).

In addition, when controlling for depression/depressive symptoms the association between greater loneliness and worse global cognitive function (Donovan et al., 2016; Tzang et al 2015; O'Luanaigh et al., 2012) and dementia (Holwerda et al., 2014) persisted. Gow et al.

(2013) was the only study to find that the significant association between greater loneliness and reduced global cognitive ability no longer persisted after controlling for symptoms of depression, suggesting that symptoms of depression partly accounted for this association among participants. Gow et al. (2013) discuss that, given this, it is possible that loneliness is affecting pathways more proximal to cognitive function, such as depression. However, a number of studies within this review indicate that increased loneliness is associated with cognitive decline, independent of depression.

Some studies found that the association between loneliness and cognitive functioning persisted after controlling for social network (Donovan et al., 2016; O'Luanaigh et al., 2012; Zhong et al., 2017) and social isolation (Wilson et al., 2007); indicating that it is not the objective situation but rather the perceived absence of social attachments that increases risk of cognitive decline.

Whilst the current literature adds to the evidence base for the association between loneliness and cognitive functioning among older adults, even after controlling for a range of demographic risk factors, it does not provide enough information to conclude upon the cause-effect relationship between these two variables. It may be those who are lonely are less cognitively stimulated. Alternatively, it is also possible that cognitive decline results in individuals withdrawing from their social world and having consequent increased feelings of loneliness. Future research is required to investigate these hypotheses.

Limitations and Implication for Future Research and Clinical Practice

This review only included studies with participants aged 65 years and above, as this is the age of individuals being seen within older adult services offering input for age-related cognitive conditions. However, this did mean the exclusion of some relevant literature assessing the association between loneliness and cognitive function that included participants under 65 years. Also, the majority of studies included Western, European samples, limiting the generalisability of results.

Future longitudinal research, which includes diverse cultures and settings, will help to explore the causal relationship between loneliness and cognitive function. Such studies should control for a range of demographic and risk factors thought to influence loneliness. In relation to this, further research is needed to explore the hypothesis that loneliness may be affecting pathways more proximal to cognitive function, such as depression. Findings from such studies will help to shape policy and support the development of appropriate interventions to help decrease loneliness and improve cognitive function among older adults.

This review has also highlighted that having social relationships that are perceived as meaningful (perhaps through having shared interests) seems to be crucial in decreasing feelings of loneliness, rather than the number of relationships in one's social network. As such, interventions aimed to reduce loneliness should focus on providing the opportunity for older adults to develop a select number of close and emotionally supportive relationships.

Conclusions

Overall, increased loneliness is associated with reduced cognitive function, particularly global cognitive function. Loneliness may therefore be an indicator of those at increased risk of cognitive decline and a potentially treatable risk factor for cognitive impairment in older adults. More longitudinal research is required to explore the causal relationship association between loneliness and cognitive function.

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CHAPTER TWO: MAJOR RESEARCH PROJECT

An exploratory study of the "active ingredients" that lead to positive outcomes following cognitive stimulation therapy in dementia care

Ashley Gibson*

Address for correspondence:
*Address for correspondence
Mental Health and Wellbeing
University of Glasgow
1st Floor, Administrative Building,
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XY
E-mail: a.gibson.2@research.gla.ac.uk

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Plain English Summary

An exploratory study of the "active ingredients" that lead to positive outcomes following cognitive stimulation therapy in dementia care

Background: Cognitive stimulation therapy (CST) is an evidence-based, psychosocial group intervention, which aims to optimise cognitive function for persons with mild to moderate dementia. Whilst CST has been shown to enhance cognitive function and quality of life (QoL) of those with a dementia (Spector, Thorgrimsen, Woods et al., 2003), less is known about the "active ingredients" of CST that lead to such positive outcomes.

CST focuses on fostering individual strengths and is carried out in a social group environment. As such, it may be that changes in QoL and cognition following participation in CST groups are related (in part) to an increase in social relationships and confidence in one's ability to accomplish tasks.

Loneliness and Social Relationships

Several studies investigating social contexts and their association with mental health and well-being among older adults have shown that having better social relationships is protective against mental ill health (e.g. Chan et al., 2011).

Older adults are especially likely to experience age-related losses that affect their social relationships. Individuals with dementia may have additional challenges making meaningful social connections due to increased difficulties with communication, increasing their risk of loneliness.

Confidence in Accomplishing Tasks

One's sense of confidence in their ability to succeed in a specific situation or accomplish a task can play a major role in how one approaches goals, tasks, and situations. Those with dementia experience a decline in independence and a significant loss of control in their lives, likely impacting upon their confidence.

Aims: To explore if social relationships, loneliness and confidence in one's ability to accomplish tasks improve for individuals following CST intervention. Also, to investigate if improvements in loneliness, social relationships and confidence in one's ability to accomplish tasks are linked to positive outcomes found in cognition and QoL following participation in CST.

Methods: Participants included older adults with a diagnosis of mild to moderate dementia who completed CST groups within Older People Community Mental Health Teams (OPCMHTs) across Greater Glasgow and Clyde. Participants were provided with information on the study by CST group organisers and were required to sign a consent form to take part. Participants completed measures assessing cognition, QoL, loneliness, social relationships and confidence in their ability to accomplish tasks prior to, during, and following completion of the CST group.

Results: 22 participants took part in this study. Significant improvements for confidence in ability to accomplish tasks and QoL were found post CST. Improvement in QoL scores were associated with improved loneliness and confidence in accomplishing tasks scores post CST intervention.

Conclusions: Results suggest that confidence in accomplishing tasks improves following CST intervention, which is a new find. Also, improvements in QoL were associated with improvements in loneliness and confidence in accomplishing tasks scores following CST intervention. Future research needs to clarify the role of loneliness and confidence in accomplishing tasks in the context of outcomes for CST intervention.

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Scientific Abstract

Background: The efficacy and effectiveness of Cognitive Stimulation Therapy (CST) in improving cognition and quality of life (QoL) in individuals with dementia has been well demonstrated (e.g. Spector Thorgrimsen, Woods et al., 2003). However, less is known about the mechanisms of change for these positive outcomes.

Objective: This study aimed to explore potential mechanisms of change for CST, including loneliness, social-connectedness and self-efficacy.

Design: A within group repeated measure study was adopted. Participants included older adults with mild-moderate dementia participating in CST groups within Older People Community Mental Health Teams across Greater Glasgow and Clyde.

Methods: Participants were asked to complete assessment measures on loneliness, social connectedness and self-efficacy prior to, during, and following CST intervention. Wilcoxon signed rank tests explored whether there were significant differences in outcome scores post CST. Spearman correlations examined the relationship between changes in cognition and QoL scores with changes in loneliness, social connectedness and self-efficacy scores post CST.

Results: Recruitment was lower than anticipated, with 22 participants recruited and 15 completing pre and post assessments. A significant improvement for self-efficacy was found post CST. Improved QoL scores were associated with decreased loneliness and improved self-efficacy post CST.

Conclusions: There are suggestions within these preliminary findings that self-efficacy improves following CST, which is a novel finding. Results also revealed that improvements in QoL were associated with improvements in loneliness and self-efficacy following CST. However, the small sample size in this study means that conclusions that can be drawn are limited. Future research needs to clarify the role of loneliness and self-efficacy in the context of outcomes for CST intervention.

Key words: older adult, dementia, cognitive stimulation, social connectedness, self-efficacy

Introduction

The ageing population is resulting in a disproportionate increase in the 'older old' i.e. those over the age of 85. As populations age, there is also an increase in age-related diseases such as dementia. Currently, there are around 47 million people with dementia worldwide, and this is projected to increase to 75 million by 2030 (WHO, 2017). As such, the need for effective and accessible treatments for dementia is paramount.

Cognitive Stimulation Therapy

Cognitive stimulation therapy (CST) is a brief, evidence-based, psychosocial group intervention, which aims to optimise cognitive function for persons with mild to moderate dementia. CST focuses on fostering individual strengths through themed sessions that incorporate therapeutic techniques such as reality orientation or reminiscence. Reality orientation is intended to facilitate memory through the presentation and repetition of information, that serves as factual reminders about the self or the environment (Douglas, James & Ballard, 2004). Reminiscence therapy involves discussion of past activities, events or experiences often using concrete prompts (Spector, Davies, Woods et al., 2000).

Evidence shows CST enhances cognition and improves quality of life (QoL) of those with dementia (Knapp, Thorgrimsen, Patel et al., 2006; Spector, Thorgrimsen, Woods et al., 2003). It is currently the only non-pharmacological intervention recommended to improve cognition for those with mild to moderate dementia (Nice, 2007). Whilst studies have evidenced the efficacy and effectiveness of CST, less attention has been paid to mechanisms of change.

Spector, Gardner & Orrell (2011) carried out a qualitative study of experiences of the people attending CST groups, carers and group facilitators. Themes from patients, carers and group facilitators indicate positive experience when commenting on the experience of patients in groups and changes in everyday life. In a recent RCT investigating individualised CST being delivered via patient family/carer dyads, results revealed this to be less effective, with no significant differences found for cognition or QoL (Orgeta, Leung, Kang et al., 2015). This suggests that the socially orientated group context of traditional CST may, in part, contribute to positive outcomes.

Loneliness and Social Connectedness

Studies investigating the association between social contexts and mental health and well-being among older adults (OA) have shown that greater social connectedness is protective against mental ill health (e.g. Chan, Malhotra, Malhotra et al, 2011; Chao, 2011; Fiori, Antonucci, & Cortina, 2006). Research has also demonstrated the benefits of active engagement in social group activity upon cognitive function among older adults for a range of groups, including reminiscence groups (Haslam, 2010) and men's clubs to reduce social isolation (Gleibs, Haslam, Haslam et al., 2011). This suggests that cognitive improvement, may result not from the specific content of the intervention, but rather the meaningful engagement in social group activity. As a result of cognitive impairment, people with dementia may be less able to sustain important social relationships than their healthy peers, with significant consequences for well-being and cognition. Indeed, social connectedness has been shown to be affected during the early stages of dementia (Hatch, 2013).

From this, it could be argued that individuals with dementia are more likely to experience feelings of loneliness. Loneliness has been defined as "a distressing feeling that

accompanies the perception that one's social needs are not being met by the quantity, or especially the quality of one's social relationships" (Hawkley & Cacioppo, 2010, pp.218). As such, when considering social connectedness and loneliness, it seems important to focus on the individual's perception of their social world, rather than for example focus on the objective number of social relationships or social contacts an individual has.

Self-Efficacy

Self-efficacy refers to a person's belief in his or her ability to succeed in a specific situation or accomplish a specific task (Bandura, 1977). Higher general self-efficacy has been related to better QoL in patients with acquired brain injury (ABI) (Brands, Kohler, Stapert et al., 2014) as well as chronic conditions, such as chronic obstructive pulmonary disease (COPD) (Bentsen, Wentzel-Larsen, Henriksen et al., 2010). Symptoms of dementia lead to significant disruptions in social and occupational participation (American Psychiatric Association, 2013) and patients experience a tremendous loss of control in their lives.

As mentioned above, CST focuses on fostering individual strengths and is carried out in a socially orientated context. As such, it may be that changes in QoL and cognition following participation in CST groups are related (in part) to an increase in social connectedness and self-efficacy and a decrease in feelings of loneliness.

Aims

To investigate whether there are changes in loneliness, social connectedness and self-efficacy from pre-to post CST group, and whether changes in these variables are associated with changes in cognition and QoL.

Hypotheses

(1) All outcome measure scores will significantly improve post CST intervention

(2) Change scores in cognition measures will be associated with change scores in loneliness, social connectedness and self-efficacy measures

(3) Change scores in QoL measures will be associated with change scores in loneliness, social connectedness and self-efficacy measures

Method

Design

A within group repeated measures design was adopted.

Participants

Participants included community-dwelling older people with a diagnosis of mild to moderate dementia. Participants were recruited by convenience sampling from those attending CST groups within five Older People Community Mental Health Teams (OPCMHTs) within Greater Glasgow and Clyde.

Inclusion Criteria

Inclusion criteria were based on the previous CST trial by Spector et al. (2003). This is also the current inclusion criteria for individuals attending clinical CST groups. These stipulated that participants (a) met the DSM-IV criteria for dementia (American Psychiatric Association, 1994), (b) scored between 10 and 24 on the Mini Mental State Examination (MMSE; Folstein, Folstein & McHugh, 1975), (c) had some ability to communicate and understand communication, with sufficient capacity to give informed consent to participate in the study (d) could see and hear well enough to participate in the group, (e) did not have a major physical illness or disability which compromised participation and (f) did not have a diagnosis of a learning disability. Both male and female participants were included, aged 65 years and above.

Exclusion Criteria

People who lacked the capacity to consent in research were excluded.

Ethical Approval

Ethical approval was obtained from the West of Scotland Research Ethics Committee No. 3 (ref:17/WS/0188) (see Appendix 2.1) and R&D approval (ref: GN17MH460) was granted by NHS Greater Glasgow and Clyde (see Appendix 2.2). Informed consent was obtained from all participants.

Procedure

Recruitment

Participants were identified by clinicians at five OPCMHTs within NHS Greater Glasgow and Clyde health board and were provided with information on the study and a 'opt' in slip. Interest was expressed by participants by completing the 'opt in' slip and consent given for their contact details to be provided to the researcher. The researcher telephoned those interested and arranged appointments to go through a participant information sheet and obtain informed consent. Recruitment took place between October 2017 and June 2018.

CST Intervention

CST intervention followed the protocol outlined in the RCT by Spector et al. (2003). This involved 14 structured 45-minute group therapy sessions, conducted twice weekly over a period of seven weeks, within participants' local OPCMHT. The groups were conducted by trained CST facilitators within each OPCMHT.

Data Collection

All groups were evaluated as per standard clinical practice within each OPCMHT using the Mini-Addenbrooke's Cognitive Examination (m-Ace; Hsieh, McGory, Leslie et al., 2014) and QoL-Alzheimer's Disease scale (QoL-AD; Logsdon, Gibbons, McCurry et al., 1999) pre and post CST intervention. The m-ACE is utilised within OPCMHTs instead of the MMSE for cognitive screening due to a change in licensing laws for the MMSE. Scores for these measures were recorded for participants in this study to assess the effectiveness of CST intervention.

All participants were asked to complete measures for loneliness and self-efficacy pre and post CST intervention. A 'group fit' questionnaire for measuring participants' social connectedness to the CST group was completed at the end of CST sessions 1, 7, and 14 in the presence of CST facilitators.

Measures

Selection of measures

There is an absence of validated measures for people with dementia regarding social connectedness and self-efficacy. However, Mak (2011) has argued that we should not assume that scales which are not designed for people with dementia cannot be completed meaningfully by people with mild to moderate dementia. Moreover, the scales that have been selected for the current study are simple and feedback from a small number of individuals participating in a CST group in Inverclyde who volunteered to review the scales was that the measures were easy to understand and use, indicating they can be completed in a meaningful way by this client group.

Primary Outcome measures

Loneliness

The Three Item Loneliness Scale (Hughes, Waite, Hawkley et al., 2004) was also administered pre and post CST intervention. This scale is based on the UCLA Loneliness Scale (UCLA) (Russell, Peplau, & Ferguson, 1978), which has been widely used in loneliness research. The Three Item Loneliness Scale correlates strongly with the UCLA (r=0.82) and has high internal consistency with Cronbach's alphas range from .89 to .94. Total scores range from 3-9.

Social connectedness

A measure of 'group fit' has been used in previous research with older adults participating in a reminiscence group (Haslam, Haslam, Ysseldyk, et al., 2014), and was used in the current study to assess participants' perceived fit with their CST groups at the end of sessions 1, 7, 14 (See Appendix 2.4). This measure provides participants with a visual scale comprised of seven pairs of circles where one circle represented the participant and the other circle represented the group. At one end of the scale there was no overlap or 'fit' between circles (scored 1) and at the other extreme there was complete overlap (scored 7). Participants were asked to choose the pair of circles that best represented the fit between them and the group for that session.

Self-Efficacy

The General Self-Efficacy scale (GSE) (Shwarze & Jerusalem, 1995) was created to assess a general sense of perceived self-efficacy with the aim of predicting coping with daily hassles as well as adaptation after experiencing stressful life events. It has been used with older people with dementia (Sprange, Mountain, Shortland et al, 2015). Cronbach's alphas range from .76 to .90. Total scores range from 10-40.

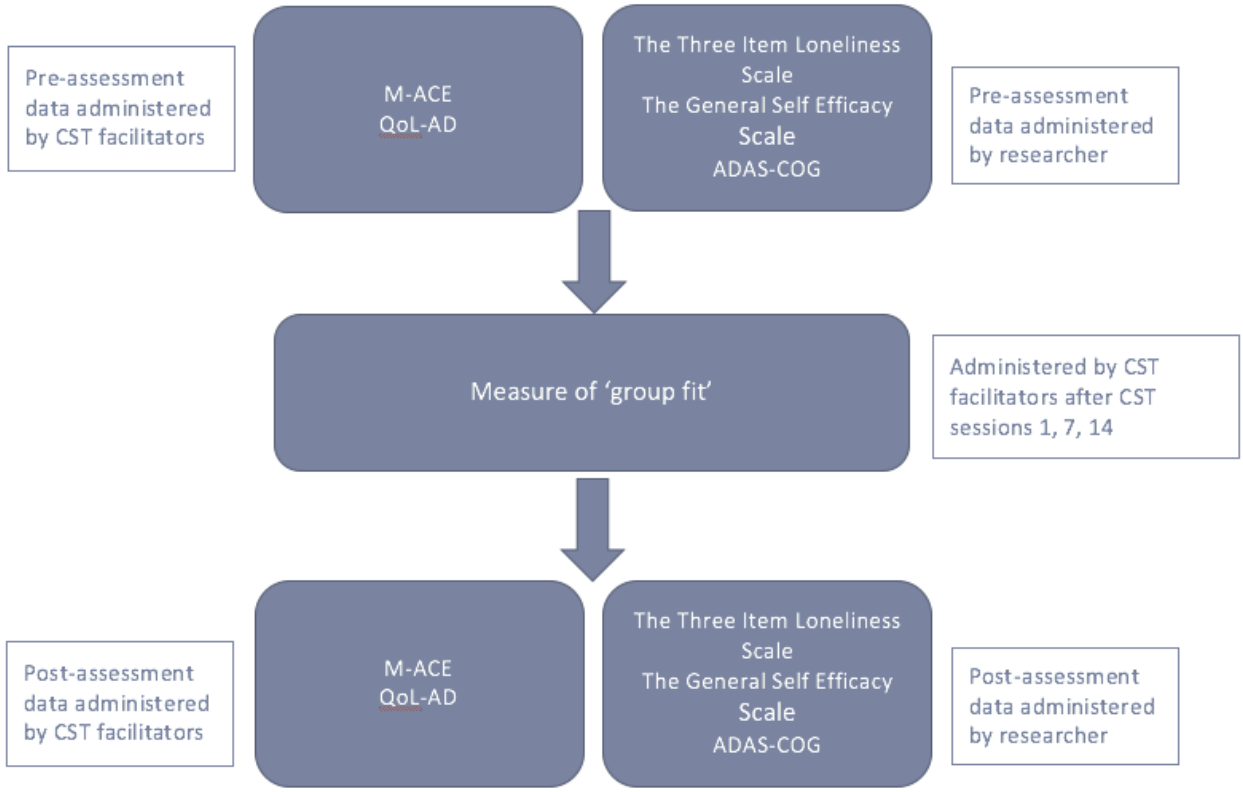
Secondary Outcome measures

Cognition and QoL

Within Spector et al. (2003), significantly improved scores for the CST group were found on the following measures of cognition and QoL - the MMSE (p=0.044, 95% CI 0.57-2.27, d=0.37) the Alzheimer's Disease Assessment scales- Cognition scales (ADAS-COG; Rosen, Mohs, Davis et al., 1984) (p=0.014, 95% CI 0.64-4.09, d=0.37) and the QoL-Alzheimer's Disease scale (QoL-AD; Logsdon, Gibbons, McCurry et al., 1999) (p=0.028, 95% CI 0.09-3.18, d=0.39).

Currently, OPCMHTs running CST groups routinely assess the efficacy and effectiveness of CST using the m-Ace and QoL-AD; scores for routine outcome measures were recorded for participants. In addition, the researcher administered the ADAS-COG pre and post CST intervention to examine change following attending the CST group. See also Figure 1 for a summary of the procedure of the administration of outcome measures.

Figure 1: Procedure for the administration of outcome measures



Sample Size

There is no existing research literature regarding effect sizes for the primary outcome measures in similar studies. However, in their study, Spector et al. (2003) achieved small – medium effect sizes on measures of cognition (d=0.37) and QoL (d=0.39). Using G Power (Faul, Erdfelder, Lang et al., 2007) a sample size of 47 would be required to detect an effect size of 0.37 using a within group t-test with a 0.05 (one-tailed) level of significance. As such, a sample size of 47 should have sufficient power to detect a change in outcome measures assessing QoL and cognition and was therefore set as the recruitment target for the current study. A sample size of 47 would have sufficient power (0.8) to detect a correlation of 0.35, with alpha at 0.05.

Statistical Analysis

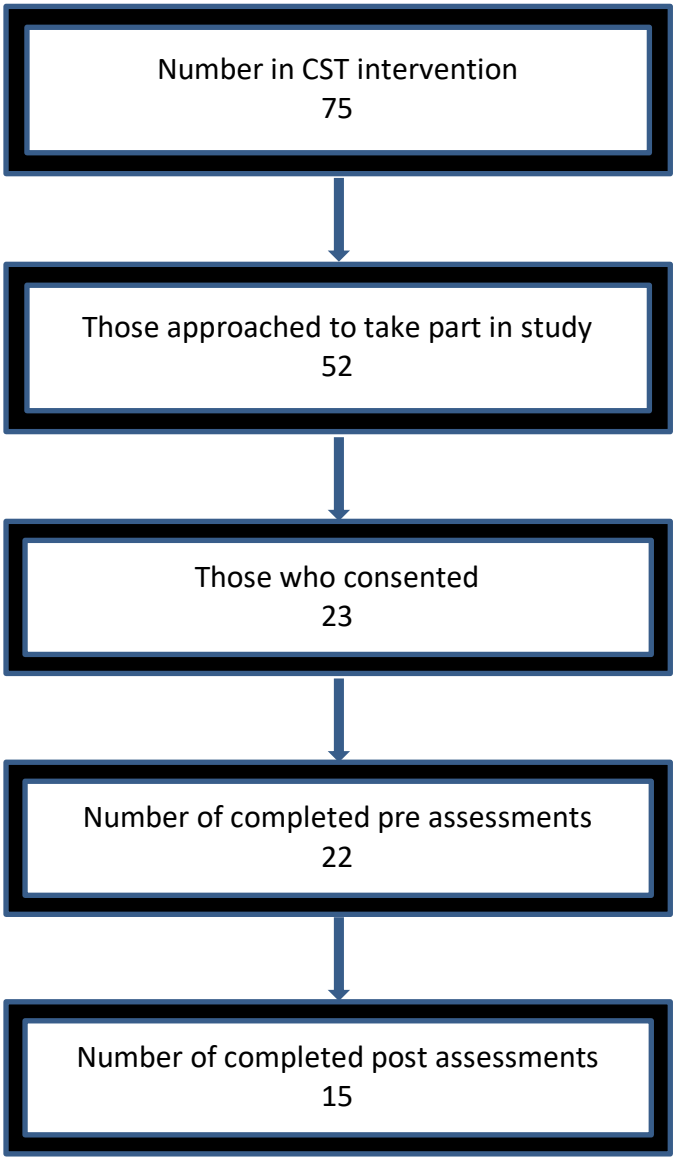
Statistical analysis was undertaken using SPSS Statistics Version 21. Descriptive statistics provide information regarding baseline demographics of participants (see Table 1). Observation of box plots, showing medians and interquartile ranges on the data did not meet parametric assumptions. This coupled with the small sample size resulted in non-parametric tests being used to analyse data. The Wilcoxon Signed Rank Test was used to compare pre and post CST intervention scores for all outcome measures. Spearman correlations were used to understand the relationship between changes in cognition and QoL with changes in loneliness, social connectedness and self-efficacy following CST intervention.

Information regarding recruitment, retention and outcome measure completion rates are reported to provide indications of feasibility for future studies (see Figure 2). Additional analysis was also carried out to determine if there was a significant difference in baseline demographics and outcome measure scores for those who completed CST intervention and therefore post assessment, and those who did not. Fisher's exact and Mann-Whitney U tests were used for this.

Results

A total of 22 participants were recruited to this study. Information regarding the number of CST groups facilitated across five OPCMHTs within GG&C in a ten month period, and recruitment and retention rates of participants for the current study are reported in Figure 2. Post assessments were not completed for seven participants due to them dropping out of CST intervention. There was missing baseline data for the ADAS-Cog for one participant who later dropped out of CST, this was due to eye sight difficulties that prevented them from completing this measure. Out of the fifteen people who completed post assessments, there was missing data for one participant's group fit measure for CST session 14 due to them not attending this session.

Figure 2: Numbers in CST intervention and recruitment and retention rates for participants



The median age of the 22 participants recruited to this study was 79 years, and participants had a median of 10 years of education. The Scottish Index of Multiple Deprivation (SIMD) categorises levels of deprivation based on postal codes into quintiles 1 (highest level of deprivation) to 5 (lowest level of deprivation). SIMD for participants is presented here as Low Deprivation and High deprivation based on quintile scores. Table 1 displays the baseline demographic information of participants recruited to this study as well as SIMD quintiles.

Table 1: Participant Baseline Demographic Information

Variable	**Participants (N=22)**	
Age	Mdn	(IQR)
	79	(76, 81)
Years of Education	Mdn	(IQR)
	10	(10, 10)
SIMD Quintile		
Low Deprivation (n, %)	6	(27.3%)
High deprivation (n, %)	16	(72.7%)
Gender		
Female (n, %)	13	(59.1%)
Male (n, %)	9	(40.9%)

Note: Scottish Index of Multiple Deprivation (SIMD), Low Deprivation = Quintiles 3-5; High Deprivation = Quintiles 1-2

Hypothesis 1: All outcome measure scores will significantly improve post CST intervention

A Wilcoxon signed-rank test revealed a statistically significant increase in QoL-AD scores from pre (Mdn=34) to post (Mdn=37; $Z=-2.209$, $p<0.05$, $r=.36$) and in General Self-

Efficacy scores from pre (Mdn=29.50) to post (34; Z=-2.012, p<0.05, r=.33), with medium effect sizes for both. See Table 2 for details.

Table 2: Difference in outcome measure scores post CST intervention

	Pre Median (IQR)	**Post Median (IQR)**	**Z statistic**	**Significance**	**Effect size Pearson's r**
m-ACE	16.50 (11.75, 21)	18.50 (13, 25)	.634	p=.526	0.10
QoL AD	34 (30.75, 40)	37(33, 40)	-2.209	p=.027*	-0.36
ADAS Cog	10 (8, 14)	9 (8, 13)	-.322	p=.747	-0.05
Loneliness Scale	4 (3, 5)	3 (3, 4)	-1.681	p=.093	-0.28
Group Fit	7 (6, 7)	7 (7, 7)	-1.725	p=.084	-0.30
GSE	29.50 (25.50, 33.75)	34 (27, 35)	-2.012	p=.044*	-0.33

Note: General Self-Efficacy (GSE), * Indicates significance of p<0.05

Hypothesis 2: Change scores in cognition will be associated with change scores in loneliness, social connectedness, and general self-efficacy

Given the absence of change scores in cognition following CST intervention, the testing of hypothesis 2 is redundant.

Hypothesis 3: Change scores in QoL will be associated with change scores in loneliness, social connectedness, and self-efficacy.

Correlations between outcome measures based on change scores are reported in Table 3.

Change scores for QoL were significantly correlated with change scores for loneliness (r=-0.59, n=15, p=0.01) and self-efficacy (r=0.49, n=15, p=0.03). Improvements with loneliness and self-efficacy were associated with improvements in QoL post CST intervention.

Table 3: Spearman correlations between outcome measures based on change scores post CST

	QoL-AD	**Loneliness**	**Group Fit**	**GSE**
	r	**r**	**r**	**r**
QoL-AD	1	-0.59*	0.04	-0.49*
Loneliness	-0.59*	1	0.24	-0.18
Group Fit	0.00	0.24	1	0.11
GSE	0.49*	-0.18	0.11	1

Note: General Self-Efficacy (GSE), *Correlation is significant at the 0.05 level (one tailed)

Additional Analysis

All demographics and baseline outcome measure scores were tested for differences between completers and non-completers of CST intervention. Fisher's exact and Mann-Whitney U tests were used to compare data. Measures of effect sizes are also reported (see Tables 4 and 5). A Mann-Whitney U test revealed a significant difference in age between completers (Mdn=80, n=15) and non-completers (Mdn=74, n=7; U=21, Z=-2.00, p=.046, r=0.19). A significant difference was also found for m-ACE scores between completers

(Mdn=17, n=15) and non-completers (Mdn=12, n=7; U=21, Z=-2.00, p=.046, r=.19) and for general self-efficacy scores between completers (Mdn=28, n=15) and non-completers (Mdn=37, n=7; U=14, Z=-2.51, p=.012, r=.30).

Table 4: Baseline age, years of education, and scores on measures for completers and non completers of CST

	Completers Mdn (IQR)	**Non-Completers Mdn (IQR)**	**Z statistic**	**Significance**	**Effect Size Pearson's r**
Age	80 (78, 81.50)	74 (73, 75)	-2.00	p=0.046*	0.19
Years of Education	10 (10, 10)	10 (9.50, 10.50)	-0.78	p=0.438	0.03
m-ACE	17 (13.50, 21.50)	12 (9.50, 16.50)	-2.00	p=0.046*	0.19
QoL-AD	34 (30.50, 37.50)	37 (34, 42)	-1.49	p=0.137	0.11
ADAS Cog	8 (8, 12.50)	11 (10, 15)	-1.46	p=0.144	0.11
Loneliness	4 (3, 5)	4.50 (3, 6)	-0.27	p=0.785	0.00
GSE	28 (25, 32.50)	37 (33, 38)	-2.51	p=0.012*	0.30
Group Fit	7 (6, 7)	7 (6, 7)	-1.28	p=0.202	0.10

General Self-Efficacy (GSE), *Significant difference at the p<0.05 level (two tailed) based on 3d.p

Table 5: Gender and level of deprivation among completers and non completers of CST

Variable	Completers (n=15) (%)	Non-Completers (n=5) (%)	Significance	Effect Size Cramer's V
Gender				
Female	9 (69.2)	4 (30.8)		
Male	7 (77.8)	2 (22.2)	p=1.0	0.66
SIMD				
Low Deprivation	5 (83.3)	1 (16.7)		
High Deprivation	11 (68.8)	5 (31.3)	p=0.63	0.15

Discussion

This study aimed to explore possible mechanisms of change for positive outcomes found in CST intervention. This is important in order to better match participants to intervention and also help inform the development of other interventions for dementia. Of note, the results of the current study are based on a sample of participants with high levels of deprivation and relatively low levels of education. The results revealed that quality of life and self-efficacy significantly improved pre to post CST intervention, providing some support for the hypothesis that these outcome variables would improve post CST (H1). Results also revealed change scores in QoL to be associated with change scores in loneliness and self-efficacy following the CST intervention, providing some support for H3. However, no support was provided for H2, in that change cognition scores were not associated with change scores for loneliness, social connectedness, or self-efficacy following CST intervention.

Outcome Measures

Results revealed that participants' quality of life significantly improved post CST intervention. When exploring descriptive statistics, there were also trends that cognitive function marginally improved for participants post CST intervention (as measured by m-ACE and ADAS-Cog). These findings are partially in line with previous studies investigating effectiveness of CST (Spector et al., 2003). The more marginal effects found in this study of improved cognitive function following CST intervention may be due to the small sample size, which resulted in this study being under powered. Of note, previous studies investigating the effectiveness of CST did not control for years of education or levels of deprivation among participants. This study included a sample of participants with

high levels of deprivation and relatively low levels of education and it may be that this also contributed to the marginal effects for positive change for cognition post CST intervention.

This study also found that self-efficacy significantly improved post CST intervention, indicating that CST had a positive impact among participants' belief in their abilities to succeed in situations and/or accomplish tasks. This is the first study to report a finding of improved self-efficacy following CST intervention.

Descriptive statistics indicate that there was a slight decrease in loneliness scores for participants post CST intervention, indicating some support that loneliness decreased post CST intervention, though this did not reach statistical significance. Social connectedness (as assessed by the group fit measure) remained stable pre to post CST intervention.

When observing raw scores for the group fit measure, participants appear to have rated social connectedness to CST group as high at the end of CST sessions 1, 7 and 14. CST facilitators, rather than an independent researcher, administered the group fit measure to participants. As such, there could be increased risk that participants were rating social connectedness to CST group as high at baseline due to social desirability bias among participants.

Understanding of Mechanisms of Change

Future studies with larger sample sizes will be able to better examine the mediators of any positive outcomes following CST intervention. In the meantime, the quantitative analysis completed here provides some support for H3, in that there were associations between

change scores for QoL with change scores for loneliness and self-efficacy following CST intervention.

The finding that improved self-efficacy is associated with improved QoL for dementia patients following CST intervention, is in line with research demonstrating higher general self-efficacy is related to better QoL for people with acquired brain injury (ABI) (Brands et al., 2014) as well as chronic health conditions, such as COPD (Bentsen et al., 2010). This provides support for the idea that, in addition to improving cognition and QoL, CST may help to increase individuals' sense of belief in themselves. This may be particularly important in the context of individuals having dementia, which results in disruptions to social and occupational participation, and a resultant experience of loss of control in one's life.

The finding that decreased loneliness was associated with increased QoL following CST intervention is in line with previous research highlighting the importance of social wellbeing to more general perceptions of wellbeing (e.g. Haslam, Haslam, Jetten et al. 2010).

The fact that there were no missing items on outcome measures that were completed for loneliness, social connectedness, and self-efficacy indicate the acceptability and feasibility of these measures for future studies. A larger scale study utilising these measures may be able to provide more definitive evidence of the possible associations between loneliness, social connectedness and self-efficacy and positive outcomes found post CST intervention.

Recruitment and Attrition Rates

Recruitment was lower than anticipated, resulting in this study being underpowered to detect some hypothesised effects. Low recruitment was due to a number of factors. Some OPCMHTs were not running as many CST groups as typical during the ten month recruitment period because of staff absences. Of the CST groups that were running, a number of older people were not approached about participating in the study. This was partly due to CST facilitators forgetting to speak to individuals about taking part in the study during the screening stage for CST intervention. Also, those individuals who appeared anxious during the screening process for CST were not approached about the research, as it was felt this may unnecessarily add to their anxieties about attending the CST intervention.

Less than half of those approached to participate in the study consented. Of those who consented to take part in the study, one individual did not go onto complete pre-assessment due to them no longer wishing to engage in the CST intervention. Seven of those who completed pre-assessments did not complete the CST intervention, resulting in post CST assessments not being carried out for these participants.

Statistical analysis of demographic and baseline data revealed that the 'older old' with better cognitive function (as measured by mACE) and lower self-efficacy were significantly more likely to complete CST intervention. Studies with larger sample sizes may wish to explore if the 'older old' with better cognitive functioning and lower self-efficacy at baseline benefit more from CST intervention than others.

Strengths and Limitations

Strengths of this study include the usefulness of feasibility information for future research aiming to explore mechanisms of change for positive outcomes found following CST intervention. As discussed previously, loneliness and social connectedness are multifaceted concepts reflecting one's subjective experience of relationships and social network. As such the use of two subjective self-report measures to assess loneliness and social connectedness was a strength of this study. A small number of patients receiving CST intervention were involved in helping to determine the outcome measures for loneliness, social connectedness, and self-efficacy used for this study, to help assure the ease of completion of these measures within this population. There were no missing items on these outcome measures completed by participants, also indicating their feasibility for future studies.

The main limitation of this study was the low participant numbers, resulting in this study being under-powered to detect some effects and limiting the conclusions that could be drawn. Depression has often been cited as part of the explanatory pathway between social resources and later health outcomes, including cognitive function. However, depressive symptoms of participants were not assessed within this study.

The group fit measure, assessing social connectedness to CST group, was administered to participants by CST facilitators rather than a researcher. It is possible that the results obtained from this measure may have been over-estimated by bias introduced via social desirability.

Future Research

There remains a lack of non-pharmacological treatments for dementia, particularly when considering the population prevalence. As such, understanding the potential underlying mechanisms of change for positive outcomes found in CST remains a priority, as it should more effectively match patients to this intervention as well as direct the development of further interventions for dementia care. This study has indicated difficulties with recruitment and retention of participants attending CST. Future studies should consider this when aiming for a larger sample size to ensure appropriate power. In relation to this, effect size was larger than anticipated within the current study, but caution is required given the small sample size. If the effect size is accurate, a sample of 22 participants would be sufficient to detect a significant difference. Given the dropout rate of 31.8% in the current study, a sample of at least 29 participants would be required for future research. Future studies should also consider an independent researcher administering any social connectedness measures when assessing participants' social connectedness to CST group to reduce risk of social desirability bias. Finally, future larger studies should explore if years of education and levels of deprivation impact upon positives outcomes found for cognition following CST intervention.

Conclusions

Overall, the findings of this study are limited due to small sample size, which resulted in the study being underpowered. There are, however, new suggestions within these preliminary findings that self-efficacy improves following CST intervention, in addition to QoL and cognitive function. Associations between improvements in QoL with loneliness and self-efficacy require further exploration, and replication. Future research needs to

clarify the role of loneliness and self-efficacy in the context of outcomes for CST intervention.

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Appendix 1.1. Author's Instructions for the *British Journal of Clinical Psychology*

Author Guidelines

The British Journal of Clinical Psychology publishes original contributions to scientific knowledge in clinical psychology and Registered Reports. This includes descriptive comparisons, as well as studies of the assessment, aetiology and treatment of people with a wide range of psychological problems in all age groups and settings. The level of analysis of studies ranges from biological influences on individual behaviour through to studies of psychological interventions and treatments on individuals, dyads, families and groups, to investigations of the relationships between explicitly social and psychological levels of analysis.

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The following types of paper are invited:

• Papers reporting original empirical investigations

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• Brief reports and comments

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• The main document must be anonymous. Please do not mention the authors' names or affiliations (including in the Method section) and refer to any previous work in the third person.

• Tables should be typed in double spacing, each on a separate page with a self-explanatory title. Tables should be comprehensible without reference to the text. They should be placed at the end of the manuscript but they must be mentioned in the text.

• Figures can be included at the end of the document or attached as separate files, carefully labelled in initial capital/lower case lettering with symbols in a form consistent with text use. Unnecessary background patterns, lines and shading should be avoided. Captions should be listed on a separate sheet. The resolution of digital images must be at least 300 dpi. All figures must be mentioned in the text.

• All papers must include a structured abstract of up to 250 words under the headings: Objectives, Methods, Results, Conclusions. Articles which report original scientific research should also include a heading 'Design' before 'Methods'. The 'Methods' section for systematic reviews and theoretical papers should include, as a minimum, a description of the methods the author(s) used to access the literature they drew upon. That is, the abstract should summarize the databases that were consulted and the search terms that were used.

• All Articles must include Practitioner Points – these are 2–4 bullet points to detail the positive clinical implications of the work, with a further 2–4 bullet points outlining cautions or limitations of the study. They should be placed below the abstract, with the heading 'Practitioner Points'.

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• SI units must be used for all measurements, rounded off to practical values if appropriate, with the imperial equivalent in parentheses.

• In normal circumstances, effect size should be incorporated.

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These allow publication of research studies and theoretical, critical or review comments with an essential contribution to make. They should be limited to 2000 words, including references. The abstract should not exceed 120 words and should be structured under these headings: Objective, Method, Results, Conclusions. There should be no more than one table or figure, which should only be included if it conveys information more efficiently than the text. Title, author name and address are not included in the word limit.

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Appendix 1.2. Table for Axis and Covariates Controlled for within Studies

Conroy et al. (2010)

	Yes/No/Don't know (Y/N/DK)	Comments
Study Design Quality		
Was the study design appropriate for the stated aims?	Y	
Was the sample size justified?	N	
Was the sample frame taken from an appropriate population base so that it closely represented the target/reference population under investigation?	Y	
Were the risk factor and outcome variables measured appropriate to the aims of the study?	Y	
Were the authors' discussions and conclusions justified by the results?	Y	
Were there any funding sources or conflicts of interest that may affect the authors' interpretation of the results?	N	
Was ethical approval or consent of participants attained?	Y	
Risk of Biases		
Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?	Y	
Were measures undertaken to address and categorise on-responders	N	
Were the risk factor and outcome variables measured correctly using instruments/measurements that had been trialled, piloted or published previously?	N	
Does the response rate raise concerns about non-response bias?	Y	RR Not reported
If appropriate, was information about non-responders described?	N	
Were the results internally consistent?	N	Table 1 n=709, versus sample N= 802
Quality of Reporting		
Were the aims/objectives of the study clear?	Y	
Was the target/reference population clearly defined?	Y	
Is it clear what was used to determine statistical significance and/or precision estimates?	Y	
Were the methods (including statistical methods) sufficiently described to enable them to be repeated?	Y	
Were the basic data adequately described?	Y	
Were the results presented for all the analysis described in the methods?	Y	
Were the limitations of the study discussed?	N	Nothing regarding non-responders
Covariates	Age, Education	

Donovan et al. (2017)

	Yes/No/Don't know (Y/N/DK)	Comments
Study Design Quality		
Was the study design appropriate for the stated aims?	Y	
Was the sample size justified?	N	
Was the sample frame taken from an appropriate population base so that it closely represented the target/reference population under investigation?	Y	
Were the risk factor and outcome variables measured appropriate to the aims of the study?	Y	
Were the authors' discussions and conclusions justified by the results?	Y	
Were there any funding sources or conflicts of interest that may affect the authors' interpretation of the results?	N	
Was ethical approval or consent of participants attained?	DK	Not mentioned
Risk of Biases		
Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?	Y	
Were measures undertaken to address and categorise on-responders	Y	
Were the risk factor and outcome variables measured correctly using instruments/measurements that had been trialled, piloted or published previously?	N	
Does the response rate raise concerns about non-response bias?	Y	
If appropriate, was information about non-responders described?	Y	
Were the results internally consistent?	Y	
Quality of Reporting		
Were the aims/objectives of the study clear?	Y	
Was the target/reference population clearly defined?	Y	
Is it clear what was used to determine statistical significance and/or precision estimates?	Y	
Were the methods (including statistical methods) sufficiently described to enable them to be repeated?	Y	
Were the basic data adequately described?	Y	
Were the results presented for all the analysis described in the methods?	Y	
Were the limitations of the study discussed?	Y	
Covariates	Age, Gender, Race, Education, Household Wealth, Household Income, Social Network, Physical Health, Depression	

Gilmour (2011)

	Yes/No/Don't know (Y/N/DK)	Comments
Study Design Quality		
Was the study design appropriate for the stated aims?	Y	
Was the sample size justified?	N	
Was the sample frame taken from an appropriate population base so that it closely represented the target/reference population under investigation?	Y	
Were the risk factor and outcome variables measured appropriate to the aims of the study?	Y	
Were the authors' discussions and conclusions justified by the results?	Y	
Were there any funding sources or conflicts of interest that may affect the authors' interpretation of the results?	N	
Was ethical approval or consent of participants attained?	DK	Not mentioned
Risk of Biases		
Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?	Y	
Were measures undertaken to address and categorise on-responders	Y	Sampling weights
Were the risk factor and outcome variables measured correctly using instruments/measurements that had been trialled, piloted or published previously?	DK	Appears to use UCLA Loneliness scale but does not call it this
Does the response rate raise concerns about non-response bias?	N	
If appropriate, was information about non-responders described?	N	
Were the results internally consistent?	DK	Unclear as no 'N' reported
Quality of Reporting		
Were the aims/objectives of the study clear?	Y	Not in abstract, but in introduction
Was the target/reference population clearly defined?	Y	
Is it clear what was used to determine statistical significance and/or precision estimates?	Y	Yes for p values but not for confidence intervals
Were the methods (including statistical methods) sufficiently described to enable them to be repeated?	N	
Were the basic data adequately described?	N	
Were the results presented for all the analysis described in the methods?	Y	
Were the limitations of the study discussed?	N	
Covariates	Age, Gender, Education	

Gow et al. (2013)

	Yes/No/Don't know (Y/N/DK)	Comments
Study Design Quality		
Was the study design appropriate for the stated aims?	Y	
Was the sample size justified?	N	
Was the sample frame taken from an appropriate population base so that it closely represented the target/reference population under investigation?	Y	
Were the risk factor and outcome variables measured appropriate to the aims of the study?	Y	
Were the authors' discussions and conclusions justified by the results?	Y	
Were there any funding sources or conflicts of interest that may affect the authors' interpretation of the results?	N	
Was ethical approval or consent of participants attained?	Y	
Risk of Biases		
Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?	Y	
Were measures undertaken to address and categorise non-responders	N	
Were the risk factor and outcome variables measured correctly using instruments/measurements that had been trialled, piloted or published previously?	N	
Does the response rate raise concerns about non-response bias?	DK	
If appropriate, was information about non-responders described?	N	
Were the results internally consistent?	Y	
Quality of Reporting		
Were the aims/objectives of the study clear?	Y	
Was the target/reference population clearly defined?	Y	
Is it clear what was used to determine statistical significance and/or precision estimates?	Y	
Were the methods (including statistical methods) sufficiently described to enable them to be repeated?	Y	
Were the basic data adequately described?	Y	
Were the results presented for all the analysis described in the methods?	Y	
Were the limitations of the study discussed?	Y	
Covariates	Age 11-IQ, Age, Gender, Social Class, Depression	

Gow & Mortensen (2016)

	Yes/No/Don't know (Y/N/DK)	Comments
Study Design Quality		
Was the study design appropriate for the stated aims?	Y	
Was the sample size justified?	N	
Was the sample frame taken from an appropriate population base so that it closely represented the target/reference population under investigation?	Y	
Were the risk factor and outcome variables measured appropriate to the aims of the study?	Y	
Were the authors' discussions and conclusions justified by the results?	Y	
Were there any funding sources or conflicts of interest that may affect the authors' interpretation of the results?	N	
Was ethical approval or consent of participants attained?	Y	
Risk of Biases		
Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?	Y	
Were measures undertaken to address and categorise non-responders	N	
Were the risk factor and outcome variables measured correctly using instruments/measurements that had been trialled, piloted or published previously?	N	
Does the response rate raise concerns about non-response bias?	N	
If appropriate, was information about non-responders described?	N	
Were the results internally consistent?	N	Participants = N wrong for age 70, age 80
Quality of Reporting		
Were the aims/objectives of the study clear?	Y	
Was the target/reference population clearly defined?	Y	
Is it clear what was used to determine statistical significance and/or precision estimates?	Y	
Were the methods (including statistical methods) sufficiently described to enable them to be repeated?	Y	
Were the basic data adequately described?	N	Referred to in another paper
Were the results presented for all the analysis described in the methods?	Y	
Were the limitations of the study discussed?	Y	
Covariates	Sex, Education, Social Class	

Gow et al. (2007)

	Yes/No/Don't know (Y/N/DK)	Comments
Study Design Quality		
Was the study design appropriate for the stated aims?	Y	Although much of analysis cross-sectional
Was the sample size justified?	N	
Was the sample frame taken from an appropriate population base so that it closely represented the target/reference population under investigation?	Y	
Were the risk factor and outcome variables measured appropriate to the aims of the study?	Y	
Were the authors' discussions and conclusions justified by the results?	Y	
Were there any funding sources or conflicts of interest that may affect the authors' interpretation of the results?	N	
Was ethical approval or consent of participants attained?	DK	Not mentioned
Risk of Biases		
Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?	Y	
Were measures undertaken to address and categorise non-responders	N	
Were the risk factor and outcome variables measured correctly using instruments/measurements that had been trialled, piloted or published previously?	N	
Does the response rate raise concerns about non-response bias?	N	
If appropriate, was information about non-responders described?	N	
Were the results internally consistent?	Y	
Quality of Reporting		
Were the aims/objectives of the study clear?	Y	Not in abstract, but in introduction
Was the target/reference population clearly defined?	Y	
Is it clear what was used to determine statistical significance and/or precision estimates?	Y	
Were the methods (including statistical methods) sufficiently described to enable them to be repeated?	Y	
Were the basic data adequately described?	N	
Were the results presented for all the analysis described in the methods?	Y	
Were the limitations of the study discussed?	Y	
Covariates	Sex, Education, Social Class, Age-11 IQ	

Holmen et al. (1992)

	Yes/No/Don't know (Y/N/DK)	Comments
Study Design Quality		
Was the study design appropriate for the stated aims?	Y	
Was the sample size justified?	N	
Was the sample frame taken from an appropriate population base so that it closely represented the target/reference population under investigation?	Y	
Were the risk factor and outcome variables measured appropriate to the aims of the study?	Y	
Were the authors' discussions and conclusions justified by the results?	Y	
Were there any funding sources or conflicts of interest that may affect the authors' interpretation of the results?	N	
Was ethical approval or consent of participants attained?	DK	Not mentioned
Risk of Biases		
Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?	Y	
Were measures undertaken to address and categorise non-responders	N	
Were the risk factor and outcome variables measured correctly using instruments/measurements that had been trialled, piloted or published previously?	N	
Does the response rate raise concerns about non-response bias?	DK	Not clear
If appropriate, was information about non-responders described?	N	
Were the results internally consistent?	DK	No 'N' Value
Quality of Reporting		
Were the aims/objectives of the study clear?	Y	
Was the target/reference population clearly defined?	Y	
Is it clear what was used to determine statistical significance and/or precision estimates?	Y	
Were the methods (including statistical methods) sufficiently described to enable them to be repeated?	N	
Were the basic data adequately described?	N	
Were the results presented for all the analysis described in the methods?	Y	
Were the limitations of the study discussed?	N	
Covariates	-	

Holwerda et al. (2014)

	Yes/No/Don't know (Y/N/DK)	Comments
Study Design Quality		
Was the study design appropriate for the stated aims?	Y	
Was the sample size justified?	N	
Was the sample frame taken from an appropriate population base so that it closely represented the target/reference population under investigation?	Y	
Were the risk factor and outcome variables measured appropriate to the aims of the study?	Y	
Were the authors' discussions and conclusions justified by the results?	Y	
Were there any funding sources or conflicts of interest that may affect the authors' interpretation of the results?	N	
Was ethical approval or consent of participants attained?	Y	
Risk of Biases		
Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?	Y	
Were measures undertaken to address and categorise non-responders	Y	
Were the risk factor and outcome variables measured correctly using instruments/measurements that had been trialled, piloted or published previously?	N	
Does the response rate raise concerns about non-response bias?	N	
If appropriate, was information about non-responders described?	N	
Were the results internally consistent?	Y	
Quality of Reporting		
Were the aims/objectives of the study clear?	Y	
Was the target/reference population clearly defined?	Y	
Is it clear what was used to determine statistical significance and/or precision estimates?	Y	
Were the methods (including statistical methods) sufficiently described to enable them to be repeated?	Y	
Were the basic data adequately described?	Y	
Were the results presented for all the analysis described in the methods?	Y	
Were the limitations of the study discussed?	Y	
Covariates	Depression, Gender, Age, Physical Health, Social Isolation, Education	

O'Luanaigh et al. (2012)

	Yes/No/Don't know (Y/N/DK)	Comments
Study Design Quality		
Was the study design appropriate for the stated aims?	Y	
Was the sample size justified?	N	
Was the sample frame taken from an appropriate population base so that it closely represented the target/reference population under investigation?	Y	
Were the risk factor and outcome variables measured appropriate to the aims of the study?	Y	
Were the authors' discussions and conclusions justified by the results?	Y	
Were there any funding sources or conflicts of interest that may affect the authors' interpretation of the results?	N	
Was ethical approval or consent of participants attained?	Y	
Risk of Biases		
Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?	Y	
Were measures undertaken to address and categorise non-responders	N	
Were the risk factor and outcome variables measured correctly using instruments/measurements that had been trialled, piloted or published previously?	Y	
Does the response rate raise concerns about non-response bias?	Y	
If appropriate, was information about non-responders described?	N	
Were the results internally consistent?	Y	
Quality of Reporting		
Were the aims/objectives of the study clear?	Y	
Was the target/reference population clearly defined?	Y	
Is it clear what was used to determine statistical significance and/or precision estimates?	Y	
Were the methods (including statistical methods) sufficiently described to enable them to be repeated?	Y	
Were the basic data adequately described?	N	N value missing
Were the results presented for all the analysis described in the methods?	Y	
Were the limitations of the study discussed?	Y	
Covariates	Social Network, Depression, Age, Gender, Social Class, Education, Marital Status	

Stessman et al. (1996)

	Yes/No/Don't know (Y/N/DK)	Comments
Study Design Quality		
Was the study design appropriate for the stated aims?	Y	
Was the sample size justified?	N	
Was the sample frame taken from an appropriate population base so that it closely represented the target/reference population under investigation?	Y	
Were the risk factor and outcome variables measured appropriate to the aims of the study?	Y	
Were the authors' discussions and conclusions justified by the results?	Y	
Were there any funding sources or conflicts of interest that may affect the authors' interpretation of the results?	N	
Was ethical approval or consent of participants attained?	DK	Not mentioned
Risk of Biases		
Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?	Y	
Were measures undertaken to address and categorise non-responders	Y	
Were the risk factor and outcome variables measured correctly using instruments/measurements that had been trialled, piloted or published previously?	N	
Does the response rate raise concerns about non-response bias?	N	
If appropriate, was information about non-responders described?	Y	
Were the results internally consistent?	Y	
Quality of Reporting		
Were the aims/objectives of the study clear?	Y	
Was the target/reference population clearly defined?	Y	
Is it clear what was used to determine statistical significance and/or precision estimates?	Y	
Were the methods (including statistical methods) sufficiently described to enable them to be repeated?	N	No mention of what test was used to assess cognitive function
Were the basic data adequately described?	N	N of female / male participants not reported
Were the results presented for all the analysis described in the methods?	Y	
Were the limitations of the study discussed?	N	
Covariates	-	

Tijhuis et al. (1999)

	Yes/No/Don't know (Y/N/DK)	Comments
Study Design Quality		
Was the study design appropriate for the stated aims?	Y	
Was the sample size justified?	N	
Was the sample frame taken from an appropriate population base so that it closely represented the target/reference population under investigation?	Y	
Were the risk factor and outcome variables measured appropriate to the aims of the study?	Y	
Were the authors' discussions and conclusions justified by the results?	Y	
Were there any funding sources or conflicts of interest that may affect the authors' interpretation of the results?	N	
Was ethical approval or consent of participants attained?	DK	Not mentioned
Risk of Biases		
Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?	Y	
Were measures undertaken to address and categorise non-responders	N	
Were the risk factor and outcome variables measured correctly using instruments/measurements that had been trialled, piloted or published previously?	Y	
Does the response rate raise concerns about non-response bias?	N	
If appropriate, was information about non-responders described?	N	
Were the results internally consistent?	Y	
Quality of Reporting		
Were the aims/objectives of the study clear?	Y	
Was the target/reference population clearly defined?	Y	
Is it clear what was used to determine statistical significance and/or precision estimates?	Y	
Were the methods (including statistical methods) sufficiently described to enable them to be repeated?	Y	
Were the basic data adequately described?	N	
Were the results presented for all the analysis described in the methods?	Y	
Were the limitations of the study discussed?	N	
Covariates	-	

Tilvis et al. (2004)

	Yes/No/Don't know (Y/N/DK)	Comments
Study Design Quality		
Was the study design appropriate for the stated aims?	Y	
Was the sample size justified?	N	
Was the sample frame taken from an appropriate population base so that it closely represented the target/reference population under investigation?	Y	
Were the risk factor and outcome variables measured appropriate to the aims of the study?	Y	
Were the authors' discussions and conclusions justified by the results?	Y	
Were there any funding sources or conflicts of interest that may affect the authors' interpretation of the results?	N	
Was ethical approval or consent of participants attained?	Y	
Risk of Biases		
Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?	Y	
Were measures undertaken to address and categorise non-responders	N	
Were the risk factor and outcome variables measured correctly using instruments/measurements that had been trialled, piloted or published previously?	Y	
Does the response rate raise concerns about non-response bias?	Y	Attrition at 10 year follow up
If appropriate, was information about non-responders described?	N	
Were the results internally consistent?	Y	
Quality of Reporting		
Were the aims/objectives of the study clear?	Y	
Was the target/reference population clearly defined?	Y	
Is it clear what was used to determine statistical significance and/or precision estimates?	Y	
Were the methods (including statistical methods) sufficiently described to enable them to be repeated?	Y	
Were the basic data adequately described?	Y	
Were the results presented for all the analysis described in the methods?	Y	
Were the limitations of the study discussed?	N	
Covariates	-	

Tzang et al. (2015)

	Yes/No/Don't know (Y/N/DK)	Comments
Study Design Quality		
Was the study design appropriate for the stated aims?	Y	
Was the sample size justified?	N	
Was the sample frame taken from an appropriate population base so that it closely represented the target/reference population under investigation?	N	Veteran housing
Were the risk factor and outcome variables measured appropriate to the aims of the study?	Y	
Were the authors' discussions and conclusions justified by the results?	Y	
Were there any funding sources or conflicts of interest that may affect the authors' interpretation of the results?	N	
Was ethical approval or consent of participants attained?	Y	
Risk of Biases		
Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?	N	
Were measures undertaken to address and categorise non-responders	N	
Were the risk factor and outcome variables measured correctly using instruments/measurements that had been trialled, piloted or published previously?	Y	
Does the response rate raise concerns about non-response bias?	N	
If appropriate, was information about non-responders described?	N	
Were the results internally consistent?	Y	
Quality of Reporting		
Were the aims/objectives of the study clear?	Y	
Was the target/reference population clearly defined?	Y	
Is it clear what was used to determine statistical significance and/or precision estimates?	Y	
Were the methods (including statistical methods) sufficiently described to enable them to be repeated?	Y	
Were the basic data adequately described?	Y	
Were the results presented for all the analysis described in the methods?	Y	
Were the limitations of the study discussed?	Y	
Covariates	Age, Education, Depression	

Zhong et al. (2017)

	Yes/No/Don't know (Y/N/DK)	Comments
Study Design Quality		
Was the study design appropriate for the stated aims?	Y	
Was the sample size justified?	N	
Was the sample frame taken from an appropriate population base so that it closely represented the target/reference population under investigation?	Y	
Were the risk factor and outcome variables measured appropriate to the aims of the study?	Y	
Were the authors' discussions and conclusions justified by the results?	Y	
Were there any funding sources or conflicts of interest that may affect the authors' interpretation of the results?	Y	One author is also director of funding institution
Was ethical approval or consent of participants attained?	DK	Not mentioned
Risk of Biases		
Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?	Y	
Were measures undertaken to address and categorise non-responders	N	
Were the risk factor and outcome variables measured correctly using instruments/measurements that had been trialled, piloted or published previously?	N	
Does the response rate raise concerns about non-response bias?	Y	Attrition at follow up
If appropriate, was information about non-responders described?	N	
Were the results internally consistent?	Y	
Quality of Reporting		
Were the aims/objectives of the study clear?	Y	
Was the target/reference population clearly defined?	Y	
Is it clear what was used to determine statistical significance and/or precision estimates?	Y	
Were the methods (including statistical methods) sufficiently described to enable them to be repeated?	Y	
Were the basic data adequately described?	Y	
Were the results presented for all the analysis described in the methods?	Y	
Were the limitations of the study discussed?	Y	
Covariates	Number of Chronic Conditions, Age, Gender, Education, Socioeconomic status, Physical Exercise, Smoking, Social Activity, Social Isolation	

Wilson et al. (2007)

	Yes/No/Don't know (Y/N/DK)	Comments
Study Design Quality		
Was the study design appropriate for the stated aims?	Y	
Was the sample size justified?	N	
Was the sample frame taken from an appropriate population base so that it closely represented the target/reference population under investigation?	Y	
Were the risk factor and outcome variables measured appropriate to the aims of the study?	Y	
Were the authors' discussions and conclusions justified by the results?	Y	
Were there any funding sources or conflicts of interest that may affect the authors' interpretation of the results?	N	
Was ethical approval or consent of participants attained?	Y	
Risk of Biases		
Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?	Y	
Were measures undertaken to address and categorise non-responders	N	
Were the risk factor and outcome variables measured correctly using instruments/measurements that had been trialled, piloted or published previously?	Y	Modified verision of de Jong Gierveld Loneliness Scale – Cronbach coefficient α was .78, comparable to original scale
Does the response rate raise concerns about non-response bias?	N	
If appropriate, was information about non-responders described?	N	
Were the results internally consistent?	Y	
Quality of Reporting		
Were the aims/objectives of the study clear?	Y	
Was the target/reference population clearly defined?	Y	
Is it clear what was used to determine statistical significance and/or precision estimates?	Y	
Were the methods (including statistical methods) sufficiently described to enable them to be repeated?	Y	
Were the basic data adequately described?	Y	
Were the results presented for all the analysis described in the methods?	Y	
Were the limitations of the study discussed?	Y	
Covariates	Age, Sex, Education, Depressive Symptoms, Social Network Size, Social Activity Frequency, Cognitive Activity, Physical Activity, , Race/Ethinicity, Income level, Disability, Vascular Risk Factors and Conditions	

Appendix 1.3. Psychometric tools used to assess loneliness

Psychometric Tool, Author	Description and Scoring	Psychometric Properties	Studies Utilising Measure within Systematic Review
De-Jong Gierveld Scale for Loneliness (De Jong Gierveld & Van Tilburg, 2006)	Six-item, Likert style questionnaire that includes three negatively worded items and three positively worded items. Negatively worded items are reverse scored and sum of the scores ranges from 0-24 with higher scores indicating greater levels of loneliness	Cronbach's $\propto$ ranging from 0.70-0.76 (De Jong Gierveld & Van Tilburg, 2006), 0.78 (Wilson et al., 2007), and 0.79 (Tijhuis et al., 1999).	Tijhuis et al. (1999) Wilson et al.. (2007) used a modified version of the scale
University of California, Los Angeles (UCLA) Loneliness Scale (version 3) (Russell, 1996),	20 items with a 4 point Likert scale (ranging from 'never' to 'often') to assess how often individuals felt the way described in the loneliness items	The measure has high internal consistency (coefficient alpha ranging from .89-.94 (Russell, 1996), but it was not reported by Tzang et al. (2015)	Tzang et al. (2015)

Appendix 2.1. NHS Research Ethics Committee Approval

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

Professor Jonathan Evans
Professor of Applied Neuropsychology, IHW,
University of Glasgow
Mental Health & Wellbeing,
Gartnavel Royal Hospital,
Glasgow
G12 0XH

West of Scotland REC 3
West of Scotland Research Ethics Service
West Glasgow Ambulatory Care Hospital
(former Royal Hospital for Sick Children Yorkhill)
Dalnair Street
Glasgow G3 8SJ
www.nhsggc.org.uk

Date 13th September 2017
Your Ref
Our Ref
Direct line 0141 232 1805
E-mail WOSREC3@ggc.scot.nhs.uk

Dear Professor Evans

Study title: **An explorative study of the "active ingredients" that lead to positive outcomes following Cognitive Stimulation Therapy in dementia care**
REC reference: **17/WS/0188**
IRAS project ID: **227237**

Thank you for your responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a Sub-Committee of the REC held between 1st and 15th September 2017. A list of the Sub-Committee members is attached.

The Sub-Committee agreed that you had addressed all of the issues outlined in the Provisional Opinion letter.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

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.

Conditions of the favourable opinion

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

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

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk 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 management permissions 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).

Ethical review of research sites

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

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering letter on headed paper [Response to REC Provisional Opinion Letter]	1	04 September 2017
GP/consultant information sheets or letters [Letter to GP]	1	26 July 2017
Letters of invitation to participant [Invitation letter for Participants]	1	06 June 2017
Non-validated questionnaire [Group fit item]	1	24 July 2017
Non-validated questionnaire [General Self-Efficacy Scale]	1	24 July 2017
Non-validated questionnaire [Three Item Loneliness Scale]	1	24 July 2017
Participant consent form [Consent Form]	2	04 September 2017
Participant information sheet (PIS) [Participant Information Sheet]	2	04 September 2017
REC Application Form [REC_Form_04082017]		04 August 2017
Research protocol or project proposal [MRP Proposal Version4]	4	01 June 2017
Summary CV for Chief Investigator (CI) [Jon Evans CV]	1	01 August 2017
Summary CV for student [CV Template]	1	24 July 2017
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Plain English Summary of Proposal]	2	01 June 2017
Validated questionnaire [ADAS-Cog]	1	01 August 2017

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 HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

17/WS/0188	**Please quote this number on all correspondence**

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

Yours sincerely

Liz Jamieson
REC Manager
On behalf of Dr Adam Burnel, Chair

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers"

Copy to: Ms Emma-Jane Gault, University of Glasgow
Ms Sophie Bagnall, R&D - NHS Greater Glasgow and Clyde

West of Scotland REC 3

Sub-Committee of the REC meeting held in correspondence between 1 and 15 September 2017

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Adam Burnel	Consultant Psychiatrist - Chair	Yes	
Dr Anne-Louise Cunnington	Consultant Geriatrician and Alternate Vice Chair	Yes	
Mrs Lorna Hammond	Senior Clinical Pharmacist	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Liz Jamieson	REC Manager

Appendix 2.2. NHSGG&C Research and Development Approval

Administrator: Sophie Bagnall
Telephone Number: 0141 232 1826
E-Mail: sophie.bagnall@ggc.scot.nhs.uk
Website: www.nhsggc.org.uk/r&d

R&D Management Office
West Glasgow ACH
Dalnair Street
Glasgow G3 8SW

16 October 2017

Ms Ashley Gibson
Trainee Clinical Psychologist
Gartnavel Royal Hospital
Mental Health and Wellbeing
1055 Great Western Road
Glasgow
G12 0XH

NHS GG&C Board Approval

Dear Ms Gibson

Study Title:	**An explorative study of the "active ingredients" that lead to positive outcomes following Cognitive Stimulation Therapy in dementia care**
Principal Investigator:	**Ms Ashley Gibson**
GG&C HB site	**Inverclyde Royal Hospital Argyll Centre, Belmont Centre Stobhill Hospital, Parkview Resource Centre, Woodlands Resource Centre, Shawmill Resource Centre, Elderpark Resource Centre**
Sponsor	**NHS Greater Glasgow & Clyde**
R&D reference:	**GN17MH460**
REC reference:	**17/WS/0188**
Protocol no:	**V4.0 01/06/2017**

I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant **Approval** for the above study.

Conditions of Approval

1. **For Clinical Trials** as defined by the Medicines for Human Use Clinical Trial Regulations, 2004

    a. During the life span of the study GGHB requires the following information relating to this site
        i. Notification of any potential serious breaches.
        ii. Notification of any regulatory inspections.

It is your responsibility to ensure that all staff involved in the study at this site have the appropriate GCP training according to the GGHB GCP policy (www.nhsggc.org.uk/content/default.asp?page=s1411), evidence of such training to be filed in the site file

2. **For all studies** the following information is required during their lifespan.
   a. Recruitment Numbers on a monthly basis
   b. Any change of staff named on the original SSI form
   c. Any amendments – Substantial or Non Substantial
   d. Notification of Trial/study end including final recruitment figures
   e. Final Report & Copies of Publications/Abstracts

Please add this approval to your study file as this letter may be subject to audit and monitoring.

Your personal information will be held on a secure national web-based NHS database.

I wish you every success with this research study

Yours sincerely,

Sophie Bagnall
Senior Research Administrator

Appendix 2.3. Major Research Project Proposal

Major Research Proposal

An explorative study of the "active ingredients" that lead to positive outcomes following Cognitive Stimulation Therapy in dementia care

Matriculation Number: 2002274g

Date of Submission: 19/02/2018

Version Number: 5

Word Count: 3301

Abstract

The efficacy and effectiveness of Cognitive Stimulation Therapy in improving cognition and quality of life (QoL) in individuals with dementia has been well demonstrated (e.g. Spector Thorgrimsen, Woods et al., 2003). However, less is known about the mechanisms of change for these outcomes. This study aims to pay attention to mechanisms of change for CST, such as social connectedness and self-efficacy. A within group repeated measure study will be adopted. Participants will include older adults with mild-moderate dementia participating in CST groups being carried out within Older People Community Mental Health Teams across Greater Glasgow and Clyde. A total of 47 participants will be asked to complete assessment measures relating to social connectedness and self-efficacy prior to, during, and following CST intervention. Dependant T-tests will be used to explore whether there is a significant difference in outcome scores pre-post intervention. A correlation analysis will be used to examine the relationship between improvements in cognition and QoL scores and improvements in social connectedness and self-efficacy scores. This research could be used to help better match patients to CST intervention, and help to develop further therapeutic approaches for use with patients with dementia.

Introduction

The age profile of Scotland's population is changing rapidly and, as populations age, it is expected that the global burden of dementia will continue to escalate. Currently, there are around 800,000 people with dementia in the UK. By 2040, the number of people with the condition is expected to double (House of Commons Library, 2016). As such, the need for effective and accessible treatments for dementia is paramount.

Cognitive Stimulation Therapy

Cognitive stimulation therapy (CST) is a brief, evidence-based, psychosocial group intervention, which aims to optimise cognitive function for persons with mild to moderate dementia. CST focuses on fostering individual strengths through themed sessions that incorporate therapeutic techniques such as reality orientation or reminiscence. Reality orientation is intended to facilitate memory through the presentation and repetition of information, that serves as factual reminders about the self or the environment (Douglas, James & Ballard, 2004). Reminiscence therapy involves discussion of past activities, events or experiences often using concrete prompts (Spector, Davies, Woods et al., 2000).

Evidence shows CST enhances cognition and improves quality of life (QoL) of those with a dementia (Knapp, Thorgrimsen, Patel et al., 2006; Spector, Thorgrimsen, Woods et al., 2003). It is currently the only nonpharmacological intervention recommended to improve cognition for those with mild to moderate dementia (Nice, 2007). Whilst studies have evidenced the efficacy and effectiveness of CST, less attention has been paid to mechanisms of change.

Spector, Gardner & Orrell (2011) carried out a qualitative study of experiences of the people attending CST groups, carers and group facilitators. Themes from patients, carers and group facilitators indicate positive experience when commenting on the experience of patients in groups and changes in everyday life. In a recent RCT investigating individualised CST being delivered via patient family/carer dyads, results revealed this to be less effective, with no significant differences found for cognition or QoL (Orgeta, Leung, Kang et al., 2015). This suggests that the socially orientated group context of traditional CST may, in part, contribute to positive outcomes.

Social Connectedness

Studies investigating social contexts and their association with mental health and well-being among older adults (OA) have shown that greater social network integration is protective against mental ill health (e.g. Chan, Malhotra, Malhotra et al, 2011; Chao, 2011; Fiori, Antonucci, & Cortina, 2006).

Older adults are particularly likely to experience age-related losses that affect their social relationships. Within those relationships that remain, individuals with dementia may have additional challenges making meaningful social connections due to increased difficulties with communication. Indeed, social connectedness has been shown to be affected during the early stages of dementia (Hatch, 2013).

Self-Efficacy

Self-efficacy refers to a person's belief in his or her ability to succeed in a specific situation or accomplish a specific task (Bandura, 1977). Higher general self-efficacy has been related to better QoL in patients with acquired brain injury (ABI) (Brands, Kohler, Stapert et al., 2014) as well as chronic conditions, such as chronic obstructive pulmonary disease (COPD) (Bentsen, Wentzel-Larsen, Henriksen et al., 2010). Symptoms of dementia lead to significant disruptions in social and occupational participation (American Psychiatric Association, 2013) and patients experience a tremendous loss of control in their lives.

As mentioned above, CST focuses on fostering individual strengths and is carried out in a socially orientated context. As such, it may be that changes in QoL and cognition following participation in CST groups are related (in part) to an increase in social connectedness and self-efficacy.

Aims and Hypothesis

This study aims to investigate whether there are changes in social connectedness and self-efficacy from pre-to post CST group, and whether changes in these variables are also related to changes in cognition and QoL.

Method

Design

A within group repeated measures design will be adopted.

Sample

Participants will include community-dwelling people with a diagnosis of mild to moderate dementia. Participants will be recruited by convenience sampling from those attending CST groups within Older People Community Mental Health Teams (OPCMHTs) within Greater Glasgow and Clyde.

Inclusion Criteria

Inclusion criteria will be as set out in the previous CST trial (Spector et al., 2003). This is also the current inclusion criteria for individuals attending clinical CST groups. These stipulated that participants (a) met the DSM-IV criteria for dementia (American Psychiatric Association, 1994), (b) scored between 10 and 24 on the Mini Mental State Examination (MMSE; Folstein, Folstein & McHugh, 1975), (c) had some ability to communicate and understand communication, (d) could see and hear well enough to participate in the group, (e) did not have a major physical illness or disability which compromised participation and (f) did not have a diagnosis of a learning disability. Both male and female participants will be included, aged 65 years and above.

Cognitive screens will be carried out using the Mini-Addenbrooke's Cognitive Examination (M-Ace; Hsieh, McGory, Leslie et al., 2014), as this is currently being routinely used within OPCMHTs due to a change in licensing laws for the MMSE. The M-ACE is scored out of 30 with two cut-offs recommended: (1) 25/30 and (2) 21/30. First, the higher cut-off of 25/30 has both high sensitivity and specificity and is at least 5 times more likely to have come from a patient with dementia than without. A lower cut-off of 21/30, by contrast, is almost certainly diagnostic of a dementia syndrome regardless of the prevalence rate.

Rather than using cut off scores as part of inclusion criteria, these will be used as guides and adequate performance on mini-ACE will be judged by clinicians completing assessment.

Exclusion Criteria

People who lack the capacity to consent in research will be excluded.

Procedure

Eligible individuals will be provided with information on the study by CST facilitators. Those expressing an interest to take part will be asked to consent to contact details being passed onto the researcher who will provide further information on the study. Written consent will be obtained before the study begins. Participants will then be invited to complete assessment measures prior to, during, and following CST intervention; administered by the researcher and CST facilitators. CST involves 14 structured 45 minute group therapy sessions, conducted twice weekly over a period of seven weeks, within participants' local OPCMHT. Pre assessment measures will be administered prior to session three of CST groups, and post assessment measures within two weeks of CST groups completing.

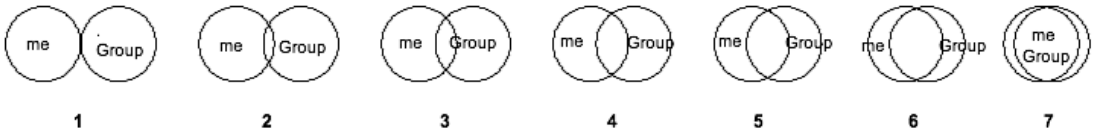
Outcome Measures

There is an absence of validated measures for people with dementia regarding social connectedness and self-efficacy. However, Mak (2011) has argued that we should not assume that scales which are not designed for people with dementia cannot be completed meaningfully by people with mild to moderate dementia. Moreover, the scales that have been selected for the current study are simple and feedback from a small number of individuals participating in a current CST group in Inverclyde who volunteered to review the scales was that the measures were easy to understand and use, indicating they can be completed in a meaningful way by this client group.

Social connectedness & Self-Efficacy

The primary outcome measures will include – a measure of 'group fit' (please see below). This measure has been used in previous research with older adults participating in a reminiscence group (Haslam, Haslam, Ysseldyk, et al., 2013), and will be used to assess participants' perceived fit with their CST groups at the end of sessions one, seven, and fourteen. This scale takes very little time to complete.

How well do you think you fit in with the group today? Choose the pair of circles below that best represents the fit between you and the group today.



A second primary outcome measure will be – The Three Item Loneliness Scale (Hughes, Waite, Hawkley et al., 2004). This scale (please see below) will be administered pre and post CST intervention, it can be completed in under five minutes.

Loneliness

The next set of statements describes how people sometimes feel. For each one, please indicate how often you feel the way described these days:

	Hardly Ever	Some of the Time	Often
How often do you feel left out?	○	○	○
How often do you feel isolated from others?	○	○	○
How often do you feel that you lack companionship?	○	○	○

A third primary outcome measure will be - The General Self-Efficacy scale (Shwarze & Jerusalem, 1995). This was created to assess a general sense of perceived self-efficacy with

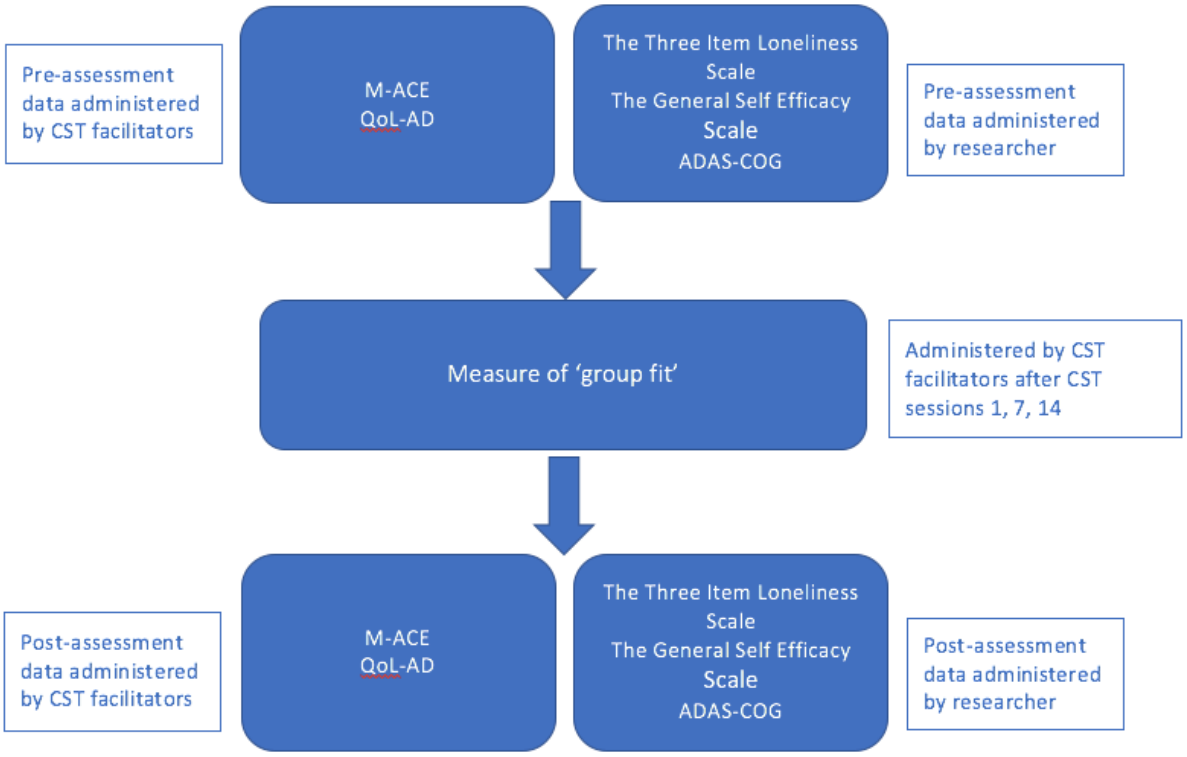
the aim of predicting coping with daily hassles as well as adaptation after experiencing stressful life events. It has been used with older people with dementia (Sprange, Mountain, Shortland et al, 2015). This will be administered pre and post CST intervention and takes 5-10 minutes to complete.

Cognition and QoL

Within Spector et al. (2003), significantly improved scores for the CST group were found on the following measures of cognition and QoL - the MMSE (p=0.044, 95% CI 0.57-2.27, d=0.37) the Alzheimer's Disease Assessment scales- Cognition scales (ADAS-COG; Rosen, Mohs, Davis et al., 1984) (p=0.014, 95% CI 0.64-4.09, d=0.37) and the QoL-Alzheimer's Disease scale (QoL-AD; Logsdon, Gibbons, McCurry et al., 1999) (p=0.028, 95% CI 0.09-3.18, d=0.39).

Currently, OPCMHTs running CST groups routinely assess the efficacy and effectiveness of CST using the M-Ace and QoL-AD; the researcher will ask for participants' consent to have access to these results. In addition, the researcher will administer the ADAS-COG pre and post CST intervention; this can take around 45 minutes to complete. These will be secondary outcome measures to help assess the efficacy and effectiveness of CST.

Table 1: Procedure for administration of outcome measures



Health and Safety Issues

Researcher

Most assessment sessions will be conducted within OPCMHTs, which have procedures in place to minimise risk to staff that are adequate for this study. Home visits will be offered to participants who may find it difficult to attend their local OPCMHT for assessment sessions. All participants will be known to the OPCMHT and risk assessments will be carried out for participants by clinicians who have had recent contact with them. The researcher will adhere to the Greater Glasgow and Clyde lone worker policy during home visits.

Participants

Assessment sessions will involve asking participants a range of questions which may cause distress. If this occurs, participants will be offered a break during the session and reminded their involvement in the study is voluntary and they can choose to discontinue at any time. Participants will also be given information on where they can seek further support should they wish (e.g. speak with their GP). The researcher will report any information given that highlights risk to the participant or another person to the clinical team.

Having cognitive function assessed could also be stressful for some participants, and there is the risk that being assessed will uncover a problem with a participant's cognitive function that they were not previously aware of. Making sure participants are fully informed and that pre-participation counselling is given should limit these risks to the participant.

Sample Size

There is no existing research literature regarding effect sizes for the primary outcome measures in similar studies. However, in their study, Spector et al. (2003) achieved small – medium effect sizes on measures of cognition (d=0.37) and QoL (d=0.39). Using G Power (Faul et al., 2007) a sample size of 47 would be required to detect an effect size of 0.37 using a within group t-test with a 0.05 (one-tailed) level of significance. As such, a sample size of 47 should have sufficient power to detect a change in outcome measure assessing QoL and cognition for the current study. A sample size of 47 would have sufficient power (0.8) to detect a correlation of 0.35, with alpha at 0.05.

Four OPCMHTs have provided data on the number of individuals typically completing CST in a 6 month period - this ranges from 68-100 depending upon uptake and drop out rates. This suggests a sample size of 47 is achievable in a six month period.

Data Handling

All raw data will be kept in secure locked filing cabinet on NHS GG&C site that only the researcher will have access to. All data will be anonymised with a code linking to identifiable data. Anonymised data will be transferred onto a password protected University computer and kept for up to 12 months; thereafter, it will be transferred to the University's Enlighten repository.

Analysis

A quantitative approach will be adopted. Descriptive statistics will be used to describe the demographic characteristics of the group. Dependant T-tests will be used to explore whether there is a significant difference in outcome scores pre-post intervention.

A correlation analysis will then be adopted to determine if there is a relationship between improvement on cognition and QoL (using change scores for the M-ACE, ADAS-Cog, QOL-AD) and change in social connectedness and self-efficacy scores.

Initial M-Ace scores will be used to determine if level of cognitive impairment moderates scores for the primary outcome measures.

In their reminiscence study, Haslam et al (2013) found that initial perceived group fit scores predicted outcomes. As such, this study may also explore scores at time point one for social connectedness and self-efficacy to assess impact upon outcomes.

Where data meets normal assumptions of distribution, parametric analysis methods will be used, otherwise non-parametric methods will be used.

Ethical Issues

Regarding informed consent – the demands of making a decision to participate in the CST intervention overlap with the demands of making a decision to participate in research. Once clinicians within OPCMHTs have deemed individuals eligible for CST and individuals have consented to this intervention, clinicians will then also identify those whom they deem as having capacity to consent to research and invite them to take part in the current study. The researcher will then provide additional information regarding the study for those expressing an interest to take part. Those identified as having capacity to consent and wishing to take part in the study will be required to complete a written consent form.

Those who lack the capacity to consent to research will be excluded. Ethical approval will be sought from the NHS West of Scotland research ethics committees.

Financial Issues

Anticipated costs will be photocopying costs for measures (£146.58) and travel expenses for the researcher (total expected to be no more than £200).

Table 2: Proposed Timetable

Date	Procedure
Ethical Approval	October 2017
Recruitment and Data Collection	October 2017-April 2018
Data Analysis and Write-up	May-July 2018

Applications

This study will contribute to the understanding of mechanisms for change with CST group interventions. This could help better match patients to CST intervention, and help to develop further therapeutic approaches for patients with dementia.

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Proposal Appendix A. Plain English Summary

An explorative study of the "active ingredients" that lead to positive outcomes following Cognitive Stimulation Therapy in dementia care

Background

Cognitive stimulation therapy (CST) is an evidence-based, psychosocial group intervention, which aims to optimise cognitive function for persons with mild to moderate dementia. Whilst CST has been shown to enhance cognitive function and quality of life (QoL) of those with a dementia (Spector, Thorgrimsen, Woods et al., 2003), less is known about the "active ingredients" of CST that lead to such positive outcomes.

CST focuses on fostering individual strengths and is carried out in a social group environment. As such, it may be that changes in QoL and cognition following participation in CST groups are related (in part) to an increase in social connectedness and self-efficacy; these are discussed further below.

Social Connectedness

Several studies investigating social contexts and their association with mental health and well-being among older adults have shown that greater social network integration is protective against mental ill health (e.g. Chan et al., 2011).

Older adults are especially likely to experience age-related losses that affect their social relationships. Individuals with dementia may have additional challenges making meaningful social connections due to increased difficulties with communication.

Self-Efficacy

One's sense of self-efficacy (a person's belief in their ability to succeed in a specific situation) can play a major role in how one approaches goals, tasks, and situations. Those with dementia experience a decline in independence and a significant loss of control in their lives, likely impacting upon their self-efficacy.

Aims

This study aims to explore if social connectedness and self-efficacy improve for individuals following CST intervention. It also aims to investigate if improvements in social connectedness and self-efficacy are linked to positive outcomes found in cognition and QoL following participation in CST.

Methods

Participants will include older adults with a diagnosis of mild to moderate dementia who will be attending CST groups within Older People Community Mental Health Teams (OPCMHTs) across Greater Glasgow and Clyde. Participants will be provided with information on the study by CST group organisers, and will be required to sign a consent form to take part. Participants will be invited to complete assessment measures assessing

cognition, QoL, social connectedness and self-efficacy prior to, during, and following completion of the CST group.

Applications

This study will contribute to the understanding of the "active ingredients" that lead to positive outcomes found with CST interventions. This could help to better match patients to CST, and help develop further therapeutic approaches for patients with dementia.

References

Chan, A., Malhotra, C. Malhotra, R., & Ostbye, T. (2011). Living arrangements, social networks and depressive symptoms among older men and women in Singapore. *International Journal of Geriatric Psychiatry*, 26(6), 630-639.

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Word count: 487

Proposal Appendix B. Health and Safety form

WEST OF SCOTLAND/ UNIVERSITY OF GLASGOW

DOCTORATE IN CLINICAL PSYCHOLOGY

HEALTH AND SAFETY FOR RESEARCHERS

1. Title of Project	An explorative study of the "active ingredients" that lead to positive outcomes following Cognitive Stimulation Therapy in dementia care.
2. Trainee	Ashley Gibson
3. University Supervisor	Professor Jon Evans
4. Other Supervisor(s)	Dr Stephanie Crawford
5. Local Lead Clinician	Dr Stephanie Crawford
6. Participants: (age, group or sub-group, pre- or post-treatment, etc)	Participants will include community-dwelling older people (65 + years) with a diagnosis of mild to moderate dementia participating in CST groups. Participants will be recruited by convenience sampling from individuals identified as suitable to attend CST groups within Older People Community Mental Health Teams (OPCMHTs) across Greater Glasgow and Clyde. This will be a within repeated measures subjects design.
7. Procedures to be applied (eg, questionnaire, interview, etc)	Participants will be invited to complete psychometric assessment measures prior to, during, and following CST intervention; these will be administered by CST facilitators and the researcher. Pre and post measures will be administered within two weeks prior to and two weeks following CST.

	Measures include: Mini-Addenbrooke's Cognitive Examination (mini-Ace; Hsieh, McGory, Leslie et al., 2014), the Alzheimer's Disease Assessment scales- Cognition scales (ADAS-COG; Rosen et al., 1984), the quality of life-Alzheimer's Disease scale (QoL-AD; Logsdon et al., 1999), a 'group fit' measure to measure perceived social connectedness to CST group, The Three Item Loneliness Scale (Hughes, Waite, Hawkley et al., 2004) and The General Self-Efficacy scale (Shwarze & Jerusalem, 1995).
8. Setting (where will procedures be carried out?) i) Details of all settings	It is intended that most assessment sessions for this study will be conducted within OPCMHTs within Greater Glasgow and Clyde that participants will be attending as part of their CST group intervention. Home visits will be offered to participants who may find it difficult to attend their local OPCMHT for assessment sessions.
ii) Are home visits involved	Y (potentially)

WEST OF SCOTLAND/ UNIVERSITY OF GLASGOW

DOCTORATE IN CLINICAL PSYCHOLOGY

HEALTH AND SAFETY FOR RESEARCHERS

9. Potential Risk Factors Considered (for researcher and participant safety): i) Participants ii) Procedures iii) Settings	Participants: The participants attending CST groups are a vulnerable client group with a diagnosis of mild to moderate dementia which raise issues regarding informed consent. Those participating in the study will have already been assessed as suitable (by assessing clinician within OPCMHT) for attending CST group. Those thought to have dangerous or unpredictable behavior, which may impact upon others within group (including attendees

	and facilitators), would not be deemed suitable to attend CST and would therefore also be excluded from this study. Procedures: The assessment sessions will involve asking participants a range of questions which may cause distress. Settings: The majority of pre and post assessment sessions will likely be carried out within OPCMHTs that participants are already attending for CST intervention. However, home visits will be offered to those participants unable to attend their local OPCMHT for pre and post assessment sessions. This does raise potential risk for the researcher – this will be addressed below. There is also the issue if participants becoming distressed either in OPCMHT or at home during assessment sessions – this is also addressed below in section 10.
10. . 10. Actions to minimise risk (refer to 9) i) Participants ii) Procedures iii) Settings	Participants: Those who lack the capacity to consent to research will be excluded from the study. Participants will be known to their local OPCMHT and will initially be assessed by clinician from OPCMHT as being suitable for attending CST group and those deemed as having dangerous or unpredictable behavior would be excluded from CST - and consequently this study. When completing assessment sessions with participants, GG&C OPMHTs have procedures in place to minimise risk to staff and these are thought to be adequate for the proposed study for the researcher. Procedures: If the procedures of the current study result in any distress for participants, they will be offered a break during the session and reminded their involvement in the study is voluntary and they can choose to discontinue at any time. Participants will also be given information on where they can seek further support should they wish (e.g. speak with their

	GP). The researcher will report any information given that highlights risk to the participant or another person to the clinical team. Settings: GG&C OPMHTs have procedures in place to minimise risk to staff and these are thought to be adequate for the proposed study for the researcher. Also, all participants will be known to the OPCMHT and as such risk assessments will be carried out by the clinical team prior to the researcher becoming involved with participants. If home visits are required, a risk assessment will be completed by a member of the clinical team who has had recent contact with the participant(s) and the researcher will familiarise themselves with any risk assessments. Any risks will be discussed with a member of the clinical team. The researcher will adhere to the Greater Glasgow and Clyde lone worker policy during any home visits and these will be conducted within working hours. If any immediate concerns arise during any home visits the researcher can contact a member of the clinical team over the telephone.

Trainee signature: .....Date: .....

University supervisor signature:..... Date: .....

Proposal Appendix C. Equipment and Expenses Form

RESEARCH EQUIPMENT, CONSUMABLES AND EXPENSES

Trainee ……Ashley Gibson…….

Year of Course ……2……. **Intake Year**…2015……..

Please refer to latest stationary costs list (available from student support team)

Item	Details and Amount Required	Cost or Specify if to Request to Borrow from Department
Stationary	Envelopes (A5) X 1 box (£8.52) Labels x 1 box (£3.17)	Subtotal: £11.69
Postage	Free post costs x 47 (£29.14)	Subtotal: £29.14
Photocopying and Laser Printing	Print black and white copies at 5p each sheet Participant invite sheet (1 page) x 47 (£2.35) Participant information sheet (4 page) x 47 copies (£9.40) Participant Consent form (1 page) x 94 copies (£4.70) Perceived 'group fit' scale (1 page) x141 copies (£7.05) QoL Alzheimer's disease scale (1 page) x 94 copies (£4.70) The Three Item Loneliness Scale (1 page) x94 copies (£4.70) Generalised Self Efficacy scale (1 page) x 94 (£4.70) Mini-Addenbrooke's Cognitive Examination (2 pages) x 94 copies (£9.40) Alzheimer's Disease Assessment Scale – Cognition (12 pages) x 94 (£56.40)	Subtotal: £105.75
Equipment and Software	N/A	

		Subtotal:
Measures	Only photocopying costs required as measures freely accessible (see above)	Subtotal:
Miscellaneous		Subtotal:
Total		£146.58

For any request over £200 please provide further justification for all items that contribute to a high total cost estimate. Please also provide justification if costing for an honorarium:

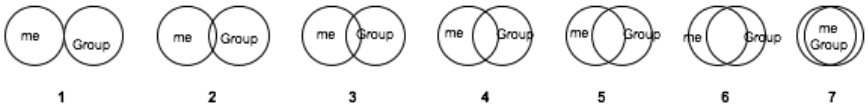
Trainee Signature…… … Date……

Supervisor's Signature …….. Date ……

Appendix 2.4. Group Fit Measure

An explorative study of the "active ingredients" that lead to positive outcomes following Cognitive Stimulation Therapy in dementia care
Version1: 24//7/17

How well do you think you fit in with the group today? Choose the pair of circles below that best represents the fit between you and the group today.



Participant ID: _____ Date of Completion: _____ CST Session: _____