# The Development of Virtual Cognitive Stimulation Therapy (vCST): Evaluation of Quality of Life and Mood Outcomes in a Feasibility Study

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**Thesis declaration form**

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

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## Overview

This three-part thesis explores the impact of Cognitive Stimulation Therapy (CST) on people with mild-to-moderate dementia. The empirical study specifically investigates the preliminary effects of CST when adapted for virtual administration, virtual CST (vCST), particularly on depressive mood and quality of life outcomes.

**Part 1: Literature Review**

The conceptual introduction is a systematic, Numbers Needed to Treat review. It reviews the current evidence for the effectiveness of CST and pharmacological interventions in terms of improving cognitive outcomes of people with mild-to-moderate dementia. The review provides a picture of the benefits of CST as an established intervention, establishing a rationale for the empirical paper.

**Part 2: Empirical Paper**

The empirical paper evaluates a recently developed vCST protocol as part of a feasibility study. It examines the preliminary effects of vCST on quality of life and depressive mood for people with mild-to-moderate dementia. This was a part of a larger joint project on the development and feasibility of vCST, where several researchers were involved. The contributions of these researchers are summarised in Appendix A.

**Part 3: Critical Appraisal**

The critical appraisal reflects on the research process, including the recruitment, data collection, study design, and data analysis processes.

## Impact Statement

The current study was part of a larger project on the development and feasibility of virtual Cognitive Stimulation Therapy (vCST). The quantitative feasibility study employed a randomised, controlled design to investigate if vCST is effective for improving quality of life (QoL) and depressive mood in people with mild-to-moderate dementia. QoL and depressive mood outcomes were compared between a treatment (vCST) and treatment-as-usual control group across time. The results indicated that there were no significant benefits of vCST on QoL and depressive mood. This suggests a need for further research in this area.

Future studies taking into account limitations of the current study and using a larger sample would be useful. For example, future studies can consider examining additional or alternative outcomes, such as level of engagement with the intervention or loneliness. More qualitative research (e.g. interviews with people with dementia and their carers) could also help to identify relevant constructs to examine with respect to vCST, as well as the less and more effective themes and aspects of vCST. This could then inform potential development and modifications to the vCST protocol. Other future directions include examining the effectiveness of vCST for different ages of onset or dementia subtypes.

Continued research on vCST, taking into account the above, can contribute to the evidence base and inform continued development of national guidelines for interventions for people with dementia. This is especially relevant as CST administered virtually has the potential to increase the accessibility of interventions to people with dementia.

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# Part 1: Literature Review

## Cognitive Stimulation Therapy and Acetylcholinesterase Inhibitors in Improving Cognitive Outcomes for People with Mild-to-moderate Dementia – A Numbers Needed to Treat Analysis

## Abstract

**Objective:** To provide an up-to-date report on a Numbers Needed to Treat (NNT) analysis of the literature through a systematic review, examining the effects of Cognitive Stimulation Therapy (CST) and Acetylcholinesterase Inhibitors (AChEIs) on cognitive outcomes for people with mild-to-moderate dementia.

**Methods:** A literature search of PsycInfo, MEDLINE, EMBASE, and Web of Science was conducted (2001 to 2021). The search was limited to human trials. The search included randomised, controlled, and blinded studies examining the impact of CST (single-blind) and AChEIs (double-blind) on cognition for people with mild-to-moderate dementia. The main outcome measure was the Alzheimer's Disease Assessment Scale – Cognition. NNTs were calculated for each trial.

**Results:** Five CST trials and four AChEI trials were included. Small numbers of patients need to be treated with CST to achieve amelioration in cognitive outcomes (NNT: 2 – 6), with the exception of one CST trial that found non-significant improvements in cognition, and therefore a non-significant NNT of 250. NNTs for CST were comparable to donepezil (NNT: 5), galantamine administered over 24 weeks (NNT: 6 – 7), and rivastigmine (NNT: 8 – 13). Non-significant NNTs were found for smaller doses of rivastigmine (NNT: 12 and 13) and galantamine administered over 12 weeks (NNT: 16).

**Conclusion:** The small NNTs suggest that CST may be an effective treatment for improving cognition in people with mild-to-moderate dementia. CST seemed comparable to donepezil, galantamine and rivastigmine, and benefits of galantamine may be more apparent when administered over a longer period.

For rivastigmine and galantamine, larger doses could be associated with more benefits. However, these results should be considered within the limitations of the review, notably the small number of studies included that limits the conclusions that can be drawn. Further research (e.g. conducting a meta-analysis) could be useful.

**Keywords:** dementia, Cognitive Stimulation Therapy, acetylcholinesterase inhibitor, Numbers Needed to Treat, cognitive functioning

# Introduction

## Dementia

Dementia is a syndrome where there is a deterioration of cognitive functioning, more than typically expected due to ageing. This may refer to the deterioration of memory, language, and other domains impacting the ability to perform everyday activities (World Health Organization, 1993; 2021). Of the different types of dementia, Alzheimer's disease (AD) is the most prevalent, possibly contributing to around 60 – 70% of cases (World Health Organization, 2021). Vascular dementia, dementia with Lewy bodies, and diseases that contribute to frontotemporal dementia are less common, as with dementias developing due to other reasons e.g. infections, physical injury, stroke, or substances.

Dementia is one of the main causes of disability later in life (World Health Organization, 2021). For example, difficulty sustaining conversation due to difficulties in language comprehension and self-expression can negatively affect interpersonal relationships, leading to social well-being being impacted, and a sense of isolation and exclusion for people with dementia (Ablitt et al., 2009). Communication difficulties can also affect the ability of a person with dementia to get their needs met, and this may contribute to psychological distress and behavioural challenges (Downs & Collins, 2015).

On a wider level, the World Health Organisation (2017), estimate that there were 47 million people worldwide living with dementia in 2015, and it is projected there will be 132 million people with dementia by the year 2050. In the UK alone, there are currently around 900,000 people with dementia, with this number projected to increase to 1.6 million by 2040. Healthcare costs in

the UK are significant, with the total cost of care being an estimated 34.7 billion pounds, and the cost of social care amounting to 15.7 billion. These are set to increase significantly in the next 20 years (Alzheimer's Society, 2022).

## Biopsychosocial Model of Dementia

Dementia is often understood within a biopsychosocial model, which posits that individual biological and psychosocial factors influence the progression and experience of dementia (Spector & Orrell, 2010). The model also postulates that biological and psychosocial factors may be tractable and amenable to change (e.g. mood and environment), or fixed and not amenable to change (e.g. age, life events) – and that these factors are inter-related. Thus, the model emphasises that identifying, understanding, and addressing tractable biological and psychosocial factors are important for developing interventions and creating a sense of hope for change (Spector & Orrell, 2010). The biopsychosocial nature of disability in dementia therefore points to the value of continued research in both pharmacological and non-pharmacological interventions to support people with dementia. This is important given the negative impact dementia can have.

## Treatments for Dementia

Several treatment options exist for dementia, including pharmacological interventions and psychosocial therapies. The National Institute for Health and Care Excellence (NICE) guidelines recommend that people with mild-to-moderate dementia should be given the opportunity to attend a structured group cognitive stimulation programme provided by health and/or social care

staff with appropriate training (National Institute for Health and Care Excellence [NICE], 2018). Indeed, symptoms of distress in dementia may be improved by meeting the needs for social engagement and stimulation for persons with dementia (Cohen-Mansfield et al., 2015; Knapp et al., 2006), especially as boredom and lack of opportunity for active engagement are often a problem (Vikström et al., 2008). Cognitive Stimulation Therapy (CST) is an established, evidence-based intervention which focuses on improving cognitive resources and social skills in people with dementia (Spector et al., 2003). Research supports the benefits of CST for persons with dementia. For example, studies have shown that CST has the potential to improve the quality of life in people with dementia (Capotosto et al., 2017; Spector et al., 2003; Woods et al., 2006), as well as cognitive functioning (Alvares-Pereira et al., 2021; Capotosto et al., 2017; Carbone et al., 2021; Spector et al., 2003; Woods et al., 2006). Evidence additionally suggests that CST may prevent or delay dependence and one's inability to self-care (Apóstolo et al., 2014). A recent systematic review also highlighted the value of CST in improving cognitive functioning and quality of life for people with dementia (Lobbia et al., 2019), and a recent network meta-analysis suggested that cognitive stimulation and CST can improve depressive symptoms (Watt et al., 2021).

In terms of pharmacological interventions, the NICE guidelines (2018) recommend that acetylcholinesterase inhibitors (AChEI) donepezil, rivastigmine, and galantamine monotherapies are used or managing mild-to-moderate AD. For dementia with Lewy bodies, donepezil or rivastigmine is recommended for people with mild-to-moderate dementia, and galantamine is

recommended if the former medications are not tolerated. AChEIs are also recommended for mild-to-moderate Parkinson's disease dementia

There is some evidence for the effectiveness of pharmacological interventions for mild-to-moderate dementia. A recent network meta-analysis found that in patients with mild-to-moderate AD, monotherapy using AChEIs was superior to placebo in improving cognitive function and activities of daily living, while this was not the case for moderate to severe AD (Tsoi et al., 2019). Other meta-analyses provided some evidence for the benefits of donepezil (Birks & Harvey, 2006) and rivastigmine (Birks & Grimley Evans, 2015) over placebo on cognitive function, activities of daily living, and clinician's global assessment, for mild-to-moderate AD – although effects were small for rivastigmine. A more recent meta-analysis found that donepezil, galantamine, and rivastigmine were beneficial for cognitive functioning in mild-to-moderate to severe AD, although the efficacy on behavioural, functional, and global assessment of change symptoms is questionable (Li et al., 2019). Regarding dementia with Lewy bodies and Parkinson's disease dementia, one meta-analysis indicated beneficial effects of both donepezil and rivastigmine for cognitive and psychiatric symptoms in dementia with Lewy bodies (Stinton et al., 2015) and another review and meta-analysis suggested that cholinesterase inhibitors enhanced cognitive function in people with dementia with Lewy bodies, Parkinson's disease dementia, and cognitive impairment in Parkinson's disease (Wang et al., 2015).

**Numbers Needed to Treat**

While the literature points to evidence of the effectiveness of both CST and AChEIs on cognition in people with dementia, few studies and reviews have compared these two interventions in terms of their benefit on cognition. Furthermore, most clinical trials report differences between mean scores or change scores between treatment and control or placebo groups. These provide valuable information on the efficacy of interventions for dementia. However, it can also be difficult to use these statistics to measure meaningful clinical responses in individual patients. To that end, the measure of Numbers Needed to Treat (NNT) was introduced and has been used as a means to extrapolate data from randomised controlled trials (RCTs) and render it meaningful for clinical decision making, due to its advantages in conveying both statistical and clinical significance of information (Cook & Sackett, 1995). The NNT is a value that represents the number of patients who need to receive a certain treatment, compared to a control or placebo, for one patient to gain a particular benefit. It is based on relative risk, a statistic that is used to measure the relative benefit of a treatment over control or placebo (Cook & Sackett, 1995). A smaller NNT therefore suggests greater benefits of a particular intervention on a specific outcome, and the higher the effect of a treatment, the lower the NNT. This value may be more intuitively understandable to professionals and patients, and its quantitative nature may make it easier in decision-making when selecting interventions for a particular outcome (Saver & Lewis, 2019). Including a 95% confidence interval (CI) may provide further information on the uncertainty of the NNT. Having the NNT

available for different interventions for the same population and outcome of interest can be useful in informing practice (McQuay & Moore, 1997).

Various dementia trials have reported this statistic to investigate the positive effects of interventions for dementia (Alvares-Pereira et al., 2021; Seltzer et al., 2004, Spector et al., 2003, Winblad et al., 2007). Livingston & Katona (2000) conducted an NNT analysis to review the usefulness of AChEIs in the treatment of Alzheimer's disease across studies and found that larger dosages may have an impact on outcomes – particularly that larger dosages of medication in controlled drug trials resulted in smaller NNTs. This paper has been widely cited but has not been updated since 2000.

**Aims**

In light of the evidence for the benefits of both CST and AChEIs, as well as increasing interest and research on non-pharmacological interventions for dementia, this review aims to examine the current evidence of both CST and AChEIs in improving cognitive outcomes in people with mild-to-moderate dementia. The study aims to examine the NNT for both AChEIs and CST across trials with respect to achieving improved cognition. This could be useful in rendering RCT data meaningful and possibly has implications for informing treatment decisions.

## Methodology

### Inclusion Criteria

The following inclusion and exclusion criteria below were imposed based on current literature and the NICE guidelines, as detailed above:

- The study was randomised and controlled, with pre- and post-assessment measures administered.
- The Alzheimer's Disease Assessment Scale - Cognition (ADAS-Cog; Rosen et al., 1984) was used as an efficacy measure for cognition. The ADAS-Cog was chosen as the primary outcome measure of interest in this review as it is a widely used scale in studies of dementia and has satisfactory psychometric properties (Sheehan, 2012). It has also been validated in different settings (Nogueira et al., 2018; Paddick et al., 2017).
- Study participants had mild-to-moderate dementia of any type.

#### *Additional Criteria*

Given differences between research on pharmacological and psychosocial interventions, additional criteria for CST and AChEI trials were imposed:

*CST trials:*

- The study was single-blind.
- The treatment was in accordance with the original CST protocol (Spector et al., 2001; Spector et al., 2003).

*AChEI trials:*

- Crossover studies were excluded due to possible carryover effects.

- Participants who were responders to dementia drug treatment in a pre-randomisation open-label phase were excluded due to potential artificial elevation of NNTs in these studies.
- The drug treatment for the given dementia type was consistent with recommended NICE guidelines (2018).

**Search Strategy**

Four databases were included in the systematic search: EMBASE, MEDLINE, PsycInfo (Ovid) and Web of Science. The search for studies on AChEI trials and CST were conducted separately, with both searches limited to the years 2001 to 2021 and limited to human trials. The search was not limited to the English language (Moher et al., 1996). For drug trials, the following terms describing the target sample (dementia OR Alzheimer's*) were combined using the term "AND" with terms for the target treatment (donepezil OR rivastigmine OR galantamine OR cholinesterase inhibitor* OR acetylcholinesterase inhibitor*) and with terms describing the study design (randomised controlled trial* OR randomized controlled trial* OR controlled trial* OR RCT OR placebo control* OR placebo-control*). For CST trials, the following terms describing the target sample (dementia OR Alzheimer's*) were combined using the term "AND" with terms for the target treatment (Cognit* stimulat* OR Cognit* stimulat* therap* OR memory therap* OR memory intervent* OR CST) and with terms for study design (randomised controlled trial* OR randomized controlled trial* OR controlled trial* OR RCT OR placebo control* OR placebo-control*).

Titles and abstracts were first screened to identify articles meeting inclusion/exclusion criteria. Full-text articles were then assessed for eligibility. For studies that did not already include either an NNT statistic or efficacy measures required to calculate an NNT (i.e. the number of patients in each group and percentage of responders were not reported), the authors were contacted via e-mail to obtain this information.

## Evaluation of Papers

The methodological quality of the papers included in the study was rated using the Revised Cochrane risk-of-bias tool for randomised trials, a widely used tool for rating the methodological quality and risk of bias of RCTs (RoB 2; Sterne et al., 2019). The RoB 2 rates the risk of bias for studies across five domains: randomisation, deviations from intervention, missing outcomes, outcome measurement and selection of reported results. A rating of “low”, “some concerns” or “high” is given to each domain. The ratings are then examined to provide an overall bias score, rated similarly. The review examined the estimated effect of assignment to intervention. The rating was conducted by two independent researchers who came to a consensus on the article ratings.

## NNT Analysis

### *Calculation of NNT*

**NNT Statistics.** NNTs were calculated according to Cook & Sackett (1995). The absolute risk reduction (ARR) was first calculated, defined as the difference between the proportion of people in the treatment group who

experienced a specified adverse outcome and the proportion of people in the control or placebo group who experienced an adverse outcome (Cook & Sackett,1995). The NNT was derived by using the formula 1/ARR. 95% confidence intervals (CI) for the NNT were calculated with the aid of an online calculator that utilised equations provided by Daly (1998) and Altman (1998). NNTs and 95% CIs were reported as whole numbers. A positive NNT indicates that people in a treatment group have gained more benefits on a certain outcome than those in a control or placebo group, whereas a negative NNT indicates the opposite (Cook & Sackett, 1995). Smaller NNTs suggest a treatment is more effective.

**Reporting non-significant NNTs and CIs.** When the treatment effect is not statistically significant or close to zero ($p > .05$), a statistically non-significant NNT is derived, and the 95% CI for the NNT will include infinity. This can lead to a discontinuous CI with a negative and positive value limit that goes through infinity and pose problems for the interpretation of the CI (Altman,1998). Specifically, a non-significant NNT and corresponding CI that includes infinity imply that an infinite number of people would need to be treated with an intervention for one person to benefit (Altman, 1998; Citrome, 2011). In such cases, one way of presenting non-significant NNTs is to report the CI limit as a number needed to harm (NNTH), and the positive CI limit is reported as a number needed to benefit (NNTB), with the scale for the NNT ranging from NNTB = 1 to NNTH = 1 via infinity (Altman, 1998) e.g. “95% CI NNTH 24 to ∞ to NNTB 5”. The NNTH represents the number of patients who need to be treated for a patient to be harmed in the worst case. Conversely, the NNTB represents the number of patients who need to be treated to benefit

from the treatment in the best case. This method of reporting the results makes explicit that the treatment has a non-significant effect, and emphasises the continuity of the CI (Altman, 1998).

Thus, in the current review, when the 95% CI for the NNT extended from a negative number (NNTH) to a positive number (NNTB), indicating a non-significant NNT, the 95% CI was expressed in these terms.

***Specified Adverse Outcome***

Specified “adverse” and “desirable” outcomes for cognition may differ according to studies. However, an improvement of at least 4 points on the ADAS-Cog is most commonly defined as a desirable cognitive outcome in RCTs. This is because a 4-point difference has been considered clinically meaningful (Rockwood et al. 2007), and was recommended by the US Food and Drug Administration (Food and Drug Administration, 1989). For studies that did not include an NNT statistic, or efficacy measures required to calculate an NNT (i.e. studies for which the authors were contacted), a pre-defined desirable outcome would expectedly not be reported in the original paper. Thus, for these studies, an improvement of at least 4 points on the ADAS-Cog was defined as the desirable cognitive outcome, consistent with the criteria for cognitive improvement in RCTs for dementia, and consistent with what has been recommended and considered clinically meaningful change (Food and Drug Administration, 1989; Rockwood et al., 2007).

***Prioritisation of Intention-to-treat Analysis***

The current review prioritised the use of intention-to-treat analyses in the calculation and reporting of NNTs. This is because an intention-to-treat analysis is meant to provide unbiased comparisons between treatment groups;

RCTs conduct intention-to-treat analyses for this reason (McCoy, 2017). Thus, in trials reporting NNT statistics for more than one analysis (e.g. observed case and intention-to-treat), the intention-to-treat analysis was prioritised.

## Results

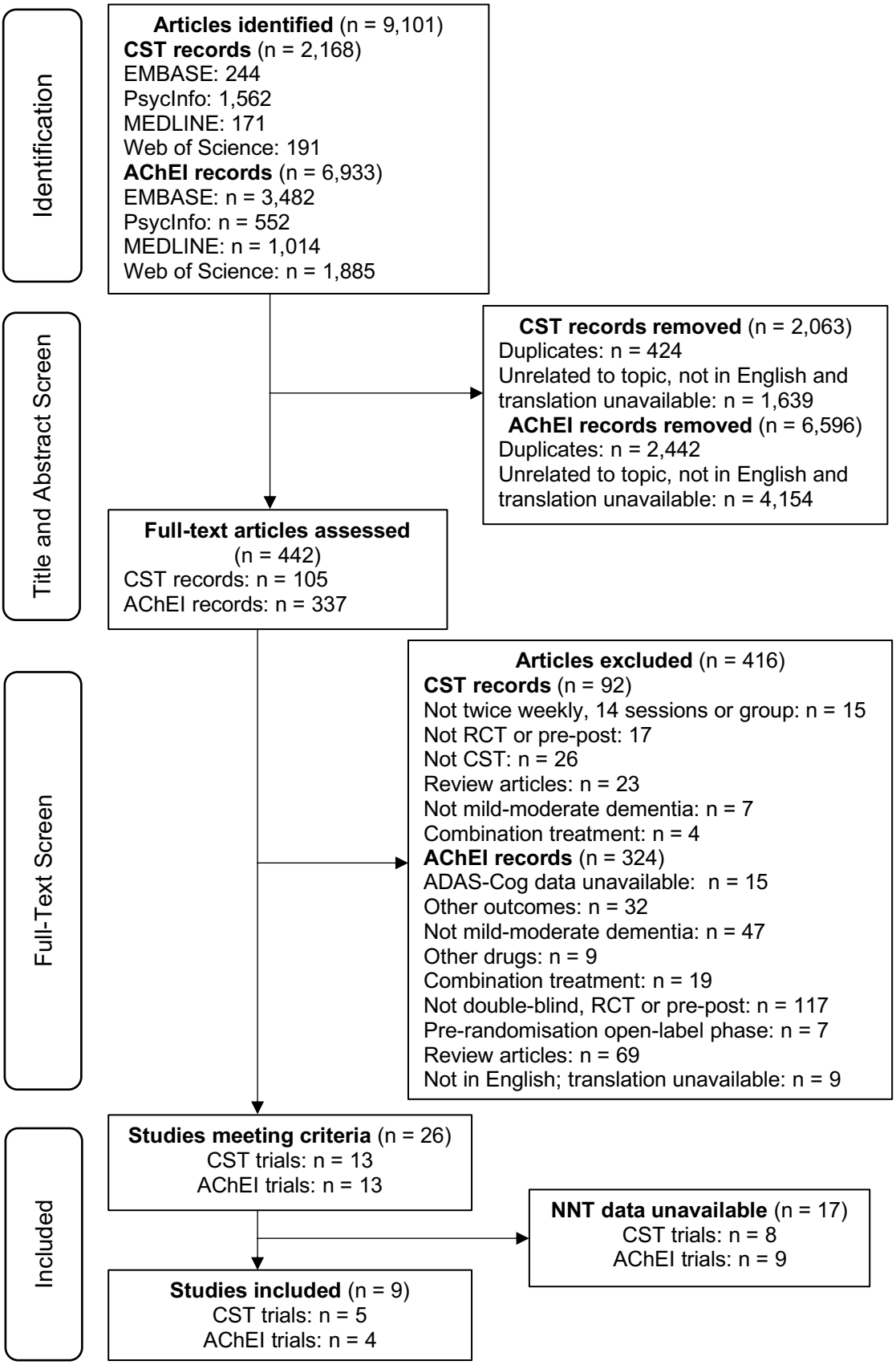
### Search Results

Figure 1 summarises the search and screening results for this review. A total of 9,101 records (2,168 for CST and 6,933 for AChEI trials) were initially identified. After a title and abstract screen, 8,659 records were removed (2,063 for CST and 6,596 for AChEI trials) because they were duplicates, unrelated to the topic of the review, or not in English. 442 records were included for a full-text screen (105 for CST and 337 for AChEI trials). A further 416 (92 for CST and 324 for AChEI trials) records were removed according to the inclusion and exclusion criteria. The search therefore yielded a total of 26 studies (13 for CST and 13 for AChEI trials), published from 2001 to 2021.

There were 17 studies (8 CST and 9 AChEI trials) that did not report an NNT analysis or provide the information required to calculate an NNT (i.e. proportions of participants who experienced an adverse outcome), and for which we were unable to obtain this information from the authors. Thus, a total of nine studies, five CST trials and four AChEI trials, were included in the current review.

**Figure 1**

*PRISMA diagram*



## Description of Studies

### *Design and Setting*

A description of each study is presented in Table 1. Four CST trials were single-blind randomised controlled trials (RCT). One trial (Paddick et al., 2017) was not an RCT, but employed a single-blind, stepped-wedge design, with participants in an immediate and delayed start group. This allowed for a comparison of outcomes as a single-blind cluster-randomised controlled trial (delayed CST group acting as control group). Each study implemented CST in a different country, including the UK, Brazil, Italy, sub-Saharan Africa and Portugal. Participants in the CST trials were people with dementia recruited from residential/care homes, day centres, rehabilitation centres and nursing homes, with the exception of one study (Paddick et al., 2017) where people with dementia were living at home in villages. Treatment groups in these studies consisted of participants who received 14 sessions of CST across seven weeks. Outcomes for the treatment groups were compared with a control group in each study, i.e. participants who did not, or have yet to, receive CST.

All four AChEI trials were double-blind, placebo-controlled RCTs. One study examined the efficacy of donepezil, one of rivastigmine, and two of galantamine. The AChEI trials were larger in scale compared to CST trials; in three studies (Rockwood et al., 2001, Wilcock, 2001; Winblad et al., 2007), participants, people with dementia, were recruited across multiple centres (hospitals, university research centres, neurology clinics, outpatient clinics) across different countries. In one study (Seltzer et al., 2004) people with dementia were recruited across multiple sites (research centres/clinics,

medical institutes, memory disorder centres) within one country (the United States). The treatment groups in these studies were participants receiving donepezil, rivastigmine, or galantamine. Placebo groups were participants who received a placebo that was similar in appearance to the administered drug. In each study, outcomes for the treatment groups were compared with the placebo group.

***Participants***

**CST inclusion criteria.** The inclusion criteria for participants were similar across CST studies as they were based on criteria set by Spector et al. (2003). Thus, all participants had a diagnosis of dementia of any subtype according to the Diagnostic and Statistical Manual of Mental Disorders 4$^{th}$ or 5$^{th}$ edition (DSM-IV or DSM-5) that fell in the mild-to-moderate range. Three studies (Alvares-Pereira et al., 2021; Marinho et al., 2021; Spector et al., 2003) further specified a mild-to-moderate range as a Mini-Mental State Examination (MMSE; Folstein et al., 1975) score between 10 and 24, and one study (Carbone et al., 2021) specified this as a score of ≥14. Exclusion criteria were similar across studies; participants were excluded if they did not have adequate ability to communicate or understand communication, physical, sensory, or intellectual disabilities that impact participation, or severe behavioural symptoms that may impact participation.

**AChEI inclusion criteria.** Compared to CST trials, the participants in the AChEI trials were limited to participants with mild-to-moderate AD. There were no AChEI trials included in this review examining dementia with Lewy bodies or Parkinson's disease dementia that met our inclusion criteria, as they did not report NNT statistics, and the authors were not contactable. Across

studies, inclusion criteria were (1) a diagnosis of probable AD according to the National Institute of Neurological and Communicative Disorders and Stroke and Alzheimer's Disease and Related Disorders Association (NINCDS/ADRDA), (2) mild-to-moderate dementia specified as a score ranging from 10 to 26 on the MMSE, and (3) living with someone in the community or in regular/daily contact with a responsible caregiver. Two studies (Seltzer et al., 2004; Winblad et al., 2007) had additional criteria of a diagnosis of AD according to the DSM-IV, and two studies (Rockwood et al., 2001; Wilcock, 2001) had an additional criteria of a score of >2 on the ADAS-Cog. Participants were excluded if they had other neurodegenerative disorders, diseases, or clinically important conditions that may prevent study completion, or if they had been previously treated with an AChEI.

**Participant age.** The mean age of participants in CST trials was over 77 years in all CST trials and over 80 years in three of these trials. One study (Paddick et al., 2017) did not report the mean age of participants, but reported a median age of 80 to 84 years across the four groups in the trial. The mean age of participants in the AChEI trials was over 70 years in all the trials, and no greater than 76 years.

***Overall Quality Rating***

The quality ratings for the studies are summarised in Table 2. One study (AChEI trial) had a low risk of bias according to the RoB 2. Six studies (four CST, two AChEI trials) had some concerns for overall risk of bias. These were mainly attributed to some concerns about risk of deviations from intended intervention and the selection of reported results. Two studies (one CST, one AChEI trial) had a high risk of bias. For one study (Seltzer et al., 2004) this

was attributed to selection of reported results, randomisation, and missing outcomes. For the other study (Carbone et al., 2021), this was attributed to randomisation, deviations from intended intervention, and missing outcomes.

***Cognitive Outcomes***

Outcomes investigated varied across the trials. In keeping with the objective of the review, cognition measured by the ADAS-Cog was examined, with other outcomes summarised in Table 1. As described previously, when interpreting an NNT and 95% CIs, it is important to hold in mind statistical significance of the results. Statistically non-significant results result in statistically non-significant NNTs, and the CI and NNT becomes difficult to describe (Altman, 1998).

Four CST studies found that CST had positive effects on cognition measured by the ADAS-Cog. Three trials (Alvares-Pereira et al., 2021; Paddick et al., 2017, Spector et al., 2003;) had some concerns for risk of bias and one had a high overall risk of bias (Carbone et al., 2021). One trial (Marinho et al., 2021) found that CST did not lead to an improvement in cognition. This trial had some concerns for risk of bias.

The donepezil, rivastigmine, and galantamine trials found that all of these drugs led to improvements in cognition. The donepezil trial (Seltzer et al., 2004) had a high risk of bias. The rivastigmine trial (Winblad et al., 2007) had some concerns for risk of bias. Both trials of galantamine (Rockwood et al., 2001; Wilcock, 2001) had a low risk and some concerns of risk of overall bias respectively. Both galantamine trials conducted multiple analyses, including observed case and intention-to-treat analyses, in order to confirm the robustness of their results taking into account dropouts. The results in these

trials were similar across analyses i.e. statistically significant improvements in cognitive functioning for the treatment over placebo group

***Desirable and Adverse Outcomes***

All studies in the review calculated an NNT, or its relevant statistics, by defining an improvement of at least 4 points on the ADAS-Cog as a desirable outcome, and anything below that as adverse. Four studies additionally calculated these statistics by defining no deterioration on the ADAS-Cog as a desirable outcome, and any deterioration as adverse (Alvares-Pereira et al., 2021; Paddick et al., 2017; Spector et al., 2003; Wilcock, 2001). One study additionally calculated these statistics by defining an improvement of at least 7 points on the ADAS-Cog as a desirable outcome, and anything below that as adverse (Seltzer et al., 2004). For the purposes of this review, only NNTs calculated and/or reported based on the criteria of a 4-point improvement on the ADAS-Cog were included and examined. Two studies did not provide an NNT or relevant statistics needed to calculate an NNT (Carbone et al., 2021; Marinho et al., 2021). For these studies, an improvement of at least 4 points on the ADAS-Cog was defined as the desirable outcome, consistent with the rest of the studies included in the review (see Methodology).

**Table 1**

*Details of articles included in the review*

| Study | Experimental Design | Treatment | Participants | Setting | Clinical Outcomes |
|---|---|---|---|---|---|
| CST trials | | | | | |
| Spector et al. (2003) | Single-blind, randomised controlled trial. CST treatment group versus control group | 14 sessions of CST, twice weekly for 7 weeks | Total: n = 201<br>Females: n = 158<br>Males: n = 43<br>Dropouts: n = 34<br>CST group: n = 115<br>Control group: n = 86<br>CST mean age (SD): 85.7 (6.2)<br>Control mean age (SD): 84.7 (7.9)<br>Dementia type: Unspecified | 18 residential homes and 5 day centres in the UK | Significant improvement in cognition (ADAS-Cog, MMSE), and quality of life (QoL-AD).<br>Trend towards significance in communication (Holden Scale).<br><br>No significant improvement in depression (Cornell Scale) or functional ability (CAPE–BRS). |
| Paddick et al. (2017) | Single-blind, stepped-wedge design, with participants in an immediate and delayed start group. Comparison of data at T1 and T2 as a single-blind cluster-randomized controlled Trial, with delayed CST group acting as control group | 14 sessions of CST, twice weekly for 7 weeks | Total: n = 34<br>Females: n = 29<br>Males: n = 5<br>Dropouts: n = 3<br>CST group: n = 16<br>Control group: n = 18<br>Median age across 4 groups: 80.0 – 84.0<br>Dementia type: 16 Alzheimer's disease, 10 vascular dementia, 2 Parkinson's disease dementia, 2 probable dementia with Lewy bodies | 6 villages in Sub-Saharan Africa | Significant improvements in cognition (ADAS-Cog) in immediate compared to delayed start group.<br><br>Pre-post CST comparison: significant improvement in cognition (ADAS-Cog) and physical health (WHOQOL-Bref). Psychological domain score (WHOQOL-Bref) not significant for immediate start group. Significant improvement in carer reports of anxiety, severity, and distress caused by BPS of dementia (NPI). |

**Table 1 (continued)**

| Study | Experimental Design | Treatment | Participants | Setting | Clinical Outcomes |
|---|---|---|---|---|---|
| Alvares-Pereira et al. (2021) | Single-blind, randomised controlled trial, CST treatment group versus control group | 14 sessions of CST, twice weekly for 7 weeks | Total: n = 112<br>Dropouts: n = 7<br>Females: n = 91<br>Males: n = 14<br>CST group: n = 55<br>Control group: n = 50<br>Mean age (SD): 83.6 (7.46)<br>Dementia type: Unspecified | 2 day centres, 2 nursing homes, 2 psychogeriatric centres, 1 hospital, 1 rehabilitation centre in Portugal | Significant difference between CST and control groups, where CST group showed more improvement in general cognition (ADAS-Cog), communication (Holden scale), behaviour/functionality (CAPE) and severity of dementia/disability (CDR).<br><br>No significant differences in quality of life (QoL-AD), depression (Cornell Scale), and anxiety (RAID). |
| Carbone et al. (2021) | Single-blind, randomised controlled trial, CST-IT treatment group versus control group | 14 sessions of CST-IT, twice weekly for 7 weeks | Total: n = 225<br>Females: n = 149<br>Males: n = 76<br>CST group: n = 123<br>Control group: n = 102<br>Dropouts: n = 1<br>CST mean age (SD): 82.57 (9.33)<br>Control mean age (SD): 84.74 (6.86)<br>Dementia type: Unspecified | 16 residential care homes or day centres in Italy | Positive trends in treatment group cognition scores (MMSE), while control group scores showed a negative trend across time. Treatment groups had improvements in cognitive measures (ADAS-Cog, Narrative Language Test), mood (Cornell scale) and behaviour (NPI), but not control group. This was maintained at follow-up. Quality of life improved in both groups (QoL-AD).<br><br>No differences observed in everyday functioning (DAD). |

**Table 1 (continued)**

| Study | Experimental Design | Treatment | Participants | Setting | Clinical Outcomes |
|---|---|---|---|---|---|
| Marinho et al. (2021) | Single-blind, randomised controlled trial, CST-Brasil treatment group versus control group | 14 sessions of CST, twice weekly for 7 weeks | Total: n = 52<br>Dropouts: n = 5<br>CST group: n = 23<br>Control group: n = 24<br>Females: n = 29<br>Males: n = 18<br>CST mean age (SD): 78.3 (8.4)<br>Control mean age (SD): 77.3 (8.4)<br>Dementia type: Unspecified | Center for Alzheimer's disease in Brazil | Comparing treatment and control, improvements in cognitive (ADAS-Cog) and in quality of life (QoL-AD) were not observed.<br><br>Significant improvements in depressive symptoms (Cornell scale) and in activities of daily living (ADCS-ADL) were observed. |
| Drug trials | | | | | |
| Rockwood et al. (2001) | Randomised, double-blind, placebo-controlled trial. | 24 – 32mg/day galantamine over 12 weeks | Total: n = 386<br>Females: 215<br>Males: 171<br>Treatment group: n = 261<br>Placebo group: n = 125<br>Dropouts: 98<br>Treatment mean age (SD): 75.2 (0.45)<br>Placebo mean age (SD): 74.6 (0.68)<br>Dementia type: Probable Alzheimer's disease | 43 centres (unspecified) in the US, Canada, Great Britain, South Africa, Australia, and New Zealand | Significant improvement in cognition (ADAS-Cog) and global response (CIBIC-plus) for treatment compared to placebo. Significant improvement in basic and instrumental activities of daily living (DAD) for treatment.<br><br>No significant change of behavioural symptoms (NPI). |

**Table 1 (continued)**

| Study | Experimental Design | Treatment | Participants | Setting | Clinical Outcomes |
|---|---|---|---|---|---|
| Wilcock (2001) | Parallel group, double-blind, randomised, placebo-controlled trial | 24mg/day galantamine or 32mg/day galantamine, over 6 months | Total: n = 653<br>Females: n = 409<br>Males: n = 244<br>Treatment group (24mg): n = 220<br>Treatment group (32mg): n = 218<br>Placebo group: n = 215<br>Dropouts: 128<br>Treatment (24mg) mean age (SD): 71.9 (8.3)<br>Treatment (32mg) mean age (SD): 72.1 (8.6)<br>Placebo mean age (SD): 72.7 (7.6)<br>Dementia type: Probable Alzheimer's disease | 86 centres (outpatient clinics) in eight countries (Canada, Finland, France, Germany, Norway, Sweden, the Netherlands, and the United Kingdom) | Significant improvements in cognition (ADAS-Cog) for both treatment groups compared to placebo. More significant improvement in global response for treatment (CIBIC-plus).<br><br>Higher dose treatment group had significantly better scores for daily functioning (DAD) than placebo. |

**Table 1 (continued)**

| Study | Experimental Design | Treatment | Participants | Setting | Clinical Outcomes |
|---|---|---|---|---|---|
| Seltzer et al. (2004) | Multicenter, randomised, double-blind, placebo-controlled trial | 10mg/day donepezil over 24 weeks | Total: n = 153<br>Females: n = 82<br>Males: n = 71<br>Treatment group: n = 96<br>Placebo group: n = 57<br>Dropouts: n = 37<br>Treatment mean age (SD): 73.3 (9.6)<br>Placebo mean age (SD): 75.1 (8.8)<br>Dementia type: Early-stage Alzheimer disease | 17 sites in the US (research centres/clinics, medical centres/institutes, memory disorder centres, medical university schools) | Significant improvement in cognition (ADAS-Cog) for treatment compared to placebo group from week 12. Significant improvement in cognition (MMSE) for treatment versus placebo from week 6. Significant improvements in verbal and visual memory (CMBT) for treatment versus placebo.<br><br>No significant improvements in other CMBT tasks. No significant difference in apathy scale, activities of daily living (CDR) or global impression (Patient Global Assessment Scale) between groups. |

**Table 1 (continued)**

| Study | Experimental Design | Treatment | Participants | Setting | Clinical Outcomes |
|---|---|---|---|---|---|
| Winblad et al. (2007) | Multicenter, double-blind, double-dummy, placebo, and active-controlled trial | 12mg/day rivastigmine capsule, or 10cm$^2$ (9.5 mg/24h rivastigmine patch, or 20cm$^2$ (17.4 mg/24h) rivastigmine patch, over 24 weeks | Total: n = 1195<br>Treatment group (10cm$^2$ patch): n = 29<br>Treatment group (20cm$^2$ patch): n = 303<br>Treatment group (capsule): n = 297<br>Placebo group n = 302<br>Dropouts n = 225<br>Males:Females only reported for safety population (n = 1190; 33.4: 66.6)<br>Treatment (10cm$^2$ patch) mean age (SD): 73.6 (7.9)<br>Treatment (20cm$^2$ patch) mean age (SD): 74.2 (7.7)<br>Treatment (capsule) mean age (SD): 72.8 (8.2)<br>Placebo group mean age (SD): 73.9 (7.3)<br>Dementia type: Alzheimer's disease | 100 study centres (hospitals, university research centres, neurology clinics) in 21 countries | For all treatment groups, significant improvement in cognition (ADAS-Cog, MMSE) over placebo; 20cm$^2$ patch non-inferior to capsule. All treatment groups significant improvement over placebo in activities of daily living (ADCS-ADL), and attention, processing speed and visual tracking (Trail-making Test A).<br><br>Significant difference in global impression of change (ADCS-CGIC) for 10cm$^2$ patch and capsule over placebo. Significant difference in ADCS-CGIC between 20cm$^2$ patch and placebo in ITT-RDO and observed case analysis, but not ITT-LOCF populations.<br><br>No significant difference in behaviour and psychiatric symptoms (NPI) and visuo-spatial and executive function (clock-drawing) between placebo and treatment groups. |

*Note.* n = number. ADAS-Cog = Alzheimer's Disease Assessment Scale-Cognition; ADCS-ADL = Alzheimer's Disease Cooperative Study – Activities of Daily Living; ADCS-CGIC = Alzheimer's Disease Cooperative Study – Clinical Global Impression of Change CAPE = Clifton Assessment Procedures For the Elderly; CAPE-BRS = Clifton Assessment Procedures For the Elderly - Behavior Rating Scale; CDR = Clinical Dementia Rating Scale; CIBIC-plus = The Clinician's Interview-Based Impression of Change Plus caregiver input; CMBT = Computerized Memory Battery Test; Cornell Scale = Cornell scale of Depression in Dementia; CST = Cognitive Stimulation Therapy; DAD = Disability Assessment for Dementia; Holden Scale = Holden Communication Scale; ITT-LOCF = Intention-to-treat – Last Observation Carried Forward; ITT-RDO = Intention-to-treat – Retrieved Drop Out; MMSE = Mini-Mental State Examination; NPI = Neuropsychiatric Inventory; QoL-AD = Quality of Life-Alzheimer's Disease; RAID = Rating Anxiety in Dementia; WHOQOL-BREF = Brief WHO Quality of Life; SD = Standard Deviation.

**Table 2**

*Methodological quality ratings for articles*

| Study | RoB 2 | | | | | |
|---|---|---|---|---|---|---|
| | Randomisation process | Deviations from intended intervention | Missing outcomes | Measurement of outcome | Selection of reported result | Overall bias |
| Alvares-Pereira et al. (2021) | + | ? | + | + | ? | ? |
| Carbone et al. (2021) | ? | - | - | + | + | - |
| Marinho et al. (2021) | + | ? | + | + | + | ? |
| Paddick et al. (2017) | + | ? | + | + | + | ? |
| Rockwood et al. (2001) | + | + | + | + | + | + |
| Seltzer et al. (2004) | ? | + | - | + | ? | - |
| Spector et al. (2003) | + | ? | ? | + | + | ? |
| Wilcock (2001) | + | + | + | + | ? | ? |
| Winblad et al. (2007) | + | + | + | + | ? | ? |

*Note.* '+' represents low risk of bias, '?' some concerns for risk of bias, and '-' high risk of bias.

## NNT Analyses

The results of the NNT analyses are summarised in Tables 3 and 4.

### *CST trials*

Results from four CST trials showed that when calculating an increase in 4 points on the ADAS-Cog as an improvement, the NNT ranged from 2 to 6, with CIs ranging from 3 – 17. The study with the lowest NNT was a trial on CST implemented in sub-Saharan Africa (NNT = 2, 95% CI unreported). This study had some concerns of risk of bias attributed to deviations from the intended intervention (Paddick et al., 2017). The NNTs for other studies that found significant improvements in cognition were comparable. Specifically, the Alvares-Pereira et al. (2021) trial for CST conducted in Portugal found an NNT of 5 (95% CI 3 – 12), and the Carbone et al. (2021) trial for CST conducted in Italy found an NNT of 4 (95% CI 3 – 6). These studies had some concerns and a high risk of bias respectively, attributed to selection of reported results, deviations from the intended intervention and missing outcomes. The Spector et al. (2003) trial for CST implemented in the UK found an NNT of 6 (95% CI 4 – 17). This study had some concerns for risk of bias attributed to deviations from intended intervention and missing outcomes.

One study (Marinho et al., 2021) found a large number of 250 (NNTH 14 to ∞ to NNTB 12) patients who need to be treated with CST to prevent the adverse outcome of anything below a 4-point improvement on the ADAS-Cog. This study had some concerns of risk of bias attributed to deviations from intended intervention. However, as this study found a statistically non-significant improvement in cognition between treatment and control, this NNT is statistically non-significant, reflected in a CI that goes through infinity.

***Donepezil***

The trial of donepezil had a high risk of bias attributed to randomisation, missing outcomes and selection of reported results, contributed by a lack of reported information. As shown in Table 4, when calculating an improvement in at least 4 points on the ADAS-Cog as desirable, after 24 weeks, the number of patients who needed to be treated with donepezil to prevent the adverse outcome was 5 (95% CI 3 – 11).

***Rivastigmine***

The trial of rivastigmine had some concerns for risk of bias attributed to selection of the reported result. As shown in Table 4, when calculating an improvement by at least 4 points on the ADAS-Cog as desirable, the number of patients who needed to be treated with a $10cm^2$ patch (equivalent to ~9.5mg) of rivastigmine to prevent the adverse outcome was 13 (NNTH 24 to ∞ to NNTB 5). This value decreased to 8 (95% CI 4 – 122) when the dose increased to a $20cm^2$ patch (equivalent to ~17.4mg), and decreased slightly to 12 (NNTH 31 to ∞ to NNTB 5) when patients were treated with rivastigmine capsule of a dose range of 3 – 12mg.

Interestingly, despite statistically significant results reported for the $10cm^2$ patch and capsule ($p < .05$), the CIs that were derived for their NNTs included infinity, indicating a statistically non-significant NNT (Altman, 1998; Citrome, 2007). These results were a result of small ARRs of 0.08 and 0.09 respectively, indicating a small difference in cognitive improvement between the treatment and control groups for the $10cm^2$ patch and capsule.

***Galantamine***

As shown in Table 4, the NNT for galantamine ranged from 5 to 16 across both studies. One study (Wilcock, 2001) had some concerns for risk of bias due to selection of the reported result. One study (Rockwood et al., 2001) had a low risk of bias.

Results from the Rockwood et al. (2001) trial showed that after 12 weeks, the number of patients who needed to be treated with 24 – 32mg of galantamine to prevent an adverse outcome of anything below a 4-point improvement on the ADAS-Cog was 16 (NNTH 18 to ∞ to NNTB 5). Again, despite statistically significant results reported in the trial ($p < .05$), the CIs that was derived included infinity, indicating a statistically non-significant NNT (Altman, 1998; Citrome, 2007). This was due to a small ARR of 0.06, implying a small difference in cognitive improvement between the treatment and control group.

Results from the Wilcock (2001) trial found that after 24 weeks, the number of patients who needed to be treated with 24mg of galantamine to prevent an adverse outcome of anything below a 4-point improvement on the ADAS-Cog was 7 (95% CI 4 – 37). The NNT decreased slightly to 6 (95% CI 4 – 18) when dosage increased to 32mg, implying fewer patients needed to be treated to prevent an adverse outcome.

**Table 3**

*NNT for CST compared to treatment-as-usual*

| Study | Treatment duration | n control group | n treatment group | % poor outcome control group | % poor outcome treatment group | ARR | NNT (95% CI) |
|---|---|---|---|---|---|---|---|
| Alvares-Pereira et al. (2021) | 14 sessions, twice weekly for 7 weeks | 50 | 55 | 90 | 70.9 | 0.23 | 5 (3 – 12) |
| Carbone et al. (2021) | 14 sessions, twice weekly for 7 weeks | 102 | 123 | 89.2 | 61.8 | 0.27 | 4 (3 – 6) |
| Marinho et al. (2021) | 14 sessions, twice weekly for 7 weeks | 24 | 23 | 91.7 | 91.3 | 0.004 | 250 (-14 – 12) |
| Paddick et al. (2017) | 14 sessions, twice weekly for 7 weeks | 18 | 16 | Not reported | Not reported | Unreported | 2 (CI unreported) |
| Spector et al. (2003) | 14 sessions, twice weekly for 7 weeks | 70 | 97 | 87 | 70 | 0.17 | 6 (4 – 17) |

*Note.* Calculations are based on a 4-point improvement on the ADAS-Cog considered as a desirable outcome, and 3-point improvement and below as an adverse outcome. ARR = absolute risk reduction; n = number; NNT = number needed to treat; CI = confidence interval

**Table 4**

*NNT for acetylcholinesterase inhibitors compared to placebo*

| Study | Treatment duration (weeks) | Treatment | n placebo group | n treatment group | % poor outcome placebo group | % poor outcome treatment group | ARR | NNT (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Seltzer et al. (2004) | 24 | Donepezil 10mg | 45 | 67 | 84.0 | 63.0 | 0.21 | 5 (3 – 11) |
| Winblad et al. (2007) | 24 | Rivastigmine 10cm$^2$ patch (9.5mg) | 281 | 248 | 80.1 | 72.6 | 0.08 | 13 (-24 – 5) |
| | 24 | Rivastigmine 20cm$^2$ patch (17.4mg) | 281 | 262 | 80.1 | 67.2 | 0.13 | 8 (4 –122) |
| | 24 | Rivastigmine 3-12mg capsule | 281 | 253 | 80.1 | 71.5 | 0.09 | 12 (-31 – 5) |
| Rockwood et al. (2001) | 12 | Galantamine 24 – 32mg | 123 | 258 | 78 | 71.7 | 0.06 | 16 (-18 – 5) |
| Wilcock (2001) | 24 | Galantamine 24mg | 215 | 220 | 85 | 71 | 0.14 | 7 (4 – 37) |
| | 24 | Galantamine 32mg | 215 | 217 | 85 | 68 | 0.17 | 6 (4 – 18) |

*Note.* Calculations are based on a 4-point improvement on the ADAS-Cog considered as a desirable outcome, and 3-point improvement and below as an adverse outcome. ARR = absolute risk reduction, n = number; NNT = number needed to treat; CI = confidence interval

## Discussion

### Interventions

#### *CST trials*

Quite small numbers of patients need to be treated with CST to achieve amelioration in cognitive outcomes. CST adapted in sub-Saharan Africa had the smallest NNTs (Paddick et al., 2017). The only exception was one study that found non-significant improvements in cognition, and therefore a non-significant NNT (Marinho et al., 2021). The study noted that a lack of significant results may be due to a small sample size and reduced power, and that the cultural adaptation of CST-Brasil could have favoured elements of the programme related to improvements in mood but not cognition.

The small numbers suggest that CST may be an effective treatment for improving cognition for people with mild-to-moderate dementia, consistent with results of a previous review on the efficacy of CST (Lobbia et al., 2019). However, while majority of the CST trials found significant NNTs that were small, the small number of CST trials overall limits the conclusions drawn from the mixed results. Eight CST trials were excluded due to insufficient information to calculate an NNT, per the methodology used in this review. This meant that only 38.4% of the available literature on CST was considered, and the results therefore do not represent the full picture of the evidence.

#### *Cholinesterase Inhibitors*

Donepezil had the smallest NNT with the most narrow CI, compared to galantamine and rivastigmine that yielded larger NNTs with comparatively wider CIs. For galantamine, the NNT was statistically non-significant for a trial that examined its efficacy over 12 weeks compared to a trial that examined its

efficacy over 24 weeks. Both trials examined similar doses of galantamine. Further, when patients were treated with galantamine over 24 weeks, the NNTs became almost comparable to that of donepezil, potentially suggesting that positive effects of galantamine may be more apparent after a longer period of time.

For rivastigmine and galantamine, larger doses were associated with a smaller NNT. This was especially apparent for rivastigmine, where smaller doses of a $10cm^2$ patch and 3 – 12mg capsule yielded statistically non-significant and larger NNTs compared to a $20cm^2$ patch. This finding is consistent with a previous NNT review of cholinesterase inhibitors that found a relationship between drug dosage and the size of the corresponding NNT (Livingston & Katona, 2000). These results are also consistent with previous meta-analyses that supported the effectiveness of these drugs (Birks & Harvey, 2006; Li et al., 2019) and that found significant albeit small effects for rivastigmine on cognition (Birks & Grimley Evans, 2015).

However, again, these conclusions are limited by the small number of trials. Nine AChEI trials were excluded due to insufficient information, which led to only 30.8% of the available literature being included in this review. This is especially significant when examining and comparing the drugs individually, given that only one trial was included for donepezil and rivastigmine, and two for galantamine. Similar to CST, the results do not represent the full picture of the evidence and are therefore difficult to generalise.

***CST Compared with Cholinesterase Inhibitors***

For the CST trials that found significant results, the NNTs were overall comparable to that of AChEIs that found significant NNTs. Particularly, the

NNTs for the CST trials were comparable to 10mg of donepezil and 24 – 32mg of galantamine administered over 24 weeks. NNTs for the CST trials were also comparable to a 20cm$^2$ patch of rivastigmine. Overall, this could imply that CST has comparable efficacy to AChEIs, which is interesting given the short duration of CST compared to AChEI trials. However, as mentioned previously, a larger sample size is required to confirm these. It is noteworthy that the sample of AChEIs was more limited and less representative than that of CST, given the larger proportion of available literature being excluded for AChEIs than for CST (69.2% versus 61.6%) due to insufficient information.

**Limitations**

This review has several limitations. The first limitation was, as discussed, the small number of studies. Overall, a total of 17 studies were excluded due to insufficient information, leading to only 34.6% of the available literature being included in this review. The excluded studies may have had different findings not captured in this review. It is therefore difficult to extrapolate findings and draw accurate comparisons between interventions, as well as between the results and results of previous reviews. The results need to be confirmed with further research and reviews in this area.

Relatedly, there were limitations in study selection. The current review only included studies that used the ADAS-Cog as it is a widely used and established scale in studies of dementia, and has satisfactory psychometric properties across settings (Sheehan, 2012; Nogueira et al., 2018; Paddick et al., 2017). The review also only selected one outcome measure for more meaningful interpretability, as the NNT is most useful when examining similar

outcomes when comparing interventions (McAlister, 2008). However, this meant that studies that did not utilise the ADAS-Cog were excluded. Future reviews could address these limitations for a more comprehensive picture, including studies that used additional or other measures of cognition. It is however worth reiterating that the ADAS-Cog is a comprehensive and widely used measure for dementia trials, found to be more precise than other cognitive screening tools such as the MMSE (Balsis et al., 2015).

Secondly, the overall quality of the evidence in this review seemed limited by the quality of the included studies. At least some concerns of overall risk of bias existed across all CST trials. One CST trial found a small NNT of 4, but had a high risk of bias. Further, one CST trial (Paddick et al., 2017) did not report confidence intervals for the reported NNTs, resulting in a lack of information on the uncertainty of the estimated NNT (Altman, 1998). This may also affect the quality of the evidence. While there do not seem to be important differences in risk of bias by trial outcome for CST, the overall evidence presented for the effectiveness of CST is limited by the abovementioned factors. For the AChEI trials, only one trial (galantamine administered over 12 weeks) had a low risk of bias, and one trial (donepezil) had a high risk of bias. This may limit the quality of the evidence, particularly for donepezil which found the lowest NNT. Even so, only few trials were included in this review for each drug, which also limits the comparability and generalisability of the results.

Thirdly, the current review calculated the NNT by deriving the ARR using simple proportions (Cook & Sackett, 1995), as it is a recommended method for estimating the NNT for RCTs (Mendes et al., 2017) that has been used in a previous systematic review of dementia drugs (Livingston & Katona,

2000). There are however other ways to estimate an NNT which the review did not consider, such as via conducting a meta-analysis of relative effect measures i.e. risk ratios or odds ratios (Mendes et al., 2017; Schünemann et al., 2022). The current study had not conducted a meta-analysis due to practical limitations. Further, the heterogeneity of studies in the current review suggests that a meta-analysis may not have been appropriate. However, reviewing more studies, such as the those that were excluded and those with necessary information e.g. to calculate relative effect measures, would likely justify a meta-analysis.

In the same vein, the NNT is most useful when the interventions are examining similar outcomes, tested in similar populations with the same condition, and over similar time frames (McAlister, 2008). There were expected differences between AChEI and CST trials that may influence generalisability. For example, CST is administered over 7 weeks, whilst AChEIs were administered over 12 to 24 weeks. The age range between CST trials and AChEI trials also differed, where the mean age of participants in CST trials was between 77 and 86 years across the CST trials, and between 71 to 76 years in the AChEI trials. In addition, AChEI trials in this review were limited to people with AD and did not include other dementia types unlike the CST trials, as it was not possible to obtain data for trials of dementia with Lewy bodies or Parkinson's disease dementia. The criteria for the diagnosis of mild-to-moderate dementia also differed between CST and AChEI trials. Furthermore, interest in CST and CST research is more recent compared to dementia drugs; the AChEI trials were conducted between 2001 and 2007, whereas CST trials were conducted between 2003 to 2021. This may have also played a role in

differing participant diagnostic inclusion criteria, which has developed over the years. Most of these differences were expected given fundamental differences in the nature of psychosocial and pharmacological research and between the interventions themselves. Differences in sample characteristics between the interventions are in fact reflected in the NICE guidelines (2018), where dementia subtype is not specified for psychosocial interventions but different medications are recommended for different dementia subtypes. Nonetheless, these differences imply that caution should be applied when comparing CST and AChEIs, and that alternative methods could be useful when doing so.

Fourth, while the NNT expresses the magnitude of cognitive improvements, it may not capture other important aspects of an intervention, such as financial costs or potential side-effects (Saver & Lewis, 2019). Individuals may also have unique characteristics that influence their responses to treatment, and this may not be captured by the NNT, or by the controlled nature of RCTs (Saver & Lewis, 2019). Characteristics of patients treated in clinical practice are often different from participants in research, which may lead to differences in NNT values in clinical practice (Francis, 2004). Moreover, the NNT represents a benefit at a specific time point, and it may be useful for trials to report NNTs over several time points if possible to capture variations in the benefits of the intervention (Saver & Lewis, 2019). Caution should thus be applied when generalising the results of the review. It could also be wise to refer to the original papers to obtain the nuances of the study results when NNTs are reported (McAlister, 2008).

Finally, while a 4-point improvement on the ADAS-Cog was used as a criteria for clinically significant change across trials in this review (Rockwood

et al., 2007; Food and Drug Administration, 1989), some studies have found that ADAS-Cog change scores could have low reliability for clinically meaningful change for people with AD or mild cognitive impairment (Grochowalski et al., 2015), and that a minimally clinically relevant change on the ADAS-Cog of 3 points is potentially more appropriate (Schrag & Schott, 2011). Further research on existing measures of cognition for mild-to-moderate dementia, as well as on the reliability of change scores and definition of clinically meaningful change, could shape future trials and reviews.

**Implications and Future Directions**

The current review found some evidence to support the efficacy of CST and AChEIs for ameliorating cognitive outcomes for people with mild-to-moderate dementia. The NNTs for CST were comparable to that of AChEIs and could suggest that similar to AChEIs, CST has a relevant place in the clinical management of mild-to-moderate dementia – consistent with NICE guidelines (2018). This is also in line with the biopsychosocial model of dementia, which suggests both biological and psychosocial interventions, tailored to the individual, are important (Spector & Orrell, 2010). Continued implementation, development, and research on CST could be valuable, including research in different settings. This is especially so as the difference in results found between CST implemented in Brazil and in sub-Saharan Africa suggests a wide variation in outcomes for CST. It could be useful to examine characteristics of CST implemented in sub-Saharan Africa to ascertain factors that led to its effectiveness to inform future adaptations of CST. It could also

be useful to examine factors that led to non-significant results for CST implemented in Brazil.

It was also interesting that some AChEI trials yielded statistically non-significant NNTs, despite significant *p*-values reported in the original paper. These trials found small differences between the proportion of people in the treatment and placebo groups who experienced an adverse outcome (small ARRs). These findings may support the notion that differences between mean scores between treatment and control groups may not necessarily capture meaningful clinical responses, unlike NNTs that convey both statistical and clinical significance (Cook & Sackett, 1995). However, while the NNT is considered an intuitive and meaningful measure, various factors and limitations stated in this review suggest a need for caution when interpreting the NNT and drawing conclusions about comparative efficacy between CST and AChEIs. It is therefore recommended that future reviews address these limitations where possible. Several future directions are suggested.

Increasing the sample size and undertaking a meta-analysis of relative effect measures (Mendes et al., 2017; Schünemann et al., 2022), or examining treatment-specific odds ratios derived from meta-analyses or individual studies, may allow for more accurate comparisons between differing interventions (Jansen et al., 2018). Moreover, relative effect measures are more stable across different risk groups in different studies (Furukawa et al., 2002; Higgins et al., 2019). If a meta-analysis is considered, it would be important to express relative effect measures as an NNT or ARR across different assumed comparator risks (McQuay & Moore, 1997; Smeeth et al., 1999). A meta-analysis could provide additional indices of magnitude of effect and provide

complementary information not captured by an NNT, allowing for more meaningful comparisons between interventions.

On top of these suggestions, future reviews that include studies of better methodological quality, lower risk of bias, more recent trials of AChEIs, or trials that administered other measures of cognition, may provide a better picture of the evidence. Future reviews may even want to consider examining other outcomes (e.g. quality of life or mood) for a more holistic evaluation of CST and AChEIs. It would also be interesting to explore if age plays a role in the efficacy of AChEIs or CST across trials.

Reviews examining drug trials for other types of dementia would also be useful. As there are limited CST trials for specific dementia subtypes, future CST trials and subsequent reviews could examine the influence of dementia subtype on efficacy. Additionally, as both CST and AChEIs showed benefits on cognition, trials and reviews examining the efficacy of a combination of both interventions could provide valuable information and shape current recommendations for interventions for dementia.

Finally, some trials in this review conducted multiple analyses, but only reported NNT statistics for one analysis i.e. intention-to-treat. While these studies had similar results across analyses, and intention-to-treat populations were prioritised in this review, future studies or reviews comparing NNTs across different analyses could provide further information on the significance of results across analyses.

## Conclusion

The current review found some evidence to support the efficacy of CST and AChEIs, where both interventions had similar NNTs for improving cognitive outcomes for people with mild-to-moderate dementia. There are however limitations in the review that should be considered when interpreting, comparing, and generalising these findings, suggesting a need for further research in this area as well as future reviews that account for the abovementioned limitations.

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## Part 2: Empirical Paper

# The Development of Virtual Cognitive Stimulation Therapy (vCST): Evaluation of Quality of Life and Mood Outcomes in a Feasibility Study

## Abstract

**Background**: The current study was part of a larger project examining the feasibility of virtual Cognitive Stimulation Therapy (vCST) for dementia, a version of CST delivered virtually. The current study aimed to evaluate any preliminary effects of vCST on quality of life (QoL) and depressive mood in people with dementia, secondary outcomes of interest, as part of the larger feasibility trial. The study was conducted in preparation for a future randomised controlled trial.

**Methods:** This was a single-blind, randomised controlled design. 46 people with dementia were recruited and randomly allocated to attend 14 sessions of twice-weekly vCST (n = 24) or treatment as usual (TAU; n = 22) over seven weeks. QoL and depressive mood were assessed pre and post-intervention. A 2x2 within-between subjects ANOVA comparing the outcomes across time and between groups was conducted.

**Results:** There were no significant effects of vCST on QoL and depressive mood; however, both the vCST and TAU groups experienced a significant improvement in QoL across time.

**Conclusion:** vCST did not lead to benefits in QoL and depressive mood for people with dementia. Contextual factors and limitations in study design may partially account for these results. However, taken together with results from the larger study which found that vCST had non-significant effects on cognition (primary outcome), the results overall suggest potential limitations in the online delivery of CST. This indicates a need for further development of vCST and potential modifications for future research. The results also suggest that alternative outcomes of well-being e.g. loneliness might be more appropriate

to examine. Given the clinical relevance of vCST and its widespread use in the NHS, a larger scale trial taking into account the study limitations could be beneficial.

**Keywords:** Cognitive Stimulation Therapy, CST, dementia, psychosocial intervention

# Introduction

## Dementia and its Impact

Dementia is a significant cause of disability and can have a negative impact on an individual in later life (World Health Organization, 2021). Dementia can be described as a syndrome encompassing the deterioration of cognitive function, usually progressive or chronic and impacting higher cortical functions including memory, comprehension, language, orientation, capacity for learning, and decision-making or judgement (World Health Organization, 1993; 2021). Various types of dementia exist with differing presentations, the most common being Alzheimer's Disease (World Health Organization, 2021).

Neuropsychiatric symptoms such as depression, agitation, apathy, sleep difficulties, and psychotic symptoms are common in people with dementia (Livingston et al., 2020; Marcinkowska et al., 2020). Studies have found that cognitive difficulties associated with dementia, such as difficulties with communication or language, can negatively impact social well-being and contribute to a sense of isolation (Ablitt et al., 2009). Social isolation and loneliness may also contribute to depression in older people (Wahyuningsih et al., 2019). In addition, dementia can contribute to difficulties communicating personal needs, which can lead to increased psychological distress and behavioural challenges (Downs & Collins, 2015).

Studies that examined the relationship between dementia and quality of life (QoL) have additionally found that neuropsychiatric symptoms in people with Alzheimer's Disease have adverse effects on the QoL of both the person with dementia and the caregiver (Shin et al., 2005), and that there are

correlations between decreased QoL and higher levels of psychological and behavioural symptoms in people with dementia (Banerjee, 2006).

Given the significant negative impact that dementia can have on an individual, it is crucial that evidence-based care and interventions are implemented to help manage the symptoms of dementia, and improve well-being and QoL.

## Interventions for Dementia

Both pharmacological and psychosocial interventions have been developed to support people with dementia. Evidence-based guidelines have also been developed to guide the provision of care. Of the pharmacological interventions available, the National Institute for Health and Care Excellence (NICE) guidelines (2018) currently state that acetylcholinesterase inhibitor monotherapy, memantine monotherapy, or a combination of both are recommended, depending on the severity and subtype of dementia. In terms of psychosocial interventions, the NICE guidelines (2018) recommend offering group cognitive stimulation therapy to people with mild-to-moderate dementia. A few other therapies were also suggested for consideration, including group reminiscence therapy and cognitive rehabilitation or occupational therapy to support functional ability (National Institute for Health and Care Excellence [NICE], 2018).

### *Cognitive Stimulation Therapy*

Consistent with the NICE guidelines (2018), various programmes based on cognitive stimulation have been implemented and studied over the years. Cognitive Stimulation Therapy (CST) is one established, evidence-based

intervention, which focuses on improving cognitive resources and social skills in people with dementia (Spector et al., 2003). It is a manualised group intervention that consists of 14 structured group sessions, and was developed based on aspects of previous psychosocial interventions that were found to be effective. Particularly, CST includes features of reminiscence therapy, reality orientation, multisensory stimulation, and principles of implicit learning (Kitwood et al., 1997; Spector et al., 2003; Woods et al., 2012). Emphasis is also placed on a person-centred approach as well as the emotional and social aspects of the intervention (Woods et al., 2012). Overall, CST not only aims to stimulate cognitive areas impacted by dementia (e.g. language, orientation, executive function), but also to facilitate improvement in the relational and psychosocial impacts dementia can have (Woods et al., 2012). The standardised CST protocol has also been adapted and implemented across various countries (Alvares-Pereira et al., 2021; Capotosto et al., 2017; Carbone et al., 2021; Marinho et al., 2021; Paddick et al., 2017; Yamanaka et al., 2013).

Research supports the benefits of CST for people with dementia. Randomised controlled trials of CST found that CST improved the cognitive functioning of people with dementia (Spector et al., 2003; Spector et al., 2010; Woods et al., 2012). Evidence additionally suggests that CST may prevent or delay dependence and inability to self-care (Apóstolo et al., 2014). Evidence from randomised controlled trials examining QoL and mood outcomes for CST seemed to vary more in their results. While some studies found significant improvements in QoL (Capotosto et al., 2017; Spector et al., 2003; Woods et al., 2006) and depressive mood outcomes (Capotosto et al., 2017; Marinho et

al., 2021; Woods et al., 2006), others found that there were no significant improvements in QoL (Aguirre et al., 2013; Alvares-Pereira et al., 2021; Marinho et al., 2021; Yamanaka et al., 2013) or depressive mood outcomes (Alvares-Pereira et al., 2021; Apóstolo et al., 2014; Paddick et al., 2017; Spector et al., 2003). A recent systematic review has however highlighted the value of CST in improving cognitive functioning and quality of life for people with dementia (Lobbia et al., 2019), and a network meta-analysis suggested that CST may have benefits in improving depressive symptoms (Watt et al., 2021). Overall, the current literature suggests that continued research on the benefits of CST across different settings could be useful to shed more light on the benefits on mood and QoL.

**Accessibility of Interventions for Dementia**

Despite the benefits of interventions such as CST, people with dementia often face difficulties accessing services and treatments to benefit their emotional and cognitive well-being. Common barriers to mobility such as transport provision, hospital access, or the desire to remain at home, often delay treatment (Bossen et al., 2015). Further, in light of the COVID-19 pandemic, accessibility to services has become more of an issue due to concerns over the protection of vulnerable groups (Wang et al., 2020). Increased isolation due to health vulnerabilities and social restrictions may also contribute to an increase in neuropsychiatric symptoms such as apathy, anxiety, and agitation in people with dementia, suggesting a need for improvements in access to dementia care and adjustments of technological support to suit people with dementia's needs (Simonetti et al., 2020).

Indeed, there has been more research in recent years on the benefits of telemedicine approaches, such as remote consultations or videoconferencing. For instance, studies have evaluated the effectiveness of remote care delivery for stroke survivors (Cramer et al., 2019) and people with Parkinson's disease (Beck et al., 2017), and found that these were effective and could save travel time. Many services have also been moving towards offering remote-access interventions such as through the use of videoconferencing software.

However, to date, CST has not yet been established for virtual or remote delivery for persons with dementia in the UK. Given the negative impact of dementia on day-to-day functioning and QoL, the gap between need and accessibility of services for people with dementia, as well as research on the effectiveness of CST and remote delivery approaches, it has become relevant and important to explore the development of an evidence-based virtual protocol that can be offered to people with dementia.

## Virtual Cognitive Stimulation Therapy (vCST)

The current literature has highlighted the need for an evidence-based therapy such as CST to be adapted for remote use. To that end, the CST protocol has been adapted for remote administration – virtual CST (vCST).

### *Larger Project and Current Study*

The current study was part of a larger project on vCST, where several researchers were involved in different aspects of the project, including its development and the evaluation of its feasibility.

Two previous trainee clinical psychologists (Luke Perkins and Cerne Felstead) were involved in the development and adaptation of the CST protocol for virtual administration. The CST manual was first developed for use over videoconferencing, and the protocol was then field tested with people with dementia in different countries, including the UK. Focus groups and qualitative interviews were also conducted with people who attended these vCST groups, as well as their carers and group facilitators. They found that the protocol was acceptable to both participants and vCST facilitators, and the feedback obtained from these groups was utilised to further refine its development (Perkins et al., 2022). These researchers administered vCST and collected data for the first half of the project sample.

Two trainee clinical psychologists (Diyanah Wahab, the author; and Wing Gi Leung) were then involved in examining the feasibility of vCST. The feasibility study undertook a randomised controlled design and was conducted in preparation for a future large scale randomised controlled trial, in line with guidelines for defining pilot and feasibility studies described by Eldridge et al. (2016). This included an investigation of the preliminary effects of vCST on cognition, mood, and QoL. The constructs were chosen based on existing literature and research on dementia and CST. These researchers administered vCST and collected data for the second half of the project sample. Specifically, Wing Gi Leung investigated the preliminary effects of vCST on improving cognitive outcomes, the primary outcome of interest, and examined other aspects of the project relevant to feasibility i.e. recruitment and retention rates, acceptability of randomisation and the intervention, attrition rate, fidelity, and use of selected outcome measures (Campbell et al., 2000). The current

paper examined the preliminary effects of vCST in improving depressive mood and QoL, secondary outcomes of interest of the larger study.

### *vCST and Cognitive Outcomes*

It is important to assess the results of the current study within the context of the larger project, given that any effects of vCST found for mood and QoL could be linked to effects found on cognitive outcomes (Downs & Collins, 2015; Woods et al., 2006). Thus, while the current study focuses on the analyses and evaluation of depression and QoL, the main findings of Leung's (2022) study are reported and referenced throughout the paper. Leung (2022) found that vCST did not lead to any significant effects of vCST on cognitive outcomes, assessed by the Alzheimer's Disease Assessment Scale - Cognitive Subscale (ADAS-Cog; Rosen et al., 1984) and Montreal Cognitive Assessment - BLIND (MOCA-BLIND; Dupuis et al., 2015). It was suggested that non-significant effects could be due to a lack of multisensory stimulation compared to CST conducted face-to-face. vCST was however found to be feasible in other domains: recruitment and retention, attendance, and fidelity.

## Aims of Current Study

As described above, the current study aims to investigate the preliminary effects of vCST, specifically its effects on the outcomes of depressive mood and QoL. These secondary outcomes are relevant to examine, given the current literature on the impact of dementia on QoL and mood, as well as the mixed evidence on the effects of CST on QoL and mood. Taken together with findings from Leung's (2022) study, results from the

current study may provide information on potential further modifications that need to be made in the vCST protocol or design for future research; for example, identifying possible effects that may be useful to follow up on in a subsequent study. This could potentially contribute to the evidence to inform more widespread implementation of an established protocol.

The study aims to achieve the above by comparing QoL and depressive mood outcomes pre- to post-intervention between a group receiving vCST and a group receiving treatment as usual (TAU).

## Methodology

### Ethical Approval

Ethical Approval for the project was obtained from the University College London Research Ethics Committee (Project ID/Title: 17127.002).

### Recruitment and Inclusion Criteria

An a priori power analysis was conducted using G*Power version 3.1 (Faul et al., 2007) in order to estimate a recommended sample size. Calculations were based on effect sizes found for the primary outcome, cognition, derived from Spector et al. (2003)'s study, which evaluated the efficacy of CST in the UK. The significance criterion was set to α =. 05, and power was set to = .80. The calculated minimum sample size needed for our analysis was n = 60. However, for a feasibility study such as the current study, sample sizes between 24 and 50 have been recommended for feasibility studies (Julious, 2005; Sim & Lewis, 2012), although no consensus exists on the recommended sample size for feasibility trials (Billingham et al., 2013). Thus, based on these recommendations, we aimed to recruit between 24 to 50 participants for our study.

People with dementia were recruited via posters disseminated to contacts with third sector organisations, such as the London Memory Services Network Group, Memory-Matters, Age UK, Camden Carers, and the Join Dementia Research (JDR) network. The JDR network is an online recruitment platform for people interested in participating in dementia research (https://www.joindementiaresearch.nihr.ac.uk/).

Participants who indicated an interest in participating, or whose interests and demographics matched our study inclusion criteria advertised on the JDR network, were contacted via phone or videoconferencing for further screening of eligibility. The project background, confidentiality, data protection, right to withdraw from the study, and use of the data collected were discussed. They were informed that their participation would not affect any care they receive. Thereafter, participants and their carers provided their informed consent if they were interested and met our eligibility criteria. Participants provided their informed consent according to the Mental Capacity Act (2005).

The following inclusion and exclusion criteria were imposed when screening and recruiting participants:

- Diagnosis of dementia of any subtype, according to the International Classification of Diseases-10 (ICD-10; World Health Organization, 1993).
- Dementia of mild-to-moderate severity, as confirmed by the person and their caregiver.
- Able to communicate verbally in English.
- Able to engage and participate in an online group for one hour.

- Had the capacity to provide informed consent to complete study measures (assessed by the lead researchers) and to consent to video recording of each CST session.
- Access to a device capable of videoconferencing, access to Zoom software, and an internet connection at home.

People were excluded if:

- They are currently accessing any other psychosocial intervention or psychological therapy.
- They had recently participated in a CST research programme that involved similar assessments included in our study, as this may lead to practice effects and bias our assessments.
- If a mental capacity assessment suggests that the participant may lack capacity to take part, with capacity assessed in line with the Mental Capacity Act (2005).

**Sample and Randomisation**

Of 141 people with dementia who were contacted, 105 people were screened for eligibility (Figure 1). Of these people, 14 did not meet our eligibility criteria as they were participating in or had recently participated in an individual CST research programme, they did not have a diagnosis of dementia, they had other cognitive difficulties, or lacked capacity to provide consent. 39 declined to participate as they were not interested, were committed to other groups, were uncomfortable with group settings, were uncomfortable with technology or had technological difficulties, were recently hospitalised, or due to reported personal reasons. Six participants withdrew from the study after

providing their informed consent as they decided to participate in an individual CST research programme, were hospitalised, or due to personal matters. Thus, a total of 46 participants were recruited.

Recruited participants were randomly allocated to receive either vCST or TAU in a 1:1 ratio. TAU was defined as the care currently being received by participants in their day-to-day contexts. Randomisation was conducted using a web-based randomisation tool and Microsoft Excel to generate randomised codes in a 1:1 ratio. Randomisation was conducted after pre-test (baseline) assessments were conducted by a researcher on the team not directly involved with the collection of data or facilitation of vCST groups. The study was single-blind (assessor blinding). Therefore, group allocation was concealed from pre and post-treatment assessors, and only made known to group facilitators.

After randomisation, 24 participants were allocated to the vCST group, and 22 were allocated to the TAU group. The full recruitment process is summarised in Figure 1. In total, there were six vCST groups that included four participants in each. An equal number of TAU participants was allocated to each group, except for one group with two TAU participants.

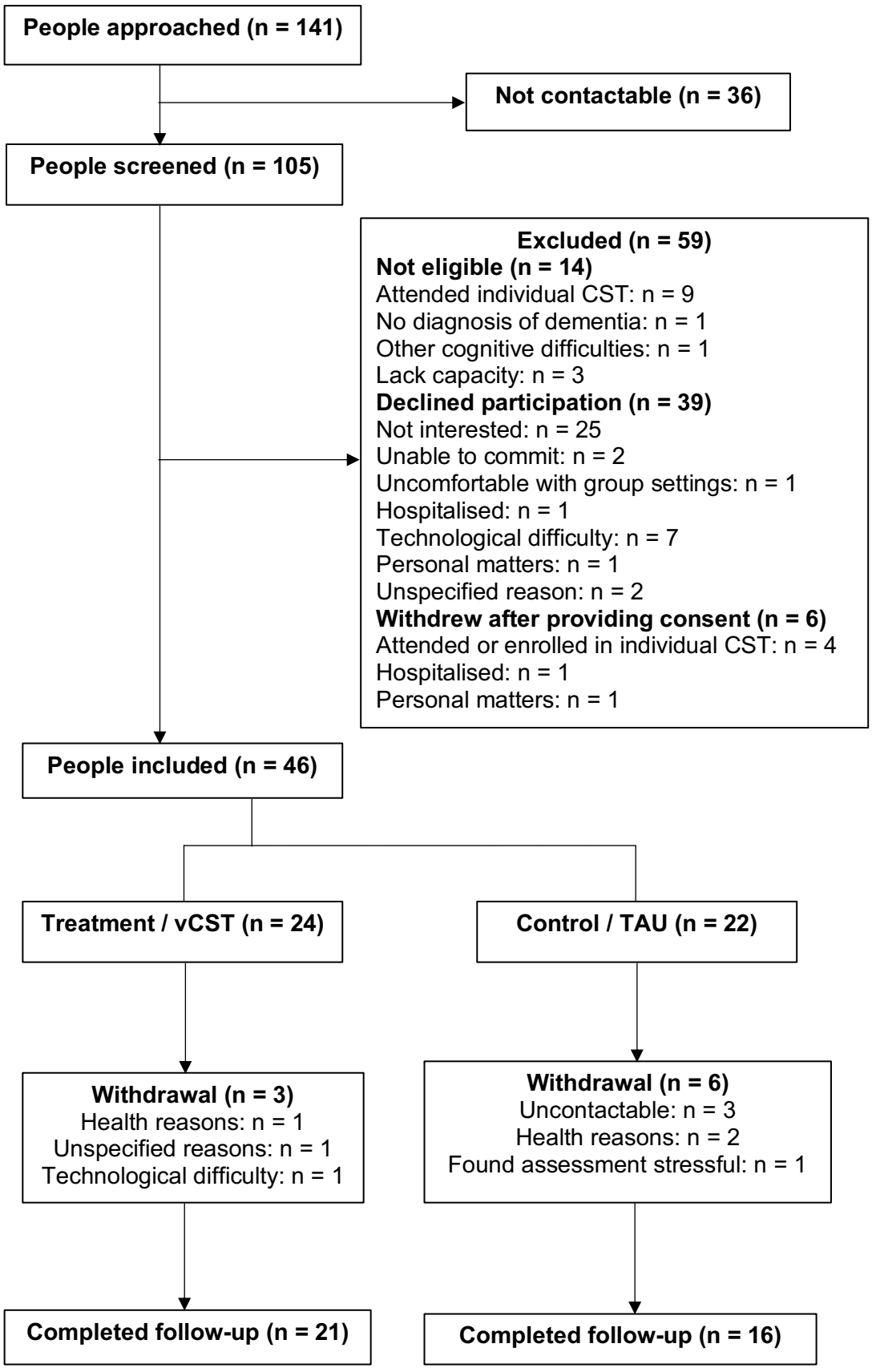
**Procedure**

All assessments and vCST sessions were delivered online via videoconferencing platform Zoom. How-to guides were provided to participants who were unfamiliar with using Zoom. Participants in the vCST group attended 14 sessions of twice-weekly vCST sessions over a period of seven weeks. The vCST sessions were adapted from the existing CST

protocol (Spector et al., 2003; Perkins et al., 2022) for online administration. The sessions were conducted by trained researchers or trainee clinical psychologists. Pre-test assessments were conducted one week before the start of the vCST groups, and post-test assessments were conducted one week following the end of the vCST groups. Pre and post-test measures of QoL and mood were administered by blinded researchers or trainee clinical psychologists who were unaware of participants' group allocation. The measures were administered in line with face-to-face administration through the use of the screen sharing function on Zoom.

**Figure 1**

*Trial Procedure and Attrition Rates*



## Measures

### *Quality of Life*

The Quality of Life in Alzheimer's Disease questionnaire (QoL-AD; Logsdon et al., 2002) was used to assess quality of life. The QoL-AD is a 13-item measure assessing QoL for people with dementia in the domains of physical health, energy, family, friends, living situation, fun, and money. Respondents provide a rating for each item on a 4-point Likert Scale ("poor", "fair", "good", and "excellent"). The ratings for the items are added to obtain a total score. A higher score on the QoL-AD indicates a better QoL. The QoL-AD has been found to have good internal consistency, reliability, and validity (Thorgrimsen et al., 2003). It has been validated across cultures, including the UK, US, Brazil, and Korea (Bowling et al., 2014).

### *Depressive Mood*

The Geriatric Depression Scale short form (GDS-15; Sheikh & Yesavage, 1986) was used to assess depressive mood. The GDS-15 is a quick and easily administered screening tool designed for depression in older adults. It consists of 15 items to be rated as "yes" or "no". Ten items indicate depression when answered "yes", and five items indicate depression when answered "no". A score greater than 5 indicates probable depression, and higher scores indicate greater depressive symptomatology (Burke et al., 1995). The GDS-15 has acceptable sensitivity, specificity, reliability and validity (Herrmann et al., 1996; Marc et al., 2008; Weeks et al., 2003). It was found to be valid for people over age 55 with cognitive impairment down to a score of 15 on the Mini-Mental State Examination (MMSE; Folstein et al., 1975; Smalbrugge et al., 2008), and for older adults aged 85 and above with a score

of 10 or more on the MMSE (Conradsson et al., 2013), where a score of 10 to 24 on the MMSE suggests mild-to-moderate dementia (Folstein et al., 1975). The GDS-15 has been validated as a screening alternative to the longer version of the GDS in people with mild-to-moderate dementia (Isella et al., 2002). The GDS-15 has additionally been shown to retain its reliability and validity when administered over telephone (Burke et al., 1995).

**Analysis**

Statistical analysis was conducted using the IBM Statistical Package for the Social Sciences version 28.0. Descriptive statistics were first calculated, including participants' demographic information and clinical profiles at baseline. Descriptive statistics of participants' scores on the outcome measures at baseline were also calculated. Independent samples t-tests and Chi-square tests were conducted to examine if there were significant differences between the vCST and TAU groups for demographic variables and characteristics. A Fisher's exact test was conducted for variables where 20% of cases had expected frequencies of less than five (Kim, 2017). An independent samples t-test, or (where appropriate due to t-test assumptions not being met) a Mann-Whitney U test was conducted to examine if there were significant differences between the groups for baseline outcome measures.

For the main analysis, an intention-to-treat analysis was conducted and a 2x2 within-between subjects mixed model ANOVA was chosen as the method of analysis. The independent variables were group assignment (vCST versus TAU) and time point (pre and post-intervention). The dependent variables were QoL and depressive mood, measured by scores on the QoL-

AD and GDS-15. This analysis allows us to investigate the effect of group assignment and time-point on outcomes, and any significant interaction effects between group membership and time-point. The interaction analysis is the primary analysis of concern, answering the question of whether there is greater change over time in QoL and depression in the CST compared to the TAU group. The data were assessed for statistical assumptions of ANOVA including normality, homogeneity of variance and sphericity.

## Results

### Missing Data and Intention-to-treat

Of 46 participants, 37 were assessed at follow-up, including 21 vCST and 16 TAU participants. Six TAU participants were lost to follow-up due to health reasons, they found the assessment too stressful, they declined to complete post-assessment measures for unspecified reasons, or they were uncontactable. Three vCST participants were lost to follow-up due to health reasons, technological difficulties, or they became unable to commit to the sessions (Figure 1). This was a 19.6% dropout rate. All 46 participants completed baseline assessments with no missing responses.

To examine whether values were missing completely at random we conducted a Little's test of Missing Completely at Random (MCAR). This was not significant ($\chi^2$ 14.287, df = 21, $p$ = .86). Thus, the data may be assumed to be MCAR. A multiple imputation using the MCMC method was used to impute missing data lost to follow-up for the main analysis.

**Baseline Demographics and Outcomes**

Baseline descriptive statistics for demographic variables, QoL-AD score, and GDS-15 score are seen in Table 1. Of the 46 participants, there were 23 males and 23 females. The mean age of the sample was 71.39 years (*SD* = 9.16). Chi-square tests, independent samples t-tests, Fisher's exact tests and a Mann-Whitney U test indicated that there were no significant differences between the vCST and TAU groups on demographic variables of age, education, gender, ethnicity, as well as baseline QoL-AD and GDS-15 scores.

**Table 1**

*Demographics of Participants at Baseline*

| Characteristics | Total Sample (n = 46) | vCST (n = 24) | TAU (n = 22) | Group Comparison |
|---|---|---|---|---|
| Age (years) | | | | |
| Mean (SD) | 71.39 (9.16) | 71.96 (9.18) | 70.77 (9.32) | $t(44) = .43$, $p = .67$ |
| Range | 48 – 88 | 56 – 88 | 48 – 84 | |
| Gender n (%) | | | | |
| Male | 23 (50.0) | 12 (50.0) | 11 (50.0) | $\chi^2$ (1, $N = 46$) = |
| Female | 23 (50.0) | 12 (50.0) | 11 (50.0) | 0.000, $p = 1.00$ |
| Ethnicity n (%) | | | | |
| White British | 33 (71.7) | 15 (62.5) | 18 (81.8) | Fisher's test = |
| White Irish | 7 (15.2) | 5 (20.8) | 2 (9.1) | 6.42, $p = .87$ |
| White Scottish | 1 (2.2) | 1 (4.2) | - | |
| White European | 2 (4.3) | 2 (8.3) | - | |
| White American | 1 (2.2) | 1 (4.2) | - | |
| Mixed white and black | 1 (2.2) | - | 1 (4.5) | |
| Other white background | 1 (2.2) | - | 1 (4.5) | |
| Years of Education n (%) | | | | |
| > 12 years | 28 (60.9) | 15 (68.2) | 13 (54.2) | $\chi^2$ (1, $N = 46$) = |
| ≤ 12 years | 18 (39.1) | 7 (31.8) | 11 (45.8) | 0.95, $p = .33$ |

**Table 1 (continued)**

| Characteristics | Total Sample (n = 46) | vCST (n = 24) | TAU (n = 22) | Group Comparison |
|---|---|---|---|---|
| Dementia subtype n (%) | | | | |
| Alzheimer's Disease | 23 (50.0) | 12 (50.0) | 11 (50.0) | Fisher's test = 7.82, $p$ = .36 |
| Vascular Dementia | 3 (6.5) | 1 (4.2) | 2 (9.1) | |
| Posterior Cortical Atrophy | 2 (4.3) | 1 (4.2) | 1 (4.5) | |
| Frontotemporal dementia | 5 (10.8) | 3 (12.5) | 2 (9.1) | |
| Mixed Dementia | 8 (17.4) | 5 (20.9) | 3 (13.5) | |
| Korsakoff Syndrome | 1 (2.2) | - | 1 (4.5) | |
| Unspecified | 4 (8.7) | 2 (8.3) | 2 (9.1) | |
| Baseline QoL-AD score | | | | |
| Mean (SD) | 35.70 (6.68) | 35.71 (6.87) | 35.68 (6.62) | $t(44)$ = .013, $p$ = .84 |
| Baseline GDS-15 score | | | | |
| Mean (SD) | 4.26 (3.71) | 4.17 (3.41) | 4.36 (4.09) | $U$ = 270.5, $p$ = .89, $Z$ = 0.14 |
| Median | 3.50 | 3.50 | 3.50 | |

*Note.* n = number of subjects, SD = standard deviation, $t$ = independent samples t-test statistic, $p$ = p-value, U = Mann-Whitney test statistic, $Z$ = Standardised test statistic. GDS-15 = Geriatric Depression Scale short form, QoL-AD = Quality of Life in Alzheimer's Disease questionnaire, TAU = treatment as usual, vCST = virtual Cognitive Stimulation Therapy

**Within-Between Subjects ANOVA**

The results are summarized in Tables 2 and 3. Mean scores are reported in Table 4.

***Quality of Life***

Levene's Test for equality of variance indicated equal variances for pre-test QoL-AD score (F (1, 44) = 0.042, $p$ = .84) and post-test QoL-AD score (F(1, 44) = 0.001, $p$ = .98). A within-between subjects ANOVA revealed that there was a significant main effect of time (F(1, 44) = 11.44, $p$ = .002) on QoL-AD score, with a large effect size (Partial $\eta^2$ = .22). All participants had significantly higher QoL-AD scores at post-test ($M$ = 37.5, $SD$ = 5.70) than at pre-test ($M$ = 35.7, $SD$ = 6.70). There was no significant main effect of group (F(1, 44) = 0.011, $p$ = .92), where mean post-test QoL-AD score was similar for participants in the vCST group ($M$ = 37.3, $SD$ = 5.46) and TAU group ($M$ = 37.7, $SD$ = 6.10). The effect size for this result was extremely small (Partial $\eta^2$ = .00). There was no significant interaction effect of time x group (F(1, 44) = 0.16, $p$ = .70) on QoL-AD score, with a small effect size (Partial $\eta^2$ = .004).

***Mood***

Pre-test and post-test GDS-15 scores were log-transformed so that scores were as close to normality as possible. The ANOVA is however robust when analysing non-normal data, with non-normal data not leading to increased Type I error (Blanca et al., 2017).

Levene's Test for equality of variance indicated equal variances for pre-test GDS-15 score (F(1, 44) = 11.44, $p$ = .002) and post-test GDS-15 score (F(1, 44) = .408, $p$ = .53). A within-between subjects ANOVA revealed that

there were no significant main effects of time ($F(1, 44) = 2.87$, $p = .097$) on GDS-15 score, with a medium effect size (Partial $\eta^2 = .06$). All participants had similar GDS-15 scores at pre-test ($M = 4.26$, $SD = 3.71$) and post-test ($M = 3.28$, $SD = 2.89$). There was no main effect of group ($F(1, 44) = 0.39$, $p = .54$), where mean post-test GDS-15 score was similar for participants in the vCST group ($M = 3.52$, $SD = 2.70$) and TAU group ($M = 3.02$, $SD = 3.12$). The effect size for this result was small (Partial $\eta^2 = .009$). There was no significant interaction effect of time x group ($F(1, 44) = 0.35$, $p = .56$), with a small effect size (Partial $\eta^2 = .008$).

**Per-protocol Analysis**

A per-protocol analysis that excluded the participants who did not complete post-test measures (n = 37) indicated similar results. There was a significant main effect of time on QoL-AD score, but no significant main effect of group or significant interaction effect of time x group. There were no significant main effects of time or group, or significant interaction effect of time x group on GDS-15 score.

**Table 2**

*Results of a Within-between Subjects ANOVA for QoL-AD Scores*

| Source of Variation | SS | *df* | Mean Square | *F* | *p* | Partial $\eta^2$ |
|---|---|---|---|---|---|---|
| Time | 74.8 | 1 | 74.8 | 11.44 | .002 | .22 |
| Group | 0.78 | 1 | 0.78 | 0.011 | .92 | .000 |
| Time x Group | 1.02 | 1 | 1.02 | 0.16 | .70 | .004 |
| Error (Time) | 287 | 44 | 6.54 | | | |
| Error (Group) | 3178 | 44 | 72.23 | | | |

*Note. df* = Degrees of freedom, SS = Type III Sum of Squares, $\eta^2$ = Eta Squared. Sphericity assumed

**Table 3**

*Results of a Within-between Subjects ANOVA for GDS-15 Scores*

| Source of Variation | SS | *df* | Mean Square | *F* | *p* | Partial $\eta^2$ |
|---|---|---|---|---|---|---|
| Time | 0.091 | 1 | 0.091 | 2.87 | .097 | .061 |
| Group | 0.071 | 1 | 0.071 | 0.39 | .54 | .009 |
| Time x Group | 0.011 | 1 | 0.011 | 0.35 | .56 | .008 |
| Error (Time) | 1.40 | 44 | 0.032 | | | |
| Error (Group) | 8.12 | 44 | 0.18 | | | |

*Note. df* = Degrees of freedom, SS = Type III Sum of Squares, $\eta^2$ = Eta Squared. Sphericity assumed.

**Table 4**

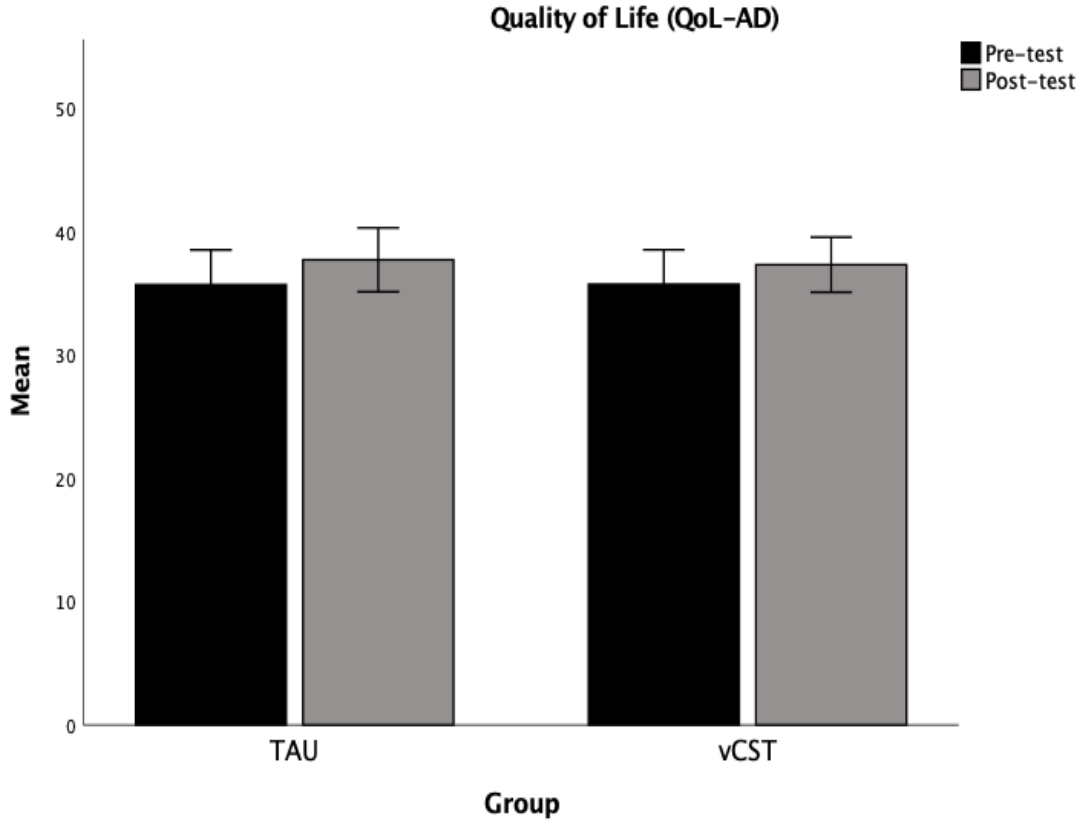
*Table of Means and Standard Deviations for QoL-AD and GDS-15 scores*

| Variable | Pre-test | Post-test |
|---|---|---|
| QoL-AD score (Mean (SD)) | | |
| vCST (n = 24) | 35.71 (6.87) | 37.30 (5.46) |
| TAU (n = 22) | 35.68 (6.62) | 37.70 (6.10) |
| Total (n = 46) | 35.70 (6.68) | 37.50 (5.70) |
| GDS-15 score (Mean (SD)) | | |
| vCST (n = 24) | 4.17 (3.41) | 3.52 (2.70) |
| TAU (n = 22) | 4.36 (4.09) | 3.02 (3.12) |
| Total (n = 46) | 4.26 (3.71) | 3.28 (2.89) |
| GDS-15 score; transformed (Mean (SD)) | | |
| vCST (n = 24) | 0.62 (0.31) | 0.57 (0.29) |
| TAU (n = 22) | 0.59 (0.39) | 0.50 (0.32) |
| Total (n = 46) | 0.60 (0.35) | 0.54 (0.30) |

*Note*. GDS-15 = Geriatric Depression Scale short form, QoL-AD = Quality of Life in Alzheimer's Disease questionnaire, TAU = treatment as usual, vCST = virtual Cognitive Stimulation Therapy. n = number of participants.

**Figure 2**

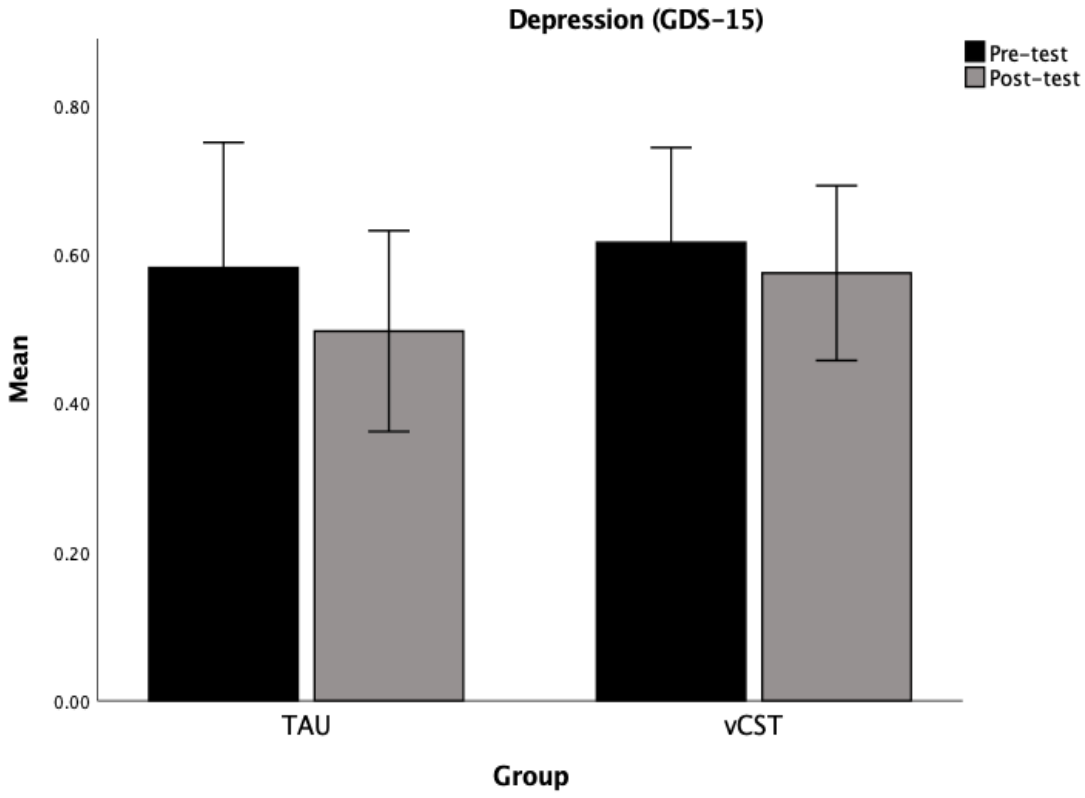
*QoL-AD score (Means and Standard Errors) Pre and Post-Intervention*




*Note.* Higher scores indicate higher quality of life. QoL-AD = Quality of Life in Alzheimer's Disease questionnaire, TAU = treatment as usual, vCST = virtual Cognitive Stimulation Therapy.

**Figure 3**

*GDS-15 score (Transformed; Means and Standard Errors) Pre and Post-Intervention*




*Note.* Higher scores indicate more severe depressive mood. GDS-15 = Geriatric Depression Scale short form, TAU = treatment as usual, vCST = virtual Cognitive Stimulation Therapy.

**Power Calculations for Future Trial**

Further analyses have been conducted to inform power calculations for a future trial. In particular, effect sizes (Cohen's d) were estimated based on calculations provided and suggested by Morris (2007). Relevant calculations are provided in Table 5 below. An estimate of the population standard deviation was obtained by pooling data from both the treatment and control groups. The effect size estimates that were calculated were corrected for bias (Morris, 2007). The estimates suggest small effect sizes for QoL-AD ($d$ = .18) and GDS-15 ($d$ = .061), using Cohen's (1988) criteria.

G*power version 3.1 (Faul et al., 2007) was used to estimate a sample size for a future trial based on these effect sizes. To have 80% power to detect a significant interaction effect for a within-subjects ANOVA design (α = .05), a sample size of n = 246 is required for QoL and n = 2112 is required for depression. It is however important to consider that the results of the current study found non-significant effects for both outcomes, and effect sizes were small. It may therefore be more appropriate to power future vCST trials based on other trials of face-to-face CST. This is discussed further below, where future directions are also suggested.

**Table 5**

*Table of Estimated Effect Size Calculations*

| | vCST group | | | | | | TAU group | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Pre-test | | Post-test | | | | Pre-test | | Post-test | | | | |
| Outcome | n | M | SD | M | SD | $M_{post} - M_{pre}$ | n | M | SD | M | SD | $M_{post} - M_{pre}$ | Pooled SD | *d* |
| GDS-15 | 24 | 4.17 | 3.41 | 3.52 | 2.70 | -0.65 | 22 | 4.36 | 4.09 | 3.02 | 3.12 | -1.34 | 3.75 | .18 |
| QoL-AD | 22 | 35.71 | 6.87 | 37.3 | 5.46 | 1.59 | 22 | 35.68 | 6.62 | 37.69 | 6.07 | 2.01 | 6.50 | .061 |

*Note*. GDS-15 = Geriatric Depression Scale short form, QoL-AD = Quality of Life in Alzheimer's Disease questionnaire, TAU = treatment as usual, vCST = virtual Cognitive Stimulation Therapy. *d* = Cohen's d, M = mean, $M_{post}$ = post-test mean, $M_{pre}$ = pre-test mean, n = number of participants, SD = standard deviation,

# Discussion

## Results

There were no significant effects of vCST on QoL, evidenced by a non-significant interaction effect of time-point and group allocation on QoL-AD scores. This result is consistent with previous studies that found non-significant effects of CST on QoL (Aguirre et al., 2013; Alvares-Pereira et al., 2021; Marinho et al., 2021; Yamanaka et al., 2013), but inconsistent with studies that did find benefit on QoL (Capotosto et al., 2017; Spector et al., 2003; Woods et al., 2006).

The results indicate there were no significant effects of vCST on depressive mood, evidenced by a non-significant interaction effect of time-point and group allocation on GDS-15 scores. This result is consistent with studies that found non-significant improvements in depressive mood for people who attended CST (Alvares-Pereira et al., 2021; Apóstolo et al., 2014; Paddick et al., 2017; Spector et al., 2003), but inconsistent with studies that found CST led to significant improvements in depressive mood (Capotosto et al., 2017; Marinho et al, 2021; Woods et al., 2006).

## Implications

As depression and QoL of people with dementia have been found to be associated (Woods et al., 2006), and depression may be a predictor of QoL in people with dementia (Kim et al., 2018), it is not unexpected that the non-significant results for depressive mood were accompanied by non-significant results for QoL. Several factors may have contributed to the lack of significance.

### *Lack of Cognitive Amelioration*

Firstly, the lack of significant QoL and mood effects may be due to the lack of cognitive improvements found in the sample, as found in Leung's (2022) study. In support of this, Woods et al. (2006) found that the effects of CST on QoL were mediated by cognitive improvements. The literature additionally suggest potential links between cognitive difficulties associated with dementia and QoL and mood (Downs & Collins, 2015; Woods et al., 2006). It could for example be that cognitive improvements contribute to positive self-evaluation.

### *Baseline Depression*

Secondly, non-significant effects found for depression could be due to low levels of baseline depression in the study sample. The mean baseline GDS-15 score was 4.26 and median baseline score was 3.50. However, a cut-off of 5 or 6 has been recommended as an indicator of depression (Herrmann et al., 1996; Osborn et al., 2002; Sheik & Yesavage, 1986). Low levels of baseline depression therefore likely played a role in a lack of significant improvement.

### *Study Design*

Another potential reason is the small sample size, which decreased statistical power. However, due to the pilot nature of this study and its feasibility aims, such limitations were expected. It is also to be noted that the analyses found small effect sizes for the interaction effects. This implies a larger sample size may not necessarily lead to statistically significant results (Sullivan & Feinn, 2012). Another potential reason for non-significant results for mood could be the presence of Type II error due to non-normally distributed post-test outcome data. Pre and post-test GDS-15 scores were transformed to be

as close to normality as possible, and the ANOVA is robust to Type I error when analysing non-normal data (Blanca et al., 2017). However, non-normal data can increase the probability of Type II error, and the ANOVA may not be robust to this error (Fayers, 2011; Lantz, 2012).

***Sample Characteristics***

Another possibility is the varied sample. Compared to previous CST studies that found significant improvements in depressive mood and QoL, the sample of the current study had a lower mean age and larger age range (48 to 88 years). In support of this, one longitudinal study found that the prevalence and incidence of symptoms such as apathy, depression, delusions, agitation, anxiety, and motor symptoms were lower in young-onset Alzheimer's Disease (i.e. before age 65) compared to late-onset Alzheimer's Disease, although large variability existed in the frequency of individual symptoms for both groups (van Vliet et al., 2012). Other studies found that people with young-onset dementia might have losses in roles related to their phase of life that may not impact people with late-onset dementia as greatly (van Vliet et al., 2013), and that people with young-onset dementia experience social difficulties that exceed that of older adults, with more individual and societal demands (Greenwood & Smith, 2016).

The sample was also varied in dementia subtypes. The proportion of participants with Frontotemporal Dementia was particularly high (10.8%) compared to previous trials of CST where dementia subtypes were specified, and it should be noted that 8.7% of the sample did not specify their dementia subtype. In comparison to Alzheimer's Disease, where everyday memory difficulties are typically observed, people with Frontotemporal Dementia tend

to experience more changes in behaviour and personality, or language difficulties (Braaten et al., 2006; Lindau et al., 2000). People with Vascular Dementia also tend to vary more in their symptoms, where the extent of memory difficulties depends on vascular pathology, compared to Alzheimer's Disease where memory difficulties are prevalent (O'Brien & Thomas, 2015).

It is plausible people with young-onset or non-Alzheimer's dementia are less likely to respond to vCST than standard populations, due to differences in symptoms experienced. vCST may therefore not sufficiently address the specific or more prevalent concerns of these populations. Nevertheless, it should also be considered that no significant differences were found between groups for age and dementia subtype, which might limit this explanation.

***Contextual and Confounding Factors***

There could be confounding or contextual factors that influenced the results. For example, COVID-19 restrictions were found to have a negative impact on negative mood and health-related QoL (Ferreira et al., 2021). In the current study, the first three vCST groups were conducted when COVID-19 lockdown was in place in the UK (January – March 2021) while the last three groups were conducted when COVID-19 restrictions were gradually being eased (July – December 2021). This could have influenced participants' ratings of QoL and mood over time, and may also explain the significant improvement in QoL over time for both groups. It was however less clear why the vCST group might have been more negatively impacted by COVID-19 compared to the TAU group, if COVID-19 did play a role. Some factors that could explain the varying impact of COVID-19 between groups include differences in the level of perceived social support between groups, perceived

community connectedness, or differences in the experience of COVID-19-related livelihood concerns – all of which were found to influence the impact of COVID-19 on well-being (White & Van Der Boor, 2020). It might for example be that the vCST group experienced less perceived social support compared to the TAU group.

Other factors that may have influenced the results include religiosity, sleep disruption, self-efficacy, and use of psychotropic medication, which have been found to may influence the QoL of people with dementia living in communities (Jing et al., 2016). Another study found that self-reported health, current emotional state assessed by recent loss, and anxiety may influence depressive mood for people with dementia (Savva et al., 2009). There could have been between-group differences for these factors that diminished the observed positive effects of vCST. However, further investigations of these factors are required to verify these explanations.

***Limitations of vCST***

Finally, non-significant results could have been due to limitations of vCST, pointing to a need for further development of the protocol. Technological unfamiliarity or the barrier of the screen may have impacted participants' attention and concentration (Perkins et al., 2022; Quail et al., 2021). In the initial development of vCST, it was found that people with dementia can find it more difficult or tiring to engage with the session online compared to face-to-face, and that digital literacy affected engagement (Perkins et al., 2022). It is also possible that participants had more difficulty recognising or remembering each other on screen, participating in an online format, or forming relationships remotely compared to face-to-face, due to a lack of physical contact (Perkins

et al., 2022). Specific aspects of the intervention may have also been harder to facilitate, such as the multisensory components of activities, due to a lack of access to physical objects (Perkins et al., 2022), possibly limiting engagement. While level of engagement was not measured, it may have accounted for a lack of significant results. Research in fact shows that meeting the needs for social engagement improves symptoms of distress in people with dementia (Cohen-Mansfield, 2018; Cohen-Mansfield et al., 2015; Knapp et al., 2006), suggesting that engagement is a relevant factor to consider for improving outcomes. More research is needed to shed light on specific limitations and aspects of virtual delivery that require modification.

**Limitations**

The study is not without limitations. There was firstly a limitation in that unblinding was not recorded. Thus, any accidental unblinding in the study, where participants inadvertently revealed their group allocation to assessors during the administration of post-test measures, was not documented. This may have biased post-test measurements. However, the current study did not find any significant improvements in QoL and mood outcomes, which could suggest that any accidental unblinding may not have influenced results. The QoL-AD and GDS-15 are also self-report measures, and perhaps less subject to the risk of assessor bias. Nonetheless, the documentation of unblinding is important to minimise the risk of conscious or unconscious bias due to knowledge of group allocation (Hróbjartsson & Boutron, 2011; Schulz et al., 2002).

Secondly, the study was limited to a sample of specific cultural backgrounds and ethnicity as it was conducted within the UK. In fact, the majority of participants were of White ethnic background, and may not represent ethnicities in the UK. Further, given the online nature of vCST, participants who did not have access to technology or who were unfamiliar with technology were excluded from our sample. It is therefore also plausible that the sample was biased toward a more educated population or population with higher socioeconomic status, due to increased availability and use of technology in these populations (Office for National Statistics, 2019). In fact, studies suggest how much of psychology and behavioural research is based on samples drawn from Western, Educated, Industrialised, Rich, and Democratic (WEIRD) societies, despite significant variability in results across populations and evidence that WEIRD participants are frequent outliers compared with the larger population (Henrich et al., 2010). These may limit the generalisability of results, and are important to consider in the evaluation of vCST.

Thirdly, there was a limitation in the outcome measures used. The QoL-AD is not validated for online administration, and there is a lack of existing measures of QoL for people with dementia validated for remote use. Furthermore, while the GDS-15 was chosen for its ease of administration, psychometric properties, and validation for remote administration and people with mild-to-moderate dementia, studies have found that the GDS-15 diminished in validity when administered to people with dementia compared to people without dementia (Kørner et al., 2006). In addition, both measures may

be subject to biases in self-reporting, which could be addressed with the use of more objective measures.

Fourth, there was a limitation in the constructs measured. While the current study examined outcomes relevant to the current literature and commonly assessed in previous CST studies, it did not consider other constructs that could be more relevant to the context. As discussed, the current study found that the sample had low scores on the GDS-15, indicating low levels of depression. This may indicate that the target population for vCST may not experience significant levels of depression common in people with dementia – although further research is required to confirm this possibility. It is possible that depression was not an appropriate outcome, and other measures of well-being, such as loneliness, may be more useful to examine, due to its prevalence and links to social isolation in people with dementia (Victor et al., 2020). Loneliness may be especially relevant given that vCST aims to increase the accessibility of CST to people with dementia who have difficulty accessing face-to-face interventions, and who may hence feel more isolated – also within the context of COVID-19 (Hwang et al., 2020; Wickens et al., 2021).

The study also did not explore anxiety, agitation, irritability and behavioural symptoms, which are common experiences for people with dementia (Savva et al., 2009), nor did it administer caregiver outcome measures, which could provide information not captured by self-report measures. Dementia has in fact been shown to negatively impact caregivers and contribute to caregiver burden (Etters et al., 2008; Papastavrou et al., 2007).

There was finally a limitation in outcome measures used. The QoL-AD is not validated for online administration, and there is a lack of existing measures of QoL for people with dementia validated for remote use. Furthermore, while the GDS-15 was chosen for its ease of administration, psychometric properties, and validation for remote administration and people with mild-to-moderate dementia, studies have found that the GDS-15 diminished in validity when administered to people with dementia compared to people without dementia (Kørner et al., 2006). In addition, both measures may be subject to biases in self-reporting.

**Future Directions**

Several future directions are suggested in light of the limitations above. Firstly, a larger scale and more fully powered randomised controlled trial could better delineate the positive effects of vCST. Despite the non-significant results found, initial qualitative feedback from participants in the development of the vCST protocol indicated positive feedback for the intervention, including how the sessions were enjoyable with stimulating activities, and how convenient they were to attend at home (Perkins et al., 2022). CST is also becoming more widely implemented virtually in services in the UK due to its increasing relevance; a recent survey of 33 memory clinics found that 80% of these clinics intend to offer hybrid virtual and face-to-face CST as a long-term option (Fisher et al., 2021). These suggest that vCST may have value not captured in this study, and that continued research remains clinically relevant. The effect sizes found for the current study may be used to estimate a sample size for a future trial. However, as discussed previously, it may be more appropriate to power

future studies based on other trials of face-to-face CST. Future trials may also want to consider the points suggested below.

Future studies on vCST could explore other outcomes perhaps more relevant to the target population, as this may provide a more accurate or holistic picture of the benefits of vCST. Qualitative interviews could provide information on domains that might be more appropriate or amenable to change following vCST, such as loneliness, informing the constructs investigated in future trials. It could also be useful for future studies on vCST to administer caregiver outcome measures, as this might provide valuable information not captured by self-report measures. It would be important for these studies to also ensure that unblinding is recorded to reduce the potential risk of bias

In relation to the above, future studies may also want to consider examining level engagement. Trials that investigate engagement with respect to specific session themes (e.g. Sounds, Childhood) are also required to further investigate the helpful and less helpful aspects of the intervention. Research conducting qualitative interviews with people with dementia and their carers could additionally provide useful information for any further modifications that need to be made.

Next, it could be useful for future research to validate QoL measures for remote use, given the increasing relevance of research on virtual interventions. The use of additional measures of depression and QoL could provide a more comprehensive evaluation of these outcomes.

In addition, it could be useful to investigate other factors that may influence the effects of vCST. For example, it would be useful to examine dementia subtype or level of engagement as predictors of the effects of vCST.

It would also be interesting to study and compare the effects of vCST for people with young-onset and late-onset dementia. This could inform future work on optimising vCST in terms of enhancing engagement or tailoring the intervention to different diagnostic subtypes or age of onset. It may also inform decision-making processes for offering vCST to people for whom it is more likely to work. Further research can additionally contribute to the evidence base and inform the continued development of national guidelines for interventions for people with dementia.

Lastly, it would be beneficial for future studies to consider the accessibility of vCST to other ethnic groups or people with dementia of lower socioeconomic status in the recruitment process for a more accurate evaluation of vCST. The accessibility of vCST to other ethnic groups may in itself be examined as a measure of the feasibility of vCST, and could be a relevant factor to consider in the development and adaptation of vCST to different cultures or ethnic groups within the UK. One possibility is via forming connections with organisations or foundations that do work around the difficulties faced by ethnic minorities. There however remains the question of increasing the accessibility of vCST to people who do not have access to the appropriate technology or knowledge of technology use. While vCST has the potential to increase the accessibility of interventions to people with dementia, it Is likely there will remain a limitation in the populations it is available to due to these larger systemic issues.

## Conclusion

The results of the current study suggest that CST administered virtually may not lead to benefits on QoL and depressive mood. Several limitations may account for a lack of significant results. Taken together with non-significant effects of vCST found on cognition, the results highlight a need to further investigate more helpful and less helpful aspects of vCST, and to continue developing and modifying the protocol for virtual administration. To that end, a larger scale trial could better delineate the effects of vCST, taking into account the limitations and future directions suggested in this paper (e.g. considering alternative outcomes) – especially as vCST has the potential to increase the accessibility of CST to service users and continues to be implemented in services. Further, vCST was found to be feasible in other domains (recruitment and retention, attendance, fidelity), further suggesting that continued research on vCST could be valuable.

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# Part 3: Critical Appraisal

## Introduction

The critical appraisal will begin with a discussion of my background as a researcher and research interests. It will then provide a reflection of the research process and challenges faced at different stages of the project, as well links to my theoretical orientation.

### Researcher Background

Prior to the DClinPsy, I was involved in various areas of research. My undergraduate research experience was a strong influence on my area of interest. As part of my undergraduate degree, I worked with a team specialising in neuropsychological research. While my project was on musical memory and less related to neuropsychology, working with the team led to an interest in the area of cognition and neuropsychological conditions. I was then involved in various projects in my work around the evaluation of interventions, including family therapy, interpersonal and social rhythm therapy, and an intervention for prison inmates. I found research evaluating interventions meaningful, especially as I was an aspiring clinical psychologist and later became closely aligned with the scientist-practitioner model and idea of evidence-based practice (Jones & Mehr, 2007). My work experiences allowed me to see that the results of such evaluations are crucial for informing and tailoring interventions to specific populations and client needs.

When I started the DClinPsy course, the project involving people with dementia was one I was immediately interested in. I thought evaluating an intervention that could help this population would be an interesting and meaningful one. I was also keen to work with Prof Aimee Spector, who has contributed significantly to research in this field.

## Conceptual Review

### Research Question

I decided on the topic of my conceptual review firstly in the view of updating a previous Numbers Needed to Treat (NNT) review on acetylcholinesterase inhibitors (AChEIs) (Livingston & Katona, 2000), and to examine the NNT for existing studies of Cognitive Stimulation Therapy (CST). Such a review for CST has not been done before despite the potential usefulness of the NNT statistic. However, while the NNT analysis provided valuable information, there were unique challenges and limitations that arose.

### Inclusion of Articles

There was firstly some difficulty with the inclusion of articles. As the NNT is a statistic that requires specific information to be calculated, and only a few studies reported such information, only few articles were originally included in the review. I therefore decided to contact the authors of the original studies that met my inclusion criteria for the required data. This was helpful, but there was still a significant number of articles that could not be included as the authors were not contactable. For the AChEI trials, some authors also expressed no longer having access to the trial data as the paper was published a significant amount of time ago. This limited the generalisability of the results of the review. More time and resources could have been useful to contact the authors and obtain data for the relevant studies where possible.

I also wondered about the less recent literature found on AChEIs compared to CST. It is possible that less funding was made available for research on donepezil, galantamine and rivastigmine over the years, given the established evidence base for these AChEIs and the emergence of new

dementia drugs such as memantine. The current NNT review only examined AChEIs recommended by current NICE guidelines for mild-to-moderate dementia (2018), and aimed to update an existing NNT review of these drugs. However, it might be useful for future reviews to examine and include more recent pharmacological interventions for mild-to-moderate dementia in comparison to CST, as they continue to be developed.

**NNT Analyses**

There were also some challenges around calculating NNTs. Some studies provided additional change scores on the ADAS-Cog as definitions for a desirable cognitive outcome, on top of a 4-point improvement commonly defined as clinically significant (e.g. 7-point improvement or no deterioration). This made the NNTs difficult to examine and compare, as not all studies provided additional cut-off scores, and different cut-off scores led to different NNTs. There was a balance that needed to be achieved between the amount of information provided in the review and how useful they are to include. The same dilemma arose when some studies provided NNT data for more than one population or analysis (i.e. intention-to-treat, per-protocol). This led to the decision to create a clearer direction for the review, and prioritise presenting information that met the aims and answered the questions of the review. Thus, NNTs were only calculated based on a 4-point improvement, and for intention-to-treat populations, with a clear rationale provided.

**Results**

It was tricky to compare NNTs between CST and dementia drugs, due to differences between the interventions discussed in the empirical paper. While the NNTs provided meaningful information and the results suggest both

interventions are comparable, there was a limit to drawing more specific conclusions about which interventions were more effective. Future reviews could therefore consider conducting a network meta-analysis to compare CST and dementia drugs for their effectiveness. This would have been an interesting alternative method to explore for the conceptual review given more time.

## Empirical Study

### Study Design

The empirical study was part of a larger project involving three other trainee clinical psychologists. Two trainees in the year above were involved in the initial development of virtual Cognitive Stimulation Therapy (vCST) and collected data for the first half of our sample. Another trainee and I in the same year were involved in examining its feasibility and collected data for the second half of the sample (Appendix). As I was only involved in the later part of the project, there was less involvement in the earlier processes such as ethical approval and decision-making on the constructs of interest. While the constructs examined in the study were important and based on current literature of CST, in hindsight, it would have been interesting to be involved in the initial stages as part of the research process and have more flexibility to consider other constructs that could be relevant to the context of this project. For example, given the impact of COVID-19, it might have been useful to consider loneliness or social isolation as outcomes. It was however in many ways time-saving and beneficial to be involved in the later part of the project and to have the support of many other trainees.

**Recruitment**

Recruitment for our study was done mainly via an online dementia research platform. There were some difficulties faced in recruiting the second half of our desired sample as we found that with time, fewer participants were expressing an interest in our study. This was perhaps due to the easing of COVID-19 restrictions during this period, which could have led to less social isolation and/or perceived need for an online intervention. Another factor that contributed to the difficulties with recruitment was the long time frame of the recruitment phase and the progressive nature of dementia. As we were looking for at least 8 participants (4 treatment, 4 control) in each run of a vCST group, when it was difficult to find enough interested participants, this meant that participants who had already provided their informed consent were left waiting for the start of their respective vCST groups until the required number was met. There were cases where recruited participants were no longer able to participate as their dementia had progressed suddenly, or due to other life circumstances that came up during the wait (e.g. health problems, other commitments). This resulted in us having to find more participants as quickly as possible to collect our data within the intended time frame of the project. It helped to take a more active approach to recruitment; instead of waiting for people to indicate an interest, we began contacting participants on the online recruitment platform whose demographic information matched with our study inclusion criteria. We then found that there were many people interested in our study who had not yet seen our study being advertised.

A few other difficulties arose, including participants we recruited who were taking part in, or who expressed a preference for, individual Cognitive

Stimulation Therapy (iCST) research. This iCST research was a separate project another researcher on the research team was involved in and was being advertised on the same recruitment website. As the principles of iCST and the evaluation measures used for that project were very similar to the principles of vCST and our project's own evaluation measures, it was not possible for participants to be involved in both projects. Thus, there was several participants who could not participate in our study or who had changed their mind about their participation. Moving forward, there needed to be active communication with the researcher of the iCST project about recruitment in order to ensure not to contact participants who were already contacted or recruited for our study – and vice versa. This helped with recruitment, although there were still a few participants who changed their mind about participating in our study as they had later come across the iCST study on their own.

**Randomisation**

The study made use of a treatment-as-usual (TAU), untreated control group. It was not possible to use waitlist controls in our study as the study was time and resource limited. The randomisation of participants into the treatment and control groups involved the use of Microsoft Excel and web-based randomisation tools, and the process and rationale were explained to participants when obtaining their informed consent. However, a number of participants allocated to the TAU group verbally expressed disappointment that they did not receive vCST after the completion of the post-test assessments. It was also apparent during recruitment that many of them were keen on the vCST groups and felt that they needed support. While these participants expressed that they understood the random allocation to either

group, and group allocation did not seem to result in any dropouts in our study, it felt unfortunate that we could not offer these participants other interventions. With a larger scope and more resources, for example if the project had involved the NHS, NHS ethical approval, and service-users, using a waitlist-controlled design could have been more ideal. If this was possible, potential ethical issues that could arise from denying participants access to treatment should also be considered (Elliott & Brown, 2002).

**Group Facilitation and Protocol**

Being involved in the facilitation vCST groups was enjoyable but had its challenges. Particularly what I found tricky was achieving balance between being supportive and directive as a facilitator, but also respecting the autonomy of the participants, people with dementia. There was for example a participant who provided feedback about the facilitation and nature of the group activities that could be perceived as infantilising. I reflected on my approach as a group facilitator, and wondered if certain activities in vCST (e.g. those involving games) may not necessarily benefit or sit well with some people with dementia, perhaps those in the milder stages of dementia who have fewer impairments or difficulties.

There were also challenges that came about due to the online nature of the groups. For instance, there were times participants would be distracted by events at home and were unable to engage in the session fully, and times where participants found it difficult to follow transitions on-screen. Participants also had different participation styles – some were more active and contributed more, and some were less active and had less of a chance to contribute. All of these were expected and understandable parts of the group process but did

make me consider the general difficulties catering to each participant's needs and preferences within each session, as well as possible differing levels of benefit of the groups for each participant.

According to Burlingame et al. (2013), various factors contribute to the effectiveness of small group treatments, including service-user characteristics, (diagnosis, personality), group structure (number of sessions, pre-group preparation), group leadership, formal change theory, and group processes (cohesion, self-disclosure, interpersonal feedback, conformity/power/conflict, leader style). The use of supervision to discuss these challenges was helpful to make adjustments, in line with the factors above. On top of being more aware of my style (e.g. adjusting tone of voice with participants), we made an effort to obtain regular qualitative session feedback from participants, especially as it is important to monitor group processes to ascertain the intervention's effectiveness (Marmarosh, 2018). We also tried to encourage participation with the use of functions that might make this easier, such as the online chat function, and offered a space for participants to interact with each other after the group so that they had the opportunity to get to know each other through informal conversation – an aspect that is missing in an online versus face-to-face format. Another adjustment we made was creating smoother transitions between slides with the use of PowerPoint such that it was less disorienting to participants.

We hoped this would also help to create an environment that fostered effective communication and increased feelings of trust and togetherness experienced in the group (Yalom & Leszcz, 2005). As the sessions continued, we did notice participants developing rapport and that an encouraging

environment was created. However, I also noted that there needed to be a level of acceptance and that it may not be possible cater to everyone's specific needs in a group, with some factors less within our control, such as service-user characteristics. Some of these factors and difficulties may have even contributed to the non-significant results of our study although they were not explored in the study design. It would be useful for future research on vCST to explore the specifics of these factors related to participant engagement.

The experience overall provided both valuable learning and information about potential adjustments to the vCST protocol. The challenges also highlighted the importance of training and supervision, especially as vCST is such a new intervention. The importance of trained staff has been highlighted in the National Institute for Health and Care Excellence (NICE) guidelines for dementia care (NICE, 2018).

**Data Analysis and Outcomes**

As this was a joint project with another trainee, there needed to be a discussion about our projects and the constructs we would be examining, such that our aims were different. It was decided that my project would be focused on quality of life and depressive mood as these constructs are not only relevant in current CST research but are also linked to well-being and closely related. The other trainee focused on cognitive outcomes and a feasibility analysis (Appendix). However, there were some challenges to this. Examining the outcomes of interest separately meant that I was unable to examine the relationship between any cognitive improvements or deterioration and quality of life and depression. In fact, one study previously found that CST's impact on quality of life could be mediated by cognitive improvements (Woods et al.,

2006). While the outcomes I examined provided relevant information on the effectiveness of vCST, it felt like a piece of the puzzle was missing in the data analysis and interpretation of results, especially as there needed to be a clear distinction between our project responsibilities and write-up of the empirical paper. The opportunity to perhaps publish our findings could present an opportunity for us to examine these outcomes in unison and provide further insight into the effectiveness of vCST.

Relatedly, it was disappointing that there were no significant results found on quality of life and depression, given that I was closely involved as a group facilitator and observed first-hand how much participants seemed to enjoy the groups. Of interest, some exploratory analyses were conducted after the main analyses, including analyses after removing significant outliers, and analyses according to different dementia subtypes. These led to similar non-significant findings.

While there were several limitations that could have led to this result, including limitations in study design and contextual factors, there also needed to be an acknowledgement of the limitations in vCST as an intervention that exploratory analyses could not delineate. Although the results were disappointing, it was important to remember as a researcher that they provided valuable information. Null findings are often seen as “negative” outcomes in the field of psychology, and the tendency to report or publish mainly significant results is one reason why there is a failure in the replication of previous studies (Mehler et al., 2019). It was important to recognise this and not be biased in the data analysis, interpretation, and reporting of the results.

## Theoretical Orientation

As mentioned earlier, I have developed a keen interest in research, especially in research evaluating clinical interventions. My involvement in this project has not changed my view that clinical research is important and meaningful and has in fact contributed to my confidence in providing evidence-based practice as a scientist-practitioner. This is especially so as I was not only involved in the evaluation of vCST, but also in the facilitation of vCST groups. I was hence able to experience both the clinical and research aspects of vCST.

The rigorous process of conducting research alongside my work on clinical placements was difficult but was a good learning experience and helped to develop my skills in planning, time management, and setting boundaries across my different responsibilities. These are all relevant skills to have moving forward as a scientist-practitioner in my future practice as well. I am keen to continue being involved in clinical research alongside clinical practice.

## Conclusion

Being involved in this project was a valuable experience and helped me to develop useful skills. There were some challenges faced, but I felt able to overcome these with the support of my research supervisors and my research partner, with whom the responsibilities were divided. Although the non-significant results of the study were not as I had hoped, it did provide important information about vCST and paves the way for future research directions in this area. I hope that my doctoral thesis has left a positive contribution to helping people with dementia.

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# Appendices

## Appendix A

### Contributions to Research Project

The project is a joint project with same-year trainee Michelle Wing Gi Leung. The project is a continuation of a project led by trainees in the previous cohort, Cerne Felstead and Luke Perkins. They were both involved in the development of the CST protocol for virtual administration and conducted focus groups and qualitative interviews for their theses. The first half of the data for the project was collected by Cerne and Luke.

Wing Gi and I were later involved in evaluating the feasibility of vCST. We analysed and reported different aspects and clinical outcomes of the study in order to investigate feasibility of vCST. We collected the second half of the data for our project in order to analyse and interpret the full set of data collected. I myself analysed and interpreted quality of life and depressive mood outcomes, secondary outcomes of the study. Wing Gi analysed and interpreted cognitive outcomes, the primary outcome of interest, and examined feasibility parameters of the study, including recruitment capability and sample characteristics, data collection procedures and outcome measures, acceptability and suitability of the intervention and study procedures, resources and ability to manage and implement the study and intervention, and participants' responses to the intervention.

The analysis of our respective outcomes and write-up of the theses were done individually.

# Appendix B

## Ethical Approval

**UCL RESEARCH ETHICS COMMITTEE**
**OFFICE FOR THE VICE PROVOST RESEARCH**

22/07/2020

Professor Aimee Spector
[department]
UCL

Dear Aimee Spector

**Notification of Ethics Approval**
**Project ID/Title: 17127.002 / Virtual CST – A collaborative proof of concept study with FaceCog HK in response to the Covid-19 pandemic.**

Further to your satisfactory responses to the Committee's comments, I am pleased to confirm in my capacity as Joint Chair of the UCL Research Ethics Committee (REC) that your study has been ethically approved by the UCL REC until **22/07/2023.**

Ethical approval is subject to the following conditions:

**Notification of Amendments to the Research**
You must seek Chair's approval for proposed amendments (to include extensions to the duration of the project) to the research for which this approval has been given. Each research project is reviewed separately and if there are significant changes to the research protocol you should seek confirmation of continued ethical approval by completing an 'Amendment Approval Request Form' http://ethics.grad.ucl.ac.uk/responsibilities.php

**Adverse Event Reporting – Serious and Non-Serious**
It is your responsibility to report to the Committee any unanticipated problems or adverse events involving risks to participants or others. The Ethics Committee should be notified of all serious adverse events via the Ethics Committee Administrator (ethics@ucl.ac.uk) immediately the incident occurs. Where the adverse incident is unexpected and serious, the Joint Chairs will decide whether the study should be terminated pending the opinion of an independent expert. For non-serious adverse events the Joint Chairs of the Ethics Committee should again be notified via the Ethics Committee Administrator within ten days of the incident occurring and provide a full written report that should include any amendments to the participant information sheet and study protocol. The Joint Chairs will confirm that the incident is non-serious and report to the Committee at the next meeting. The final view of the Committee will be communicated to you.

**Covid-19**
In view of the fast developments of the pandemic, the numerous projects being initiated and the constantly changing framework, please provide us with regular updates **every 4 months** regarding the ethical aspects of your project and the specific problems (if any) that you have encountered. At the end of the study, as part of the final report you have to submit to the UCL REC, please include

alongside a brief outline of the research outcomes, any experiences which would be valuable for informing the fast-track COVID review process, and in turn subsequent fast-tracked studies.

**Final Report**
At the end of the data collection element of your research we ask that you submit a very brief report (1-2 paragraphs will suffice) which includes in particular issues relating to the ethical implications of the research i.e. issues obtaining consent, participants withdrawing from the research, confidentiality, protection of participants from physical and mental harm etc.

In addition, please:

- ensure that you follow all relevant guidance as laid out in UCL's Code of Conduct for Research: www.ucl.ac.uk/srs/governance-and-committees/research-governance
- note that you are required to adhere to all research data/records management and storage procedures agreed as part of your application. This will be expected even after completion of the study.

With best wishes for the research.

Yours sincerely

**Professor Michael Heinrich**
**Joint Chair, UCL Research Ethics Committee**

## Appendix C

### Participant Information Sheet

CLINICAL, EDUCATIONAL & HEALTH PSYCHOLOGY

**Participant Information Sheet for CST Participants**
UCL Research Ethics Committee Approval ID Number: 17127.002

**YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET**

**Title of Study:** Group CST using zoom: A proof of concept study

**Department:**
**Clinical, Education & Health Psychology, Division of Psychology & Language Sciences**

**Name and Contact Details of the Researcher(s):**
**Michelle Leung**
**Diyanah Wahab**

**Name and Contact Details of the Principal Researcher:**
**Professor Aimee Spector**

**Invitation Paragraph**
You are being invited to take part in a research project. This research is being conducted by University College London in collaboration with Hong Kong University. Before you decide, it is important for you to understand why the research is being done and what participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

**What is the project's purpose?**
Cognitive Stimulation Therapy (CST) is a group-based dementia treatment that has been found to have positive effects in cognitive skills (such as memory) and quality of life, as well as being fun and enjoyable. However, practical issues such as transport may stop people being able to access CST, especially during the Covid-19 crisis. In this study, we aim to test out whether it is possible to run CST groups online via video conferencing in a similar way to running them face-to-face, and still have positive treatment effects.

**Why have I been chosen?**
We are looking to recruit people in the earlier stages of dementia. You must have access to the video conferencing app 'Zoom' and be comfortable joining a virtual group with approximately 3 other people for 60 minute sessions, twice a week for 7 weeks. We are also looking for people who are able to speak English, as we are regretfully unable to deliver the training in any other language at the moment.

1

**Do I have to take part?**
If you have the capacity to do so, then it is up to you to decide whether or not to take part. Your choosing to participate or not, will not in any way effect the care you receive from the health or charity service you access. If we are unsure about your capacity to decide, we might ask you some questions and give you some more information to check capacity. If we feel that something about your dementia makes it difficult for you to decide, then we will not ask you participate. This is because we want to make 100% sure that this is ***your*** informed decision.

If you *do* decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. You can withdraw at any time without giving a reason and without it affecting any benefits that you are entitled to. If you decide to withdraw, you will be asked what you wish to happen to the data that you have provided up to that point.

If you decide to withdraw at any point during the study or decide not to take part at all, your relationship with the organisation that you were recruited through will not be affected in any way.

**What will happen to me if I take part?**
If you choose to take part, you will be randomly assigned to either a 'zoom CST' group or a 'control' group. There is an equal, 50/50 chance of you being in either group. If you are in the control-group you will not receive zoom-CST.

- In the week before the first CST session, we will complete some questionnaires with you individually in a phone or zoom session. This will take approximately one hour.
- If you have been randomly allocated to the 'zoom-CST' group, we will then invite you to take part in the CST sessions online. This involves attending two, 60 minute sessions per week for seven weeks (14 sessions in total) via zoom. These are group-sessions that will be attended by approximately three other people.

  If you have you been randomly allocated to the 'control' group, we will not ask you to do anything, or attend our group during this time. You can access your usual treatment as you would if you were not taking part in this study.
- In the week after the last CST session, we will complete the same questionnaires with you individually in a phone or zoom session.
- We may then ask you to complete a feedback interview individually via phone or zoom about your experience of the group. This will last one hour or less.

**Will I be recorded and how will the recorded media be used?**
Except for the questionnaire sessions, all sessions will be video-recorded so that we can analyse how easy it is to engage with the group and the feedback you give. These recordings will only be used for the purposes described, will be anonymised as much as possible and will be destroyed once the analysis is complete. We will be using the video conferencing app 'Zoom'. Please read Zoom's privacy notice before consenting to take part. It can be found at: https://zoom.us/privacy.

**What are the possible disadvantages and risks of taking part?**
We do not expect that taking part in the study will cause you any distress. However, if we believe that you may be feeling distressed for any reason, we will try to check in with you, to see if we can support you in any way.

In the unlikely event that you become distressed during the sessions, one of our facilitators will try to call you to offer you support. If we are unable to reach you or we feel that you need further support once we have spoken to you, we will contact your carer or next of kin. We will seek to discuss this with you as best as we can before we do this but may not always be able to do so, for example if we are unable to contact you directly.

**What are the possible benefits of taking part?**
Our aim is to test whether running such groups via Zoom is feasible and if taking part has any benefits to your cognition (e.g. memory and language) and quality of life. This could lead to new methods of delivering treatments and improving access within health and care services for people diagnosed with dementia in the future.

**What if something goes wrong?**
We do not expect for anything to go wrong during the study, but if something should happen then please contact the researchers immediately using the contact details provided so that they can support you to try to resolve this. If you have any complaints regarding your treatment by researchers at any point, please contact the principal researcher at
If you feel that your complaint has not been handled to your satisfaction, please contact the Chair of the UCL Research Ethics Committee at ethics@ucl.ac.uk.

**Will my taking part in this project be kept confidential?**
All the information that we collect about you during the course of the research will be kept strictly secure and confidential. You will not be able to be identified in any reports or publications as your data will be fully anonymised. The researchers will be the only people who will have access to your data. All confidential information will be disposed of securely once it is no longer needed for the study.

**Limits to confidentiality**
Confidentiality will be maintained as far as it is possible, unless during our conversation we hear anything which makes us worried that you or someone else might be in danger of harm. In these cases, we will ask your permission to inform the relevant service to support you (e.g. your GP).

**What will happen to the results of the research project?**
Once you have completed the sessions and we have collected all of your information, we will analyse the results and write a report. If you have so requested, we will send you a copy of the findings. Your data will be fully-anonymised in any report or publication. You can choose to opt-out and have your data removed from the study up until Spring 2024. To do this please contact Prof. Aimee Spector using the details below.

**Local Data Protection Privacy Notice**
**Notice:**
The controller for this project will be University College London (UCL). The UCL Data Protection Officer oversees how we process your personal data, and can be contacted at data-protection@ucl.ac.uk

This 'local' privacy notice sets out the information that applies to this particular study. Further information on how UCL uses participant information can be found in our 'general' privacy notice:

> https://www.ucl.ac.uk/legal-services/privacy/ucl-general-privacy-notice-participants-and-researchers-health-and-care-research-studies

The information that we are required to give to you under data protection legislation (GDPR and DPA 2018) is provided across both the 'local' and 'general' privacy notices.

The categories of personal data used will be as follows:

*Name, Address, Telephone number, Email address, Age, Gender, Ethnicity, Type of dementia (if known), Name, relationship and phone number of carer/next of kin, GP Name and contact details*

The lawful basis that we use to process your personal data is that the study is being carried out in the public interest. The lawful basis used to process special category personal data will be for scientific and historical research or statistical purposes.

Your personal data will be used as long as it is required for the research project. All identifiable data will be destroyed upon completion of the project in Spring 2024. All fully-

anonymised data will be kept and archived 5 years following completion of the study. We will seek to anonymise the data as much as possible.

If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at data-protection@ucl.ac.uk.

**Who is organising and funding the research?**
This research is organised and funded by UCL as part of the Clinical Psychology Doctoral programme.

**Contact for further information**
Should you wish to contact the researchers for further information, please use the following contact details:

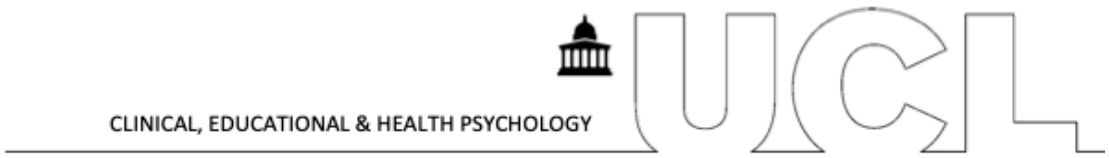
***Principal Researcher**: Professor Aimee Spector*
***Address:** Clinical, Education & Health Psychology, Division of Psychology & Language Sciences, 1-19 Torrington Place, London, WC1E 7HB*
***Telephone:***

If at any time you are feeling low in mood, please visit your GP in the first instance. If you feel unable to keep yourself, or someone else, safe then please attend A&E and seek support. You can also seek support with the Samaritans (24hours) by telephoning 116 123.

**Thank you for reading this information sheet and for considering to take part in this research study.**

## Appendix D

### Participant Consent Form




**CONSENT FORM FOR ONLINE CST GROUP PARTICIPANTS**

**Please complete this form after you have read the Information sheet and/or listened to an explanation about the research.**

**Title of Study:** Group CST using zoom: A proof of concept study

**Department:** Clinical, Educational and Health Psychology
**Name and Contact Details of the Researcher(s):**
Ms. Diyanah Wahab
Ms. Michelle Leung
**Name and Contact Details of the Principal Researcher:**
Professor Aimee Spector

**Name and Contact Details of the UCL Data Protection Officer:**
Alex Potts

**This study has been approved by the UCL Research Ethics Committee: Project ID number: 17127/002**

Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

**I confirm that by emailing the researcher the following statement I am consenting to the 16 elements of the study written below:**

*"I NAME and my carer NAME, have read the information sheet and consent forms for the study titled 'Group CST using zoom: A proof of concept study'. With this email, I hereby electronically 'sign' and consent to taking part in the study and to the 16 items outlined on the consent form."*

| | |
|---|---|
| 1. | I confirm that I have read and understood the Information Sheet for the above study. I have had an opportunity to consider the information and what will be expected of me.<br><br>I have also had the opportunity to ask questions which have been answered to my satisfaction and would like to take part in:<br>- *an appointment to complete questionnaires prior to my attendance at the online CST group sessions.*<br>- *14 sessions of an online CST group intervention, if allocated to the 'zoom-CST' group.*<br>- *an appointment to complete questionnaires after attendance at the online CST group sessions.*<br>- *an appointment at the end, where I will be asked some questions about my experience of participating in the group.* |
| 2. | I understand that my personal information (*name, age, gender, ethnicity, address, telephone number, email address, dementia type, questionnaire answers and session recordings)* will be used *only* for the purposes explained to me. I understand that according to data protection legislation, 'public task' will be the lawful basis for processing. |
| 3. | I understand that the online CST sessions will be video-recorded for research purposes only. I consent to this recording. |
| 4. | I confirm that I have read the 'Zoom' privacy policy (Here: https://zoom.us/privacy) and that I consent to the use of 'Zoom' for the delivery of the online CST sessions. |
| 5. | I understand that all personal information will remain confidential and that all efforts will be made to ensure I cannot be identified. |
| 6. | I understand that if I disclose anything which indicates that I, or someone else may be at risk of harm, that the researchers have the responsibility to report this to the relevant services. |
| 7. | I understand the direct/indirect benefits of participating and any potential risks. I am aware of the support that I can access should I become distressed during the course of the research. I consent for the facilitators to contact my carer/next of kin in the unlikely event that I become distressed during the study and the |

| | |
|---|---|
| | facilitator is unable to contact me directly or believes that I may need further support once they have spoken to me. I understand that they will seek to inform me before they do this but this may not always be possible. |
| 8. | I understand that the data will not be made available to any commercial organisations but is solely the responsibility of the researcher(s) undertaking this study. |
| 9. | I consent to my fully-anonymised data being shared with collaborating researchers. |
| 10. | I understand that I will not benefit financially from this study or from any possible outcome it may result in in the future. |
| 11. | I understand that the information I have submitted will be published as a report and that I can request to receive of copy of this report. |
| 12. | I have informed the researcher of any other research in which I am currently involved or have been involved in during the past 12 months. |
| 13. | I am aware of who I should contact if I wish to lodge a complaint. |
| 14. | I voluntarily agree to take part in this study. I understand that I can withdraw at any time, in which case any personal data I have provided up to that point will be deleted unless I agree otherwise. |
| 15. | I would be happy for the fully-anonymised data I provide to be archived at UCL and may be used for future research |
| 16. | I consent to be contacted by the researchers in order to arrange pre/post appointments. |

**If you consent to the above 16 items, and you would like to participate in the study please email or with the statement below.Please insert your name and the name of your carer (if appropriate).**

*"I NAME and my carer NAME, have read the information sheet and consent forms for the study titled 'Group CST using zoom: A proof of concept study'. With this email, I hereby electronically 'sign' and consent to taking part in the study and to the 16 items outlined on the consent form."*

## Appendix E

### Recruitment Poster


CLINICAL, EDUCATIONAL & HEALTH PSYCHOLOGY UCL

**Do you have dementia and would like to receive support online?**

**Would you like to take part in our research study?**

Cognitive Stimulation Therapy (CST) is an evidence-based treatment for people with dementia. It is regarded as the **best non-medical treatment for improving cognitive skills** and therefore the main treatment offered by the NHS. Research shows that it can **significantly improve quality of life and reduce depression**. CST is usually offered as face-to-face group sessions, often within memory services. The groups are intended to be fun, engaging and social, whilst following structured activities. We are trialling a CST group online through 'video-call' so that people with dementia can access this treatment from their home.

**We are looking for...**

- People with mild-moderate dementia.
- People who speak English.
- People who have access to a tablet or computer, & internet at home.
- People who would be happy to attend two sessions a week, over seven weeks in May 2021 – December 2021.

*"After the sessions, she came out a brighter, happier person."* - Carer

*"Oh it was fun... More fun because you were in a group."* - Group member

UCL Research Ethics Committee Approval ID: 17127.002

## Appendix F

# Demographics Questionnaire

CLINICAL, EDUCATIONAL & HEALTH PSYCHOLOGY

### PARTICIPANT DETAILS

All the information that we collect about you during the course of the research will be kept strictly secure and confidential. You will not be able to be identified in any reports or publications as your data will be fully anonymised. The researchers will be the only people who will have access to your data. All confidential information will be disposed of securely once it is no longer needed for the study.

| | |
|---|---|
| **Participant Full Name** | Click or tap here to enter text. |
| **D.O.B** | Click or tap to enter a date. |
| **Gender Identity** | Male ☐ Female ☐ Non-Binary ☐<br>Prefer not to say ☐ Other: Click or tap here to enter text. |
| **Ethnicity** | ☐ Arab<br>☐ Asian or Asian British – Indian<br>☐ Asian or Asian British – Pakistani<br>☐ Asian or Asian British – Bangladeshi<br>☐ Asian or Asian British – any other Asian background<br>☐ Black or Black British – Caribbean<br>☐ Black or Black British – African<br>☐ Black or Black British – any other Black background<br>☐ Chinese<br>☐ Mixed – White and Black Caribbean<br>☐ Mixed – White and Black African<br>☐ Mixed – White and Asian<br>☐ Mixed – Any other mixed background<br>☐ White – British<br>☐ White – Irish<br>☐ White – any other White background<br>☐ Any other ethnic origin group: Click or tap here to enter text. |
| **Dementia Type** | ☐ Alzheimer's disease<br>☐ Lewy body dementia<br>☐ Vascular dementia |

| | |
|---|---|
| | ☐ Frontotemporal dementia<br>☐ Creutzfeldt-Jakob disease<br>☐ Wernicke-Korsakoff's dementia<br>☐ Parkinson's-related dementia<br>☐ Huntington's-related dementia<br>☐ Other: Click or tap here to enter text. |
| **Address** | Click or tap here to enter text. |
| **Telephone No.** | Click or tap here to enter text. |
| **Email address**<br>***(we will send group joining details to this address)*** | Click or tap here to enter text. |
| **GP Details** | Click or tap here to enter text. |

| | |
|---|---|
| **Carer Full Name** | Click or tap here to enter text. |
| **Relationship** | Click or tap here to enter text. |
| **Address** | Click or tap here to enter text. |
| **Telephone No.** | Click or tap here to enter text. |

| *For Office Use* | |
|---|---|
| **Capacity to consent** | Yes ☐ No ☐<br>Click or tap here to enter text. |
| **Access to device/internet?** | Click or tap here to enter text. |
| **Random Group Assignment** | vCST ☐ TAU ☐ |
| **Identity Code for Anonymisation** | Click or tap here to enter text. |