Effectiveness of virtual Cognitive Stimulation Therapy (vCST)

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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.

Signatur 

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Date: 26th June 2022

Overview

The three-part thesis explored the effectiveness of Cognitive Stimulation Therapy (CST) and its adaption to virtual implementation. The feasibility of the virtual CST and its impact on cognition were investigated.

Part One: Systematic Review – A systematic review and meta-analysis was conducted to investigate the effectiveness of Cognitive Stimulation Therapy and its clinical implications. Only studies that adopted Spector et al 2001., and Spector et al., 2003 CST framework, and randomised controlled trials were included in the synthesis.

Part Two: Empirical Paper – The feasibility of vCST and its impact on cognition were investigated in this study. Outcome measures on cognition were used to demonstrate any effectiveness found after the implementation of vCST. This project was a joint project with Nur Diyanah Abdul Wahab (DClinPsy, 2022). The distribution of work is summarised in Appendix A.

Part Three: Critical Appraisal – The critical appraisal adopted a reflective standpoint to discuss the research process, including the feasibility of the study, study design, data analysis and personal and research challenges faced.

Impact Statement

The present study investigated the feasibility of virtual Cognitive Stimulation Therapy (vCST) and its impact on cognition in people with dementia (PwD). No effects were found in cognition after vCST. The study used a quantitative approach to explore the effectiveness of vCST. With the global pandemic happening for almost two years, this current study paved for future CST studies to demonstrate possible methods to implement virtual interventions, through the delivery of group CST through a virtual platform, Zoom.

Future research is recommended to explore the methods to adopt a more multisensory approach while implementing vCST and including PwD from various cultural backgrounds to increase the diversity of the sample. As the present study is a pilot study with a small sample size, future research could conduct a randomised controlled trial with larger sample size. Future studies could also investigate the social and emotional loneliness of PwD.

In terms of clinical implication, the delivery of vCST could be beneficial to PwD with mobility issues or who are geographically isolated from the public.

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Finally, to all the precious friendships I have made throughout the doctorate and my lovely friends from all over the world, I am grateful for the prompt and empathetic support from you throughout this challenging period of time.

Part One- The effectiveness of cognitive stimulation therapy (CST) for people with mild-to-moderate Dementia- a systematic review and meta-analysis

Abstract:

Objective:

This study aims to provide an up-to-date systematic review and meta-analysis, following Spector et al. (2003)'s protocol, of the effectiveness of cognitive stimulation therapy (CST) on general cognition, psychological, social and behavioural functioning and quality of life in people with dementia and carers.

Methods:

As this research is an update of a 2018 systematic review, a literature search was performed on databases of PUBMED, Web of Science, PsycINFO and SCOPUS between March 2017 to March 2022. Only randomised controlled trials investigating the effectiveness of CST were included in this quantitative synthesis. Outcome measures of general cognitive functioning, specific cognitive domains (i.e. language and memory), psychological, social and behavioural functioning, and quality of life were included. Three studies included caregivers' general health and quality of life, which were also involved in the synthesis.

Results:

A total of 252 papers were screened and 12 were finally included after inclusion/ exclusion criteria were applied. The studies' qualities were analysed qualitatively using the Stroke Prevention and Educational Awareness Diffusion (SPREAD) and The Jadad Scale method. A random effects meta-analysis was performed to calculate effect sizes of CST. Pooling results from seven and nine studies, positive effect was found in improving general cognitive functioning and alleviating depressive symptoms respectively. No effect was found in quality of life, specific cognitive domains i.e. memory and language, everyday functioning, communication,

dementia severity and anxiety in people with dementia. In terms of caregivers, their health status and quality of life showed no effect from CST.

Conclusion:

We found that CST has a positive impact on general cognitive functioning and depression among people with dementia. Future studies could adopt a more rigorous methodology to investigate the efficacy of CST in other domains, i.e. reaching a consensus on outcome measures being included in studies for future data synthesis.

Introduction:

Dementia is an umbrella term for a number of conditions affecting individuals cognitively and behaviourally, including memory loss, problems with reasoning and communication, change in personality and reduction in performing daily activities. It is estimated that 55 million people are living with dementia worldwide. Nearly 10 million new cases are diagnosed per year, with a new estimate of 78 million by 2030 and 139 million by 2050 (World Health Organisation, 2021). In addition to the direct impact on people with dementia (PwD) and their caregivers, dementia is associated with significant health and social care costs (World Health Organisation, 2021). In the absence of a cure for any major cause of dementia, a large and growing body of research studies have examined psychosocial interventions aimed at improving cognition and social and emotional impact of dementia on PWD and caregivers.

Various methods of psychosocial interventions have been implemented in the past decades to improve general cognition and reduce the emotional and social impact of PwD and their caregivers. Cognitive Stimulation Therapy (CST) is a well-established, manualised psychosocial intervention developed in 2003 by Spector et al. (2003). It consists of engaging PwD in enjoyable social interactive activities, which promote general stimulation for thinking, concentration and memory. It is led

in small groups, delivered by dementia care personnel, and has been shown to have improved the quality of life and slowed down cognition deterioration in PwD (Woods et al., 2006) compared to treatment as usual. It is also found to positively impact neuropsychiatric symptoms and reported loneliness (Capotosto et al., 2017). Furthermore, CST has proven to be cost-effective and was recommended by the National Institute for Health and Care Excellence (NICE) as an effective treatment to improve cognition, independence and well-being for PwD with mild to moderate dementia (National Institute for Health and Care Excellence, 2018).

The CST protocol comprises 14 group sessions, 45 minutes each, twice weekly for seven weeks. CST integrates features of reminiscence therapy, implicit learning principles and multisensory stimulation, where in each session, a designated theme will be introduced to participants, through the combination of the above-mentioned features. During CST, individuals are invited to participate in activities that focus on stimulating their behavioural, emotional and interpersonal aspects (Woods et al., 2012), aiming to stimulate their cognition, memory, executive functioning and spoken and comprehension of language to improve overall well-being and quality of life of people with dementia, i.e. depression, anxiety, everyday living and communication. CST has shown to be effective in previous studies and reviews (Aguirre et al., 2013; Spector et al., 2010; Spector et al., 2003; Woods et al., 2006). Recently, studies had also included exercises (i.e. Taiichi), fall prevention techniques for older adults and Parkinson-adapted method in conjunction with CST, and found promising results in promoting the wellbeing of PwD (Binns et al., 2020; McCormick et al., 2017; Skov et al., 2022; Young, 2020).

Lobbia. et al. (2019) conducted a systematic review of studies analysing the efficacy of CST on both randomised controlled trials (RCTs) and pre-post design clinical

trials up to 2017. The effects of CST on general cognitive functioning and psychological, social and behavioural functioning of PwD were investigated. A moderate level of evidence was found in general cognitive functioning, quality of life, spoken language and comprehension. However, weaker levels of evidence were found in short-term memory, depression, praxis, orientation, social loneliness, depression, communication and behaviour in people with dementia. A more recent meta-analysis (Y. L. Wong et al., 2021) evaluated 20 RCTs on ranges of cognitive stimulation activities as well as manualised CST (Spector et al., 2003). The results demonstrated improvements in general cognitive functioning, but inconclusive effects were found on the quality of life and depressive mood of PwD (Y. L. Wong et al., 2021). Considering the variation in protocols, contents, method of delivery, programme durations and dosages, cognitive stimulation activities are considered different to manualised CST, though they share some similarities.

To date, there was no systematic review and meta-analysis focused exclusively on RCTs of the 14-sessions manualised CST by Spector et al. (2003). The recent reviews either evaluated two design methodologies or included both cognitive stimulation activities and CST as one sort of intervention. Following the literature search of Lobbia. et al. (2019), this current study aims to provide an updated systematic review and a meta-analysis on the effectiveness of 14 session group CST run according to the Spector et al's protocol (Spector et al., 2001) and its impact on the general cognitive functioning, social and psychological domains of PwD and their caregivers' well-being and perceived burden.

Method

Criteria for Inclusion of Studies in This Review

Only RCTs were included in this study. Included studies were then combined with the reviewed RCTs that were published by Lobbia. et al. (2019) from 2001-to 2017. Inclusion criteria include : (1). published in peer review journal, in English, full-text, between March 2017- April 2022, (2). adopting the original 14 sessions CST manual (Spector et al., 2001; Spector et al., 2003) or a culturally adapted version, (3) participants included in the studies were all diagnosed with mild-to-moderate dementia according to the Diagnostic and Statistical Manual of Mental Disorder (DSM-fourth edition or fifth edition). Full-text articles that were not RCT, not CST protocol by Spector et al (2001,2003), CST combined with other modalities, maintenance, individual, virtual or expanded CST programme, qualitative and review articles were excluded.

Some studies that involved family caregivers were also included, either by directly or peripherally collecting data on the dyad's relationships. Outcome domains of CST of PwD were analysed independently from caregivers. They were categorised as primary and secondary domains, where the former assessed the improvements in general cognitive function and specific cognitive domains, including memory and language of PwD (see below tables), while the latter captured improvements in PwDs' quality of life, psychological functioning including mood, behavioural and everyday life functioning, communication and dementia severity (see below tables). In terms of caregivers, their general health status and perceived burden were assessed (see below tables). Outcome measures immediately after interventions were included, while follow-up data were excluded in this current review.

Literature Search Strategies

Databases, i.e. PubMed, Web of Science, PsycINFO (Ovid) and SCOPUS were searched systematically. Keywords were used to identify the targeted sample, i.e. "Alzheimer's disease", 'dementia', 'people with dementia' using the Boolean term "OR" while combining using the Boolean term "AND" with keywords for a specific intervention, i.e., Cognitive Stimulation Therapy and CST, and specific clinical trials, i.e. RCT, based on Lobbia. et al. (2019). Reference lists of previous reviews and RCT on CST interventions for dementia were also reviewed to identify additional articles. Titles and abstracts were screened initially to narrow down the selection. Full texts were then assessed thoroughly to ensure the studies' designs met the mentioned inclusion criteria to get the final selection.

Identification of New Studies and Data Extraction

Eligible studies were identified, and duplicated records were removed. The study was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. See the flowchart below for the identification of new studies for the current review. Data extraction was conducted using an excel sheet with headers capturing specific information needed for each trial, including publication author, year, intervention settings, sample descriptors, outcome measures for effect size calculation. The results were cross-checked with second reviewers for accuracy. Disagreements regarding data extraction were resolved by consensus or by the third author.

Quality assessment process

For data extraction, all selected studies were described in tabular form, taking into consideration the following different key aspects: characteristics of the sample, design and procedure of the study, activities of the control group, inclusion/exclusion

criteria and outcome measures of the intervention. The overall methodological quality of each study was examined using the Jadad Scale (Jadad et al., 1996) and SPREAD method (Inzitari & Carlucci, 2006). They were then rated by two reviewers (NDW, EH) independently. The scale enables researchers to monitor the possibility of bias in research reports, scoring up to 5 points, based on the following criteria: whether the study was (I) randomised and/or (II) blinded, and (III) whether details were provided regarding the randomisation and (IV) double-blinding methods, and (V) dropouts. Points would be deducted if the method of randomisation/ or double blinding was inappropriate. A study that scored from 3 to 5 was classified as "high-quality", scored as a 2 was graded as "medium-quality", and "low-quality" if it scored 0 or 1 (Jadad et al., 1996).

In addition, the level of evidence derived from each study was categorised using the SPREAD method (Inzitari & Carlucci, 2006) as follows:

a. 1++ for high-quality individual RCTs with small confidence intervals (CIs) and highly significant results
b. 1+ for good-quality individual RCTs with small CIs and highly significant results
c. 2++ for high-quality cohort studies with small CIs and/ or highly significant results
d. 2+ for good-quality cohort studies with small CIs and/ or highly significant results

Studies with large CIs and/or scarcely significant results were graded with a minus (—) sign. The related strength of evidence (grade of recommendation) was rated as follows:

a. grade B for studies with levels of evidence 1++ or 1+

b. grade C for studies with levels of evidence 2++ or 2+

c. grade D for studies with a level of evidence of 2+, or studies classified with a minus (—) sign, regardless of the level of evidence.

All studies included in this current review were RCTs, they were being classified as 1+ or 1- and grade B or D depending on the CI and the scarcity of significant results. The final ratings were reached by consensus between the two judges.

Meta-analysis:

Primary Outcomes:

In order to perform a meta-analysis of the effects of CST on cognitive functioning, data extraction was conducted through gathering of general cognitive functioning measures. Effects on specific cognitive domains, such as language and memory were extracted from measure. See table 2 for details of primary outcomes.

Secondary Outcomes:

In addition to cognitive functioning, secondary outcome data extractions were also conducted for measures including PwD's quality of life, behavioural functioning measured by PwD's everyday functioning, psychological functioning measured by PwD's mood in depression and anxiety, PwD's communication and caregiver's quality of life. See table 2 for details of secondary outcomes.

Data synthesis:

Effect sizes were calculated of RCTs outcome measures as recommended(Morris, 2008). The calculation of the effect size was based on the mean pre- and post-change (Post-Pre) minus the mean change pre-post in control group (Post-Pre), divided by the pooled standard deviation (SD). Thus, the raw mean difference and pooled SD was first calculated and followed by the calculation of the SMD effect size (Cohen's d) for both the treatment group and control group.

Data analysis:

Meta-analysis was used to analyse general cognitive functioning, cognitive functioning in specific cognitive domains as well as quality of life, psychological, i.e. mood in depression and anxiety and behavioural outcomes, i.e. PwD's everyday life functioning, communication, and caregiver's quality of life. Outcome measures were grouped when there was more than one study reported the same outcome in a random-effects meta-analysis.

Results

The literature search identified a total of 252 records. A detailed PRISMA flow diagram of trail identification and selection is presented in Figure 1. After reviewing the titles and abstracts, 66 articles were excluded because they were duplicates, not in English, or irrelevant to the topic of the current review. In the analysis of full text, of the 186 records, articles that were 1) not CST protocol by (Spector et al., 2001; Spector et al., 2003), 2) Cognitive stimulation combined with other modalities, 3) Maintenance, individual, virtual or expanded CST programme, 4) Qualitative and other studies, 5) Review articles and 6) not RCTs were excluded. In total, the review considered four RCTs published from March 2017 to April 2022 (see Figure 1 for details). Three (Spector et al., 2010; Spector et al., 2003; Woods et al., 2006) investigated different aspects of CST's effectiveness in the same sample as Spector et al. (2003) and were consequently considered as one single study. Combined with the 6 RCTs included by Lobbia et al. (2019), this review included 10 RCTs in total for quantitative synthesis. See Table 1 for the characteristics of the studies.

Description of the reviewed studies

Experimental design:

All studies included in this current quantitative synthesis were single-blinded RCTs. Six of the studies were conducted in multiple centres across different settings (see table 1).

Sample:

Participants were from various settings, including residential care homes, long-term care facilities, day centres, community mental health teams, voluntary sector, nursing homes, rehabilitation centres, hospitals, dementia care services or living at home. Some of the studies were conducted in other countries, including Japan, Italy, Brazil and Portugal.

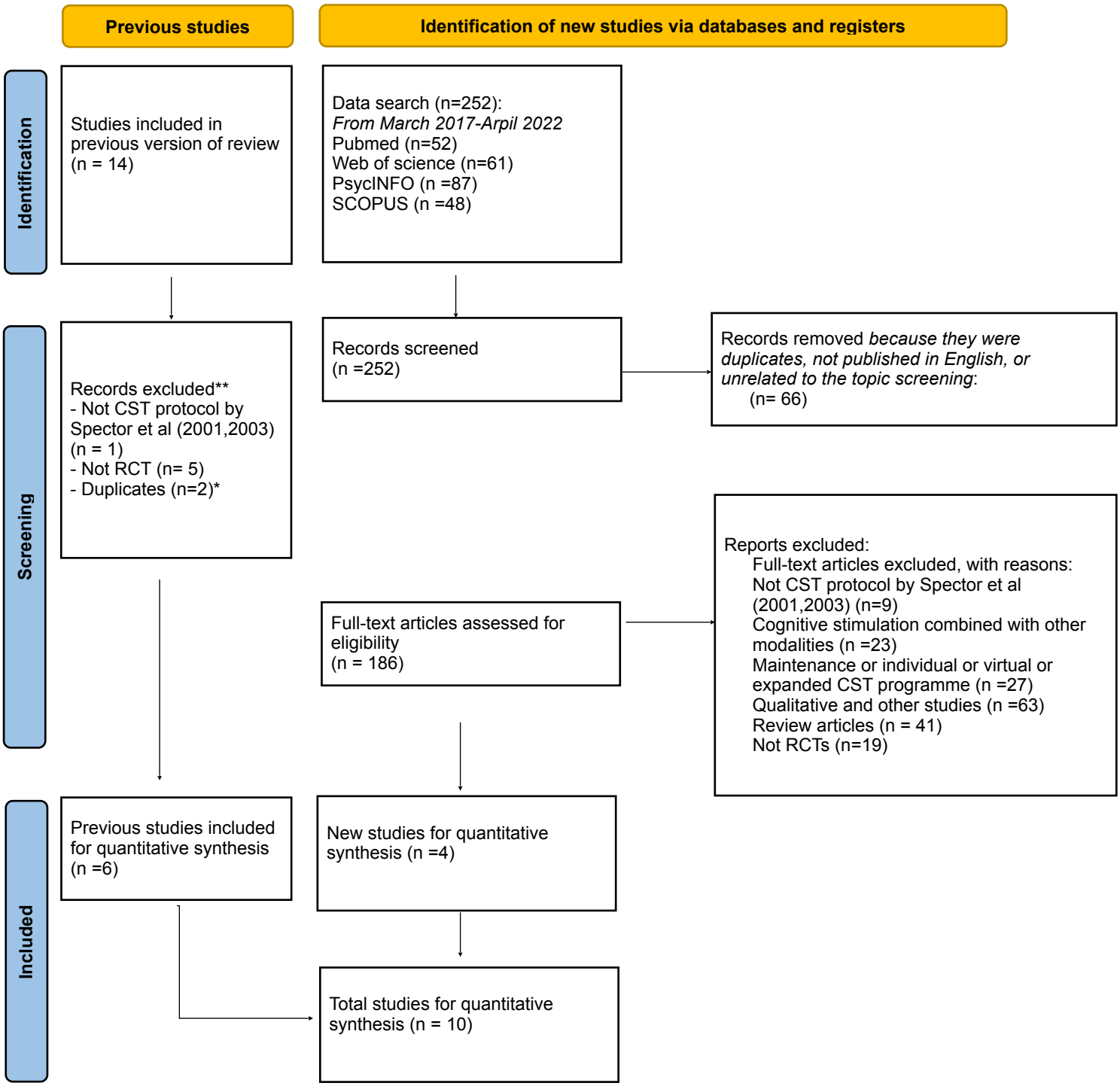


Figure 1. PRISMA Flowchart showing the number of studies identified included and excluded. *Three studies out of the 13 included (Spector et al., 2010; Spector et al., 2003; Woods et al., 2006) looked into different aspects of CST's efficacy by analysing the sample of Spector et al. (2003) and were consequently considered as one single study. Thus, only one study, Spector et al., 2003, was included for synthesis.

Participants:

There were 833 participants included in this review. Their mean age ranged from 77.3 to 86.5 years old. All studies reported gender distribution except Spector et al. (2001) (n=35); most included mainly female participants (573 females; 225 males). All studies used validated diagnostic guidelines including DSM-III, DSM-III-R, DSM-IV and DSM-V and ICD-10. All studies reported the subtypes of dementia, and nearly all of them included those with Alzheimer's disease, except for one study that included those only with Vascular Dementia (Piras et al., 2017). One study reported the number of each subtype of dementia within the sample (Piras et al., 2017). Eight studies reported the severity of dementia (mainly mild to moderate dementia). Two of the 10 studies considered caregivers (Marinho et al., 2021; Spector et al., 2001) (see Table 1).

Group facilitators

The CST groups were conducted by different allied health professionals, including graduate specialists in ageing, clinical psychologists, nurses, occupational therapists, care workers, and researchers.

Control Groups

Eight of the 10 studies involved comparing CST treatment group with the treatment as usual (TAU) control group, i.e. their usual care. Three of the studies involved with CST treatment group compared with active control groups, consisting of 14 sessions, which included usual activities organised at the centres of setting, i.e., reading stories/newspapers, group discussion, group games, creating activities that involved arts and crafts, singing and music, and low-impact exercise (see Table 1).

Caregivers

Four of 10 studies involved caregivers (Marinho et al., 2021; Piras et al., 2017; Spector et al., 2001; Yamanaka et al., 2013). Caregivers were invited to attend two individual assessment sessions, similar to the treatment group, before and immediately after CST intervention. They were encouraged to fill out one to two questionnaires (see Table 1).

Table 1. Description of the 10 Randomised Controlled Trials (RCT) studies on the CST protocol by Spector et al. (2003).

Authors	RCT	Dementia Diagno	Sample	Gender and Mean	Setting	OUTCOMES	Quality rating and comments
(1) Spector et al (2001)	RCT Pilot study CST treatment group versus control group	:	35 PWD CST group: n = 21 TAU Control group: n = 14 Dropout: n = 8 ; Carers: n = 10	Female: - Male:- Mean age: 85.7 years (SD = 6.7).	Living situation: at home (12); in a residential home (23). Setting: 3 residential homes ; 1-day care	*Sig. improvement in:* depressive, p=0.02 (Cornell Scale); Sig. Improvement in carers' general psychological distress, p=0.04 (GHQ-12) *Non-sig. improvement:* Trend towards Improvements in: general cognition (ADAS-Cog; MMSE); Trend towards improvement in anxiety symptoms (RAID); Severity of dementia (CDR) increased for controls but Marginal decline in Behaviour (CAPE-BRS) and communication (Holden Scale) in both the CST and control groups;	JADAD High (3/5) SPREAD Level of evidence: 1— Grade of recommendation: D Pos: described as randomized, description of the method of randomization included, description of drop- outs included. Neg*: Small
(2a) Spector et al (2003) (2b) Woods et al (2006) (2c) Spect	RCT Multi-centre Single blind CST treatment group versus control group	: not specified.	201 PWD CST group: n = 115 TAU Control group: n = 86 Dropout: n =	Female: 158 Male: 43 Mean age: 85.3 years (SD = 7.0).	18 residential homes ; 5 day care centres.	*Sig. Improvements in*: general cognition, p=0.044; p=0.014 (MMSE; ADAS-Cog), quality of life, p=0.028 (QoL-AD) *No sig. improvements in:* functional ability (CAPE–BRS), anxiety (RAID), or depression (Cornell Scale), communication (Holden Scale).	JADAD Medium (2/5) SPREAD Level of evidence: 1+ Grade of recommendation: B Pos: described as randomized, good description of the method of randomization,

Table 1. (Continued)

Authors	RCT	Dementia Diagno	Sample	Mean Age	Setting	OUTCOMES	Quality rating and comments

(3) Cohen (2011)	RCT CST treatment group versus control group	Dementia diagnosis sub-type: not specified. Setting: Dementia severity: mild to moderate.	27 PWD CST group: n = 14 Control group ^: n = 13 Dropout: not specified.	Female: 14 Male: 13 Mean age of CST group: 78.4 years (SD = 5.0). Mean age of control group: 81.3 years (SD = 6.2).	2 long-term care facilities; 1 private nursing home.	*Sig. Improvements in*: general cognition p=0.013 (MMSE), quality of life p=0.055 (QoL-AD) *No sig. improvements in:* anxiety symptoms (RAID); Severity of dementia (CDR); the depressive symptoms (GDS-15) or functional ability (CAPE–BRS)	JADAD Low (1/5) SPREAD Level of evidence: 1 Grade of recommendation: D Pos: described as randomised, blind assessor, included observational measures. Neg*: no details provided of randomization method, no description of withdrawals and dropouts, small sample size.

Table 1. (Continued)

Authors	RCT	Dementia Diagno	Sample	Mean Age	Setting	OUTCOMES	Quality rating and comments

(4) Yamanaka et al (2013)	RCT Single blind CST treatment group versus control group	Dementia diagnosis sub-type: not specified.	56 PWD CST group: n = 26 TAU Control group: n = 30 Dropout: n = 9	Female: 44 Male: 12 Mean age: 83.91 years (SD = 5.98).	3 residential homes; 1 nursing home in the Tokyo metropolitan area	*Sig. Improvements in*: general cognition, p=0.00051, p=0.003 (COGNISTAT; MMSE); mood: depression p=0.009, p=0.017 (Face Scale) (both self-reported ratings and proxy ratings); No sig. improvements in: quality of life (QoL-AD; EQ-5D) rated by participants themselves. Trend toward an improvement in: quality of life (QoL-AD) rated by proxies	JADAD High (3/5) SPREAD Level of evidence: 1+ Grade of recommendation: B Pos: described as randomized, description of method of randomization included, good description of withdrawals and
(5) Apóstolo et al (2014)	RCT Multicentre Single blind CST treatment group versus control group	Dementia diagnosis sub-type: not specified.	56 PWD CST group: n = 27 TAU Control group: n = 29 Dropout: n = 8	Female: 33 Male: 15 Mean age: 81.65 years (SD = 5.64).	Portuguese nursing homes (NHs).	*Sig. Improvements in:* general cognition (MoCA), p=0.005 *No sig. improvement:* decrease in the depressive symptoms (GDS-15).	JADAD High (3/5) SPREAD Level of evidence: 1+ Grade of recommendation: B Pos: described as randomized, description of method of randomization included, good description of

Table 1. (Continued)

Authors	RCT	Dementia Diagno	Sample	Mean Age	Setting	OUTCOMES	Quality rating and comments

(6) Capotosto et al (2017)	RCT Multicentre Single blind CST treatment group versus control group	Dementia diagnosis sub-type: not specified.	39 PWD CST group: n = 20 Active Control group: n = 19 Dropout: n = 5	Female: 27 Male: 12 Mean age of CST group: 88.25 years (SD = 5.15). Mean age of control group:	2 residential homes.	*Sig Improvements in:* general cognition p= 0.007 (ADAS-Cog); MMSE, p=0.045, language p=0.023 (subscale of ADAS-Cog); mood, depression, p=0.023 and loneliness p=0.009 (Cornell Scale, Social and Emotional Loneliness Scale – with a decrease in reported loneliness); *No sig. improvements in:*	JADAD Medium (2/5) SPREAD Level of evidence: 1+ Grade of recommendation: B Pos: described as randomized, description of withdrawals and dropouts included,
(7) Piras et al (2017)	RCT single-blind, Multi-centre, treatment group versus control group	Vascular dementia	35 PWD CST group: n = 21 Active Control group: n = 14	Female: 28 Male: 7 Mean age of CST group: 83.81 years (SD = 10.93). Mean age of control group: 85.43 years (SD = 5.18).	Italian residential homes for the elderly	*Sig improvement in:* general cognitive functioning, p<0.05 (MMSE; ADAS-Cog) *No sig. improvement:* short-term memory (Backwards Digit Span); quality of life of PWD (QoL-AD);quality of life carers (QoL-AD); Narrative Language test; mood (Cornell Scale, Social and Emotional Loneliness Scale); behaviour (Neuropsychiatric Inventory NPI); activities of daily living (The Disability Assessment for Dementia	JADAD Low (1/5) SPREAD Level of evidence: 1— Grade of recommendation: D Pos: described as randomized, active control group used. Neg*: no details provided of randomization method, no description of withdrawals and

Table 1. (Continued)

Authors	RCT	Dementia Diagno	Sample	Mean Age	Setting	OUTCOMES	Quality rating and comments
(8) Alvares-Pereira et al (2021)	RCT single-blind, Multi-centre, treatment group versus control group	Dementia diagnosis sub-type: not specified.	112PWD CST group n= 55 TAU Control group n=57 drop out =	Female: 91 Male: 14 Mean age of CST group: 83.00 years (SD = 6.627).	2 day centres, 2 nursing homes, 2 psychogeriatric centres,	*Sig. improvements in:* cognitive functioning, p=0.013 (ADAS-Cog) , communication and social functioning p=0.045 (HCS), behaviour, p=0.017 (CAPE-BRS) and global rating of dementia, p=0.008 (CDR). *No sig. improvement in:* Language (ADAS-Cog subscale), Quality of life,	JADAD High (3/5) SPREAD Level of evidence: 1+ Grade of recommendation: B Pos: described as randomized, good description of the method of

(9) Marinho et al. (2021)	RCT single-blind, treatment group versus control group"	Dementia diagnosis sub-type: not specified.	47 PWD CST group: n = 23 TAU Control group: n = 24 ;drop out = 3 (2 without informant and 1 drop	Female: 29 Male: 18 Mean age of CST group: 78.3 years (SD = 8.4). Mean age of control group: 77.3 years (SD =	outpatient participants in Brazil	*Sig. Improvements in:* Depression p<0.001 (CDSS), Daily life functioning p=0.039(Activity of Daily Life ADL) . *No sig. improvement in:* cognitive functioning (ADAS-Cog), quality of life (PwD QOL), Caregiver burden (The Zarit Burden Interview)	JADAD High (3/5) SPREAD Level of evidence: 1+ Grade of recommendation: B Pos: described as randomized, intention-to-treat analysis used, description of withdrawals and dropouts, details on assessors, Neg*: small sample size; did not state caregivers

Table 1. (Continued)

Authors	RCT	Dementia Diagno	Sample	Mean Age	Setting	OUTCOMES	Quality rating and comments
(10) Carbone et al (2021)	RCT single-blind, multicentre, treatment group versus control group	Dementia diagnosis sub-type: not specified.	225PWD CST group n= 123 Active Control group n=102 drop	Female: 149 Male: 76 Mean age of CST group: 82.57 years (SD =	16 Italian residential care homes or day centres	*Sig. Improvements in:* cognitive functioning (MMSE; ADAS-cog), language (Narrative Language test), Mood and behaviour (Cornell scale; NPI). (This study did not report p-value, but with effect size, *d*) *No sig. improvement in:* everyday life functioning (DAD). Quality of life	JADAD High (3/5) SPREAD Level of evidence: 1+ Grade of recommendation: B Pos: described as randomized; blind assessor, calculated,

Notes. ^Treatment-as-usual control group. Jadad: The maximum score (5) requires double-blinding and an appropriate double-blinding method, but only single blinding is possible in psychological research, so studies in this review could only be awarded a maximum score of 3.
AChEIs = Acetylcholinesterase inhibitors; ADAS-Cog = Alzheimer's Disease Assessment Scale-Cognition; ADL = Activities of daily living; CAPE-BRS = Clifton Assessment Procedures For the Elderly-Behavior Rating Scale; CDR = Clinical Dementia Rating Scale (Hughes, Berg, Danziger, Coben, & Martin, 1982); COGNISTAT = Neurobehavioral Cognitive Status Examination; Cornell Scale = Cornel scale of Depression in Dementia; CST = Cognitive Stimulation Therapy; DAD = Disability Assessment for Dementia; EQ-5D = health-related quality of life; GDS-15 = Geriatric Depression Scale-15; GHQ-12 = General Health Questionnaire-12; Holden Scale = Holden Communication Scale; JADAD = Jadad Scale; MMSE = Mini-Mental State Examination; MoCA = Montreal Cognitive Assessment; Neg = negative points; NPI = Neuropsychiatric Inventory; Pos = positive points; PWD = People with dementia; QoL-AD = Quality of

Life-Alzheimer's Disease; RAID = Rating Anxiety in Dementia; RCT = Randomized controlled trial; RS = Relatives' Stress; SD = Standard Deviation; Sig. = significant; SPREAD = Stroke Prevention and Educational Awareness Diffusion scale. TAU=Treatment-as-usual

Table 2. Primary and Secondary outcome measures for people with dementia, and outcome measures for caregivers/relatives involved in the ten studies reviews

Outcome Measures		No. of
Primary outcome measures for		
General Cognition Functioning	MMSE; ADAS-Cog (Rosen et al., 1984); COGNISTAT (Northern California Neurobehavioral	10^
Cognitive Functioning in specific		
- *Language*	Narrative Language Test (Carlomagno et al., 2013)	3
- *Memory*	Digit Span (De Beni et al., 2008)	2
Secondary outcome measures for people with dementia		
- *Quality of life*	QoL-AD (Logsdon et al., 1999); Dementia Specific Health Related Quality of Life Measures (Smith et al.,	8
- *Psychological and behavioural*		10
Mood: Depression	Cornell Scale (Alexopoulos, Abrams, Young, & Shamoian, 1988); Geriatric Depression Scale-15 (Sheikh &Yesavage, 1986); Face Scale (Lorish &	10
Mood : Anxiety	RAID (Shankar et al., 1999)	4
Mood: Social-Emotional Loneliness	Social and Emotional Loneliness Scale (adapted from De Jong & Van Tilburg, 2006)	2
Behaviour	CAPE-BRS (Pattie & Gilleard, 1979); NPI	7
Everyday life functioning	Alzheimer's Disease Co-operative Study-Activities of Daily Living Inventory (Galasko et al., 1997); DAD (Gélinas, Gauthier, McIntyre, & Gauthier, 1999)	8
Communication	Holden Communication Scale (Holden & Woods,	3
Global Functioning		
- *Dementia Severity*	The Clinical Dementia Rating (CDR, Hughes, Berg, Danziger,Coben, & Martin, 1982)	3
Caregiver Outcomes		
- *General health status*	GHQ-12 (Goldberg, 1978)	1
- *Caregiver Burden*	Relative's Stress Scale (Greene et al., 1982); Zarit Burden Inventory (Zarit et al., 1980).	2

Notes. ^Two studies (Alvares-Pereira et al 2021; Spector et al., 2010) assessed CST effectiveness in specific cognitive domains by considering the subscales of the ADAS-Cog. CAPE- BRS = Clifton Assessment Procedures For the Elderly-Behaviour Rating Scale; COGNISTAT = Neurobehavioral Cognitive Status Examination; Cornell Scale = Cornel scale of Depression in Dementia; DAD = Disability Assessment for Dementia; GDS-15 = Geriatric Depression Scale-15; GHQ-12 = General Health Questionnaire-12; Holden Scale = Holden Communication Scale; MMSE = Mini-Mental State Examination; MoCA = Montreal Cognitive Assessment; NPI = Neuropsychiatric Inventory;; QoL-AD = Quality of Life-Alzheimer's Disease; RAID = Rating Anxiety in Dementia.

Cognitive Stimulation Therapy Outcomes

Systematic review:

People with Dementia (PwD)

Primary outcomes

General cognitive functioning. Nine of the 10 studies found that CST showed significant improvement in the general cognitive functioning of people with dementia. Of these nine studies (see Table 3), six were of medium-to-high-quality (level of evidence 1+, grade of recommendation B), and two were low-quality (level of evidence 1—, grade of recommendation D). Two studies found no significant improvement in general cognitive functioning, both were high-quality individual RCT, however one was graded with the level of evidence 1+, recommendation B while the other was as 1-, graded of recommendation D. (see Table 3).

Specific cognitive domains, i.e. languages and/or memory were evaluated by four studies (Capotosto et al., 2017; Piras et al., 2017; Spector et al., 2010; Spector et al., 2003). The benefit of CST was found in a medium-quality study (level of evidence of 1+, grade of recommendation B) by Spector et al. (2010), which followed Spector et al. (2003), showing significant improvement in ADAS Cog "spoken language" subscale. However, a contradictory result was reported on the same subscale, suggesting no improvements were found after CST intervention on spoken language (high-quality study conducted by Alvares Pereira et al. (2020) (level of evidence of 1+, grade of recommendation B)). Capotosto et al. (2017), a medium-quality study - level of evidence 1+, grade of recommendation B, examined language comprehension and production and found that CST intervention was beneficial to people with dementia. The same study also examined short-term memory, but no

improvements were found in their participants. Nevertheless, Piras et al. (2017) conducted a low-quality study (level of evidence 1—, grade of recommendation D) and found a trend toward improvement in short term short-term memory of individuals with dementia after CST intervention.

Secondary outcomes

Quality of life. Nine RCTs out of 10 examined the quality of life perceived by the participants with dementia, three studies (Capotosto et al., 2017; Coen et al., 2011; Spector et al., 2003) found significant improvements in this domain. Two studies were rated as medium quality (level of evidence 1+, grade of recommendation B), while Coen et al. (2011) was rated as a low-quality study (level of evidence 1—, grade of recommendation D) (see Table 3). Two studies found a trend toward an improvement in Quality of life, (Piras et al., 2017; Yamanaka et al., 2013), where the former was rated as a low-quality study (level of evidence 1—, grade of recommendation D) and the latter was high-quality study - evidence 1+, grade of recommendation B. Three studies found no benefits in the quality of life of people with dementia, both rated as high-quality studies – level of evidence 1+, grade of recommendation B. The differences found between studies suggest mixed findings on the effectiveness of CST on quality of life.

Psychological functioning: Depression. All ten studies reviewed the benefits of CST intervention on depression. Five studies, four high-quality studies (level of evidence 1+, grade of recommendation B) and one medium-quality study (level of evidence 1+, grade of recommendation B) found a positive impact on people with dementia's mood (Capotosto et al., 2017; Elena Carbone et al., 2021; Marinho et al., 2021; Spector et al., 2001; Yamanaka et al., 2013). Five studies, ranging from low to high quality, three rated as a level of evidence 1+, grade of recommendation B and two

rated as a level of evidence 1—, grade of recommendation D, found no significant effect on depressive mood after participating CST. Similarly to the quality of life domain, mixed findings were found on the effectiveness of CST in improving mood of depression.

Psychological functioning: Anxiety. Four studies examined the effect of CST on anxiety. None of the studies found a beneficial effect on anxiety for people with dementia after CST (Alvares Pereira et al., 2020; Coen et al., 2011; Spector et al., 2001; Spector et al., 2003). They consisted of low to high-quality studies, two were rated as having a level of evidence 1+, grade of recommendation B and two were a level of evidence 1-, grade of recommendation D.

Psychological functioning. Social-Emotional Loneliness. Two studies examined the social aspects of people with dementia. The medium-quality study by Capotosto et al. (2017) (level of evidence 1+, grade of recommendation B) found improvement in the social-emotional loneliness scale, while a low-quality study by Piras et al. (2017) suggested that people with dementia did not report a reduction in loneliness.

Behavioural functioning. Behaviour symptoms of PwD. Six studies reviewed the impact of CST intervention on the behavioural functioning of people with dementia. Two medium to high-quality studies (level of evidence 1+, grade of recommendation B) reported a significant reduction in behavioural symptoms after participating in CST (Alvares-Pereira et al., 2021; Elena Carbone et al., 2021), while four studies reported otherwise, RCTs quality ranging from low to high-quality. Two rated level

evidence of 1+, grade of recommendation B, and two rated as level evidence of 1-, grade of recommendation D.

Everyday life functioning. One high-quality study (level of evidence 1+, grade of recommendation B) out of seven that reviewed everyday life functioning found a positive impact on people with dementia after CST intervention (Marinho et al., 2021). The remaining seven studies showed no improvement in this domain. These studies included two low-quality studies (level evidence of 1-, grade of recommendation D) (Coen et al., 2011; Piras et al., 2017), two medium-quality studies (level of evidence 1+, grade of recommendation B) (Capotosto et al., 2017; Spector et al., 2003) and two high-quality studies by Spector et al. (2001) and Elena Carbone et al. (2021), former with a level of evidence of 1-, grade of recommendation of D, and the latter has a level of evidence 1+, grade of recommendation B.

Communication skill. Two out of three studies found positive impact on communications, with a medium study by Spector et al. (2003) and a high-quality study by Alvares-Pereira et al. (2021), both rated as a level of evidence 1+, grade of recommendation B. One high-quality study (level of evidence of 1-, grade of recommendation of D) found no improvement in the same domain (Spector et al., 2001).

Global functioning. One high-quality study (level of evidence 1+, grade of recommendation B) reviewed the severity of dementia after CST intervention and found significant improvement in the global functioning of people with dementia

(Alvares-Pereira et al., 2021). Two low to medium-quality study found no improvement in the same domain, both rated as level of evidence 1-, grade of recommendation D (Coen et al., 2011; Spector et al., 2001).

Caregivers

Of the four studies that included caregivers, a high-quality study (level of evidence 1+, grade of recommendation B) by Spector et al. (2001) found improvement in caregivers' general health status. However, no reduction in relative's stress and caregivers' burden was found in both Spector et al. (2001) and Marinho et al. (2021) studies respectively, both high-quality studies, with the former rated as a level of evidence of 1-, grade of recommendation of D and latter rated as a level of evidence 1+, grade of recommendation B. Similarly, no improvement of caregivers' quality of life was found in three studies, two high-quality studies, both rated as level of evidence 1+, graded of recommendation B (Marinho et al., 2021; Yamanaka et al., 2013)and one low-quality studies, rated as level of evidence 1-, graded of recommendation D (Piras et al., 2017).

Table 3. Reviewed studies reporting significant versus non-significant results, according to outcome domains, in people with dementia and family caregivers, and summary of the Jadad Scale and the

	Significant results				Non-Significant results			
	No. of studies	Study	Quality		No. of	Study	Quality	
Primary outcome measures for	10		Jadad	SREAD			Jadad	SPREAD
General Cognition	8	Carbone et al. (2021)	High	1+, B	2	Spector et al. (2001)	High	1-, D
		Apóstolo et al.	High	1+, B		Marinho et al.	High	1+, B
		Capotosto et al.	Medi	1+, B				
		Coen et al. (2011)	Low	1-, D				
		Spector et al.	Medi	1+, B				
		Yamanaka et al.	High	1+, B				
		Piras et al. (2017)	Low	1-, D				
		Alvares-Pereira et	High	1+, B				
Cognitive Functioning in	4							
- Language	2	Capotosto et al.	Medi	1+, B	2	Alvares-Pereira et	High	1+, B
		Spector et al. [ADAS-Cog commands and spoken language	Medium	1+, B		[ADAS-Cog commands and spoken language subscales	Low	1-, D
- Memory					2	Capotosto et al.	Medi	1+, B
						Piras et al. (2017) [a trend towards an improvement in memory]	Low	1-, D

Table 3. (Continued)

	Significant results				Non-Significant results			

	No. of studies	Study	Quality		No. of	Study	Quality	
Secondary outcome measures for								
- Quality of life	3	Coen et al. (2011)	Low	1-, D	5	Yamanaka et al.	High	1+, B
		Spector et al.	Medi	1+, B		[but improvements		
		Capotosto et al.	Medi	1+, B		EQ-5D and a trend		
						an improvement in the QoL- AD		
						Piras et al. (2017)	Low	1-, D
						[a trend towards an improvement in QoL, CST group >		
						Alvares-Pereira et	High	1+, B
						Marinho et al.	High	1+, B
						Carbone et al.	High	1+, B
- Psychological and behavioural								
Mood:	5	Capotosto et al.	Medi	1+, B	5	Apóstolo et al.	High	1+, B
		Spector et al.	High	1—,		Coen et al. (2011)	Low	1—, D
		Yamanaka et al.	High	1+, B		Spector et al.	Medi	1+, B
		Marinho et al.	High	1+, B		Piras et al. (2017)	Low	1-, D
		Carbone et al.	High	1+, B		Alvares-Pereira et	High	1+, B
Mood : Anxiety					4	Coen et al. (2011)	Low	1—, D
						Spector et al.	High	1—, D
						Spector et al.	Medi	1+, B
						Alvares-Pereira et	High	1+, B

Table 3. (Continued)

	Significant results	Non-Significant results

	No. of studies	Study	Quality		No. of	Study	Quality	
Behaviour	2	Alvares-Pereira et	High	1+, B	3	Capotosto et al.	Medi	1+, B
		Carbone et al.	High	1+, B		Coen et al. (2011)	Low	1—, D
						Piras et al. (2017)	Low	1-, D
Everyday life	1	Marinho et al.	High	1+, B	6	Carbone et al.	High	1+, B
						Capotosto et al.	Medi	1+, B
						Coen et al. (2011)	Low	1—, D
						Spector et al.	High	1—, D
						Spector et al.	Medi	1+, B
						Piras et al. (2017)	Low	1-, D
Communication	2	Spector et al.	Medi	1+, B	1	Spector et al.	High	1—, D
		Alvares-Pereira et	High	1+, B				
Caregiver								
- General health	1	Spector et al.	High	1—,				
- Relative's					1	Spector et al.	High	1-, D
- Caregiver					1	Marinho et al.	High	1+, B
- Caregiver					3	Piras et al. (2017)	Low	1-, D
						Marinho et al.	High	1+, B
						(2021)	High	1+, B
Global	3							
- Dementia	1	Alvares-Pereira et	High	1+, B	2	Coen et al. (2011)	Low	1-, D
						Spector et al.	High	1-, D

Note. ADAS-Cog = Alzheimer's Disease Assessment Scale-Cognition; NPI = Neuropsychiatric Inventory; QoL-AD = Quality of Life-Alzheimer's Disease; EQ-5D = Health-Related Quality of Life.

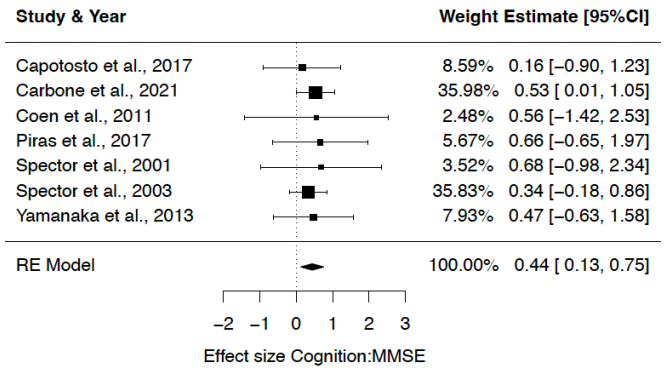
Meta-analysis on the effect of CST

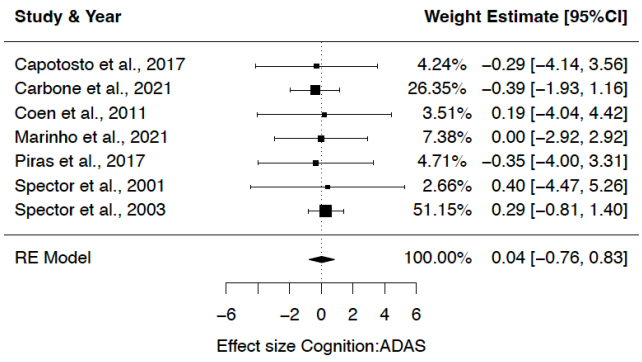
Primary outcome:

General Cognitive Functioning:

Pooling the results from seven studies, CST was found to have a positive significant effect measured by the MMSE (SMD=0.44, 95%CI: 0.13; 0.75, p=.006) with non-significant levels of heterogeneity (X^2=0.74, df=6, p=0.99, I^2= 0%). However, no significant effect of CST was found measured by ADAS-Cog, also pooling from seven studies (SMD=0.38, 95%CI: -0.76; 0.83, p=.93) with non-significant levels of heterogeneity (X^2=0.59, df=6, p=0.99, I^2= 0%). See figure 2.

Figure 2. Forest plots of CST effect on Cognition: MMSE and ADAS-Cog

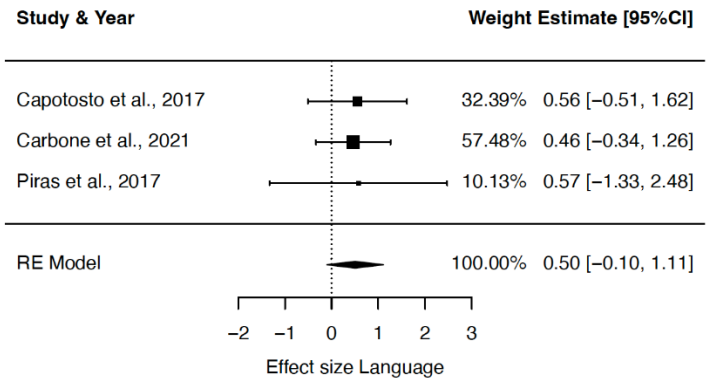


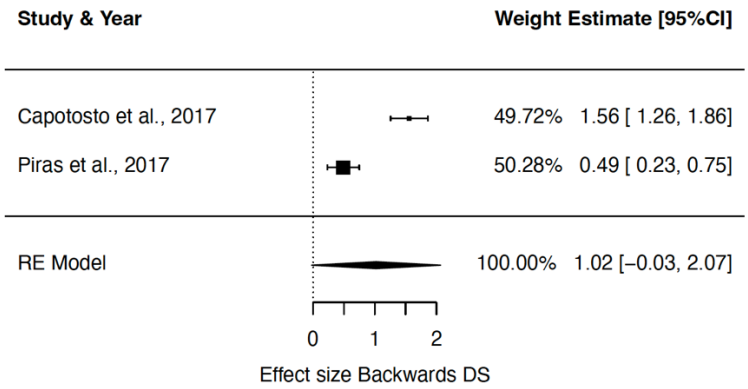


Cognitive Functioning in specific cognitive domains- Language and Memory

Pooling the results from three studies, CST was not found to have significant effect on language, measured by Narrative Language Test (SMD=0.51, 95%CI: -0.10;1.11, p=0.11) with non-significant levels of heterogeneity (X^2=0.02, df=2, p=0.99, I^2= 0%). Similarly, CST was not found to have a positive effect on memory of PwD, measured by Backwards Digit Span, pooling results from two studies (SMD=1.02, 95%CI: -0.03;2.07, p=0.06) with significant levels of heterogeneity (X^2=27.9, df=1, p=<0.0001, I^2= 96.41%). See Figure 3.

Figure 3. Forest plots of CST effect on Specific Cognitive Domains: Language and Working Memory.





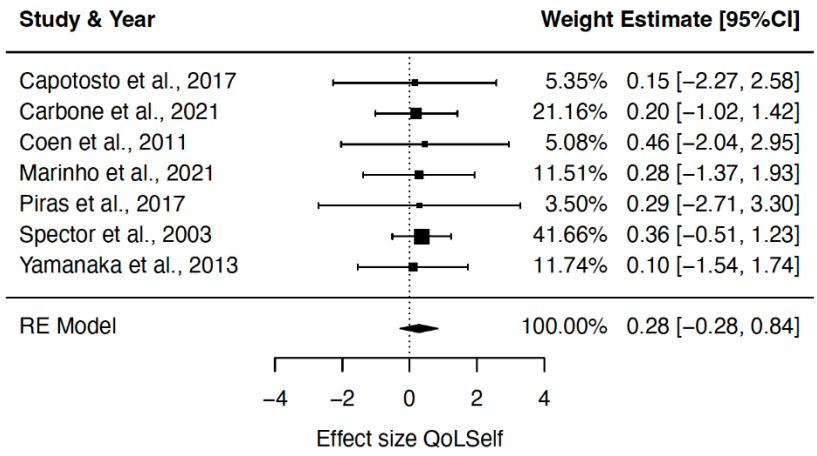
Secondary outcomes:

Quality of life of People with Dementia

Pooling the results from seven studies, No significant CST effect on quality of life of PwD was found (SMD=0.28, 95%CI: -0.28;0.84, p=0.33) with non-significant levels of heterogeneity (X^2=0.13, df=6, p=1.00, I^2= 0%).

See Figure 4.

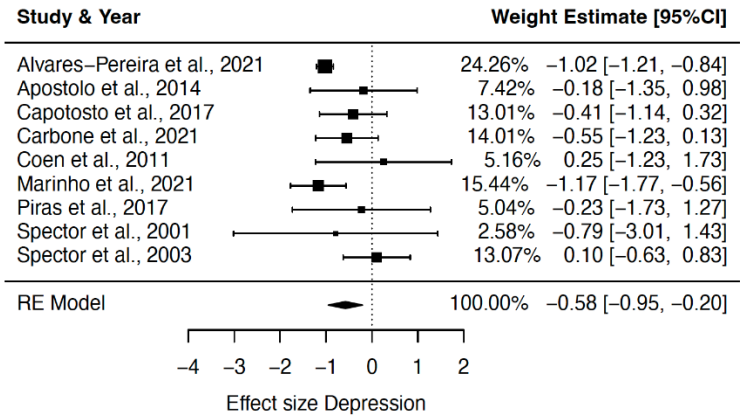
Figure 4. Forest plots of CST effect on Quality of Life of PWD.

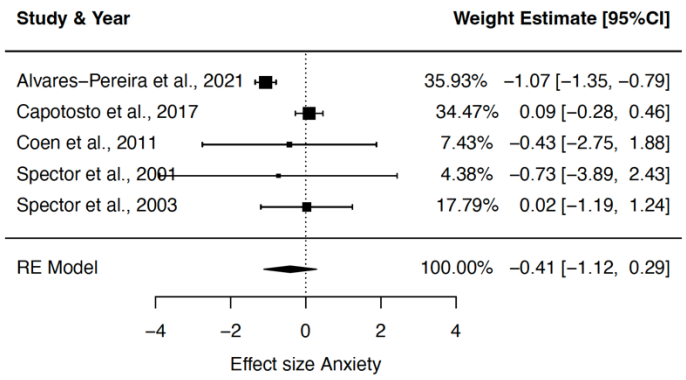


Psychological functioning: Mood – Depression and Anxiety

Pooling the results from nine studies, a positive significant effect on depression was found after CST among PwD(SMD= -0.58, 95%CI: -0.95; -0.20, p=.003) with a significant level of heterogeneity (X^2=16.9, df=8, p=0.03, I^2= 54.8%). In contrast, pooling from five studies, no significant effect was found on anxiety after CST (SMD= -0.41, 95%CI: -1.12; 0.29, p=0.25) with a significant level of heterogeneity (X^2=25.4, df=4, p=0.0001, I^2= 77.9%). See Figure 5.

Figure 5. Forest plots of CST effect on depression and anxiety among people with dementia

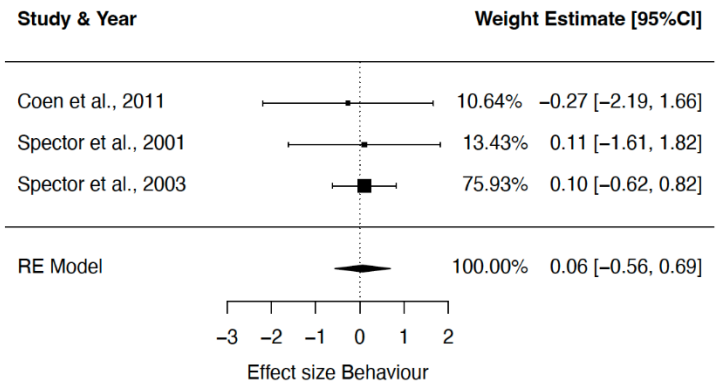


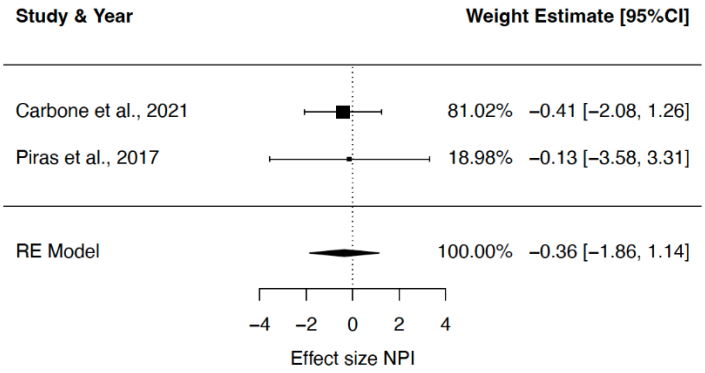


Behavioural functioning, everyday life functioning, communication and global functioning

Pooling the results from three studies, CST was found not to have an effect on everyday life functioning of people with dementia (SMD=0.06, 95%CI: -0.56; 0.69, p=.003) with a non-significant level of heterogeneity (X^2=0.13, df=2, p=0.94, I^2=0%). Similar result was found by measuring neuropsychiatric inventory on PwD's behavioural functioning. CST found no positive effect on behavioural functioning among PwD (SMD=-0.36, 95%CI: -1.86; 1.14, p=0.64) with a non-significant level of heterogeneity (X^2=0.02, df=1, p=0.89, I^2=0%). See Figure 6.

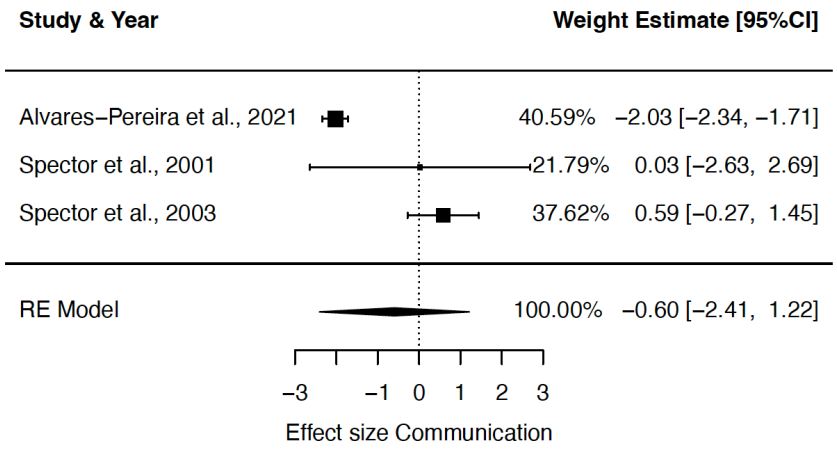
Figure 6. Forest plots of effects of cognitive stimulation therapy on behaviour functioning among people with dementia.





Pooling the results from three studies, CST was found to have no effect on improving communication among PwD (SMD= -0.60, 95%CI: -2.41;1.22, p=0.52) with a significant level of heterogeneity (X^2 =33.0, df=2, p<.0001, I^2= 91.4%). See Figure 7.

Figure 7. Forest plot of CST effect on communication among PwD.



Pooling the results from three studies, CST was found to have no effect on reducing dementia severity among PwD (SMD= -0.66, 95%CI: -1.80;1.22, p=0.48) with a significant level of heterogeneity (X^2 =105.8, df=2, p<.0001, I^2= 98.0%). See Figure 8.

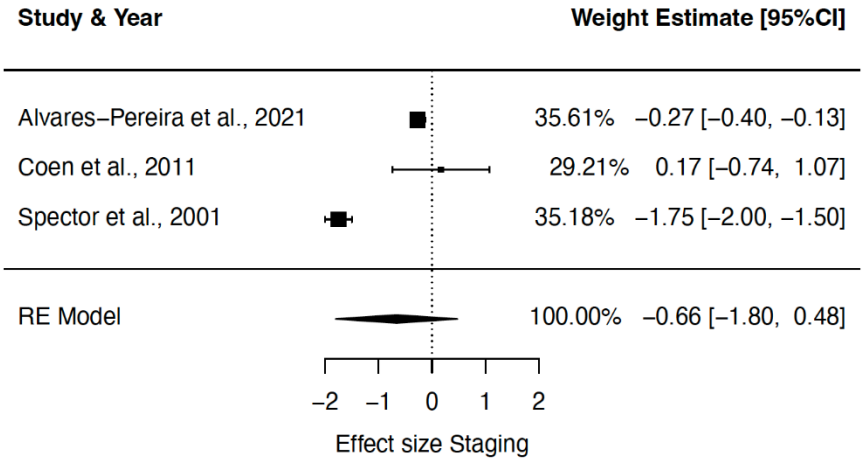


Figure 8. Forest plot of CST effect on dementia severity among PwD.

Caregiver's outcome: Quality of Life

Pooling the results from three studies, CST has no effect on improving the caregivers' quality of life (SMD= 0.21, 95%CI: -1.81;1.22, p=0.69) with a non-significant level of heterogeneity (X^2 =0.08, df=2, p=0.96, I^2= 0%). See Figure 9.

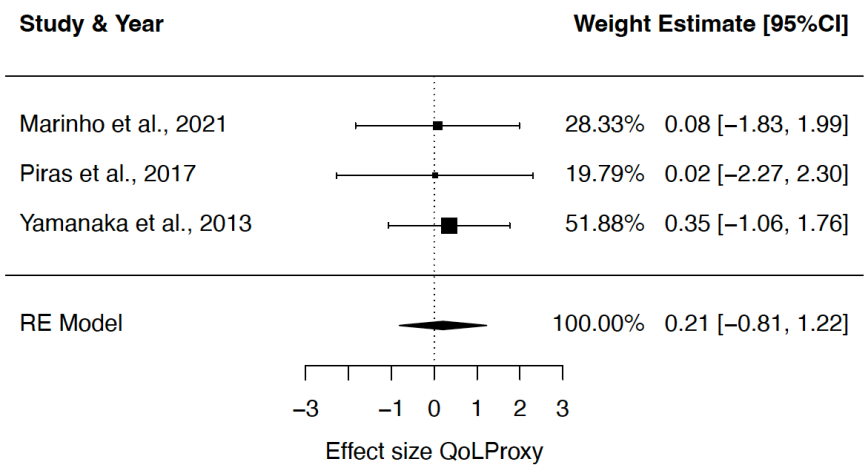


Figure 9. Forest plot of CST effect on caregivers' quality of life.

Discussion

Finding Summary

The current systematic review and meta-analysis aims to examine the quality of ten RCTs regarding the effectiveness of CST, using the protocol first published by Spector et al. (2003). It is also an updated and more rigorous review of the evidence following Lobbia et al. (2019)'s methodology while including a meta-analysis component, to provide a more substantive conclusion on the effect of CST on PwD. Results of the meta-analysis revealed beneficial effects of CST among PwD, suggesting its effectiveness in promoting general cognition (although this was only

the case when measured using MMSE and not ADAS-cog) and reducing depressive symptoms among PwD.

Primary outcomes

The current meta-analysis revealed provided good evidence for improving the MMSE outcome of PwD after CST intervention, yielding a small to medium effect. It also revealed good evidence on the effectiveness of adapting the CST protocol across different cultural background after including several new studies into the synthesis (Alvares-Pereira et al., 2021; Elena Carbone et al., 2021; Piras et al., 2017). The results also found to be consistent with several recent published meta-analysis, including studies that delivered CST in varies formats as well as based on Spector's manual (Cafferata et al., 2021; Saragih et al., 2022; Y.-L. Wong et al., 2021), all found a positive effect in general cognition. It was however important to note that the effect was captured using MMSE instead of ADAS-Cog and MoCA, potentially may suggest that MMSE has a high sensitivity in capturing cognitive improvement among PwD. Nonetheless, while the Lobbia et al. (2019)'s study showed moderate evidence on specific cognitive domains, contradictory results were found in this meta-analysis, suggesting that CST may not be effective in promoting language and working memory. Only three RCTs examined specific cognitive domains, with evidence for spoken language and memory following CST intervention rather limited. A trend of improvement was found in one study on memory (Piras et al., 2017) Also, only two studies included outcome measures of specific cognitive domains, suggesting future larger RCT trials may consider including specific cognitive domains for investigation of CST effect. A note worth mentioning was that dementia has a neurodegenerative nature, where the effect of maintaining the ability of these cognitive domains should be taken into consideration. Nevertheless, this should be addressed through the

inclusion of a no-treatment control and the differences found in this current study in comparison to Lobbia et al. (2019) demonstrated that as research quality increased, i.e. conducting RCT, the effects of CST on spoken language and memory were not found.

Secondary outcomes

Quality of life in people with dementia. The results from the meta-analysis revealed that no effect on improving quality of life was found among PwD after participating CST. While some studies showed some improvement in quality of life in PwD and two RCTs showing trends toward improvement (Piras et al., 2017; Yamanaka et al., 2013), most of the RCT studies newly included in this review suggested no impact.

Psychological functioning – Mood in depression and anxiety. Meta-analysis results showed evidence in alleviating depressive symptoms among PwD after joining CST, yielding a medium effect size. One potential mechanism is that activities conducted during CST created joyful moments among PwD and elicited positive feelings that could potentially reduce reported depressed mood. However, in line with the previous study, this current review did not capture any impact on reducing anxiety.

Behavioural functioning - Everyday life functioning, communication and global functioning. No impact was found on reducing behavioural symptoms, suggested by the meta-analysis results. Only a two to three RCTs included everyday life functioning, neuropsychiatric inventory for PwD behaviour, communication and dementia severity. This suggested the impact of CST on behavioural functioning could be further investigated in future larger RCTs trials.

Caregivers.

No effect on improving caregivers' quality of life was found from the meta-analysis. Only three RCTs investigated caregivers' outcomes suggesting a lack of research into caregivers' wellbeing and quality of life and CST's impact on them. This might be beneficial to examine in future research.

Limitations

Even though the study aims to further strengthen the evidence found by Lobbia. et al. (2019) on CST's efficacy, several limitations were identified in the present study. Firstly, despite the attempt to analyse only RCTs, removing pre-post studies, and examining a variety of outcome measures; only four RCTs examined the cognitive functioning in specific cognitive domains, i.e. language and memory, communication and behaviour. This made it difficult to conclude the efficacy of CST in the stated domains. Secondly, studies included in this current systematic review mostly evaluated the effectiveness of CST within Caucasian populations meaning there was a lack of representation of CST in diverse ethnic populations. Thirdly, the research of caregivers of people with dementia after participating in CST was still under-researched, only three included studies attempt to capture any effects on the quality of life of caregivers. Fourthly, the quality of studies was assessed based on two selected study quality methods, which was based on previous systematic review by Lobbia's group(Lobbia. et al., 2019). Other quality assessing method, such as Grading of Recommendations, Assessment, Development and Evaluations (GRADE) (Guyatt et al., 2008) could be considered for further systematic reviews to ensure a more comprehensive evaluation of study quality. Finally, as mentioned in the paper by Lobbia. et al. (2019), it is worth noting that the sample of all included studies was heterogeneous regarding the types and severity of dementia. In this current review,

there was a lack of evidence showing the impact of CST on a specific subtype of dementia diagnosis. Only one study (Piras et al., 2017) involved solely vascular dementia diagnoses and found a positive impact on general cognitive functioning

Implications for future research

Future RCTs could attempt to include the same set of outcome measures or reach a consensus on the type of measures that should be included consistently across studies. This would then potentially enable a more coherent analysis to ascertain the gains of CST. If there were a chance for future CST trials, rigorous evaluations on CST within other populations, e.g. Asian populations, this would enable further strengthening of the effectiveness of CST cultural adaptation. Knowing the importance of the role of caregivers in caring for PwD and their psychological being, further research could investigate the impact of caregivers after CST on the global health and quality of life of caregivers. Finally, further studies could focus on looking into subtypes of dementia to understand whether positive results could be yielded.

Conclusion and Clinical Implications:

In conclusion, this current meta-analysis suggests a good impact on improving general cognitive functioning at least when measured using the MMSE and on reducing depressive mood. CST is a very simple manualised intervention that any individual with an allied health background can facilitate. Given CST's flexible structure, with limited training requirements, this review supports the recommendation by National Institute for Health and Care Excellence guidelines (NICE) (National Institute for Health and Care Excellence, 2018) that people with mild to moderate dementia should be offered CST. We further suggest that given its simplicity and manualised nature, CST can also be easily adapted to varied cultural

contexts which could enable additional clinical support for individuals from various cultural backgrounds and countries.

Reference:

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Part Two: Empirical Paper- A feasibility randomised controlled trial of virtual Cognitive Stimulation Therapy (vCST) for People with Dementia: Impact on Cognition

Abstract:

Background: Cognitive Stimulation Therapy (CST) is a psychosocial programme to promote quality of life and the deceleration of cognition deterioration in People with Dementia (PwD). The current research aimed to investigate the feasibility of a 14-session of virtual CST for PwD and evaluate changes in cognition.

Method: The vCST programme was adopted from an existing CST manual for group implementation. 46 PwD participated in the study, 24 PwD were randomly assigned to vCST while 22 were assigned to the treatment as usual group. The feasibility of vCST was evaluated using a framework for feasibility research. Outcome measures of cognitive functioning were also included, where participants were assessed prior to and after vCST, to evaluate the effectiveness of vCST on cognition.

Results: High attendance and adherence rate were reported. Strong evidence on the practicability of vCST suggested that it is a feasible treatment for PwD. Analysis of variance indicated no significant improvement in cognition after vCST between vCST and Treatment and usual conditions.

Conclusion: The delivery of 14 sessions of vCST was feasible for PwD who were familiar with using technology. However, no significant impact on cognition after vCST could be due to the lack of multisensory stimulation during vCST relative to face-to-face CST. Future research could compare vCST and face-to-face group CST on their effectiveness in cognition and psychosocial domains. Further qualitative research could conduct interviews to capture any positive experience of vCST from PwD and their caregivers.

Introduction:

According to the World Health Organisation, "Dementia is a syndrome in which there is deterioration in cognitive function beyond what might be expected from the usual consequences of biological ageing. It has physical, psychological, social and economic impacts, not only for people living with dementia but also for their caregivers, families and society at large." It is estimated that approximately 50 million people are living with dementia worldwide and nearly 10 million new cases every year (World Health Organisation, 2021). Given the nature of dementia causes detrimental impacts on an individual's intrapersonal and interpersonal, emotional, social and financial aspects, there is an increasing research interest globally in developing effective support for people living with dementia and their caregivers.

Cognitive Stimulation Therapy (CST) is a well-established psychosocial intervention (Spector et al., 2003). It consists of engaging People with Dementia (PwD) in pleasurable social interactive activities, through the promotion of general stimulation for thinking, reminiscing, concentrating and memory and the use of a multi-sensory approach (Spector et al., 2008). CST is led in small groups, delivered by dementia care personnel, and has shown to be effective in promoting quality of life and the deceleration of cognition deterioration in PwD (Woods et al., 2012). It has also demonstrated positive impacts on neuropsychiatric symptoms and loneliness (Capotosto et al., 2017; Niu et al., 2010). CST has proven to be cost-effective and was recommended by the National Institute for Health and Care Excellence (NICE) as a treatment for improving cognition in PwD with mild to moderate dementia (National Institute for Health and Care Excellence, 2018).

According to the NICE guidelines, it is important to increase the accessibility of services to as many PwD as possible. Yet, individuals with dementia often struggle to

access psychological services and treatments that are beneficial to their psychological well-being, for reasons such as transport provision, hospital access, follow-up appointments and restricted mobility. In addition, the Coronavirus disease-19 (Covid-19) pandemic further restricted timely hospital access and face-to-face treatment (Yang et al., 2020), where psychological services were unable to offer their best care and support to PwD across the UK. Moreover, older adults are most at-risk for Covid-19, with its mortality risk increasing with age (Lloyd-Sherlock et al., 2020). As part of protecting older adults from Covid-19, the UK government specifically advised clinically extreme vulnerable adults with comorbid health conditions to adopt extra precautions during the peak of the pandemic. Older adults were recommended to practise social distancing and shield themselves from the public (Public Health England, 2020). Such drastic measures inevitably caused direct and indirect impacts on the psychosocial well-being of older adults and their caregivers. Some older adults experienced increased loneliness due to the constraints on connecting with families and friends while some were restricted in getting access to their usual community services during the pandemic (Armitage & Nellums, 2020). The isolation and lockdown were also associated with decreased cognitive functioning of PwD and people with mild cognitive impairment (Canevelli et al., 2020), which led to further distress in the dementia population.

Consequently, remotely accessed therapies, specifically the use of video-conferencing apps, i.e. Zoom, could be a potential method to effectively deliver remote psychosocial interventions to PwD. This could not only solve the problem of restricted access to services but could also increase the social connectedness of PwD and their caregivers. Due to the pandemic, many psychological services were forced to transition their services to providing online treatment, where psychotherapists

reported positive attitudes toward the delivery of virtual psychotherapy (Békés & Aafjes-van Doorn, 2020). This strengthened the possibility of conducting CST online and potentially provided an alternative way to access CST for PwD who were homebound during this critical time. Several studies had found positive impact on promoting wellbeing of PwD through the use of tablets or computers delivering music therapy (Dowson & Schneider, 2021), online group support with caregivers of PwD during the pandemic (Weems et al., 2021) and moving an offline CST group to virtual group (Cheung & Peri, 2021), all hoping to create a continuity of care and social connectedness during COVID-19 for PwD. One study reported the older adults appreciated the strengths of group facilitators during the pandemic and that it enhanced further social connectedness via virtual support (Weems et al., 2021). Nevertheless, barriers of delivery were inevitable. A study recently identified several barriers during the implementation of Zoom-CST (Cheung & Peri, 2021), with issues including accessing the internet and electronic devices, impaired cognitive abilities in using technology and adherence rate. This study however only demonstrated the feasibility of Zoom-CST when the group members had met previously offline and transitioned to online due to lockdown.

The aim of current research focused on the feasibility of delivering vCST in the UK, during the Covid-19 pandemic. This research followed a similar research method to a previous study investigating the feasibility of individual CST (Gibbor et al., 2021). Parameters including the recruitment, research study retention rate, acceptability of randomisation and intervention, the attrition rate of vCST intervention, fidelity and use of selected outcome measures were explored based on part of a framework for the development and evaluation of RCTs (Campbell et al., 2000). The impact on cognitive functioning as a result of the vCST intervention was also investigated.

Method:

The current project was conducted jointly by four trainee clinical psychologists as their thesis for DClinPsy. Two trainees conducted vCST project development evaluation and vCST participants' feedback interviews during the first phase of the study. The current phase was then split between two trainees, one evaluated the quality of life and mood impact after vCST (Abdul Wahab., 2022), and the author conducted the feasibility of vCST and its impact on cognition.

Ethics

Ethical approval was received from the University College London Research Ethics Committee (project ID. 17127.002). Participants provided informed consent following the Mental Capacity Act (2005). They were informed that they could withdraw from the study at any time. Consent to participate in the activities and assessments of vCST was reviewed during the 14 sessions.

Design

The study was a single-blinded, randomised controlled feasibility study.

Sample size

Using G*Power version 3.1, a prior power analysis was conducted to estimate a recommended sample size. Based on the effect size on outcome measure of cognition by Spector et al. (2003), a calculated minimum sample sized needed for cognition analysis was 60. As the current study was a feasibility study, an alternative way of estimating sample size was based on the a rule of thumb of recruiting a sample between 24 and 50 (Julious, 2005; Sim & Lewis, 2012). There was however no consensus between all previous studies on sample size. Based on these suggestions, the study aimed to recruit between 24-50 participants.

Participants

As this study was conducted during the pandemic, and the nature of the study was a virtual version of group CST, most participants were recruited through an online recruitment website, the Join Dementia Research platform, where the information sheet of the study was uploaded onto the webpage (https://www.joindementiaresearch.nihr.ac.uk/). Participants who were interested in the study were marked "interested" on the website. A small number of participants were recruited via third-sector organisations, such as the London Memory Services Network Group, Camden Carers, Age UK and Memory-Matters. Researchers of the current study screened for eligible participants using the inclusion and exclusion criteria adapted from the original CST trial (Spector et al., 2003) for online delivery: (i) a diagnosis of major neurocognitive disorder (of any dementia subtypes) according to the ICD-10 in the mild-to-moderate range, (b) adequate capability to understand and communicate with group members and facilitators; (c) no neurodevelopmental disorders, premorbid intellectual disabilities, or current physical illness/disability reported that might interfere with their participation; (d) no known disruptive behavioural symptoms that might interrupt participation; (e) no diagnosed comorbid psychiatric disorders (e.g., severe depression); and (f) have access to technology for vCST.

Sample:

Forty-six people were recruited, of whom 24 were randomised to the intervention vCST group, while 22 were in the Treatment as usual group. Six groups were conducted, each with 3–4 participants attending the 7-week programme.

Randomisation Procedure

A member of the team who was external to the current study performed the randomisation process using a web-based randomisation system and Microsoft Excel, based on randomly mixed numbers and generating sets of treatment versus treatment as usual. A member who facilitated the vCST group (unblinded) (but who did not complete the pre or post-assessments) informed participants of their assigned groups. All assessments were conducted a week before and following the vCST intervention by members of the team who were blinded to group allocations.

Procedure:

After the screening process, each participant who met the criteria was invited to a Zoom meeting. The study rationale, duration of the programme, potential benefits and risks, and the importance of having access to the internet were thoroughly explained to the participants before inviting them to sign the consent forms. All participants were randomised into two groups, group vCST and group treatment as usual before being invited to complete a baseline assessment a week before the start of the vCST programme. An invitation email along with an attached Zoom session link was sent to those who were assigned to vCST. Group members who were not assigned to the vCST group were encouraged to continue with their usual activities (i.e. Treatment as usual). A week after the end of the programme, participants were invited to complete the same set of cognitive assessments, conducted by the same assessors.

Virtual Cognitive Stimulation Therapy:

The vCST was an adaption from the manualised CST programme (Spector et al., 2003). Facilitators were trainee clinical psychologists and PhD students from University College London, who were all familiar with CST protocol before

conducting the sessions. The vCST programme consisted of 14 structured sessions, twice weekly for 7 weeks, each lasting approximately 60 minutes, in small groups of 3-4 participants. All sessions were structured and delivered in a similar way to provide consistency, through screen sharing of a PowerPoint presentation on Zoom. The sessions consisted of a 10-minute warm-up, including personal welcoming slides showing the group name and a theme song. It also included a warm-up activity relating to the suggested theme of the day, followed by a discussion on the weather, the day, date, month, time of the day and the latest current affairs. Prompting questions were shown on the slides subsequently to encourage additional thought processes of the participants after watching a video on current affairs. A main cognitive stimulation activity (25 minutes) based on the theme of the week (i.e. childhood history, food, current affairs, word association and so on, see table 4) was then introduced, followed by a 10-minute conclusion, summing up any thoughts and feedback towards the session, thanking group members' participations; and reminding them of the time, date and theme of the next session.

Table 4. Themes of each vCST session.

Sessions	Theme	Sessions	Theme
1	Physical Games	8	Being Creative
2	Sounds	9	Categorising Objects
3	Childhood	10	Orientation
4	Food	11	Using Money
5	Current Affairs	12	Number Games
6	Faces and Scenes	13	Word Games
7	Word Association	14	Team Quiz

Feasibility Quantitative Evaluation:

The feasibility of the study was evaluated based on several feasibility parameters:

Feasibility of recruitment and research retention:

This was assessed by (i) successful recruitment of representatives of the target population within a recruitment period span of ten months (Jan 2021-Oct 2021); (ii) An attrition rate of <25% from recruitment, through to follow-up data collection in both groups and (iii) Full completion of ≥75% of the outcome measures requested of participating PwD in both groups.

Acceptability of the randomisation:

Acceptability of randomisation was determined by measuring whether there was a greater loss at follow-up after being assigned to vCST or treatment as usual group.

Acceptability of the Intervention: Attendance, retention to intervention and adverse event.

This was assessed by (i) overall attendance and retention rates amongst the vCST participants (over 60%); (ii) any negative or adverse events related to the intervention.

Fidelity:

This was assessed by inviting all facilitators to complete the fidelity checklist version 1 and version 2 following each session. Two versions of the same fidelity checklist were completed by three of the vCST group facilitators. Version two of the checklist is an updated version of version one. There were 15 items in version one and 16 items in version two, with a total score of 0-33 and 0-34 respectively. The mean fidelity score and the percentage of the fidelity scores (fidelity score /total score of the checklist x 100%) were calculated for each vCST session. 80% to 100%

adherence to the fidelity checklist was interpreted as high fidelity, 51% to 79% as moderate and 50% or below as low fidelity (i.e., >80% of items on the checklist were implemented). (An et al., 2020).

Outcome measures:

The Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-Cog)

The Alzheimer's Disease Assessment Scale- Cognitive Subscale (ADAS-Cog) was derived by Rosen et al. (1984) and consists of 11 tasks assessing various cognitive domains, including memory, language, attention, command understanding, praxis, orientation, spoken language and comprehension. The tool has a total score of 0-75, where a lower score indicates better cognitive performance. It is widely used for measuring cognition as a primary outcome and has shown to have good reliability and validity (Sheehan, 2012).

The Montreal cognitive assessment (MOCA- BLIND)

This assessment tool is an adaptation of Montreal cognitive assessment (MOCA), MOCA- BLIND, which enables phone delivery of the assessment. It is similar to the original MOCA, only visual items are removed (Dupuis et al., 2015). The test has been proven to be effective in screening the trajectory of developing dementia in individuals with mild cognitive impairment (Nasreddine et al., 2005). It consists of 6 tasks, assessing cognitive domains including orientation, attention, memory, language and abstract thinking. MOCA-BLIND has a total score of 0-22. A score of 19 and above is considered normal. A higher score indicates better cognitive performance.

Statistical Analysis:

For feasibility outcome measures, inferential statistics were not used. For cognition outcomes measures, all statistical analyses were conducted using version 28,

Statistical Package for Social Sciences (SPSS) software (Nie et al., 1975). Data were assessed for normality and heterogeneity. An Independent-sample t-test and chi-square were then conducted to assess differences in baseline demographics. A mixed plot repeated measure of analysis of variance (ANOVA) was performed to analyse any changes found over time between the baseline and follow-up assessments prior to and after vCST versus treatment as usual. Interaction effects were also examined to identify any greater changes in outcome measures of vCST as opposed to treatment as usual group. A significance level of 0.05 was established for all performed statistical analyses. All dependent variables were normally distributed except ADAS-Cog, where both baseline and follow-up data were transformed using Log10. Intercorrelations and Homogeneity of variance were assumed. Sphericity was not assumed as an assumption as there were only two levels of repeated measures.

Missing Data and dropouts:

A Missing Completely At Random (MCAR) test was conducted to determine whether the data were missing completely at random prior to multiple imputations. Adopting the Markov Chain Monte Carlo (MCMC) method, multiple imputation was used to impute missing values lost during follow up assessments.

Results:

The age of participants ranged from 48-88 years old, on average 71.39 (SD=9.164). Half of the participants were male (12 males and 11 females in both vCST and treatment as usual groups). In terms of educational level, 28 participants had less than 12 years of education (60.0%). All participants took part in the study online in their own homes using computers or electronic tablets that enabled them to join the session via the videoconferencing software programme, Zoom. No significant

differences were found in age, gender and years of education between groups. See table 5 for participants' demographics.

Table 5. Participant demographics at baseline

Characteristics	All participants (n=46)	vCST (n=24)	Treatment as usual (n=22)
Age (years)			
Mean (SD)	71.39 (9.164)	71.96 (9.18)	70.77 (9.32)
Range	48-88	48-84	56-88
Ethnicity (%)			
German	1 (2.2)	1 (4.2)	1 (4.5)
Mixed White and Black Caribbean	1 (2.2)	0 (0)	1 (4.5)
White American	1 (2.2)	1(4.2)	0 (0)
White British	33 (71.7)	15 (62.5)	17 (77.3)
White European	1 (2.2)	1 (4.2)	0 (0)
White Irish	7 (15.2)	5 (20.8)	2 (9.1)
White Scottish	1 (2.2)	1 (4.2)	0 (0)
White (other)	1 (2.2)	0 (0)	1 (4.5)
Gender (%)			
Male	23 (50)	12 (50)	11 (50)
Female	23 (50)	12 (50)	11 (50)
Years of Education (%)			
Less than 12 years	28 (60.9)	13 (54.2)	15 (68.2)
More than 12 years	18 (39.1)	11 (45.8)	7 (31.8)

Feasibility of vCST

Feasibility of recruitment and research retention:

141 participants were approached within ten months recruitment period, via the Join Dementia Research (JDR) Platform, London carer service, London Age UK, Ireland CST research group and through the network of the research team. 52 out of 141 PwD agreed to participate, 39 declined the study invitation, 14 were not eligible for

reasons due to not having a diagnosis of dementia, having a diagnosis of down's syndrome, unable to retain information to provide consent and enrolled in another form of psychosocial interventions. 36 participants from JDR did not respond to emails after showing interest in the study. 25 were not interested in the nature of the vCST, i.e. uncomfortable with technology (n=7) or group settings (n=1). One was hospitalised and one declined due to personal reasons. They were all marked as declining in the study (n=39). Six participants withdrew from the study after providing consent, for reasons due to attending another psychosocial programme, hospitalised and personal reasons. Overall, the study had a high research retention rate of 80.4% whereby 46 PwD completed baseline assessments and 37 PwD completed the follow-up study. See Figure 2 for the participant flow diagram.

Figure 2. Recruitment and retention flow diagram.

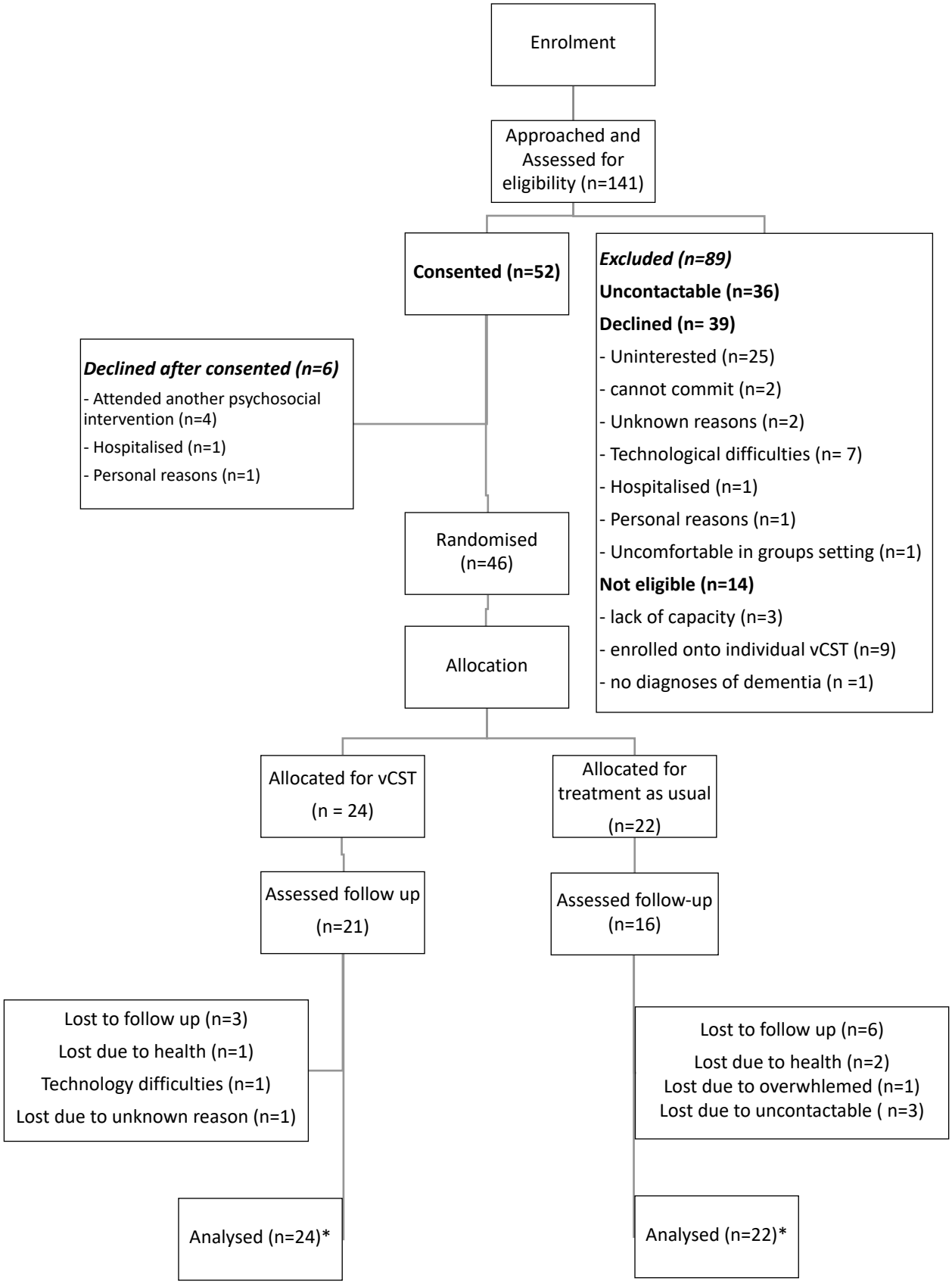
*Multiple imputation method was used to impute missing data.

Acceptability of the randomisation:

The randomisation procedure appeared to be not acceptable to some participants. The dropout rate was higher in the treatment as usual group (27.2%) than in the vCST group (12.5%). Six participants received treatment as usual and three participants in the vCST group dropped out of the study for reasons due to medical conditions, were overwhelmed by the set-up of technology and were uncontactable during follow-up.

Acceptability of the Intervention: Attendance, retention to intervention and adverse event.

In terms of retention to vCST intervention, 11 out of 21 (52.4%) of the participants completed all 14 sessions of vCST, 7 people missed one session, and 3 missed two sessions of the intervention. The mean attendance rate was high, with an average of 13.6 sessions (SD=0.50; Median=14), ranging from 12 to 14 sessions. Reasons for



missing were medical appointments, personal commitments, caregivers were not available on the day and forgetting the session. Three participants were excluded due to dropping out of the study after 2 sessions. One reported struggling with technical problems, one's dementia progressed and one lost interest in the study. One

participant from Treatment as usual had a recent fall and was unable to complete a follow-up assessment. No other adverse events were reported by any participants.

Fidelity.

The total average fidelity score of version one checklist was 27.1 (SD= 5.61; range= 0-37) and 33 (SD= 3.76; range= 0-38) for version two. The percentage of version one was 73.2% (SD= 15.2), and version two was 86.8% (SD=9.89), suggested a moderate and high fidelity respectively in adhering to the CST protocol.

Outcome measures feasibility.

It was intended that each researcher who completed the baseline assessments also conducted the follow-up assessments for their assigned participants. Only two participants had assessments by two different researchers due to researcher unavailability. Excluding the participants who did not complete the follow-up test, all participants completed all questionnaires in both baselines and follow-up outcome measures except for the level of education of MOCA-blind.

Missing Data Analysis:

Nine participants dropped out of the intervention, seven due to not completing follow-up assessments and three only attended less than two sessions of vCST. A little MCAR test was conducted to ensure the missing data happened at random (($\chi^2$14.287, df=21,p=0.86). The non-significant of little MCAR test suggesting the data missing were happened at random. Thus, a multiple imputation using MCMC method was then performed to impute the missing values lost during follow-up studies. Two different methods of data analysis, n=46 with imputed dataset, and n=37 without missing data, were conducted as a form of sensitivity analysis to determine whether the robustness of results would be different due to the changes of statistical analysis method. As no differences were derived from both methods of data

analysing, the final data analyses were conducted on the imputed dataset, vCST n=24; treatment as usual n=22. See below table 6 for the imputed means of each group.

Table 6. ADAS-Cog and MOCA-BLIND Means of vCST versus treatment as usual.

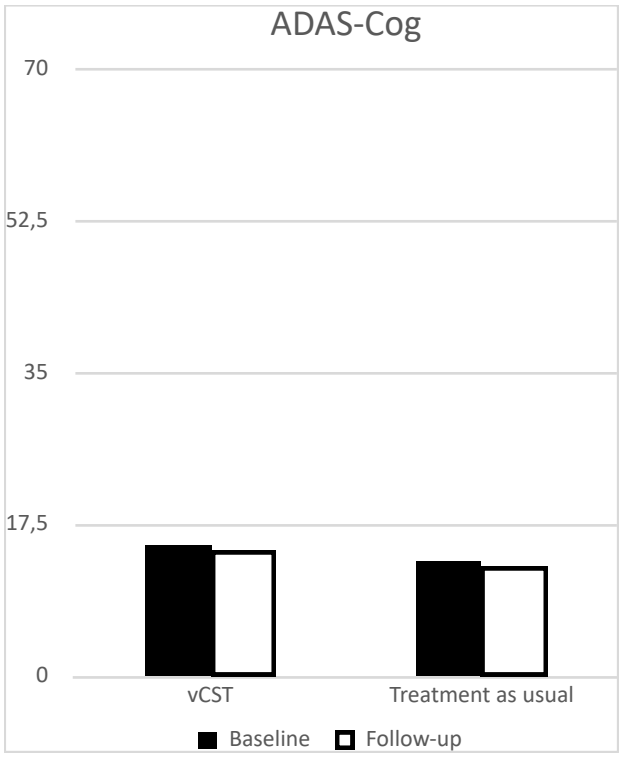
	Scores at baseline		Baseline Mean difference between group	Scores at follow up		ANOVA Between group	Post-Pre Mean difference:	
	vCST mean (SD) n=24	Treatment as usual mean (SD) n=22		vCST mean (SD) n=24	Treatment as usual mean (SD) n=22		Post-Pre vCST Mean (SD)	Post-Pre treatment as usual Mean (SD)
ADAS-Cog	14.97 (10.43)	13.15 (9.62)	t (44) = 0.271, p=0.543	14.51 (11.43)	12.54 (9.35)	F(1,44)= 0.30, p=0.587	-0.46 (4.62)	-0.62 (5.98)
MOCA-BLIND	14.46 (4.90)	14.82 (3.79)	t (44) = -0.277, p=0.783	14.33 (4.58)	14.23 (3.67)	F(1,44)= 0.011, p=0.918	-0.12 (3.03)	-0.59 (2.17)

ADAS-Cog, Alzheimer's Disease Assessment Scale cognitive subscale; MOCA-BLIND, The Montreal cognitive assessment (MOCA)- BLIND; vCST, virtual cognitive stimulation therapy

ADAS-COG:

There was no significant main effect of time, F (1,44) = 0.969, p=0.33, ηp^2 =0.022. Similarly, no significant main effect of group was found, F (1.44) =0.30, p=0.587, ηp^2 =0.007. No significant interaction effect was found between vCST and treatment as usual (F [1, 44] = 0.73, p = 0.789, ηp^2 =0.002). See Figure 3.

Figure 3. ADAS-COG Mean baseline and follow-up scores for vCST and treatment as usual.



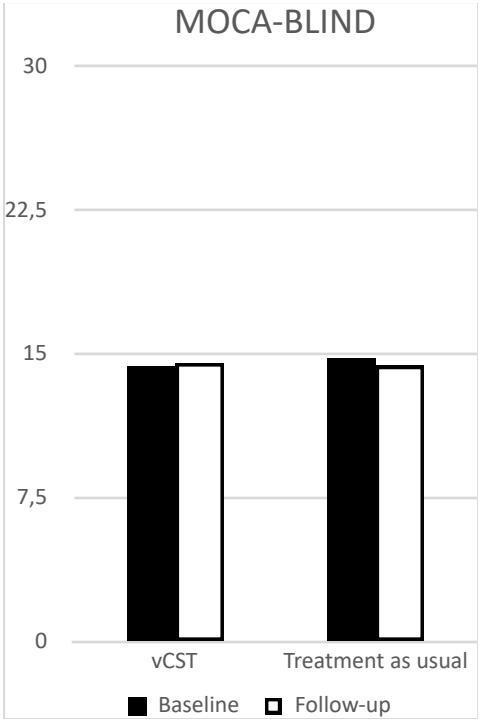
ADAS-Cog, Alzheimer's Disease Assessment Scale cognitive subscale; vCST, virtual cognitive stimulation therapy; treatment as usual, treatment as usual. Higher scores indicate worse cognition.

MOCA-BLIND:

There was no significant main effect of time, F (1,44) = 0.818, p=0.371, ηp^2 =0.018. Similarly, no significant main effect of group was found, F (1.44) =0.11, p=0.918,

ηp^2 =0.00). No significant interaction effect was found between vCST and treatment as usual (F [1, 44] = 0.368, p = 0.547, ηp^2 =0.008). See Figure 4.

Figure 4. MOCA-BLIND Mean baseline and follow-up scores for vCST and treatment as usual.



MOCA-BLIND, The Montreal cognitive assessment (MOCA)- BLIND; vCST, virtual cognitive stimulation therapy; treatment as usual, treatment as usual. Lower scores indicate worse cognition.

Discussion:

Results from this present study suggest that vCST was feasible and acceptable to PwD. The research team recruited the targeted sample within ten months. A retention rate to the research project overall was 80.4%, suggested that PwD of both vCST and control group of stayed on the study after 8 weeks. There were minimal difficulties when recruiting PwD, though a few expressed feeling uncomfortable with

technology or preferring an individualised intervention. The randomisation of the study appeared to be not fully acceptable to some PwD, with a total of nine participants dropping out of the study, with a higher dropout rate found in the treatment as usual group than in vCST. The intervention attendance and retention rates of vCST were high overall, where PwD attended an average number of 13.6 sessions out of 14 sessions. 52.4% of the participants completed the full dosage of vCST and 87.6% of them completed at least 10 sessions, suggesting a high retention rate to intervention. The percentage of the fidelity scores was moderate to high, suggesting good adherence to the protocol by facilitators, and the outcome measures on cognition adopted in this study were feasible and accepted by PwD.

Contrary to previous findings (Spector et al., 2010; Woods et al., 2006), no significant improvement in cognition was found after vCST of both cognitive outcome measures. Future research is warranted perhaps including outcome measures of psychosocial functioning (i.e. social and emotional loneliness) to thoroughly investigate the effectiveness of vCST. Nevertheless, this study was building further from a field testing research on the development of vCST protocol (Perkins et al., 2022), where positive feedback were sought qualitatively through stakeholder consultation. It also suggested that vCST is feasible and acceptable to facilitators and the protocol was adaptable across various culture. Further research could focus interviewing participants through a qualitative method, and perhaps investigate any positive impact that may not be captured quantitatively by this current research.

Interpretation and Implications of the findings:

Feasibility of vCST

The recruiting of older adults through an online platform was effective during the lockdown of Covid-19 when all the out-patient clinics were closed, and care homes were shielded from the public. The current study yielded a high attendance and adherence rate, suggesting that some PwD were accepting of this novel approach to the virtual CST. It is however worth mentioning that majority of the PwD and their caregivers who showed interest in the study were all very familiar with the use of technology and had easy access to a device and the internet. Social distancing, lockdown and isolation perhaps also increased the number of PwD accessing the internet to maintain social connectedness with their families and the community (Greenwood-Hickman et al., 2021). This demonstrated the acceptability of virtual CST when technology can be accessed easily (Cheung & Peri, 2021). Nevertheless, several PwD and caregivers declined to join the study due to worries about setting up Zoom, having unstable internet and lack of devices. One PwD who dropped out of our vCST group experienced instability of the device and internet. Moreover, some PwD were highly dependent on their caregivers' support to join vCST. A few of the participants missed their sessions due to caregivers' unavailability on the day.

Cognition:

Recent studies investigated the impact of the Covid-19 pandemic and the cognitive decline of PwD, with strong evidence showing a worsening of cognitive functioning. During the pandemic, individuals with dementia were more likely to experience a reduction in stimulation, distractions and social interactions, which contributed to further decline of cognition during lockdown (Canevelli et al., 2020; Ismail et al., 2021; Tsapanou et al., 2021). Besides, with the nature of dementia, cognitive decline

is an intrinsic part of the condition. However, no cognitive decline was found in both groups of participants. In this study, both vCST and the treatment as usual group showed no significant changes in cognitive functioning, suggesting that the virtual treatment may not be beneficial to our participants in improving their cognitive functioning. One possible reason for no changes in cognition could be due to the lack of multi-sensory stimulation. It has been shown that a multi-sensory environment has been beneficial for PwD (Jakob & Collier, 2017; Sánchez et al., 2013), where face-to-face group CST is based on (D'Onofrio et al., 2016; Spector et al., 2008). In the current study, all communication conducted during vCST was solely dependent on a flat and two-dimensional screen, where the body gestures and postures of PwD were sedentary throughout. This might lead to a lacking richness in experiencing multisensory cues and receiving physical reciprocation between PwD that they typically would gain from face-to-face CST. Even though vCST attempted to increase the virtual social interactions and reminiscing among PwD, the programme was heavily focused on providing auditory and visual stimulation, with a diminished stimulation of the other senses, i.e. tactile, olfactory and gustatory. Moreover, a possible ceiling effect could be another reason contributing to the insignificant results found in the study. Participants in both vCST and treatment as usual groups all scored relatively well in ADAS-Cog, meaning they were doing better in cognition than PwD in previous studies (Elena Carbone et al., 2021; Piras et al., 2017), suggesting there could be less scope to improve for vCST group. Another possible explanation is that there might be a type II error given the sample size of the study, resulting in not finding an effect on cognition when there could be one.

Strengths and limitations

One strength of this study is that PwD who are geographically inaccessible from social services or have restricted mobility could get access to services virtually when they were given technological support. Besides, those who participated in the current study were based in various locations in the United Kingdom, including London, Birmingham, York, Scotland etc., demonstrating a representation of PwD who were geographically dispersed in the UK. Another strength could be the heterogeneity of facilitators because in the overall CST research, PwD showed improvement in various domains even though facilitators are heterogenous. In our current research, all six groups were conducted by a combination of ten facilitators, some were trainee clinical psychologists, and some were PhD students of the research team. All facilitators underwent the same CST training prior to group facilitation and were given the same CST manual to conduct vCST. It is also important to note that if any intervention effects were captured, the significance found could solely be due to the effectiveness of the programme itself, rather than the effect of facilitation. All training materials can be found on the international CST training centre: https://www.ucl.ac.uk/international-cognitive-stimulation-therapy/international-cognitive-stimulation-therapy-cst-centre.

A limitation of the study was the difficulty in retaining participants in the treatment as usual group. Three were uncontactable for the week 8 follow-up assessment (13.6%), suggesting that the randomisation process was not very acceptable to some of the participants. Nevertheless, this finding could guide future studies, informing us those uncontactable participants were to be expected from the treatment as usual groups of virtual research. Also, two versions of the fidelity checklist were implemented as it was still under development during the initial stage of vCST.

Future studies could improve the checklist and implement one standardised fidelity checklist for further group facilitation.

Future research:

Feasibility of vCST

Future research could consider the accessibility of technology of PwD, as well as its reliability and stability, to ensure the delivery of effective vCST treatment. Further studies could develop approaches to increase the accessibility of stable technological devices for those who are interested in virtual treatment due to restricted mobility, covid isolation or not living close to services. Training on setting up devices and accessing zoom could also be provided to PwD and their caregivers before the vCST, to reduce experiencing any emotional distress caused during the setup of Zoom. Further investigation could also focus on caregivers' perspectives on supporting PwD in setting up virtual meetings, their quality of life and their wellbeing before and after vCST. As self-reported fidelity test could potentially generate biased result, further research could adopt on-screen video recordings of the sessions rated by individuals that were not facilitator of the groups to generate a non-biased fidelity test. Interrater reliability analysis could also be implemented to ensure a good agreement between raters. Record videos could also be beneficial to capture any good practices conducted by facilitators if there were future vCST trials. For future bigger randomised controlled trials, the acceptability of randomisation could be addressed by providing waitlist control groups or having active control groups where other type of CST unrelated intervention could be provided, aiming to retain more participants that could be loss due to the nature of the study design.

Cognition

Addressing the lack of multi-sensory approaches, future studies could compare the virtual CST and face-to-face CST and investigate any multi-sensory components that could be essential to implementing effective CST. In addition, it is undoubtedly that the COVID-19 pandemic had led to a reduction in social support and increased the loneliness of PwD. Previous CST trials reported a significant impact on improving the social and emotional loneliness of PwD (Capotosto et al., 2017). Future research could explore any impact of vCST on the reduction of subjective social and emotional loneliness of PwD.

Conclusion:

In conclusion, the 14-session vCST for PwD was successfully implemented with high attendance and retention rate to intervention, suggesting vCST is highly acceptable and feasible. It is also suggested to be feasible for future clinical implications for PwD and may offer an alternative CST treatment to people who have mobility difficulties. This could also provide further support to PwD who are geographically isolated from the public. Although no significant improvement in cognition was found during the current investigation, the acceptability and feasibility of this current vCST study may suggest that larger trials in the future including the exploration of multi-sensory stimulation may shed light on future vCST trials on improving cognition of PwD.

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Part Three: Critical Appraisal

Introduction:

This critical appraisal will begin with a discussion of the reasons that drew me to dementia research, followed by a critical reflection on this journey and the stages of conducting this study. The appraisal will end with considerations of conducting research as a trainee clinical psychologist, followed by a conclusion.

Researcher Background:

Even though I did not have much exposure to the older adult population clinically before training, I was curious to formulate and understand how the experiences of ageing individuals shaped them into who they were. I perceived older adults as human libraries where each of them had their own stories and experiences to tell. However, witnessing how ageing led to the unsatisfying quality of life for some of them increased my eagerness to further learn to be able to support their well-being holistically. Dementia, specifically, struck me most because of its regressive nature and contribution to people with dementia (PwD) loss of identity. They not

only lose the ability to tell their own stories but also the ability to take care of themselves as an individual. It would also lead to massive changes within a family, not only affecting the PwD individually but also their caregivers.

During my first year, I was extremely excited to be able to pick a doctoral thesis topic that I was passionate about and would enjoy conducting. I was also hoping to be able to conduct research from the very beginning, through recruitment to data collection and analysis. The project on dementia and virtual Cognitive Stimulation Therapy (vCST) met all my hopes for a thesis topic. I would be able to run the vCST groups as a psychologist and analyse and write up the data collected as a researcher, under the supervision of two very supportive and thoughtful supervisors, Professor Aimee Spector and Dr Joshua Stott.

Recruitment:

The empirical study was a joint project with three Trainee Clinical Psychologists at UCL, two from the year above, and one from the same DClinPsy cohort as me, Diyanah. Together, Diyanah and I aimed to recruit approximately an additional 25-30 PwD for our study as the other two trainees had run the vCST groups and recruited 22 PwD at the time, bringing a total of around 50 PwD. During our first year, Covid-19 hit the globe, where our recruitment was mostly conducted through a website (www.joindementiaresearch.co.uk). I was also in Hong Kong at the time for my second-year placement. Having such huge time differences (8 hours) between Hong Kong and the UK, Diyanah and I managed to connect through Zoom for project discussions, though it would always be at night time on my end. The time differences did however make the recruitment procedure more difficult. As I was in Hong Kong, it was difficult to contact potential PwD through phone calls. In the end, I managed to sign up for a skype account, which enabled me to ring the participants

from home. Nevertheless, as the recruitment procedure was rather slow initially, we decided to conduct the groups in a staggered way. Each group was run as soon as we had recruited eight PwD, four in the vCST group and four in the control group.

Study Design:

The nature of the study was a randomised controlled trial. Recent studies have suggested that the randomisation procedures were acceptable by PwD (Alvares-Pereira et al., 2021; E. Carbone et al., 2021). In our current study, all participants were told at the recruitment stage that the chance of getting onto vCST was random, with 50% being allocated to the vCST group, and 50% to treatment as usual. Many expressed their wishes to be allocated to vCST during our online meetings, even though they were mindful of the allocation procedures. Some explained it would be lovely to connect with people who were going through similar situations as they were through zoom. A few expressed that they had enjoyed being involved in dementia research. They were hoping that people who shared similar diagnoses could get the support needed. Whilst feeling uncertain about the diagnoses themselves, I am struck by how optimistic they are. I admired their resiliency and ways of coping.

The current research was a novel approach, investigating the impact of delivering CST through an online platform. With the global pandemic taking place, many interventions had moved towards practising through online video conferencing platforms due to social distancing measures and lockdown. Likewise in supporting the dementia population, growing research was attempting to prove the efficacy of online interventions for PwD and their caregivers(Fossey et al., 2021; Henderson et al., 2022; Kishita et al., 2021). During our recruitment, a few potential participants explained that they had low confidence in setting up video conferencing platforms, i.e. Zoom. They also expressed foreseeing feeling overwhelmed by it and

subsequently turned down the study invitation. Nevertheless, those who agreed to participate in this study were frequent users of online video conferencing or were keen but required support from their caregivers to set up the technology. It was however noticeable that some PwD were more dependent on their caregivers to get access to zoom. On several occasions, I made telephone contacts with the caregivers during the initial stage of vCST to support their loved ones to set up zoom. It made me realise that these caregivers showed lots of patience with their family members. At times we would also make small talks before the start of vCST groups. This made me reflect on how those little interactions could potentially build rapport with the family and PwD, and that they were more willing to reach out for help when struggling with the technology.

Data collection:

The research of feasibility studies involved collecting data guided by the Medical Research Committee (MRC) framework for developing complex health service interventions. Under the guidelines for feasibility studies, parameters such as the recruitment and retention rate to the research study, acceptability of randomisation and intervention, the attrition rate of vCST intervention, fidelity and use of selected outcome measures were included and explored (Campbell et al., 2000). The data collection for the feasibility aspect of vCST went smoothly overall. All data were captured efficiently through a shared excel document among the four trainee clinical psychologists. Any feasibility-related data were instantly uploaded onto the excel sheets. I was grateful for the hard work of all the facilitators involved in the study, who tried to capture the attendance, missing sessions, and any feedback or disappointment of randomisation. They also completed all the fidelity measures and conducted follow-up assessments with minimal missing data.

Baseline and follow-up assessments were conducted to investigate the effectiveness of vCST on cognitive functioning using two outcome measures on cognition. Several difficulties of data collection were captured. Few participants were uncontactable 8 weeks after the baseline assessment. One particular participant agreed to meet over Zoom at a certain time but never showed up. The facilitator in the end rescheduled the session three times but the participants never attended. I found myself thinking whether being allocated in the treatment as usual group, and meeting over zoom may impede data collection at the follow-up time point. It was also at the time when all lockdown measures were lifted in the UK, and I wonder whether it could be a possible explanation for the unattended assessments. Thankfully, only three out of 22 participants in the treatment as usual groups were uncontactable.

My experience with data collecting overall put me into the perspective of how life was for the PwD and their caregivers. Few encounters I had with the PwD made me appreciate how strong and resilient human beings could be. A PwD was struggling with forgetfulness and personal life issues at the same time. It took us three sessions to complete the assessment across the week as she forgot about the appointment. She was also going through a hard time looking for a suitable school for her son who had learning difficulties while trying to get through the GP for her medications (which was very difficult during covid times). She apologised sincerely for each of the missed encounters. We both agreed that life happens, and it was challenging enough to cope with her problems. Another encounter I had that struck me was how caregivers were desperate to support their family members by providing hints during the memory tests, hoping to reduce any frustrations the PwD would have towards themselves. Even though I had politely suggested that it was essential for the

PwD to provide an answer independently, I found it difficult to witness how disappointed some caregivers were, when they realised how poorly the memory of their loved ones had regressed through dementia. These valuable encounters I shared with the PwD made me reflect on how challenging life was for these older adults. I found myself thinking if I were them, I would feel hopeless as well. Nevertheless, witnessing how hard they were coping and making sure their loved ones were well taken care of showed me how resilient one could be. I admire the courage they showed in managing life.

Group Facilitation of vCST:

Facilitating vCST was challenging initially as it was a novel method that I had no experience of. I am grateful for all the materials provided by the previous trainees in this project, which guided me through group facilitations overall, along with the CST manual. I am also thankful for the co-facilitators who were there to support me when we were going through some difficulties with our groups.

I facilitated two vCST groups. Thinking retrospectively, they were both very different in their ways, even though similar contents were delivered to the PwD. We went through various setbacks initially, including group cooperation, attendance and dynamics. From setting up technology, gradually getting to know each other, learning about agreeing to disagreements, to finally building up rapports not only between the facilitators and the group members but also within each of them were invaluable experiences. There were times I found myself reflecting a lot more after facilitating a particular session. A specific memory that struck me till today was an argument between an English, ex-teacher, atheist, PwD in her 90s and an American ex-army, Christian, PwD in his 70s. They discussed heatedly topics related to faith, religion, politics to war (the group was facilitated during the US Stroops retreating from

Afghanistan). Both shared their lived experiences, and it seemed that they did not agree and disliked talking with one another. The other two PwD in the same group kept quiet throughout the heated conversations. However, as we were moving toward the final few sessions, they found consensus on parenting styles and perspectives on world war II, which then opened further communications between themselves and facilitated more agreeing to disagreeing conversations.

Self-disclosure of therapists has been a controversial topic. A definition by a group of researchers suggests that "therapist self-disclosures involve a verbal revelation about the therapist's life outside of therapy" (Hill et al., 2018). During the facilitation of vCST groups, a few PwD were very curious about my personal life outside of vCST. I found myself having the urge to reveal more of my life aiming to build better interpersonal rapport. I was comfortable sharing my circumstances and reasons as to why I was in Hong Kong during the group. However, the conversation then went on about my family and personal relationships which made me hesitate and decided to move on to the next agenda slowly and gently. Reflecting retrospectively, I was flattered that the PwD were curious about me, though I was also mindful that I should only reveal topics that I feel comfortable with.

The social graces framework (Burnham, 1993) was introduced to me throughout my training at UCL and undoubtedly enabled lots of self-reflection throughout vCST group facilitation. I found myself reflecting on visible and invisible graces. As we all got to know each other further within the group, more of the invisible graces were talked about. The majority of the participants were middle-class, Caucasian, Christian, and British. Some of them were highly educated, i.e. a psychiatrist, teachers, and nurses. One completed multiple master's courses. Most of them were having long-term health conditions, such as diabetes, heart conditions,

high blood pressure etc. On the first session of vCST, PwD were invited to talk about the weather of their locations. One of them was very curious and made comments such as " you are near the south of the UK, where all the rich people are", or "you are up north, there are many coloured people around". I recalled our co-facilitator quickly responded to him saying "indeed, it is a very diverse population", and I appreciated her swift reply. Nevertheless, this PwD never offended any participants or the facilitators directly and we all shared lots of laughter throughout. It was however fascinating that I was never particularly upset. I did find myself thinking it was rather inappropriate and was worried about how the other participants felt at the time. The co-facilitator and I discussed it immediately after the group and shared similar concerns. We took it to supervision, and I found it very helpful to be able to speak up about my thoughts. Partly, I was wondering whether naming it would have been helpful, but I was also mindful that his memory was regressing and potentially naming the issue might have created negative emotions and experiences within the group. If there were a chance of running the groups again, I would have done the same by not naming it, however, would stress the importance of mutual respect was to be expected at all times for all discussions within the groups.

Covid – 19:

Relative to many other forms of research, in my opinion, Covid-19 had not impacted my doctoral thesis significantly. As the mode of intervention was online, most aspects of the research were conducted rather smoothly. Even though we struggled a little bit during the recruitment phase, we managed to meet the targeted sample size in the end and completed all of the groups by November 2021. I am grateful for the support I had from my project partner, group co-facilitators and supervisors who were all very flexible and supportive during the pandemic. I am also

thankful that all the participated PwD did not catch Covid-19 and that they were coping alright overall during the groups.

As most of the PwD had long-term health conditions, they were advised by the UK government to shield themselves from the public. Many expressed they were satisfied that the group enabled them to meet others online, as it was inevitable for some of them to feel lonely during lockdown or shielding. They also mentioned wishing they could meet their families and it saddened me how limited the PwD could engage with the world during the pandemic. Most of the PwD in our groups stayed in touch with their families through online video calls, i.e. Zoom, Facetime, and Skype, which led them to be very accepting of the mode of delivery of vCST. Covid-19 nevertheless enabled many discussions throughout the groups. Some shared their views on vaccination and encouraged each other to get vaccinated. Some were worried about the number of covid cases, while some showed less concern overall. The mixed perspectives generated more discussions and acted as a form of stimulation during the group.

Data Analysis:

We conducted statistical analysis through missing data imputation. I was disappointed by the non-significant results found. Partly I was very convinced that the programme was effective. I had a blissful time with the PwD, and they provided positive verbal feedback about the groups. In the end, I spent a lot of the time trying to analyse the data in various ways, i.e. eliminating all the outliers and removing all missing data points. Yet, the results were still non-significant, and I eventually accepted it. Throughout my research journey, I came to realise the importance of learning from non-significant results. Certainly, we would always wish to publish significant findings, as I thought there were more accepting journal articles.

However, when significant results were published more than non-significant findings, this creates publication bias (Easterbrook et al., 1991). Even though I had a hard time accepting the non-significant results, these findings of our study could inform better future research directions instead of viewing it as a merely failed study.

Conducting research as a trainee clinical psychologist:

What I found most challenging as a trainee clinical psychologist while working on a doctoral thesis was time management. I found myself juggling between both placement and research work, as they were equally important to me. Nevertheless, the research has further developed my time management and organisational skills. I was however mindful that I was falling behind at placement progress and hoping to pick up as soon as possible after thesis submission.

There were also perks of being a trainee clinical psychologist and a scientist-practitioner. It enabled us to conduct research that influences our applied clinical practice. It was particularly beneficial when I was running vCST groups while completing my older adult placement. I found the skillsets I gained from both placement and vCST groups applicable between both settings. As I was completing the older adult placement during the pandemic, the service lead at the time was keen to conduct vCST groups to support PwD and their caregivers within the borough. I was given the opportunity to share my insights and experiences on implementing vCST and that allowed me to complete a full circle of being a scientist and a practitioner concurrently.

Conclusion:

Being able to experience and conduct older adult research was fascinating. I was fortunate that the study was not impacted by Covid-19 entirely and that I had

created memories with the PwD and their caregivers. I am thankful for all the support I was given during my journey of completing the doctoral thesis and it will always be a fond memory of mine.

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Appendices:

Appendix A: Contributions to the Joint Research Project

Contributions to the Research Project both Luke Perkins (DClinPsy 2021) and Cerne Felstead (DClinPsy 2021) completed the ethics application and designed the project. The development of the project was carried out by Luke and Cerne in 2020. First half of the participant recruitment and data collection (2019-2020) was carried out by Luke and Cerne while the second half was conducted by Nur Diyanah Abdul Wahab (DClinpsy 2022) and Wing Gi Leung (DClinPsy 2022). The data was entered by Diyanah and Wing Gi Jointly. Analysis of results, and the write-up of the theses were carried out individually.

Appendix B: Ethical Approval

UCL RESEARCH ETHICS
COMMITTEE OFFICE FOR THE
VICE PROVOST RESEARCH

22/07/2020

Professor
Aimee
Spector
[departmen
t]
UCL

Dear Aimee Spector

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

Further to your satisfactory responses to the Committee's comments, I am pleased to confirm in mycapacity 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 ofthe 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 incidentoccurs. 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 reportthat 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. Atthe 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 forResearch: 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 completionof the study.

With best wishes for

the research.Yours

[redacted]

sincerely

Professor Michael Heinrich
Joint Chair, UCL Research Ethics Committee

Appendix C: Participant Information Sheet

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 Cognitive Stimulation Therapy using zoom: A proof of concept study

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Clinical, Education & Health Psychology, Division of Psychology & Language Sciences

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Name and Contact Details of the Researcher(s):
Michelle Wing Gi Leung –w.leung.19@ucl.ac.uk
Diyanah Nur Abdul Wahab – nur.wahab.19@ucl.ac.uk

Name and Contact Details of the Principal Researcher:
Professor Aimee Spector – a.spector@ucl.ac.uk

Invitation Paragraph
You are being invited to take part in a research project in collaboration with the Older Person Services at Our Lady's Hospice & Care Services, Harold's Cross.

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.

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.

What is the difference between the 'zoom CST' group and the 'control' group?

<u>Zoom CST Group:</u>

- 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.
- 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.
- We may then ask you to complete a feedback interview individually via phone or zoom about your experience. This will last one hour or less.

<u>Control Group:</u>

- If you are in the 'control' group, you will be asked to wait a little while (approximately 9 weeks) before attending your CST sessions.

- Instead, we will ask you to complete some questionnaires which will take approximately one hour, at two separate appointments which are 7-weeks apart. During this time you can access your usual treatment as you would if you were not taking part in this study.

- After approximately 9 weeks waiting time, your CST groups will begin. At this point you will be invited to attend 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

Will I be recorded and how will the recorded media be used?
None of your sessions will be recorded.

What is Zoom?
We will be using the video conferencing app 'Zoom', which allows us to call one another over the internet with audio and a camera. 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 a.spector@ucl.ac.uk. 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:** 0207 679 1844*

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

CLINICAL, EDUCATIONAL & HEALTH
PSYCHOLOGY

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. Wing Gi Leung –w.leung.19@ucl.ac.uk
Ms. Nur Diyanah Abdul Wahab - nur.wahab.19@ucl.ac.uk
Name and Contact Details of the Principal Researcher:
Professor Aimee Spector **-** a.spector@ucl.ac.uk
Tel: 020 7679 1844
Name and Contact Details of the UCL Data Protection Officer:
Alex Potts - a.potts@ucl.ac.uk

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. I have also had the opportunity to ask questions which have been answered to my satisfaction and would like to take part in: • *an appointment to complete questionnaires prior to my attendance at the online CST group sessions.* • *14 sessions of an online CST group intervention, if allocated to the 'zoom-CST' group.* • *an appointment to complete questionnaires after attendance at the online CST group sessions.* • *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 nur.wahab.19@ucl.ac.uk or w.leung.19@ucl.ac.uk 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

If you would like to know more please contact us. Or ask your carer, support worker etc. to pass on your contact details to Diyanah & Michelle.

nur.wahab.19@ucl.ac.uk
w.leung.19@ucl.ac.uk

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: Recruitment Email to Participants

RE: **Join Dementia Research - Group Cognitive Stimulation Therapy using Zoom**

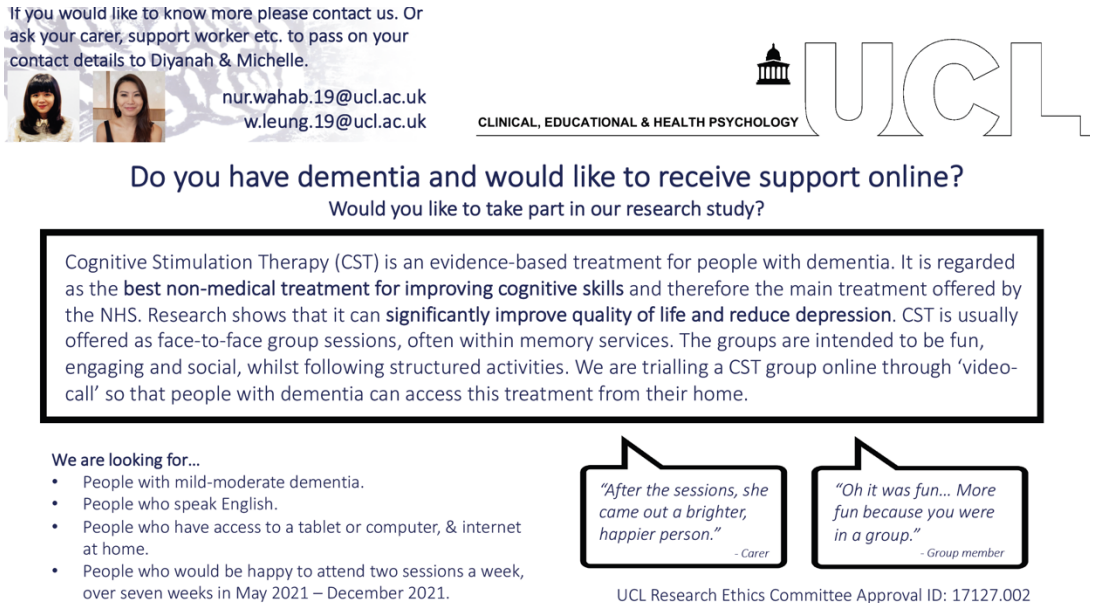
Dear XXX,

We hope this e-mail finds you well.

We are getting in touch with you regarding our study on Join Dementia Research that you showed interest in: **Group Cognitive Stimulation Therapy using Zoom: A proof of concept study.** Great news! We are starting the group CST research in June, and are currently looking for people to join us.

If you are still interested, do reply to this e-mail, and we can arrange a date and time to discuss the study more with you.

Here is the poster for our study:



Warm Regards,

Diyanah and Michelle
Trainee Clinical Psychologists
University College London

Appendix G: Confirmation of consent, Pre-assessment invitation email for Participants

Dear XXXX,

Thank you for giving your consent to participate in our study, virtual Cognitive Stimulation Therapy. As we discussed, we are getting in touch with enrolled participants because we will be starting to run the online group CST on the 19th of July. Our team members will get in touch with you in the next few days to run the pre-assessment with you the week before the group starts, as we have discussed. After this pre-group assessment, we will then let you know whether you are assigned to the CST group, or the control group (as we went through together in the information sheet). ☺▪

Please respond to this e-mail to let us know you have any questions. If you haven't returned the consent email back to us indicating your consent, please do so by the 9th of July ☺ We really appreciate it, and we look forward to hearing from you!

Warm Regards,

Diyanah and Michelle

Trainee Clinical Psychologists

UCL

Appendix H: 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 □ Prefer not to say □ Other: Click or tap here to enter text.
Ethnicity	□ Arab □ Asian or Asian British – Indian □ Asian or Asian British – Pakistani □ Asian or Asian British – Bangladeshi □ Asian or Asian British – any other Asian background □ Black or Black British – Caribbean □ Black or Black British – African □ Black or Black British – any other Black background □ Chinese □ Mixed – White and Black Caribbean □ Mixed – White and Black African □ Mixed – White and Asian □ Mixed – Any other mixed background □ White – British □ White – Irish □ White – any other White background □ Any other ethnic origin group: Click or tap here to enter text.

Dementia Type	☐ Alzheimer's disease ☐ Lewy body dementia ☐ Vascular dementia ☐ Frontotemporal dementia ☐ Creutzfeldt-Jakob disease ☐ Wernicke-Korsakoff's dementia ☐ Parkinson's-related dementia ☐ Huntington's-related dementia ☐ Other: Click or tap here to enter text.
Address	Clic k or tap here to enter text.
Telephone No.	Clic k or tap here to enter text.
Email address ***(we will send group joining details to this address)***	Clic k or tap here to enter text.
GP Details	Clic k or tap here to enter text.

Carer Full Name	Clic k or tap here to enter text.
Relationship	Clic k or tap here to enter text.
Address	Clic k or tap here to enter text.
Telephone No.	Clic k or tap here to enter text.

For Office Use	
Capacity to consent	Yes ☐ No ☐ 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.