Adapting Cognitive Stimulation Therapy (CST) for Pre-Frail Stroke Survivors: Intervention Development and Acceptability

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Thesis Portfolio Abstract

Background: Frailty, marked by unintentional weight loss, exhaustion, weakness, slow walking speed, and low physical activity, is common in stroke survivors and linked to poorer outcomes. Multicomponent interventions (MCIs) show potential for reducing or preventing frailty, and may be helpful for a stroke survivor population. Given both frailty and stroke are associated with psychological difficulties such as cognitive impairment, depression, poor quality of life, there is a rationale for including psychological components within MCIs for post-stroke frailty.

Method: A systematic review was conducted on psychological outcomes of MCIs for frail or pre-frail individuals. Using a theory- and evidence-based approach, Cognitive Stimulation Therapy was adapted for stroke survivors (sCST) and a small-scale, single-arm pilot acceptability study was conducted. Pre-frail stroke survivors attended eight sample sessions of sCST and provided quantitative and qualitative acceptability feedback via a questionnaire and interview, respectively.

Results: Narrative synthesis of 16 studies indicated that MCIs are associated with improved depression, cognition, processing speed, visuospatial skills, and verbal fluency and highlighted that inclusion of cognitive or psychosocial intervention components increases the likelihood of these outcomes. Framework analysis of interviews with four pre-frail stroke survivors identified 22 sub-themes relating to the acceptability of sCST spanning the seven constructs of the Theoretical Framework of Acceptability: affective attitude, burden, ethicality, coherence, opportunity costs, perceived effectiveness, and self-efficacy. Notably, participants found sessions enjoyable and beneficial but highlighted issues with intervention location, clarity of purpose, and difficulty level.

Conclusions: Clinical Psychologists can contribute to frailty management research through exploration of the relationships between frailty, cognition, mood, and self-efficacy. Further refinements of sCST are required and research to assess its effectiveness as it may have useful applications for frailty prevention after stroke. ¹

 $^{^{\}scriptscriptstyle \rm I}$ I acknowledge that where appropriate, material from my thesis proposal has been re-used within this thesis portfolio.

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Chapter 1 – Introduction

Word count: 948

This chapter offers a brief introduction to key topics discussed in this Clinical Psychology doctoral thesis portfolio and outlines the aims and structure of the thesis.

Key Topics and Terms

Frailty

Frailty is a medical syndrome characterised by reduced strength, endurance, and physical function that increases risk of dependency and mortality (Morley et al., 2013). "Pre-frailty" has also been identified as an intermediate state, whereby individuals are at an increased risk of becoming frail in the following few years (Gill et al., 2006; Sezgin et al., 2020). Importantly, Gill et al. (2006) identified that intervention at the pre-frail stage could reverse frailty, or prevent further deterioration.

It must be noted, however, that different operationalisations of both frailty and pre-frailty have been proposed. For example, Fried (2001) suggested that individuals are considered frail if they meet three of the following five phenotype criteria, and pre-frail if they meet one or two criteria: unintentional weight loss, exhaustion, weakness, slow walking speed, and low physical activity. An alternative method involves calculating an index score, between 0 and 1, based on the number of pre-defined clinical characteristics or co-morbidities present in an individual (Rockwood & Mitnitski, 2007). Using this method, scores greater than 0.25 indicate frailty, scores less than 0.15 indicate no frailty and all scores in between indicate pre-frailty.

"Cognitive frailty" refers to the co-occurrence of physical frailty and cognitive impairment (Sugimoto et al., 2022). This definition was proposed because frail individuals frequently also have cognitive difficulties (Robertson et al., 2013) and are at increased risk of developing a dementia (Chu et al., 2021; Kulmala et al., 2014). However, other psychological difficulties associated with frailty have also been identified such as loneliness (Hoogendijk et al., 2016) and depression (Soysal et al., 2017). As a result, several definitions of "psychological frailty" have also been proposed, which consider these psychological difficulties as well as cognitive difficulties and fatigue-related problems (Zhao et al., 2023).

Multicomponent Interventions

A promising approach for the reversal or prevention of frailty at the pre-frail stage is the use of multicomponent interventions (MCIs), consisting of a physical exercise intervention combined with nutritional, cognitive, social and/or other interventions (Apóstolo et al., 2018; Dedeyne et al., 2017; Tam et al., 2022). Due to the associations of frailty with cognitive impairment and psychological difficulties outlined

above, MCIs often include a cognitive or psychological intervention component, such as cognitive training (Belleville et al., 2023), psychological skills training (van Lieshout et al., 2018), a psychosocial intervention (Seino et al., 2017) or cognitive stimulation therapy (Tan et al., 2023).

Cognitive Stimulation Therapy

Cognitive Stimulation Therapy (CST; (Spector et al., 2001, 2020) is a non-pharmacological treatment which is recommended by the National Institute of Health and Care Excellence (NICE) for individuals with dementia in England (NICE, 2018). Cognitive stimulation is an approach that aims to improve both cognitive and psychosocial functioning via group discussion and activity (Clare & Woods, 2004). CST has been found to improve cognition and quality of life and reduce symptoms of depression in individuals with dementia (e.g., Aguirre et al., 2013; Cao et al., 2023; Lobbia et al., 2019). As a result, it has been adapted for a range of different languages and cultures (e.g., Alvares Pereira et al., 2022; Wong et al., 2018) and adopted internationally (University College London, 2021).

Stroke

A stroke, sometimes referred to as a cerebrovascular accident or CVA, is an injury to the brain that occurs when cerebral blood flow is obstructed or disrupted via a blood clot (ischemic) or ruptured blood vessel (haemorrhagic). Strokes cause a sudden onset of neurological symptoms, such as muscle weakness, language difficulties and cognitive impairment (Caplan, 2006).

In the UK, approximately 100,000 strokes occur each year and, in 2021, 1.3 million people were estimated to be living with stroke (Stroke Association, n.d.). Common consequences of stroke include depression, anxiety, dementia, disability and mortality (Craig et al., 2022; Hackett & Pickles, 2014; Ivan et al., 2004; Knapp et al., 2020).

A James Lind Alliance stroke priority-setting partnership led by the Stroke Association identified that the top two research priorities for stroke rehabilitation and long-term care concern the need for greater understanding of psychological and cognitive consequences of stroke and appropriate interventions (James Lind Alliance, 2025b), highlighting the importance of Clinical Psychology involvement in stroke research and services.

Frailty is prevalent amongst stroke survivors, with 21% meeting frailty criteria (Palmer et al., 2019). Post-stroke frailty is associated with increased risk of adverse

outcomes, such as increased length of hospital stay, disability and mortality (Ahmad et al., 2023; Burton et al., 2022; Evans et al., 2020, 2022; J. Li et al., 2024).

Thesis Aims and Structure

This thesis portfolio aims to increase understanding of cognitive and psychosocial outcomes of MCIs and then develop and evaluate an intervention for stroke survivors designed to improve cognitive and psychosocial functioning which could, in future, be adopted into an MCI to prevent or reverse progression of frailty post-stroke.

Three papers are presented. Chapter 2 presents a systematic review exploring the cognitive and psychosocial (e.g. depression, anxiety and quality-of-life) outcomes of multicomponent interventions for frailty and considering which combinations of interventions appear to result in the best psychological outcomes. In Chapter 3, the adaptation of Cognitive Stimulation Therapy for stroke survivors is described, with the intention that this intervention could be used as part of a multi-component intervention to prevent frailty post-stroke. Chapter 4 then reports a single-arm acceptability pilot of the newly developed stroke CST (sCST) intervention for individuals within 12 months post-stroke to explore how acceptable the intervention is to pre-frail stroke survivors and inform any further refinements that may be required. Finally, a Critical Appraisal and Discussion of the research presented is provided in Chapter 5.

Chapter 2 – Systematic Review

The Cognitive and Psychosocial Outcomes of Multi-Component Interventions for Frail and Pre-frail Adults: A Systematic Review

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The following systematic review was written and formatted following the author guidelines for the journal, *Frontiers in Aging* (Appendix A)

Word limit: 12,000

Abstract word count: 209

Word count (excluding abstract, figures, tables, and references): 8,020

Number of figures and tables: 7

Please contact Sophie Livsey with any queries regarding this review via email: s.livsey@uea.ac.uk

Abstract

Background: Frailty is linked to cognitive decline and psychosocial difficulties like depression, anxiety, and reduced quality of life. Multicomponent interventions (MCIs) show promise in reversing or preventing frailty in older adults. This systematic review examines cognitive and psychosocial outcomes of MCIs in frail or pre-frail individuals and identifies components contributing to better outcomes.

Methods: Five databases (CINAHL, EMBASE, MEDLINE, PsycINFO, Web of Science) were searched for randomised controlled trials (RCTs) assessing at least one cognitive or psychosocial outcome in frail or pre-frail participants receiving MCIs compared to controls. Risk of bias was assessed using the JBI appraisal tool, and results were synthesised narratively due to study heterogeneity.

Results: Eighteen publications (16 studies) were included; 10 evaluated cognitive outcomes, and 12 evaluated psychosocial outcomes. MCIs varied in their duration, components, and delivery. Findings suggest MCIs improve symptoms of depression, global cognition, processing speed, visuospatial skills, and verbal fluency. Results for other cognitive domains and quality-of-life measures were mixed.

Discussion: Heterogeneity in outcome measures and intervention characteristics were key limitations. Five studies also showed a high risk of bias. Despite this, the review highlights MCIs as an effective strategy for addressing cognitive and psychosocial aspects of frailty.

Other: The review protocol was registered with PROSPERO (CRD42024540925). No funding was received.

Keywords: Frailty, Cognition, Psychosocial Functioning, Multicomponent Interventions, Systematic Review

1 Introduction

The definition of frailty was first operationalised by Fried et al. (2001) as the presence of at least three out of the following five clinical indicators: unintentional weight loss, exhaustion, weakness, slow walking speed and low level of physical activity. They also defined an "intermediate frailty status", now referred to as "pre-frailty", as the occurrence of one or two of the five criteria. Individuals assessed as frail are 3-5 times more likely to die than those who are not, depending on the length of the follow-up period, and those assessed as pre-frail have an increased risk of becoming frail in the following few years (Gill et al. 2006). However, Gill et al. (2006) identified that frailty is potentially reversible at the pre-frail stage. As such, researchers have sought to understand the factors associated with frailty and develop interventions that could help to reverse it.

Frailty is associated with increased risk of cognitive decline and dementia in older adults (Borges et al. 2019). The associations between frailty and cognition are so established that "cognitive frailty" has been proposed as an expansion of frailty whereby cognitive impairment, but not dementia, is present alongside the physical frailty phenotypes outlined by Fried et al. (2001; Buchman and Bennett 2013). There is mixed evidence relating to the specific cognitive domains that appear to be affected in frail individuals. Robertson, Savva, and Kenny (2013) suggested that executive functioning and attention were most associated with frailty, but Brigola et al. (2015) instead found evidence suggestive of impairment in memory domains, closely followed by processing speed, temporal orientation and visuospatial skills. Robertson, Savva, and Kenny (2013) proposed inflammation, nutrition and cardiovascular health as possible mediating factors in the association between frailty and cognitive impairment and concluded that frailty interventions should aim to prevent or reverse cognitive decline. Indeed, cognitive training interventions can have a positive impact on frailty ratings (Ng et al. 2015)

There are also reported associations between the incidence of frailty and depression (Buigues et al. 2015; Ní Mhaoláin et al. 2012; Soysal et al. 2017; Vaughan, Goveas, and Corbin 2015), anxiety (Ní Mhaoláin et al. 2012; M. Tan, Bhanu, and Frost 2023), psychological wellbeing (Andrew, Fisk, and Rockwood 2012; Biçak Ayik, Cengiz, and Isik 2024) and quality of life (Crocker et al. 2019; Kojima et al. 1979). In acknowledgement of this, various definitions of "psychological frailty" have been proposed which take into account depression, anxiety, loneliness and fatigue, as well as cognitive difficulties, occurring alongside physical frailty (Zhao et al. 2023).

A particular focus of the research in this area has been the relationship between frailty and depression. Soysal et al. (2017) found that the incidence of depression is four times greater in frail older adults than in non-frail older adults and, similarly, the incidence of frailty is far greater in older adults with depression than in those without. Some have proposed that depression and frailty may be influenced by another common factor or factors (Mayerl, Stolz, and Freidl 2020), although further research is required to determine what these factors may be. Others argue that the association between depression and frailty may be bidirectional and reciprocal, with each contributing to, and exacerbating, the other (e.g., Sang et al. 2023; Shin et al. 2024). The relationship of frailty with anxiety, on the other hand, has been researched far less. A 2023 systematic review identified that frail individuals score significantly higher on anxiety measures such as the Hospital Anxiety and Depression Scale than non-frail individuals (M. Tan, Bhanu, and Frost 2023), but the possible reasons for this remain unclear.

One promising approach for reversing frailty is the use of multicomponent interventions (MCIs), consisting of a physical exercise intervention combined with nutritional, cognitive, social and/or other interventions, which have been shown to reduce frailty ratings in pre-frail older adults (aged 65 or above) (e.g., Apóstolo et al. 2018; Dedeyne et al. 2017; Tam et al. 2022). Given the reported associations between frailty, cognition and psychosocial functioning, it would be helpful to understand whether MCIs for frailty adequately target these aspects of functioning.

In 2017, Dedeyne et al. conducted a systematic review to explore the frailty, functional and cognitive outcomes of MCIs for frailty, but they reported inconclusive results for both cognitive and psychosocial outcomes. Only one of the 12 included studies (Van De Rest et al. 2014) assessed and reported cognitive outcomes, and inconsistent findings relating to psychosocial functioning were reported by five of the studies. One key recommendation from Dedeyne et al.'s (2017) review was for MCI researchers to focus on cognitive and psychosocial outcomes. Therefore, eight years later, there is a clear rationale for another systematic review to identify such research and synthesise its findings.

As the component interventions used within MCIs vary greatly in terms of the component interventions used, it would be useful to identify the types of MCIs that have the greatest impact on cognitive and psychosocial outcomes.

This systematic review aimed to answer the following research questions:

1. What is the impact of MCIs on cognitive outcomes?

- 2. What is the impact of MCIs on psychosocial outcomes, such as depression and anxiety?
- 3. What types of MCIs result in better cognitive outcomes?
- 4. What types of MCIs result in better psychosocial outcomes, such as depression and anxiety?

2 Methods

This review was pre-registered with PROSPERO, the international prospective register of systematic review protocols (CRD42024540925). Some amendments were made to the protocol since initial registration to clarify the inclusion criteria and research questions, which were reviewed and approved by PROSPERO.

This systematic review is reported according to PRISMA guidelines (Appendix B). No specific funding or grants were sought or received.

2.1 Search Strategy

Searches were conducted on five databases (CINAHL, MEDLINE, EMBASE, PsychINFO and Web of Science) on 5th May 2024. The search strategy was developed to identify published randomised controlled trials that measured cognitive or psychosocial outcomes in frail or pre-frail adults after a multi-component intervention. The full search strategy for each database can be found in Appendix C. The search strategy and inclusion criteria were developed and refined according to the PICOS framework; population, intervention, comparison, outcomes and study design (Amir-Behghadami and Janati 2020; Table 1).

Table 1Inclusion and Exclusion Criteria According to PICOS Framework

PICOS	Inclusion Criteria	Exclusion Criteria
Participants	Over 18 years of age	Definition or operationalisation of frailty of pre-frailty not
	Any setting: community, residential/nursing home or hospital	explicitly explained.
	Frail or pre-frail according to an operationalised definition (such as Fried's criteria; Fried et al. 2001) or assessment tool (such as the Clinical Edmonton Frail Scale, EFS; Rolfson et al. 2019)	
	Where samples also included non-frail participants, outcomes for frail and pre-frail participants were reported separately and, therefore, could be isolated	
Intervention	Multi-component interventions (MCI) - defined as an intervention consisting of at least two distinct	Individualised MCIs where there were no consistent, core

PICOS	Inclusion Criteria	Exclusion Criteria
	components targeting different aspects of frailty (e.g., exercise/physical activity, nutrition, cognition) All MCI participants undertook at least two consistent, core components of the intervention. Additional components may have been added on an individual basis.	elements delivered to all participants
Control	Inclusion of comparison group, such as a waitlist control group, a treatment-as-usual group, a single component intervention group, or an active control group.	The comparison group was another type of MCI
Outcomes	At least one cognitive or psychosocial outcome using standardised outcome measures including but not limited to: Cognitive screening measures (e.g., the Montreal Cognitive Assessment [MoCA]) Assessments of specific cognitive domains (e.g., Trail Making Test [TMT]) Depression measures (e.g., Geriatric Depression Scale [GDS]) Quality-of-life measures (e.g., EuroQoL 5 dimension [EQ-5D])	Cognitive or psychosocial outcomes reported at baseline only. Absence of between-group comparisons between MCI and comparison groups
Study Design	Randomised controlled trials, including sub-types such as cluster-randomised controlled trials and randomised crossover-controlled trials Published in the English language.	Systematic reviews, meta- analyses and study protocol papers Non-randomised trials Poster and presentation abstracts

2.2 Selection Process

The papers identified were imported into Rayyan, a systematic review web application. Using built-in artificial intelligence, Rayyan identified potential duplicates, each reviewed individually for removal or retention. Remaining studies were screened in Rayyan according to their titles and abstracts. Search filters were used to more easily identify systematic reviews, meta-analyses and study protocols for exclusion. The 136 studies requiring further review were imported into a CSV file and saved as a Microsoft Excel spreadsheet for management during full-text screening.

A portion of the papers identified for inclusion (29.5%, n=5) were also screened by a second rater for confirmation that all inclusion criteria had been met. There was 100% consensus between raters.

2.3 Appraisal of Studies and Risk of Bias Assessment

Eligible studies were appraised using the Joanna Briggs Institution Checklist for Randomized Controlled Trials (Tufanaru et al. 2020). This tool assesses internal validity (via four domains of bias: selection and allocation; administration of intervention; assessment, detection and measurement of the outcome; and participant retention) and statistical analysis validity.

A portion of the studies (29.5%, n=5), selected at random, were also appraised by a second rater. The initial consensus between the researcher and second-rater for these studies was 70%. Disagreements were managed through discussion, with each rater explaining their reasons for ratings until 100% consensus was reached.

2.4 Data Extraction

The following data were extracted from each included study and tabulated: Study characteristics (country, design and outcome assessment time points, frailty definition/tool used), participant characteristics (sample size, percentage of female participants, mean age, frailty status), characteristics of the interventions used (duration, MCI components, nature of the comparison groups), cognitive outcome measures and results, and psychosocial outcome measures and results.

Outcome scores are reported as mean change scores, mean change scores \pm standard deviation, mean change scores (95% confidence intervals), mean scores \pm standard deviation, or mean scores (95% confidence intervals).

Primary outcomes were cognition scores and scores on measurements of psychosocial functioning, including depression, anxiety and quality of life.

Only post-intervention and follow-up outcomes were extracted, despite some studies also assessing and reporting outcomes mid-intervention. Only the outcomes of the MCI group and comparison group (CG) were extracted and, where there were additional experimental groups, the overall group X time interaction effects were not extracted. Only the p-values of significant effects were extracted.

2.5 Narrative Synthesis

A narrative synthesis of the data was conducted following published guidance (Popay et al. 2006). Study characteristics and intervention characteristics were summarised. The effects of the interventions on cognitive and psychosocial outcomes were described, and patterns were identified where possible. Meta-analysis could not be conducted due to the heterogeneity of MCIs, CGs and outcome measures.

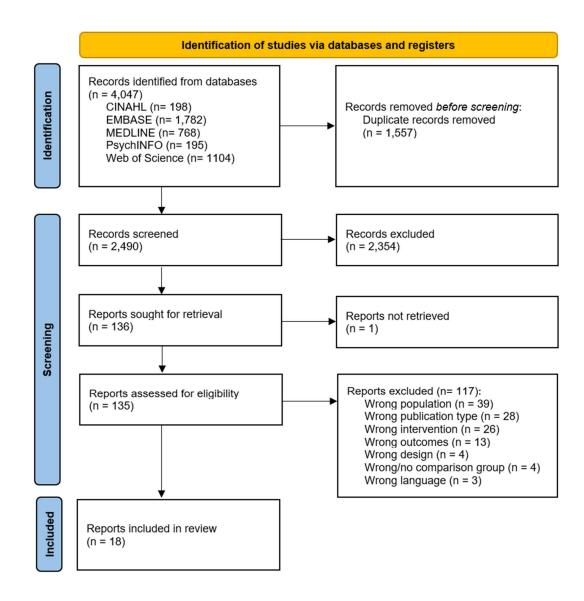
3 Results

3.1 Study Selection

The flow of study identification, inclusion and exclusion is presented as a PRISMA 2020 flow diagram in Figure 1.

Figure 1

PRISMA 2020 Flow Diagram of Study Selection



Note: This flow diagram was adapted from a template (Page et al. 2021) and is licensed under CC BY 4.0. To view a copy of this license, visit https://creativecommons.org/licenses/by/4.0/

There were occasions where it was unclear whether a publication met inclusion criteria. Firstly, some publications (Chen et al. 2020; Liang et al. 2024) claimed in their methods section that participants were frail and/or pre-frail, but later reported in the baseline participant characteristics tables that some participants had been assessed to be non-frail. A decision was made to exclude these papers, except Kapan et al. (2017), wherein only one of 80 participants was assessed as non-frail. However, this observation does raise a potential challenge resulting from the lack of consensus about

how frailty should be assessed in research and questions about the consistency with which frailty is operationalised during different phases of the same research. Other publications (e.g., Chin A Paw et al. 2002), although having an experimental group that received an intervention meeting the proposed MCI definition, analysed data from the experimental groups in a way that did not allow extraction of outcome data for the MCI group in isolation and were therefore excluded.

Eighteen papers were identified for inclusion, relating to 16 individual studies. One study is reported in two papers, with one (Belleville et al. 2023a) being a correction to the other (Belleville et al. 2023b). Also, the cognitive outcomes of another study are reported separately (Ng et al. 2018) from its psychosocial outcomes (Ng et al. 2017).

3.2 Study Appraisal and Risk of Bias

3.2.1 Risk of Bias

The risk of bias (ROB) ratings for each included paper are presented in Table 2. Percentages of positive ratings were calculated for each paper; papers with scores of 70% or above are considered to have a low ROB, those with scores of 50-69% are considered to have moderate ROB, and those with scores of 49% or less are considered to have a high ROB. These classifications have been used in previous studies (e.g., Alqarni et al. 2023; Azmiardi et al. 2022; Polmann et al. 2021; Rahardian, Putri, and Maulina 2024). Only items 1-10 were included when calculating the percentages, as suggested by the authors of the JBI checklist (Barker et al. 2023) due to the fact the last three items all assess statistical conclusion validity rather than internal validity and are therefore not relevant to ROB. The average score across all papers was 54%, indicating that the included papers had a moderate ROB overall.

One publication, (Belleville et al. 2023a), was not independently appraised as this paper presents a correction to another included paper. Of the 17 publications assessed, 24% (n=4) achieved a score of 70%, indicating a low ROB (Belleville et al. 2023b; Han et al. 2023; Hsieh et al. 2019; Romera-Liebana et al. 2018) and 29% (n=5) achieved a score below 50%, indicating a high ROB (Faes et al. 2011; Gené Huguet et al. 2018; Liang et al. 2021; Nakazeko et al. 2023; L. F. Tan et al. 2023). The eight remaining papers were assessed as having moderate ROB.

Items 1-3 assess the ROB relating allocation of participants; 23.5% of papers (n=4; Han et al. 2023; Ng et al. 2018; 2017; Romera-Liebana et al. 2018) achieved positive ratings for all three of these items, and 11.7% (n=2; Liang et al. 2021; L. F. Tan et al. 2023) achieved no positive ratings for these items.

Items 4-6 assess the ROB relating the administration of the intervention; no papers achieved positive ratings for all three items but 17.6% (n=3; Faes et al. 2011; Van De Rest et al. 2014; Yu et al. 2020) failed to achieve any positive ratings in this domain. This domain appears to be an area of relative weakness for all papers included. This is because, due to the nature of the interventions, it wasn't possible to blind those delivering or participating in them. Belleville et al. (2023a, 2023b) attempted to blind the participants by using an active control intervention and not revealing details about the hypothesis.

ROB relating to the assessment of outcomes is assessed by items 7-9; 17.6% (n=3; Hsieh et al. 2019; Van De Rest et al. 2014; Yu et al. 2020) papers achieved positive ratings for all three items within this domain. All papers achieved a positive rating in at least one of these items, in fact 76.4% (n=13) achieved a positive rating in at least two items. This domain appears to be a relative strength for the papers included in this review. The item upon which most papers failed in this domain was item 9 'Were outcomes measured in a reliable way?'. Unfortunately, very few of the papers were explicit about the measures taken (if any) to ensure inter- and intra-rater reliability in assessing the outcomes.

Item 10 assesses ROB relating to participant retention, 41.2% of papers (n=7; Faes et al. 2011; Gené Huguet et al. 2018; Liang et al. 2021; Nakazeko et al. 2023; Ng et al. 2017; 2018; Seino et al. 2017) did not achieve a positive rating for this item because they did not clearly describe the reasons for drop out for each experimental group.

3.2.2 Statistical Conclusion Validity

Items 11-13 of the JBI checklist all assess statistical conclusion validity. The ratings were largely positive in this domain, except for four studies (Faes et al. 2011; Gené Huguet et al. 2018; Liang et al. 2021; Tan et al. 2023) who were not explicit about whether they had used 'intention-to-treat' analysis. L. F. Tan et al. (2023), who used a cluster-RCT design, were also not explicit about any attempts to assess intra-cluster correlations.

Table 2The JBI Critical Appraisal Tool for Assessment of Risk of Bias for Randomized Controlled Trials

Question number:	1	2	3	4	5	6	7	8	9	10	11	12	13	RoB %
Category: Study Domain:	IV A	IV A	IV A	IV I/E	IV I/E	IV I/E	IV O	IV O	IV O	IV PR	SCV	SCV	SCV	70
Belleville et al. 2023b	Y	U	Y	Y	U	Y	Y	Y	U	Y	Y	Y	Y	70
Chan et al. 2012	Y	U	Y	N	N	Y	Y	Y	U	Y	Y	Y	Y	60
Faes et al. 2011	Y	U	Y	N	N	U	Y	Y	U	N	U	Y	Y	40
Gené Huguet et al. 2018	Y	U	Y	U	U	Y	N	Y	U	N	U	Y	Y	40
Han et al. 2023	Y	Y	Y	N	N	Y	Y	Y	U	Y	Y	Y	Y	70
Hsieh et al. 2019	Y	U	Y	N	U	Y	Y	Y	Y	Y	Y	Y	Y	70
Kapan et al. 2017	Y	U	Y	N	N	Y	N/A	Y	U	Y	Y	Y	Y	50
Liang et al. 2021	U	U	N	N	U	Y	U	Y	Y	N	U	Y	Y	30
Nakazeko et al. 2023	Y	U	Y	U	U	Y	U	Y	U	N	Y	Y	Y	40
Ng et al. 2017	Y	Y	Y	N	U	Y	Y	Y	U	N	Y	Y	Y	60
Ng et al. 2018	Y	Y	Y	N	U	Y	Y	Y	U	N	Y	Y	Y	60
Romera-Liebana et al. 2018	Y	Y	Y	N	U	Y	Y	Y	U	Y	Y	Y	Y	70
Seino et al. 2017	Y	U	Y	N	N	Y	Y	Y	U	N	Y	Y	Y	50
L. F. Tan et al. 20233	N	N	N	N	U	Y	N	Y	Y	Y	U	Y	U	40
Van De Rest et al. 2014	Y	U	Y	U	U	U	Y	Y	Y	Y	Y	Y	Y	60
van Lieshout et al. 2018	Y	U	Y	U	U	Y	U	Y	U	Y	Y	Y	Y	50
Yu et al. 2020	Y	U	Y	U	U	U	Y	Y	Y	Y	Y	Y	Y	60

Note: Categories - IV; internal validity, SCV, statistical conclusion validity; Domains - A; bias relating to selection and allocation, I/E; bias relating to administration of intervention/exposure, O; bias relating to assessment, detection and measurement of outcomes, PR; bias relating to participant retention. Q1: true randomization, Q2: concealed allocation, Q3: similar at the baseline, Q4: blinding of participants, Q5: blinding of treatment deliverers, Q6: groups treated identically, Q7: blinding of assessors, Q8: outcomes measured in the same way, Q9: outcomes measured in a reliable way, Q10: differences in follow-up adequately described and analysed, Q11: participants analysed in the groups to which they were randomized, Q12: appropriate statistical analysis used, Q13: trial design appropriate and any deviations accounted for

3.3 Study Characteristics

An overview of the characteristics of the 16 included studies is provided in Table 3. The studies included were RCTs; most were parallel group RCTs, but two were cluster RCTs (Liang et al. 2021; L. F. Tan et al. 2023) and one was a crossover RCT (Seino et al. 2017). Eight studies took place in Eastern countries (Singapore, Taiwan, Japan, or China), and eight in Western countries (The Netherlands, Spain, Austria, Australia, Canada, Switzerland and Belgium). The mean age of participants ranged from 62.2 (Yu et al. 2020) to 84.5 years (Gené Huguet et al. 2018). The percentage of female participants in the studies ranged from 39.8 (Hsieh et al. 2019) to 88.2 (Yu et al. 2020) . Most studies included participants who were either pre-frail or frail, except for Belleville et al. (2023a, 2023b), who had a sub-group of participants who were pre-frail only, and Gené Huguet et al. (2018), who included participants who were frail only.

Intervention durations ranged from 11 weeks (Faes et al. 2011) to one year (Liang et al. 2021). Eight had durations that were approximately 3 months (11-15 weeks; Faes et al. 2011; Chan et al. 2012; Kapan et al. 2017; Seino et al. 2017; Romera-Liebana et al. 2018; Yu et al. 2020; Han et al. 2023; Nakazeko et al. 2023) seven had durations of approximately 6 months (23-26 weeks; Belleville et al. 2023a, 2023b; Gené Huguet et al. 2018; Hsieh et al. 2019; Ng et al. 2017; 2018; L. F. Tan et al. 2023; Van De Rest et al. 2014; van Lieshout et al. 2018).

Table 3Study Characteristics

Study, Country	Design	N	Participants:	Definition of frailty used	MCI Duration	Baseline	Post- MCI	3 month follow up	6 month follow up	Other (time)
Belleville et al. 2022 Canada, Switzerland, Belgium	RCT	120	65.83% female, mean age 71.33 years, non-frail (75) and pre-frail (45). Outcomes reported for total sample and pre-frail participants only.	'Fried's frailty index' (Fried criteria)	26 weeks	X	X			
Chan et al. 2012 Taiwan	RCT	117	59% female, mean age 71.4 years, pre-frail (102) and frail (15)	CCSHA_CFS_TV	3 months	X	X	X	X	X (9 months)
Faes et al. 2011 Netherlands	RCT	36	Approximately 70% female, mean age 78.3 years, frail (36)	'widely accepted frailty indicators' (Fried criteria)	11 weeks	X	X	X		
Gené Huguet et al. 2018 Spain	RCT	200	64.5% female, mean age 84.5 years, pre-frail (200)	Fried criteria	6 months	X	X	X		
Han et al. 2023 Australia	RCT	32	62.5% female, mean age 79.2 years, pre-frail (12) and frail (20)	Edmonton Frail Scale	Hospital stay (3-18 days) plus 3 months	X	X	X		
Hsieh et al. 2019 Taiwan	RCT	319	39.8% female, mean age 71.6 years, pre-frail (286) and frail (33)	CHS criteria	3-month intervention, 3-month self- maintenance	X	X			
Kapan et al. 2017 Austria	RCT	80	84% female, mean age 82.6 years, non-frail (1), pre-frail (28) and frail (51)	SHARE-FI	12 weeks	X	X			
Liang et al. 2021 Taiwan	Cluster RCT	733	66% female, mean age 74.0 years, 'Physio-cognitive decline syndrome' (205), mobility-type	Modified CHS criteria	12 months	X	X			

Study, Country	Design	N	Participants:	Definition of frailty used	MCI Duration	Baseline	Post- MCI	3 month follow up	6 month follow up	Other (time)
			frailty only (224), cognitive dysfunction only (110) and 'normal' (194)							
Nakazeko et al. 2023 Japan	RCT	110	50% female, mean age 64.9 years, pre-frail (97) and frail (13)	Revised J-CHS standards	12 weeks	X	X			
Ng et al. 2017 Ng et al. 2018 Singapore	RCT	246	61% female, mean age 70.0 years, pre-frail (178) and frail (68)	Fried criteria	24 weeks	X	X		X	
Romera- Liebana et al. 2018 Spain	RCT	352	75.3% female, mean age 72.3 years, pre-frail (89) and frail (263)	Modified Fried criteria	12 weeks	X	X			X (15 months)
Seino et al. 2017 Japan	Cross- over RCT	77	68.9% female, mean age 74.6 years, pre-frail (56) and frail (21)	CL15	3 months	X	X	X*		
L. F. Tan et al. 2023 Singapore	Cluster RCT	324	55.6% female, mean age 72.3 years, frail or pre-frail (34)	FRAIL scale	6 months	X	X		X	
Van de Rest et al. 2014 The Netherlands	RCT	127	61% female, mean age 79 years, pre-frail (98) and frail (29)	Fried criteria	24 weeks	X	X			
van Lieshout et al. 2018 The Netherlands	RCT	710 -> 290	Based on N=281 55.2% female, mean age 74.0 years, pre-frail (167) or frail (114)	Groningen Frailty Indicator	23 weeks	X	X		X	
Yu et al. 2020 China	RCT	134	Based on n=127 88.2% female, mean age 62.2 years, pre-frail (127)	FRAIL scale	12 weeks	X	X			

^{*}Due to crossover trial design, no comparison data was collected at this timepoint therefore this data from this timepoint has not been extracted for this review.

Note. RCT, Randomised controlled trial, CHS, Cardiovascular Health Study; SHARE-FI, Survey of Health, Ageing and Retirement in Europe Frailty Instrument; CCHSA_CFS_TV, The Chinese Canadian Study of Health and Aging Clinical Frailty Scale Telephone Version; J-CHS, Japanese version of the Cardiovascular Health Study; CL15; Check-List 15

3.4 Multi-component Intervention Characteristics

The MCIs trialled in each of the studies are summarised in Table 4.

Seven studies combined two interventions in their MCIs (Faes et al. 2011; Han et al. 2023; Hsieh et al. 2019; Kapan et al. 2017; Nakazeko et al. 2023; L. F. Tan et al. 2023; Van De Rest et al. 2014), four combined three interventions (Chan et al. 2012; Ng et al. 2018, 2017; Seino et al. 2017; Yu et al. 2020), and the remaining five studies combined four interventions (Belleville et al. 2023a, 2023b; Gené Huguet et al. 2018; Liang et al. 2021; Romera-Liebana et al. 2018; van Lieshout et al. 2018).

All 16 studies involved an exercise or physical activity component within their MCI. Twelve studies involved a nutrition component (Chan et al. 2012; Gené Huguet et al. 2018; Han et al. 2023; Hsieh et al. 2019; Kapan et al. 2017; Liang et al. 2021; Nakazeko et al. 2023; Ng et al. 2018, 2017; Romera-Liebana et al. 2018; Seino et al. 2017; Van De Rest et al. 2014; van Lieshout et al. 2018), three studies involved a polypharmacy/medication review intervention (Gené Huguet et al. 2018; Romera-Liebana et al. 2018; van Lieshout et al. 2018), one study involved an environment and social support intervention (Gené Huguet et al. 2018), and one study involved a disease education intervention (Liang et al. 2021).

Ten studies involved at least one cognitive, psychological or psychosocial component. A cognitive training (CT) intervention was used in five studies (Belleville et al. 2023a, 2023b; Liang et al. 2021; Ng et al. 2018, 2017; Romera-Liebana et al. 2018; Yu et al. 2020), psychoeducation or skills training was used in three studies (Belleville et al. 2023a, 2023b; Faes et al. 2011; van Lieshout et al. 2018) and a psychosocial intervention was used in three studies (Seino et al. 2017; L. F. Tan et al. 2023; Yu et al. 2020). Chan et al. (2012) used a psychotherapy intervention, and (Belleville et al. 2023a, 2023b) allowed participants access to a shared chat-room to share strategies and support.

Table 4Intervention Characteristics

Study	Multicomponent Intervention (MCI)	Control
Belleville et al.	StayFitLonger programme	Active control intervention.
2023	Exercise	Computerised information
	$3\ days\ per\ week\ for\ 30\text{-}45\ minutes.\ Computerised, tablet-based\ programme\ consisting\ of\ strength,\ balance\ and\ mobility\ exercises$	booklet including tips about
	with various difficulty levels. Individuals choose 8 exercises to include in their programme from a choice of 50.	how to stay physically active
	Cognitive Training	and information about 12
	3x 15-minute sessions per week. Four computerised, tablet-based activities designed to target and teach strategies for divided	standard exercises. This is
	attention, problem solving, semantic memory and prospective memory. Activities include a quiz game that involves learning	thought to be close to
	word-image associations and teaches memory strategies, a categorising game that aims to increase cognitive flexibility, a game	'standard care'.
	that requires divided attention in order to complete the goals, and task that asks participants to complete a simple task at a	Commercially available
	certain time.	cognitive activities that are not
	As desired.	targeted towards specific
	Chat room	cognitive processes or
	A chat room, bult into the computerised programme, allows participants to communicate with other users about tips and	strategies, including
	strategies for real-life problems	crosswords, sudoku, etc.
	Psychoeducation	
	22 topics available relating to physical, psychological and cognitive health	
Chan et al. 2012	Exercise and nutritional programme	Individuals received monthly
	Structured exercise course	check-ins about whether they
	3x per week for 1 hour at the hospital. Each session involved: 15m warm up, 10m brisk walks, stretching of major joints and	had read the booklet and how
	muscles for 5 reps each, 20-30m resistance training with rubber bands and bottled water for weights for 10-15 reps of each	they incorporated the advice.
	exercise, 10m postural control and balance training, 5min cool down with relaxation	
	Diet	Half of individuals not in the
	During/after exercise sessions, participants were asked about their dietary compliance and given answers to individual questions	exercise and nutrition
	6 sessions	intervention did receive the
	Problem Solving Therapy (PST)	PST intervention

Study	Multicomponent Intervention (MCI)	Control
	Half of all participants (target intervention and control group) also received problem solving therapy conducted by trained case	
	managers. This therapy teaches people how to solve problems relating to their mood and increase self-efficacy.	
	Other	
	All participants in all groups provided with an educational booklet covering: frailty, healthy diet, exercise protocol, and coping	
	strategies.	
Faes et al. 2011	Fall Prevention Programme	Usual care of geriatric
	10 sessions (2 sessions per week) followed by one booster session 6 weeks later, both components covered in each 2-hour session. Physical Training	outpatient clinic
	Group sessions delivered by a geriatric physiotherapist. Training in a range of everyday physical activities such as: getting out of	
	bed, rising from a chair, walking etc.	
	Psychological teaching and training	
	Group sessions delivered by a geriatric psychologist. Psychoeducation and skills training in a range of topics such as: causes of	
	falls, home safety, vicious cycle of fear of falling, impulsiveness, stop-think-go, etc.	
Gené Huguet et al.	Assessment of inadequate prescription	Standard treatment at primary
2018	Using published criteria. Treatment changes recommended to family physicians.	healthcare centre
	Mediterranean Diet	
	One group session, led by a nurse who advised individual nutritional changes	
	Physical Exercise Program	
	Led by a physician and nurse. Illustrated pamphlet for exercise instruction.	
	Recommendations were: 30-60 minutes of walking at least 3 days per week, 9x fortnightly guided sessions of strength, resistance,	
	balance and coordination exercises, 3-4 days a week of home exercise sessions, 10 reps initially recommended, rising to 15 after 2	
	months. One minute rest between reps.	
	Review of personal and environmental conditions and support	
	Telephone assessment of personal and environmental conditions and social support. Home telecare recommended where	
	required.	
Han et al. 2023	Exercise	Usual care from hospital,
	Hospital programme - In addition to usual physiotherapy, offered supervised, individualised physical activity up to 30 minutes	community services and
	daily (5 days a week). Sessions included: Walking (if possible), Chair stands and heel raises (after a warm-up), that could be made	involved healthcare

Multicomponent Intervention (MCI) Study **Control** easier or more difficult. Three sets of 8-12 reps of each exercise. professionals. Usual onward referrals, if required. Home programme - Strength and resistance training 3x per week consisting of six exercises (front knee, back knee, side hip, toe raises, calf raises and sit-to-stand). Performed with ankle cuff weights that can be individualised to the person. Three sets of 8-10 reps **Nutrition Therapy** Hospital programme - Individualised nutrition care plan to maintain or improve diet. Focused on ensuring 100% energy requirement and meeting recommended protein intake. Depending on need, also involved use of commercial oral nutrition supplements, mid-meal snacks and/or food fortification. Nutrition counselling provided before discharge to ensure continuity at Home programme - When participants were discharged home they received four telephone calls and four home visits in the 3month period. Other The intervention programme was informed by a self-management model where the patient takes the lead. Involved a 12-question 'partners in health' module incorporating knowledge, coping, recognition and management of symptoms, and treatment adherence. These questions are discussed and then lead to goal setting and formulation of a personalised care plan led by the participant. Control groups received usual Hsieh et al. 2019 Exercise 3-7 sessions per week. Time per session and/or number of reps was individualised. Combination of strength, flexibility, balance care plus two telephone and endurance training. Equipment (e.g., resistance bands, grip-balls, pedometers) was supplied. contacts. Nutrition Participants supplied with a set of customised dishware (plate with four compartments, a bowl, a mug and a tablespoon) along with a coloured meal pad to indicate personalised food amounts on the dishware. This was to help participants eat the required amounts of dairy; protein rich foods; vegetables; fruits; nuts, seeds and plant oils; and grains or roots. Two food supplements were provided: 25g of skim milk powder a day and 10g of mixed nuts a day. Half of participants receiving the nutrition intervention also received 3x 500mg fish oil capsule and 1x 200mg vegetable and fruit concentrate capsule per day. Fish oil capsules contained 140 mg of eicosapentaenoic acid and 95g of docosahexaenoic acid.

Vegetable and fruit capsules contained water and ethanol-extracted vegetable and fruit concentrate with an anti-oxidative

potential equivalent to four services of fruits and vegetables.

Study	Multicomponent Intervention (MCI)	Control
Kapan et al. 2017	Physical training and nutritional intervention	The control group consisted of
	Trained volunteer 'buddies' visited the participants 2x per week for approx. 1hr.	the buddies visiting the
	Exercise training	participants for a social
	30 mins, including 5 min warm up and six strength exercises. Strength training consisted of 2x sets of 12-15 reps of: mini squats,	meeting only. This time could
	"beetles", standing hip extensions, reverse butterflies, chest presses, shoulder presses.	be spent how participants
	trained volunteer 'buddies' visited the participants 2x per week for approx. 1hr.	wished but some ideas for
	Nutritional messages	cognitive games were
	Eight nutritional messages were discussed during each visit including topics such as: fluid intake, protein, energy intake.	provided.
	A handbook was also provided covering all themes. Participants were also given the "Healthy for Life Plate" to show the	
	difference between recommended and actual food intake.	
Liang et al. 2021	4 2-hour sessions in month 1, 2 sessions in month 2, 1 session per month in months 3-12	Usual health education and
	Physical fitness	advice.
	45 mins of physical fitness activities, consisting of 5 mins warm up, 30 mins strength and balance exercise using body weight or	
	equipment such as resistance bands, exercise balls) and 10 mins stretching and flexibility	
	Cognitive training	
	1 hour of cognitive training including logic puzzles, pattern recognition tasks, mnemonic strategies for remembering verbal	
	information	
	Nutritional advice	
	15 mins of nutritional advice based on a Taiwan national dietary guideline focused on balanced dietary choices and maintaining	
	adequate protein intake	
	Disease education	
	3-4 sessions, one every 3-4 months. Each session was 30-60mins long and provided information on successful aging, dementia,	
	cardiovascular risk factors, osteoporosis and sarcopenia.	
Nakazeko et al.	Resistant exercise	Control group completed the
2023	4 x group sessions of resistant exercise (weeks 1, 4, 8, 10) for 20 minutes each, where exercise therapists were on-site to supervise	exercise intervention only.
	and guide the exercises. 3-5 x 20-minute home sessions per week following instructions received from group session, in a	
	textbook and in a recorded instruction video. Exercises included: knee circles, knee raises, squats, heel raises.	
	Meal replacement	
	Participants were asked to replace two meals per day with test meals that were adjusted to contain certain levels of various	

Study	Multicomponent Intervention (MCI)	Control
	nutrients, vitamins and minerals and asked to complete a daily diary.	
Ng et al. 2018	Physical intervention	Control group had access to
	2x 90-minute sessions per week in supervised groups for 12 weeks and then at home for 12 weeks. Resistance and functional	standard community-based
	exercises involving 8-10 major muscle groups. Single sets of 8-15 reps. Exercises	care and day care
	Nutritional intervention	rehabilitation services and
	Daily supplements designed to provide one third of daily recommended allowances of vitamins and minerals. Supplements	were given placebo liquid
	consisted of: commercial formula (Fortisip Multi Fibre, Nutricia), iron and folate supplement, vitamin B6 and vitamin B12,	capsules and tablet
	calcium and vitamin D	formulations.
	Cognitive training	
	1x 2-hour group training session per week for 12 weeks and then booster/recap sessions 1x per fortnight for 12 weeks. Delivered	Three additional groups:
	by a psychologist trainer and nurse facilitators. Interactive activities deigned to target short-term memory, attention,	-Cognitive intervention
	$information\ processing\ skills,\ perceptual\ organisation,\ reasoning\ and\ logic\ and\ problem-solving.\ Participants\ learned\ strategies$	alone
	and used these to work through cognitive games and puzzles.	-Exercise intervention alone
		Nutrition intervention alone
Romera-Liebana	Groups of 16 participants	Usual care plus the diet,
et al. 2018	Structured physical activity	lifestyle and hazards
	2x 60-minute sessions per week delivered by physiotherapists at primary healthcare centres. Consisted of aerobic and resistance	counselling.
	exercises, flexibility, balance, strengthening and stretching for arms and legs. Progress was reviewed every 2 weeks and	
	adaptations made to intensity and number of reps. Exercises included chest presses, arm presses, standing from a chair, knee	
	extensions an heel raises.	
	Hyperproteic nutritional shakes	
	1x nutritional shake taken daily for 6 weeks during the exercise training. Each bottle contained 11.8g protein, 17g carbohydrate,	
	4.4g fat, 0.8g fibre, 10 vitamins, 8 minerals and 156kcal.	
	Memory workshops	
	2x 90-minute sessions per week delivered by speech therapists. Consisted of a variety of tasks and games designed to target	
	memory, language, sensory activation and reasoning and calculation. Including: crosswords, completing unfinished sentences,	
	spot-the-difference, trail-making tasks, drawing from memory, recognition of logos, etc.	
	Medication review	
	Medication review following STOPP criteria, focussing on psychotropic drugs. Recommendations for changes were sent to GPs in	

Study	Multicomponent Intervention (MCI)	Control
	first the month of intervention.	
	Other	
	Counselling regarding dietary habits, lifestyle recommendations and domestic hazards.	
Seino et al. 2017	2x 100-minute session per week	Delayed intervention.
	Resistance exercise	
	60-minutes focused on maintaining or improving strength and mobility. Each session consisted of 5 mins warm-up, 50 mins	Normal activities, received
	exercise and 5 mins cool down. Exercises included heel raises, knee lifts, knee extensions, and rowing with a resistance band. The	information shared in
	number of reps increased progressively up to 2x sets of 20 reps of each exercise in the final month. There was a 10-minute rest	psychosocial intervention
	before moving on to the other component of the session.	regarding community
	Nutritional program	resources.
	30-minutes in 50% of the twice weekly sessions focused on improving dietary variety and intake. The program consisted of a	
	general lecture on functions of nutrients and foods and importance of dietary variety, practical and group activities. Activities	
	included using a checklist to assess dietary variety and discussing favourite restaurants and supermarkets.	
	Psychosocial program	
	30-minutes in 50% of the twice weekly sessions aimed to enhance social capital. The program consisted of practical and group	
	activities, such as discussing hobbies, experiences and resources. This was completed in groups of 5-6 with 1 or 2 staff members	
	per group.	
L. F. Tan et al.	Multicomponent exercise program	General health education
2023	2x 60-minute sessions per week of aerobic training, resistance training, dual task and balance training.	advice.
	Cognitive Stimulation Therapy (CST)	
	2x 30-minute sessions per week of CST for the first 3 months only, delivered by trained study team members. Topics of sessions	
	included games, food, current affairs, art and word association	
Van de Rest et al.	Resistance-type exercise program	The comparison group
2014	2x supervised sessions per week of exercise training. Sessions consisted of 5min warm up on cycling machine and 4x sets of 10-	received the protein beverage
	15reps of each exercise using exercise equipment/machines. Exercises were: leg-press, pulldown, pec-deck (chest fly) and vertical	but not exercise.
	row. Resistance was initially set at 50% of each participant's 1-rep maximum but was reviewed at weeks 4, 8, 12, 16 and 20 to	
	allow for individualised progression.	
	Protein supplementation	

Study	Multicomponent Intervention (MCI)	Control
	2x 250ml protein supplemented beverage per day: one after breakfast and one after lunch. Beverages were vanilla-flavoured and	
	contained 15g protein, 7.1g lactose, 0.5g fat and 0.4g calcium.	
van Lieshout et al.	Physical fitness improvement	Waiting-list control, receiving
2018	60-minute sessions 2x per week for 12 weeks in groups of 8-10, conducted by a physical therapist in a local gym. Training was	care as usual and normal
	tailored to the capacity of each individual and aimed to improve muscle strength and walking speed and reduce fatigue. It	access to health services
	included training in daily activities such as stairs, moving outdoors and standing from a chair or bed.	
	Improvement of nutritional status	
	1x 150-minute session up to three times in groups of 8-10. It aimed to raise awareness of a healthy diet and increase dietary self-	
	care.	
	Information was provided about health food relating to age, body weight and illness. Consequences of poor nutrition were	
	discussed. Participants were also asked to complete a food and nutrition diary.	
	Empowerment of social skills	
	1x 150-minute meeting per week for five weeks in groups of 8-10, delivered by a community nurse at a local community centre.	
	It aimed to improve self-confidence, and self-management skills and consisted of training on assertiveness, communication	
	styles, asking for help, self-appreciation, saying 'no', giving one's opinion and making plans for the future. Participants wee also	
	asked to complete an assertiveness diary.	
	Optimisation of medication use	
	1x 15-minute interview performed individually at a pharmacy, led by a pharmacist who consulted a GP regarding any	
	recommended changes. Medication review was carried out using the Prescribing Optimization Method (POM) for those with at	
	least four prescribed medications. Those with 1-3 medications could also join this intervention on a voluntary basis.	
Yu et al. 2020	2 x 2-hour sessions per week in groups of approximately 10.	Details unclear
	Exercise	
	60-minutes per session delivered by a trained exercise coach and a trained assistant. Consisted of a warm-up an aerobic circuit,	
	resistance training using TheraBands and a cool-down. 4 stages; intensity of exercises and number of reps increased through the	
	stages.	
	Cognitive training	
	30 minutes per session of computer-assisted cognitive training (Brainastic) immediately after exercise. A facilitator was present	
	to assist if required. Training consisted of 15 interactive touchscreen video games designed to train memory, attention, executive	
	functioning, flexibility and visuospatial ability. Each session focussed on one domain. Difficulty increased gradually according to	

Study	Multicomponent Intervention (MCI)	Control
	individual performance.	
	Board games activities	
	30 minutes per session immediately after the cognitive training. 6 board games were played in total, each one was played	
	consecutively for 4 sessions before changing to another. These aimed to enhance interactions and friendships.	

3.5 Cognitive Outcomes

Cognitive outcomes were assessed in 10 studies; the outcomes, and the measures used, are summarised in Table 5.

Five of the studies opted to use a screening tool such as the Mini Mental State Examination (MMSE; Chan et al. 2012; Han et al. 2023), the Montreal Cognitive Assessment (MoCA; Liang et al. 2021; L. F. Tan et al. 2023) or the Mild Cognitive Impairment Screen (MCIS; Nakazeko et al. 2023). Two used assessment batteries; Ng et al. (2018) used the Repeatable Battery of Neuropsychological Status (RBANS) and Romera-Liebana et al. (2018) selected subtests from the Barcelona Test (BT). The remaining three studies (Belleville et al. 2023a, 2023b; Van De Rest et al. 2014; Yu et al. 2020) administered a selection of domain-specific tests. Examples of tests chosen for the memory domain were the Word Learning Test (WLT) or the California Verbal Learning Test (CVLT); for the executive functioning domain, the Trail Making Test (TMT) and the Stroop test; for processing speed, the Wechsler Digit Symbol Substitution Test (DSST) and the TMT part A; for the attention and working memory domain, the Wechsler Digit Span Test (DST). Belleville et al. (2023a, 2023b) and Van de Rest et al. (2014) opted to derive composite scores for different cognitive domains based on the scores from their selected tests.

Table 5Cognitive Outcomes

Study	Outcome	Timepoint	MCI Group ^a	Comparison Group ^a	Significance
Belleville et al.	Global cognition CS	Post-intervention	0.20 (0.01, 0.38)	-0.14 (-0.32, -0.40)	Significant effect, p<0.01. MCI group experienced
2023					significant improvement compared to CG.
(Pre-frail participants only)	Executive functioning CS	Post-intervention			NS
•	Memory CS	Post-intervention			NS
	Processing speed CS	Post-intervention	0.38 (0.15, 0.62)	-0.06 (-0.29, 0.17)	Significant effect, p<0.01. MCI group experienced significant improvement compared to CG.
Chan et al. 2012	MMSE	9-month FU	-0.15 ± 2.53	0.06 ± 2.52	NS
Han et al. 2023	MMSE	Post-intervention 3-month FU	0.3 ± 2.1 0.8 ± 1.8	-1.8 ± 3.0 0.6 ± 1.6	Significant effect at post-intervention only, p=0.029. MCI group experienced significant improvement compared to CG immediately after intervention.
Liang et al. 2021 (Physiocognitive decline	MoCA global	Post-intervention 6-month FU	-0.7 0.5	-1.1 -1.6	Significant effect at 6-month FU only, p=0.004. MCI group experienced significant improvement compared to CG at FU.
syndrome participants only)	MoCA visuospatial executive	Post-intervention 6-month FU	0.01	0.16 0.12	NS
	MoCA naming	Post-intervention	-0.13	-0.20	

Study	Outcome	Timepoint	MCI Group ^a	Comparison Group ^a	Significance
		6-month FU	0.25	-0.22	Significant effect at 6-month FU only, p=0.001. MCI group
			0		experienced significant improvement compared to CG at
					FU.
	MoCA concentration	Post-intervention	0.35	-0.26	Significant effect at both post-intervention, p=0.007, and
		6-month FU	0.52	-0.37	6-month FU, p<0.001. MCI group experienced significant improvement compared to CG at both timepoints.
	MoCA language	Post-intervention	-0.16	-0.20	NS
		6-month FU	-0.08	-0.22	
	MoCA abstract thinking	Post-intervention	-0.14	-0.22	NS
		6-month FU	-0.15	-0.29	
	MoCA delayed recall	Post-intervention	-0.46	-0.30	NS
		6-month FU	0.29	-0.43	
	MoCA orientation	Post-intervention	-0.06	-0.15	NS
		6-month FU	-0.08	-0.11	
Liang et al. 2021	MoCA global	Post-intervention	-1.1	-1.5	NS
(Mobility-type		6-month FU	-0.6	-0.5	
frailty	MoCA visuospatial	Post-intervention	0.11	-0.30	Significant effect at post-intervention only, p=0.020. MCI
participants only)	executive	6-month FU	0.18	0.21	group experienced significant improvement compared to CG immediately after intervention.
	MoCA naming	Post-intervention	-0.05	0.01	NS
		6-month FU	-0.01	0.02	

Study	Outcome	Timepoint	MCI Group ^a	Comparison Group ^a	Significance
	MoCA concentration	Post-intervention	-0.16	-0.33	NS
		6-month FU	-0.26	-0.15	
	MoCA language	Post-intervention	-0.19	-0.26	NS
		6-month FU	-0.16	-0.15	
	MoCA abstract thinking	Post-intervention	-0.20	-0.07	NS
		6-month FU	-0.09	-0.01	
	MoCA delayed recall	Post-intervention	-0.54	-0.41	NS
		6-month FU	-0.05	-0.16	
	MoCA orientation	Post-intervention	-0.06	-0.15	NS
		6-month FU	-0.21	-0.30	
Nakazeko et al.	Japanese MCIS - MPI	Post-intervention	Baseline mean: 65.0	Baseline mean: 65.8 ± 7.2	Significant effect, p=0.038. MCI group experienced
2023	1		±7.4	Post mean: 66.4 ± 7.3	significantly greater improvement compared to CG.
			Post mean: 68.1 ± 6.9		
Ng et al. 2018	RBANS global	Post-intervention	0.005 (-0.102 - 0.112)	-0.174 (-0.2800.067)	Significant effect at 6-month FU, p=0.016. MCI group
		6-month FU	0.039 (-0.070 - 0.148)	-0.154 (-0.2660.042)	experienced significant improvement compared to CG at $$ FU.
	RBANS attention	Post-intervention	-0.055 (-0.221 - 0.112)	-0.162 (-0.331 - 0.006)	NS
	TEPTI TO ULLCITION	6-month FU	0.046 (-0.127 - 0.19)	-0.121 (-0.301 - 0.059)	1.0
		o month i c	0.040 (0.12) 0.19)	0.121 (0.301 0.039)	
	RBANS language	Post-intervention	-0.015 (-0.204 - 0.173)	-0.126 (-0.31 - 0.063)	Significant effect at 6-month FU only, p=0.023. MCI group
		6-month FU	0.076 (-0.115 - 0.268)	-0.245 (-0.4440.046)	experienced significant improvement compared to CG at FU.
	RBANS visuospatial	Post-intervention	0.215 (0.026 - 0.404)	-0.141 (-0.335 - 0.054)	

Study	Outcome	Timepoint	MCI Group ^a	Comparison Group ^a	Significance
			(((,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
		6-month FU	0.166 (-0.028 - 0.360)	-0.180 (-0.380 - 0.020)	Significant effect at both post-intervention, p=0.010, and
					6-month FU, p=0.016. MCI group experienced significant
					improvement compared to CG at both timepoints.
	RBANS immediate	Post-intervention	-0.009 (-0.227 - 0.208)	-0.244 (-0.462 - 0.027)	NS
	memory	6-month FU	0.076 (-0.140 - 0.293)	-0.142 (-0.364 - 0.080)	
	RBANS delayed memory	Post-intervention	0.000 (-0.171 - 0.171)	-0.211 (-0.3830.039)	NS
		6-month FU	-0.062 (-0.224 - 0.120)	-0.100 (-0.288 - 0.088)	
Romera-Liebana	BT – short-term verbal	Post-intervention	Baseline mean: 5.3 ± 2.7	Baseline mean: 5.6 ± 2.5	Significant effect of group at post-intervention, p<0.001,
et al. 2018	memory		Post mean: 5.9 ± 2.7	Post mean: 6.0 ± 2.2	and 15-month FU, p=0.015. MCI group experienced
		15-month FU	FU mean: 5.3 ± 2.2	FU mean: 5.0 ± 2.4	significantly greater improvement compared to CG
					immediately after intervention and significantly less
					decline compared to CG at FU.
	BT – medium-term	Post-intervention	Baseline mean: 3.9 ± 2.4	Baseline mean: 4.0 ± 2.3	Significant effect of group at post-intervention, p<0.001,
	verbal memory		Post mean: 4.9 ± 2.4	Post mean: 3.8 ± 1.9	and 15-month FU, p=0.016. MCI group experienced
	v	15-month FU	FU mean: 4.0 ± 2.1	FU mean: 3.4 ± 2.2	significant improvement compared to CG at both
					timepoints.
	BT – animal naming test	Post-intervention	Baseline mean: 15.2 ±	Baseline mean: 15.0 ± 5.1	Significant effect of group at post-intervention, p<0.001,
	(verbal fluency)		4.6	Post mean: 14.4 ± 4.9	and 15-month FU, p=0.026. MCI group experienced
	(Post mean: 16.6 ± 4.8		significant improvement compared to CG at both
		15-month FU	FU mean: 15.9 ± 4.7	FU mean: 14.7 ± 5.3	timepoints.
	BT – Evocation of words	Post-intervention	Baseline mean: 19.4 ±	Baseline mean: 19.1 ± 7.9	Significant effect of group at post-intervention, p<0.001,
		Post-intervention			and 15-month FU, p=0.010. MCI group experienced
	beginning with one		8.5 Post mean: 21.9 ± 8.8	Post mean: 17.8 ± 7.1	
	explicit letter	45 month EII	,	EII maan 19 0	significant improvement compared to CG at both
	(verbal fluency)	15-month FU	FU mean: 20.8 ± 8.0	FU mean: 18.3 ± 7.9	timepoints.

Study	Outcome	Timepoint	MCI Group ^a	Comparison Group ^a	Significance
	BT – Designation of	Post-intervention	Baseline mean: 20.8 ±	Baseline mean: 19.8 ± 6.1	Significant effect of group at post-intervention only,
	famous people's names	Post-intervention	6.2	Post mean: 19.1 ± 5.8	p<0.001. MCI group experienced significant improvement
	(naming)		Post mean: 22.1 ± 6.1	10st mean. 19.1 ± 5.0	compared to CG immediately after intervention.
	(naming)	15-month FU	FU mean: 22.4 ± 6.2	FU mean: 20.7 ± 6.3	compared to CG infinediately after intervention.
	BT – Verbal designation	Post-intervention	Baseline mean: 13.1 ±	Baseline mean: 13.1 ± 1.2	Significant effect of group at post-intervention, p<0.001,
	of images	rost-intervention	1.4	Post mean: 12.8 ± 1.6	and at 15-month FU, p=0.002. MCI group experienced
	(naming)		Post mean: 13.5 ± 1.1	1 05t mean. 12.0 ± 1.0	significant improvement compared to CG at both
	(numing)	15-month FU	FU mean: 13.4 ± 1.2	FU mean: 12.9 ± 1.6	timepoints.
	BT – verbal abstraction of word pairs	Post-intervention	Baseline mean: 3.5 ± 1.5 Post mean: 3.6 ± 1.5	Baseline mean: 3.5 ± 1.4 Post mean: 3.2 ± 1.3	Significant effect of group at post-intervention, p<0.001, and at 15-month FU, p=0.032. MCI group experienced
	(abstract thinking)	15-month FU	FU mean: 3.1 ± 1.6	FU mean: 2.7 ± 1.5	significant improvement compared to CG immediately after intervention and significantly less decline compared to CG at FU.
L. F. Tan et al.	MoCA	Post-intervention	1.67 (0.56 - 2.78)	-0.03 (-0.52 - 0.58)	Significant effect of group at post-intervention only,
2023		6-month FU	1.03 (0.12 - 1.94)	0.31(-0.15 - 0.76)	p=0.005. MCI group experienced significant improvement compared to CG immediately after intervention.
Van de Rest et al. 2014	Episodic memory z-core	Post-intervention	0.07 ± 0.62	0.01 ± 0.57	NS
	WLT – immediate recall	Post-intervention	3.3 ± 7.4	2.9 ± 7.6	NS
	WLT – delayed recall	Post-intervention	0.6 ± 1.9	0.2 ± 2.3	NS
	WLT – decay	Post-intervention	-0.2 ± 2.6	0.1 ± 2.4	NS
	WLT – recognition	Post-intervention	0.0 ± 2.3	-0.7 ± 1.9	NS

Study	Outcome	Timepoint	MCI Group ^a	Comparison Group ^a	Significance
	Attention and working	Post-intervention	0.19 ± 0.63	0.04 ± 0.57	NS
	memory z-score	1 ost-intervention	0.19 ± 0.03	0.04 ± 0.5/	140
	DS forward	Post-intervention	0.1 ± 1.4	0.1 ± 1.4	NS
	DS backward	Post-intervention	0.6 ± 1.5	0.0 ± 1.2	NS
	Information processing speed z-score	Post-intervention	0.08 ± 0.51	-0.23 ± 0.19	Significant group effect, p=0.04. MCI group experienced significant improvement compared to CG.
	TMT-A b	Post-intervention	-1.1 ± 24.2	3.7 ± 20.1	NS
	Stroop 1	Post-intervention	0.0 ± 0.2	-0.0 ± 0.2	NS
	Stroop 2	Post-intervention	0.0 ± 0.2	0.1 ± 0.1	NS
	Reaction time, uncued ^b	Post-intervention	-90 ± 162	-42 ± 122	NS
	Reaction time, cued ^b	Post-intervention	-104 ± 149	-63 ± 107	NS
	Executive functioning z-	Post-intervention	0.04 ± 0.44	0.17 ± 0.43	NS
	score Stroop interference	Post-intervention	0.0 ± 0.2	0.1 ± 0.2	NS
	VF – Animals	Post-intervention	-0.6 ± 4.1	2.4 ± 4.1	Significant group effect, p<0.01. MCI group experienced significant decline compared to CG.
	VF – Letter P	Post-intervention	0.6 ± 4.3	0.0 ± 4.9	NS
	TMT B/A b	Post-intervention	0.01 ± 0.76	0.01 ± 0.60	NS

Study	Outcome	Timepoint	MCI Group ^a	Comparison Group ^a	Significance
Yu et al. 2020	Verbal fluency: dual task gait speed ^b	Post-intervention	-0.5 ± 2.2	0.3 ± 1.9	Significant group effect, p=0.039. MCI group experienced significant improvement compared to CG.
	Attention and working memory: Wechsler DS	Post-intervention	0.7 ± 1.9	-0.2 ± 1.6	Significant group effect, p=0.001. MCI group experienced significant improvement compared to CG.
	score Attention and working memory: Wechsler digit sequence score	Post-intervention	0.6 ± 1.9	0.2 ± 1.7	Significant group effect, p=0.031. MCI group experienced significantly greater improvement compared to CG.
	Executive functioning:	Post-intervention	2.0 ± 3.2	0.0 ± 2.8	Significant group effect, p<0.001. MCI group experienced significant improvement compared to CG.

^a Outcome scores are reported as mean change scores, mean change scores ± standard deviation, mean change scores (95% confidence intervals), mean scores ± standard deviation, or mean scores (95% confidence intervals).

Note. CS, composite score; NS, non-significant; FU, follow-up; MMSE, Mini Mental State Examination; MoCA, Montreal Cognitive Assessment; MCIS – MPI, Mild Cognitive Impairment Screen – Memory Performance Index; RBANS, Repeatable Battery for the Assessment of Neuropsychological Status; BT, Barcelona Test; WLT, word learning test; DS(T), digit span test; DSST, digit symbol substitution test; TMT, Trail Making Test; Stroop, Stroop colour-word test; VF, verbal fluency; FAB, frontal assessment battery

^b Negative change indicates favourable outcome.

3.5.1 Global cognition

Seven studies assessed global cognition. Han et al. (2023) and Chan et al. (2012), both of whom used MCIs focused on exercise and nutrition, assessed cognition via the MMSE, but Han et al. (2023) was assessed to have a lower ROB. Han et al. (2023) found a significant benefit for MCI participants post-intervention, but this effect was not maintained at follow-up. Chan et al. (2012) only assessed cognition after a 9-month follow-up; they also found no significant long-term effects.

Liang et al. (2021), who combined exercise, nutrition, CT and disease education components, used the MoCA to assess global cognition, as did L. F. Tan et al. (2023), who used a psychosocial component combined with exercise. Both of these studies were assessed as having a high ROB. L. F. Tan et al.'s (2023) participants experienced a significant improvement in MoCA scores compared to the CG post-intervention, but this effect was not maintained 6 months later. Conversely, Liang et al. (2021) found a significant difference in favour of the MCI group at the 6-month follow-up, despite finding no such difference immediately post-intervention; however, this effect was only observed in participants that had been assessed as having cognitive dysfunction in addition to frailty at baseline.

The remaining studies that assessed global cognition are Nakazeko et al. (2023), whose MCI was focused on exercise and nutrition alone, Ng et al. (2018), who used CT in addition to exercise and nutrition, and Belleville et al. (2023a, 2023b), who used a combination of exercise, CT, psychoeducation and access to an online chat-room. Of these, Belleville et al. (2023a, 2023b) had the lowest ROB and Nakazeko et al. (2023), the highest, but both of these studies found a beneficial effect for their MCI groups at post-intervention, using a composite score and the MCIS, respectively. Neither completed any follow-up assessments. Ng et al. (2018) only observed a beneficial effect on the RBANS global score 6-months after the intervention had finished.

3.5.2 Memory

Five studies reported outcomes specific to memory, with two reporting a domain score from a screening test or battery (MoCA; Liang et al. 2021 and RBANS; Ng et al. 2018), two more calculating composite scores from a custom selection of tests (Belleville et al. 2023a, 2023b) and Van de Rest et al. 2014), and one using specific tests of memory (short and medium-term memory tests from the BT; Romera-Liebana et al. 2018). No two studies used the same measures or tests. All except one (Van de Rest et al. 2014) of these studies included a CT component in their MCIs.

Romera-Liebana et al. (2018), with low ROB, found that MCI participants demonstrated a significant benefit when compared to the CG on short and mediumterm verbal memory tests from the BT, both immediately after the intervention and after a 15-month follow-up period. All four other studies reported no significant effects in memory performance.

3.5.3 Executive functioning

Five studies reported outcomes specific to executive functioning, with one reporting the total score on a battery of executive functioning assessments (FAB; Yu et al. 2020), one reporting a domain score from a screening test (MoCA; Liang et al. 2021), two calculating a composite score from a custom selection of tests (Belleville et al. 2023a, 2023b; Van de Rest et al. 2014), and one using a specific test of executive functioning (verbal abstraction of word pairs from the BT; Romera-Liebana et al. 2018). No two studies used the same measures or tests. All except one (Van de Rest et al. 2014) of these studies included a CT component in their MCIs.

Of these five studies, only Romera-Liebana et al. (2018) and Yu et al. (2020), with low and moderate ROB, respectively, reported any significant effects on executive functioning. Romera-Liebana et al.'s (2018) MCI group demonstrated a significant benefit compared to the CG on a test of abstract thinking immediately post-intervention and after a 15-month follow-up period. Yu et al. (2020) also noted a significant effect favouring the MCI group post-intervention, but no follow-up assessments were completed.

3.5.4 Language and naming

Five studies reported outcomes specific to language or naming. Two reported domain scores from a screening test or battery (MoCA; Liang et al. 2021 and RBANS; Ng et al. 2018), and three reported scores from specific tests of language or naming (Yu et al. 2020; Romera-Liebana et al. 2018 and Van de Rest et al. 2014). All except one (Van de Rest et al. 2014) of these studies included a CT component in their MCIs.

For those reporting a domain score, Ng et al.'s (2018) MCI resulted in a significant benefit for participants in the language domain of the RBANS, but only 6-months after the intervention ended. Liang et al. (2021) found no significant effects on the language domain of the MoCA but did find a significant effect favouring the MCI group at 6-month follow-up for the naming domain. However, this effect was only observed for participants who had been assessed at baseline to have cognitive dysfunction and

frailty. Of these, Ng et al. (2018) was assessed to have a moderate ROB, and Liang et al. (2021) was assessed to have a high ROB.

Romera-Liebana et al. (2018) used two specific tests of naming (designation of famous people's names and verbal designation of images). On both, a significant effect favouring the MCI group was observed post-intervention, but this effect was only maintained at the 15-month follow-up for "verbal designation of images" (naming).

Three studies assessed verbal fluency. Yu et al. (2020) conducted a dual-task verbal fluency test, where the score was the time taken to complete a walking task whilst naming animals. They observed a significant improvement in speed for the MCI group compared to the CG post-intervention, but no follow-up assessment was completed. Romera-Liebana et al. (2018) and Van de Rest et al. (2014) both used animal and letter verbal fluency tests. Romera-Liebana et al. (2018) observed significant effects in favour of the MCI group for both tests at both time points (post-intervention and 15-month follow-up), but Van de Rest et al. (2014) observed no significant effect for letter fluency at post-intervention and a significant decline in animal fluency for the MCI group. Of these, Romera-Liebana et al. (2018) had the lowest ROB.

3.5.5 Attention and working memory

Four studies reported outcomes relating to attention and working memory, with two reporting a domain score from a screening test or battery (MoCA; Liang et al. 2021 and RBANS; Ng et al. 2018), one calculating composite score from a custom selection of tests (Van de Rest et al. 2014), and one using specific tests of working memory (Wechsler Digit Span and Digit Sequencing; Yu et al. 2020). Although Van de Rest et al. (2014) also used the Wechsler Digit Span subtest to calculate their z-score, they reported scores for forward and backward spans separately, whereas Yu et al. (2020) reported one combined score. All except one (Van de Rest et al. 2014) of these studies included a CT component in their MCIs, and all except one (Yu et al. 2020) included a nutrition component.

For those reporting a domain score, Ng et al. (2018) found no significant effect of the MCI on the RBANS attention domain. However, Liang et al. (2021) observed a significant improvement for their MCI group on the concentration domain of the MoCA at post-intervention and after a 6-month follow-up period, but only for participants who had been assessed to have cognitive dysfunction and frailty at baseline. However, Liang et al.'s (2021) study was assessed as having a higher ROB.

Van de Rest et al. (2014) used the Digit Span forward and backward scores to calculate a composite score for attention and working memory. They observed no significant effects in either test or the overall composite score. On the other hand, Yu et al. (2020) observed a significant benefit post-intervention for their MCI group based on Digit Span and Sequence scores. Both studies had a moderate ROB.

3.5.6 Processing speed

Belleville et al. (2023a, 2023b) and Van de Rest et al. (2014) reported outcomes specific to processing speed via calculating a composite score based on specific selections of tests, and both observed significant benefits for their MCI groups post-intervention. Belleville et al. (2023a, 2023b) had combined exercise with CT, psychoeducation and access to a chat room for their MCI and had a low ROB, whereas Van de Rest et al. (2014) had only combined exercise and nutrition components and had a moderate ROB.

3.5.7 Visuospatial skills

Liang et al. (2021) and Ng et al. (2018) reported domain scores for visuospatial skills; Liang et al. (2021) used the MoCA visuospatial executive domain score, and Ng et al. (2018) used the RBANS visuospatial domain score. Ng et al. (2018) observed a significant beneficial effect from their exercise, nutrition and CT MCI at both time points (post-intervention and 6-month follow up). Liang et al. (2021)'s MCI was similar but included an additional disease education component and was twice as long in duration; they found this resulted in significant improvement in visuospatial skills at post-intervention only, and only for frail participants without comorbid cognitive impairment at baseline. Ng et al. (2018) was assessed as having a lower ROB than Liang et al. (2021).

3.5.8 Orientation

Liang et al. (2021) was the only study to report outcomes for orientation, using the domain score on the MoCA, but they observed no significant effects for either of their two frail samples (frailty with comorbid cognitive dysfunction and frailty alone).

3.6 Psychosocial Outcomes

Psychosocial outcomes were assessed in 12 studies; the outcomes, and the measures used, are summarised in Table 6.

Table 6Psychosocial Outcomes

Study	Outcome	Timepoint	MCI Group ^a	Comparison Group ^a	Significance
Chan et al. 2012	PRIME-MD b	Post-intervention	-0.96 ± 2.92	-1.29 ± 4.50	NS
		3-month FU	-0.05 ± 2.84	-0.65 ± 4.03	
		9-month FU	-0.16 ± 3.17	-0.77 ± 3.65	
	EQ-5D	Post-intervention	0.02 ± 0.08	0.03 ± 0.08	NS
		3-month FU	-0.004 ± 0.12	0.004 ± 0.12	
		9-month FU	0.01 ± 0.09	-0.02 ± 0.10	
Faes et al. 2011	HADS-A ^b	Post-intervention	-0.76 ± 3.42	-2.82 ± 2.93	Significant group effect at 3/6-month FU, p=0.003
		3/6-month FU	0.83 ± 2.70	-2.77 ± 2.2	MCI group reported significant increase in anxiety compared to CG at FU
	GDS b	Post-intervention	-0.27 ± 1.91	-0.54 ± 1.68	Significant group effect at 3/6-month FU, p=0.002
		3/6-month FU	1.47 ± 2.23	-1.33 ± 1.97	MCI group reported significant increase in depression compared to CG at FU
	EQ-VAS	Post-intervention	-4.07 ± 12.18	4.25 ± 16.38	NS
		3/6-month FU	-10.54 ± 17.19	9.19 ± 15.64	
	FES b	Post-intervention	1.78 ± 8.51	-3.62 ± 8.59	Significant group effect at 3/6-month FU, p=0.038
		3/6-month FU	6.68 ± 6.98	-1.06 ± 8.73	MCI group reported significant increase in fear of falling compared CG at FU
	Mastery	Post-intervention	-0.27 ± 4.18	-2.00 ± 2.67	Significant group effect at 3/6-month FU, p=0.002
		3/6-month FU	1.14 ± 1.94	-2.05 ± 2.10	MCI group reported significant improvement in sense of mastery compared to CG at FU

Study	Outcome	Timepoint	MCI Group ^a	Comparison Group ^a	Significance
Gené Huguet et al. 2018	EQ-5D	6-month FU	Baseline: 7.1 ± 1.5 6-month FU: 6.2 ± 1.1	Baseline: 6.7 ± 1.3 6-month FU: 6.9 ± 1.5	Significant group effect, p<0.001. Direction unclear. MCI group reported significant improvement in quality of life compared to CG at FU
Han et al. 2023	GDS ^b	Post-intervention 3-month FU	-2.2 ± 3.1 -2.3 ± 3.2	-0.6 ± 2.2 0.2 ± 2.3	NS
	EQ-5D-5L	Post-intervention 3-month FU	0.3 ± 0.5 0.3 ± 0.5	0.1 ± 0.3 0.1 ± 0.3	NS
	EQ-VAS	Post-intervention 3-month FU	8.8 ± 19.6 8.8 ± 19.6	8.5 ± 26.5 86 ± 13.0	NS
Hsieh et al. 2019	GDS ^b	Post-intervention 3-month FU	Baseline mean: 2.4 ± 1.6 Post mean: 2.3 ± 1.6 FU mean: 2.2 ± 1.5	Baseline mean: 2.2 ± 1.7 Post mean: 2.5 ± 1.8 FU mean: 2.3 ± 1.6	NS
	SF-12 MCS	Post-intervention 3-month FU	Baseline mean: 55.8 ± 7.0 Post mean: 57.0 ± 6.3 FU mean: 57.3 ± 6.6	Baseline mean: 53.8 ± 7.9 Post mean: 54.0 ± 7.7 FU mean: 54.3 ± 7.1	NS
Kapan et al. 2017	WHOQOL-BREF - Overall QoL	Post-intervention	5.6 (0.95 - 10.33)	2.5 (-1.66 - 6.54)	NS
	WHOQOL-BREF - Physical health	Post-intervention	3.3 (-1.33 - 7.92)	3.4 (-0.59 - 7.73)	NS
	WHOQOL-BREF - Psychological health	Post-intervention	2.9 (-0.67 - 6.52)	3 0.2 (-2.84 - 3.04)	NS

Study	Outcome	Timepoint	MCI Group ^a	Comparison Group ^a	Significance
	WHOQOL-BREF - Social health	Post-intervention	4.5 (0.38 - 8.59)	1.5 (-4.34 - 7.38)	NS
	WHOQOL-BREF – Environment	Post-intervention	1.4 (-2.15 - 4.87)	1.2 (-2.53 - 4.96)	NS
	WHOQOL-OLD - Sensory abilities	Post-intervention	4.5 (-1.36 - 10.34)	0.6 (-3.83 - 5.04)	NS
	WHOQOL-OLD – Autonomy	Post-intervention	2.7 (-0.45 - 5.97)	1.5 (-2.60 - 5.61)	NS
	WHOQOL-OLD - Past, present and future activities	Post-intervention	4.7 (1.99 - 7.42)	-0.1 (-3.23 - 2.95)	Significant group effect, p=0.039. MCI group reported significant improvement compared to CG.
	WHOQOL-OLD - Social participation	Post-intervention	3.8 (0.12 - 7.57)	2.5(-1.33 - 6.46)	NS
Nakazeko et al. 2023	WHO-5 -Total Score	Post-intervention	Baseline mean: 14.3 ± 4.3 Post mean: 16.6 ± 3.4	Baseline mean: 15.4 ± 4.3 Post mean: 16.1 ± 3.5	Significant group effect, p=0.027. MCI group reported significantly greater improvement compared to CG.
	WHO-5 - I have felt cheerful and in good spirits	Post-intervention	Baseline mean: 3.0 ± 1.0 Post mean: 3.4 ± 0.8	Baseline mean: 3.0 ± 1.0 Post mean: 3.3 ± 0.9	NS
	WHO-5 - I have felt calm and relaxed	Post-intervention	Baseline mean: 3.0 ± 1.0 Post mean: 3.6 ± 0.8	Baseline mean: 3.0 ± 1.0 Post mean: 3.5 ± 0.8	NS
	WHO-5 - I have felt active and vigorous	Post-intervention	Baseline mean: 2.7 ± 1.0 Post mean: 3.3 ± 0.9	Baseline mean: 3.1 ± 1.1 Post mean: 3.2 ± 0.9	Significant group effect, p=0.013. MCI group reported significantly greater improvement compared to CG.

Study	Outcome	Timepoint	MCI Group ^a	Comparison Group ^a	Significance
	WHO-5 - I woke up	Post-intervention	Baseline mean: 2.8 ± 1.1	Baseline mean: 3.2 ± 1.1	Significant group effect, p=0.040.
	feeling fresh and rested		Post mean: 3.3 ± 0.9	Post mean: 3.2 ± 0.9	MCI group reported significant improvement compared to CG.
	WHO-5 - My daily life has been filled with things that interest me	Post-intervention	Baseline mean: 2.8 ± 1.1 Post mean: 3.2 ± 0.9	Baseline mean: 3.2 ± 1.1 Post mean: 3.2 ± 1.1	NS
Ng et al. 2017	GDS-15 ^b	Post-intervention	Baseline mean: 0.69 ± 1.75 Post mean: 0.32 ± 0.66	Baseline mean: 0.52 ± 0.86 Post mean: 0.74 ± 0.90	Significant effect of group at post-intervention, p=0.012, and 6-month FU, p=0.005. MCI group reported significant reduction in depression compared to CG both immediately after intervention and at follow up.
		6-month FU	FU mean: 0.30 ± 0.59	FU mean: 0.83 ± 1.06	
Seino et al. 2017	SFHS - PCS	Post-intervention	Baseline mean: 46.5 ± 7.7	Baseline mean: 46.8 ± 9.5	NS
			Post mean: 45.6 ± 8.4	Post mean: 47.3 ± 8.8	
	SFHS - MCS	Post-intervention	Baseline mean: 49.7 ± 10.7	Baseline mean: 49.8 ± 9.5 Post mean: 51.0 ± 7.7	NS
	GDS-15 ^b	Post-intervention	Post mean: 51.3 ± 10.5 Baseline mean: 4.9 ± 3.5	Baseline mean: 3.9 ± 2.8	Significant group effect, p=0.037. MCI group reported
	GD5-15 *	1 ost-intervention	Post mean: 4.1 ± 3.3	Post mean: 4.1 ± 2.9	significant reduction in depression compared to CG.
L. F. Tan et al.	GDS b	Post-intervention	-1.23 (-2.440.02)	0.52 (-0.09 - 1.12)	Significant group effect at post-intervention only, p=0.010.
2023		6-month FU	0.32 (-0.63 - 1.26)	0.23 (-0.20 - 0.67)	MCI group reported significantly greater reduction in depression compared to CG immediately after intervention
	EQ-VAS	Post-intervention	11.16 (-0.13 - 22.44)	-1.84 (-5.14 - 1.47)	Significant group effect at 6-month FU only, p=0.012. MCI
		6-month FU	6.03 (1.19 - 10.87)	-1.23 (-3.43 - 0.98)	group reported significant improvement in quality of life compared to CG at FU.

Study	Outcome	Timepoint	MCI Group ^a	Comparison Group ^a	Significance
van Lieshout et	SF-12 PCS	6-month FU	Baseline mean: 45.0 ±	Baseline mean: 46.3 ±	NS
al. 2018			10.55	10.53	
			FU adjusted mean: 45.5	FU adjusted mean: 45.1	
			(42.83 - 48.08)	(42.74 - 47.52)	
	SF-12 MCS	6-month FU	Baseline mean: 48.3 ± 9.6	Baseline mean: 48.0 ±	NS
			FU adjusted mean: 48.0	10.0	
			(45.45 - 50.53)	FU adjusted mean: 47.4	
				(45.42 - 49.35)	
Yu et al. 2020	Life satisfaction	Post-intervention	0.5 ± 1.1	0.4 ± 1.1	NS

^a Outcome scores are reported as mean change scores, mean change scores ± standard deviation, mean change scores (95% confidence intervals), mean scores ± standard deviation, or mean scores (95% confidence intervals).

Note. PRIME-MD, Primary Care Evaluation of Mental Disorders; NS, non-significant; FU, follow-up; EQ-5D, EuroQol 5 Dimension; HADS-A, Hospital Anxiety and Depression Scale – Anxiety subscale; GDS, Geriatric Depression Scale; EQ-VAS, EuroQol Visual Analogue Scale; FES, Falls Efficacy Scale; Mastery, 5-item Pearlin Mastery Scale; EQ-5D-5L, 5-level EuroQol 5 Dimension; SF12, 12 item Short Form Health Survey; PCS, physical composite score; MCS, mental composite score; WHOQOL-BREF, World Health Organisation Quality of Life Scale; WHOQOL-OLD, World Health Organisation Quality of Life Scale add-on for older adults; WHO-5, World Health Organisation-Five Well-Being Index; GDS-15, 12-item short form Geriatric Depression Scale; SFHS, Short Form Health Survey.

^b Negative change indicates more favourable outcome.

3.6.1 Depression

Depression was measured in seven studies, using the using the Geriatric Depression Scale (GDS or GDS-15) or the Primary Care Evaluation of Mental Disorders (PRIME-MD).

Faes et al. (2011), Han et al. (2023), Hsieh et al. (2019), and L. F. Tan et al. (2023) used the GDS to evaluate the effects of MCIs on depression. Tan et al. (2023), assessed to have a high ROB, included a psychosocial component (CST) in their MCI and reported a significant reduction in depression for the MCI group compared to the CG post-intervention only. Neither Han et al. (2023) nor Hsieh et al. (2019) included any psychological or psychosocial component in their exercise and nutrition-focused MCIs. Although both observed a decline in scores for their MCI groups, these effects were insignificant. Both of these studies were assessed to have a low ROB. The psychoeducational component of Faes et al.'s (2011) 11-week MCI was related to understanding and reducing fear of falling, but their MCI group experienced an increase in symptoms of depression at long-term follow-up, rather than a decrease. This study has been assessed to have a high ROB.

Ng et al. (2017) and Seino et al. (2017) used the shorter GDS-15 to assess depression. Seino et al.'s (2017) MCI added a psychosocial component to enhance social capital in addition to exercise and nutritional interventions, but Ng et al. (2017) added group CT instead. Both studies were assessed to have a moderate ROB and reported significant improvements in GDS-15 scores for their MCI groups post-intervention. Ng et al. (2017) repeated the measures at the 6-month follow-up and found the benefit had been maintained.

Chan et al. (2012)'s MCI was focused on exercise and nutrition, although half of the participants also participated in problem-solving therapy (PST), along with half of the CG participants. Using the PRIME-MD, they observed that the MCI had no beneficial effect on depression symptoms compared to the CG. This study was assessed to have moderate ROB.

3.6.2 Anxiety

Anxiety was measured in only one study using the Hospital Anxiety and Depression Scale – anxiety subscale (HADS-A; Faes et al. 2011). The exercise and psychoeducational MCI designed to prevent falls resulted in significantly increased anxiety ratings compared to the CG at long-term follow-up, however this study was assessed as having high ROB.

3.6.3 Quality of life and wellbeing

Quality of life or wellbeing was measured in 11 studies.

Chan et al. (2012), Gené Huguet et al. (2018) and Han et al. (2023) all used the EuroQol 5-dimension (EQ-5D) to assess quality of life. Neither Chan et al. (2012) nor Han et al. (2023) observed any significant effects on this measure following their exercise and nutrition-focused MCIs. Gené Huguet et al.'s (2018) 6-month long MCI consisting of pharmacological, exercise, nutrition and environmental components resulted in significant improvement compared to the CG. Of these studies, Han et al. (2023) was assessed to have a low ROB and Gené Huguet et al. (2018), a high risk.

Faes et al. (2011), Han et al. (2023) and Tan et al. (2023) used the visual analogue scale (VAS) of the EQ-5D in isolation. Neither Faes et al. (2011) nor Han et al. (2023) included any psychosocial components within their MCIs, although Faes et al. (2011) did include some psychoeducation and skills training focussed on fall prevention. Neither study observed any significant effects using this measure, with Faes et al.'s (2011) MCI group trending towards declining quality-of-life ratings. On the other hand, L. F. Tan et al. (2023), who involved a psychosocial component within their longer MCI, reported significant improvement in quality of life on the EQ-VAS at the 6-month follow-up only. Both Faes et al. (2011) and L. F. Tan et al. (2023) have been assessed to have a high ROB.

Hsieh et al. (2019), Seino et al. (2017) and van Lieshout et al. (2018) used the SFHS or SF-12 to assess perceptions of health. These measures generate a physical composite score (PCS) and a mental composite score (MCS). Hsieh et al. (2019) only reported the MCS outcomes, but the other studies reported both the MCS and PCS. All three of these studies used MCIs that had exercise and nutrition components. Seino et al. (2017) also included a psychosocial component, and van Lieshout et al. (2018) included a psychoeducational group that taught social skills and conducted medication reviews. Despite the variety in the MCIs used, none of these studies reported any significant effects between the groups in MCS or PCS scores. Hsieh et al. (2019) was assessed to have the lowest ROB of these studies.

Kapan et al. (2017), whose MCI focused on exercise and nutrition alone, used the WHOQOL-BREF and the WHOQOL-OLD to assess quality of life. The WHOQOL-BREF is a brief measure of general quality of life, and the WHOQOL-OLD is an optional add-on module that asks questions more specific to an older adult population. They observed a significant improvement in ratings of past, present and future

activities on the WHOQOL-OLD for the MCI group, but all other domains of these questionnaires showed no significant effects. This study has a moderate ROB

Nakazeko et al. (2023), assessed to have a high ROB, used the World Health Organisation-Five Wellbeing Index (WHO-5). Their exercise and nutrition-focused MCI resulted in significant improvements in the total WHO-5 score and the scores for items 3 ('I have felt active and vigorous') and 4 ('I woke up feeling fresh and rested') of the questionnaire when compared to the CG.

Finally, Yu et al. (2020), assessed to have a moderate ROB, used the simple question 'Are you satisfied with life?' to assess life satisfaction, with participants answering using a 0-10 scale. Their MCI consisted of a psychosocial board game activity group in addition to CT and exercise, but they observed no significant effect on life satisfaction.

3.6.5 Other psychosocial measures

Faes et al. (2011) also used two other psychosocial outcome measures: the Falls Efficacy Scale (FES) to assess fear of falling and the 5-item Pearlin Mastery Scale to assess mastery. Despite their exercise and psychoeducational MCI being more focused towards fall prevention, FES scores for the MCI group increased significantly at long-term follow-up compared to the CG, suggesting an increase in fear of falling. However, on the mastery scale, the MCI group demonstrated a significant improvement compared to the CG. This study was assessed to have a high ROB

4 Discussion

This systematic review sought to synthesise papers that evaluated the cognitive or psychosocial outcomes of MCIs for frail or pre-frail individuals and to identify the component interventions or combinations of components more likely to benefit cognitive and psychosocial functioning. Eighteen papers were identified but one of these corrected the results of another included paper, and two reported different sets of outcomes for the same RCT. Therefore, 16 RCT studies are described and discussed in this review.

4.1. Summary of cognitive outcome results

Nine of the ten studies that assessed cognitive outcomes reported significant effects in at least one measure, on at least one time point. The only study to not report significant effects in cognitive outcomes was Chan et al. (2012), who used an MCI focused on exercise and nutrition interventions. However, it must be noted that this study was assessed as having a high ROB and used the MMSE to assess cognition, which is less

sensitive to changes in cognitive function than the MoCA (Markwick, Zamboni, and De Jager 2012; Siqueira et al. 2019).

Five of the studies that assessed cognition and observed positive outcomes involved a CT component in their MCIs and one additional study (L. F. Tan et al. 2023) involved cognitive stimulation via CST, a psychosocial group intervention. However, three studies observed a cognitive benefit without an intervention component targeting this directly. This is in keeping with research that has found physical exercise interventions alone can have a positive impact on cognition in frail older adults (Rossi et al. 2021).

Except for Chan et al. (2012), every study that evaluated global cognition (n=7) observed a significant benefit for their MCI groups, although two studies did not observe this until follow-up. Liang et al. (2021) only observed a benefit at follow-up for participants who had been assessed to have physio-cognitive decline syndrome (meaning they had cognitive dysfunction as well as mobility-type frailty), and not those who were frail with no cognitive dysfunction. However, it must be noted that 'cognitive dysfunction' was defined as impairment on at least one domain of the MoCA, which means that those assessed as frail with no cognitive dysfunction were likely scoring very close to the maximum of 30. Therefore, reassessments may not have been sensitive to cognitive improvements within this population.

All five studies that used a CT component completed cognitive assessments that provided some insight into performance in different domains of cognition, and overall, these appeared to result in improvements in visuospatial skills, information processing speed, and verbal fluency but not memory. Interestingly, these are difficulties commonly identified in those with vascular cognitive impairment (Iadecola et al. 2019). Of the five studies that did not use a CT component, only one (Van de Rest et al. 2014) made an effort to assess different cognitive domains; they demonstrated that an exercise and nutrition-focused MCI, without any explicit CT or cognitive stimulation, can also result in improvements in information processing speed. This domain of cognition has been frequently identified as being associated with frailty (e.g., Brigola et al. 2015; Langlois et al. 2012).

Longer interventions did not appear to have any superior impact on the cognitive outcomes or how long benefits were maintained, with Romera-Liebana et al. (2018) and Yu et al. (2020) both reporting multiple significant outcomes after only a 12-week intervention, many of which Romera-Liebana et al. (2018) found had been maintained after a long, 15-month follow-up period.

Overall, there appears to be relatively strong evidence to suggest that MCIs do have a positive impact on global cognition, but the inclusion of a CT component within the MCI may enhance this benefit. MCIs without a CT component appear to have a positive impact on information processing speed, but the addition of a CT component results in additional benefits in visuospatial skills and verbal fluency.

4.2 Summary of psychosocial outcome results

Of the 12 studies that assessed psychosocial outcomes, eight reported significant benefits for their MCI groups on at least one measure, either immediately after intervention or after a follow-up period. The main outcomes assessed were depression and quality of life. There was stronger evidence for positive outcomes on measures of depression and weaker evidence for positive outcomes on quality-of-life measures.

Two (Seino et al. 2017; L. F. Tan et al. 2023) of the three studies that reported significant improvements in depression included a psychosocial component within their MCI, and the third (Ng et al. 2017) included a group-based interactive CT intervention, which likely involved social interaction. Whereas, of those that resulted in non-significant outcomes (Chan et al. 2012; Han et al. 2023; Hsieh et al. 2019) none had used a psychosocial component. This might, therefore, suggest that MCIs with psychosocial components are more likely to reduce depressive symptoms than those without. However, it must be noted that one of the studies reporting significant findings was assessed as having a high ROB (L. F. Tan et al. 2023), whereas two studies reporting non-significant findings were assessed as having a low ROB (Hsieh et al. 2019; Han et al. 2023).

Of the eleven studies that explored quality-of-life outcomes, only four studies reported significant effects in these measures, all improvements (Gené Huguet et al. 2018; Kapan et al. 2017; Nakazeko et al. 2023; L. F. Tan et al. 2023). However, three of these four studies were assessed as having a high ROB (Gené Huguet et al. 2018; Nakazeko et al. 2023; L. F. Tan et al. 2023), and the fourth a moderate risk (Kapan et al. 2017).

The EQ-5D is an important measure because it is the preferred health-related quality of life of the National Institution of Health and Care Excellence (NICE), who use costbenefit analyses using this measure to inform their medication and treatment recommendations in the UK (NICE 2013). It is, therefore, somewhat concerning that only one of the five studies (L. F. Tan et al. 2023) using this measure found clear improvements as a result of their MCI. Perhaps it was this study's inclusion of a psychosocial component that helped contribute towards the observed improvement, but it must also be noted that this study was assessed to have a high ROB.

One curious finding from this review is the lack of assessment of anxiety symptoms. The only study that assessed anxiety was Faes et al. (2011), who were interested in the impact of the MCI on falls and fear of falling. They found that their intervention increased anxiety; they theorised that this may be because it increased preoccupation with, and awareness of, falling. Research has suggested that frailty is associated with higher levels of anxiety (M. Tan, Bhanu, and Frost 2023), so it seems strange that this has not been more routinely assessed in frailty intervention studies.

Overall, there appears to be evidence that MCIs can reduce symptoms of depression and improve quality of life in frail individuals. However, psychosocial intervention components may increase the likelihood of the MCI resulting in these positive outcomes.

4.1 Implications for research

This review has demonstrated that, since Dedeyne et al.'s review in 2017, more researchers are assessing cognitive and psychological outcomes, and many appear to be incorporating cognitive or psychosocial components into their MCIs. This means that research is growing and expanding in a way that will help us to understand how we can better target the cognitive and psychosocial aspects that are known to be associated with frailty and frailty transition. However, there is still scope for further improvements in the research. This review has highlighted substantial heterogeneity in measures and approaches used to assess cognitive outcomes in MCI and frailty research and a lack of assessment of anxiety outcomes.

There are differences in opinion regarding which cognitive domains are most associated with frailty (Brigola et al. 2015; Robertson, Savva, and Kenny 2013), therefore, future research should seek to better understand the relationship between frailty and different cognitive domains. This would help researchers to target the components within the MCIs to the most important cognitive domains. Many of the studies included in this review used brief cognitive screening tools, which, although they may be able to identify changes in global cognition, do not provide robust data relating to the individual cognitive domains (Coen et al. 2016; Koshimoto et al. 2023). Researchers should use more robust and sensitive measures to assess different domains of cognition without risk of ceiling effects. Further research should aim to identify the most appropriate cognitive assessment tools to identify cognitive improvements in frail or pre-frail individuals. This will help to reduce the heterogeneity in the measures used in frailty research.

Evidence of positive outcomes in quality-of-life measures seems somewhat weak; future research should explore which aspects of quality-of-life are most associated with frailty and what factors or components of MCIs for frailty may contribute to positive outcomes. As with the cognitive outcomes, it may also be beneficial to further explore which quality-of-life measures may be the most appropriate and sensitive for use in a frail population so that a more consistent approach to measurement across research can evolve. Future research on MCIs for frail individuals must also consider using measures to assess anxiety, which is associated with frailty (M. Tan, Bhanu, and Frost 2023) but has been neglected in the research discussed in this review.

This review has presented evidence that MCIs can improve cognitive and psychosocial functioning. It would be interesting to explore whether there are associations between the observed improvements in cognitive and psychosocial functioning and improvements in frailty measures. This was not a research question of the current systematic review, and only two of the studies included in this study completed such analyses. This would be a helpful question to explore as more research takes place.

Further research is also required to explore other factors that may contribute to the improvements discussed here. For example, some studies included here involved remotely delivered MCIs, whilst others were delivered in-person at a local health centre; some were delivered individually, and others in groups. Furthermore, nearly one-third of the studies included in this review were assessed as having a high ROB. Therefore, researchers should aim to improve the quality of research, particularly by improving the procedures and reporting relating to randomisation, blinding and reliability of outcome measurement.

4.2 Clinical implications

This review demonstrates that MCIs for frailty positively affect cognition, mood and quality of life in frail individuals. It, therefore, adds to the evidence base in support of using MCIs to improve outcomes for frail or pre-frail individuals. Due to their strong associations with frailty, it has been proposed that cognition and depression should be targets for intervention (Robertson, Savva, and Kenny 2013; Sang et al. 2023; Shin et al. 2024). This review demonstrates that MCIs are a promising approach to frailty intervention and effectively target psychological aspects of frailty such as cognition and mood.

The evidence presented here suggests that MCIs with a CT or psychosocial component may result in greater improvements in cognition and mood in frail or pre-frail individuals than MCIs without such components. This indicates a clear role and need for clinical psychology professionals in managing and preventing frailty. Clinical Psychologists have the expertise to develop, adapt and deliver these psychological components effectively and to work with other disciplines to ensure that all components work together as a cohesive, manageable and successful MCI.

4.3 Strengths and Limitations

This systematic review makes a significant contribution to frailty research. Although it is not the first systematic review to explore cognitive and psychosocial outcomes of MCIs for frail or pre-frail individuals, this is the first, to our knowledge, that has been able to draw conclusions about these outcomes. However, there are also limitations to consider. Firstly, studies included within this study were heterogeneous in many aspects: the measurements used, the sample sizes, the durations of the interventions, the numbers and combinations of component interventions, and the modality of intervention development. This heterogeneity meant no meta-analyses could be carried out, and narrative synthesis was more complicated. The conclusions drawn should therefore be applied with caution.

Furthermore, five of the 17 included publications were assessed to have a high ROB meaning that the data reported by these studies should also be interpreted cautiously. A particular area of weakness for the included studies was the ROB relating to administration of the intervention as this made it difficult to blind both the participants and those delivering the interventions to group allocation.

4.4 Conclusions

Due to the heterogeneity within the research exploring cognitive and psychosocial outcomes of MCIs, there are limits to the conclusions that can be drawn from this review. However, the evidence available suggests that MCIs can lead to improvements in global cognition, information processing and symptoms of depression in frail and pre-frail individuals. Adding psychosocial and CT component interventions may increase the likelihood of reducing symptoms of depression and of additional benefits in visuospatial skills and verbal fluency, respectively.

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Chapter 3 – Intervention Adaptation (Additional Chapter)

Adaptation of Cognitive Stimulation Therapy for Stroke Survivors (sCST)

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The following original research paper was written and formatted following the author guidelines for the journal, *Clinical Interventions in Aging*. (Appendix D)

Word limit: No word limit.

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Abstract

Objectives: This paper outlines the adaptation of Cognitive Stimulation Therapy (CST) for stroke survivors, following specific guidance for adapting healthcare interventions within the Medical Research Council's framework for complex interventions.

Methods: An adaptation team, including a stroke survivor and her husband as patient and public involvement (PPI) representatives, informed the process. Six phases guided the adaptation: i) literature review on CST and psychological interventions for stroke, ii) consultation with PPI stakeholders, iii) identification of adaptations, iv) drafting of sCST, v) professional stakeholder review, and vi) finalisation.

Results: New principles introduced to sCST included learning strategies, vicarious experiences of success, positive reinforcement and feedback, and values. Psychoeducational materials were added as a novel component to benefit stroke survivors and enhance carer involvement.

Discussion: The adapted intervention retains key CST elements while introducing stroke-specific additions and modifications. Strengths of this study include adherence to published guidance, engagement with diverse stakeholders, and a theoretically grounded approach. However, a broader range of professional stakeholders and more robust data collection and analysis methods might strengthen the process. The resulting intervention could have significant implications in stroke care, both in the context of frailty prevention and more broadly. Further research is needed to assess its benefits and applications.

Conclusions: This paper demonstrates a theory- and evidence-based intervention adaptation using PPI. Adapted CST for stroke survivors (sCST) has promise for frailty prevention and cognitive and psychosocial functioning post-stroke.

Keywords: Stroke, Cognitive Stimulation Therapy, Intervention Adaptation, Frailty, Multicomponent Interventions

Introduction

Multicomponent Interventions for Frailty

There is growing evidence of the effectiveness of multicomponent interventions (MCIs) for reversing or preventing the progression of frailty in older adult populations ^{1–3}. MCIs are interventions that combine two or more component interventions, each targeting different aspects of health associated with frailty, such as exercise (strength and balance), nutrition, and cognition. Given their promising effects in the general older adult population, researchers have begun to explore the effectiveness of MCIs in preventing frailty progression in more specific clinical populations; so far, positive results have been reported for those with type-2 diabetes ⁴ and cardiovascular disease ⁵.

Frailty also affects approximately 21% of stroke survivors, with another 48% meeting criteria for pre-frailty ⁶, increasing their risk of adverse outcomes ^{5,7–10}. It would, therefore, be helpful to understand whether MCIs could also prove effective in preventing frailty progression in stroke survivors.

Cognitive and Psychosocial Interventions for Frailty and Stroke

The rationale for including cognitive and psychosocial interventions within frailty MCIs comes from evidence that frailty is associated with cognitive difficulties ^{11,12}, depression ^{13–16}, anxiety ^{14,17}, psychological well-being ^{18,19}, and quality of life ^{20,21}. A recent systematic review (Chapter 2) has demonstrated that cognitive and psychosocial component interventions can, respectively, result in additional benefits to cognition and increase the likelihood of reducing symptoms of depression in frail or pre-frail individuals.

Stroke survivors also have a high prevalence of cognitive difficulties 22,23 and depression and anxiety $^{24-27}$. Therefore, it is important to ensure an MCI for stroke survivors addresses these elements by including a cognitive and psychosocial component. However, identifying suitable interventions is challenging. While clinical guidelines recommend cognitive rehabilitation strategies and psychosocial interventions for stroke survivors, no single approach has sufficiently robust evidence to be recommended $^{28-30}$.

There is also no clear consensus as to which cognitive and psychosocial interventions are the most effective in MCIs for frailty. Previously published MCI studies have described using a range of different approaches within their cognitive and psychosocial components, such as: psychological skills training ³¹, psychoeducation ³², cognitive training ^{33,34} and cognitive stimulation ^{35,36}.

Cognitive stimulation, a group-based intervention that promotes cognitive and social functioning through structured activities and discussions ³⁷. Its dual focus on both cognitive and social functioning may make it well-suited for inclusion within MCIs, including for stroke survivor populations.

Cognitive Stimulation Therapy

Cognitive Stimulation Therapy (CST) is a National Institute of Health and Care Excellence-recommended non-pharmacological treatment for dementia in England ³⁸ and is delivered in 39 countries worldwide ³⁹. Originally developed for easy and effective use within residential homes and care centres, CST is a structured, manualised cognitive stimulation intervention informed by approaches such as Reality Orientation, Reminiscence Therapy, and Validation Therapy ⁴⁰.

CST follows 18 guiding principles, all of which are considered the "essential ingredients" that make the intervention unique (Table 1) ⁴¹. The three principles considered the most important are i) mental stimulation, ii) giving "opinions rather than facts", and iii) generating new thoughts, ideas, and associations. The CST manual ⁴¹, provides 14 themed session plans and recommends that groups of five to eight people attend two 45–60-minute sessions per week. The suggested session structure includes a 10-minute introduction (including a discussion orientating to time and place, a group song, and consistent introductory activity), a 25-minute themed main activity, and a 10-minute conclusion.

Table 1The 18 Principles of Cognitive Stimulation Therapy, Adapted from Spector et al 41

CST Principle	Definition	How to achieve
Mental stimulation	Improving cognition and communication through mentally stimulating discussion	Activities should be pitched so that group members have to make an effort but are not too difficult
New ideas, thoughts and associations	Encouraging new ideas and opinions by making new semantic connections	Rather than testing people's existing knowledge and memory, ask questions that might elicit new thought processes.
Using orientation, sensitively and implicitly	Integrating orientation information into general discussion	Rehearsal of orientation information or asking directly can put people on the spot, instead ask questions or open conversations that will prompt orientation indirectly. For example, rather than asking about what month it is, ask 'Do you think this weather is normal for October?'
Opinions rather than facts	Using topics to generate opinions rather than testing facts	Don't focus too much on facts; instead, ask about peoples' opinions as these cannot be right or wrong. Rather than asking 'Where did you go on

CST Principle	Definition	How to achieve
	2011111111	holiday as a child?', ask 'Where is your favourite place to go on holiday?'
Using reminiscence as an aid to the here and now	Comparing old and new to promote orientation.	Memory of the past is often a strength for people with dementia and can often be enjoyable. However, some group members may have some painful memories of the past so it is important not to push people too hard
Physical movement	Exercising motor skills through movement and games	Movement is important for those with dementia. Movement should be encouraged at the beginning of every decision and wherever possible in the main activities
Providing triggers and prompts to aid recall and concentration	Supporting learning through multisensory cues and an information board	Use an orientation board with the group name, date and other key information. Encourage use of various senses, such as smells and sounds, to prompt memories and ideas.
Continuity and consistency between sessions	Using consistency of sessions to help continuity and familiarity	Run the groups in the same way each time – use the same room and use the same activities and group song to start each session
Implicit (rather than explicit) learning	Let learning and remembering happen naturally	Asking direct questions about knowledge or ideas can put people on the spot or expose difficulties, instead learning should happen via indirect questions and discussions around a topic
Stimulating language	Promoting communication and conversation	Incorporate activities that stimulate language abilities such as naming and word associations
Stimulating executive functioning	Using activities to support planning and organising thoughts	Incorporate activities that require planning or drawing new connections between objects, ideas or concepts
Person-centred	Seeing the person and their uniqueness	Consider and embrace the strengths, preferences and interests of each group member
Respect	Respect and dignity for all	Facilitators must make sure all group members are respected and that no one feels vulnerable or exposed
Involvement and inclusion	Keep everyone involved	The facilitator should not be doing most of the talking, group members should be encouraged to respond to one another
Choice	Activities are flexible and should be adapted for the participants	Activities are flexible and choices should be made available to group members to allow them the chance to make the group their own
Fun	Make it fun and enjoyable	The intervention should provide a fun and enjoyable environment for, and approach to, learning
Maximising potential	Optimise the learning environment to support people's potential	Provide the right amount of encouragement for each individual group member to facilitate more experiences of success
Building / strengthening relationships	Becoming friends	The intervention aims to strengthen relationships between group members and between members and facilitators

Adapting Cognitive Stimulation Therapy for Stroke Survivors

Experiencing a stroke can double one's risk of developing dementia ⁴², with both stroke and dementia sharing common risk factors ⁴³. However, there are also important differences. Dementias are progressive conditions with difficulties worsening over time, often affecting cognitive processes and behaviour first ⁴⁴. Stroke, on the other hand, is a sudden-onset medical emergency that may affect a variety of neurological functions such as cognitive processes, sensory abilities, physical functions, or a combination of these, to varying degrees of severity ⁴⁵. Accordingly, dementia interventions focus on slowing the progression of the condition and maintaining quality of life ^{46,47} whilst stroke rehabilitation aims to improve or recover lost abilities and manage the impact of longer-term effects ⁴⁸.

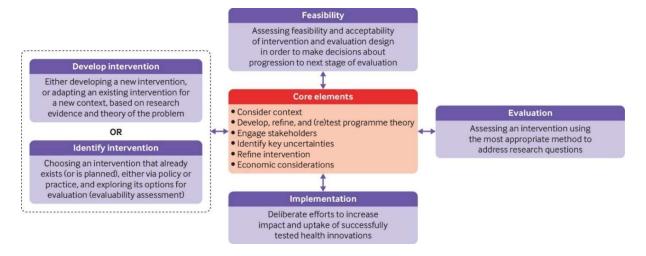
Given these differences, adapting CST for stroke survivors is essential to ensure its relevance to the different clinical needs. Indeed, it is recommended that interventions are adapted before use in new contexts ⁴⁹. Encouragingly, CST has already been proven to be adaptable, having been successfully adapted into a virtual intervention ⁵⁰, for multiple different cultures ^{51–53} and for more specific dementia diagnoses such as Parkinson's Disease dementia and dementia with Lewy bodies ^{54–56}.

Intervention Development

Healthcare advancements rely on the development, evaluation and implementation of new interventions; the Medical Research Council (MRC) has provided a framework to support researchers with these processes (Figure 1) ⁵⁷. According to O'Cathain et al, the MRC Framework approach falls under the category of *theory and evidence-based* approaches to intervention development, as opposed to other categories, such as *partnership* approaches within which co-production is a key feature ⁵⁸.

The MRC acknowledges that some interventions may be newly developed based on the needs of the population and emerging theory and evidence, while others are adapted from existing interventions ⁵⁷. To support adaptation processes, the MRC funded further research to inform the development of the ADAPT guidance, which outlines four key steps to adapting interventions to new contexts (Figure 2) ⁴⁹.

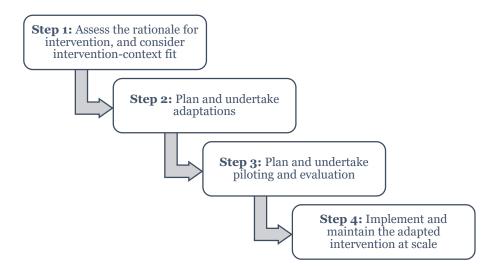
Figure 1
Framework for Developing and Evaluating Complex Interventions



Note. Figure taken from Skivington et al ⁵⁷. CC BY-NC https://www.bmj.com/content/374/bmj.n2061

Figure 2

The Four Steps of Intervention Adaptation, Adapted from Moore et al 49



Objectives

This paper details the theory and evidence-based adaptation of CST for stroke survivors following the MRC framework for developing and evaluating complex interventions ⁵⁷ and steps 1 and 2 of ADAPT guidance ⁴⁹. Step 3, planning and

undertaking piloting of the adapted intervention, will be reported separately (Chapter 4).

The MRC framework is a *theory and evidence-based* approach to intervention development based on combining relevant theories and evidence ⁵⁸. In line with both the MRC framework and ADAPT guidance, stakeholder engagement and patient and public involvement (PPI) were also utilised to inform decisions ^{49,57}. Carer burden is a significant issue ⁵⁹, and carers often feel 'left out' of the care of those they support ⁶⁰. Therefore, it was important to include a carer in this PPI work, as well as a stroke survivor.

It was hypothesized that some CST principles would require adaptation to better suit stroke survivors, such as introducing more structured cognitive training and rehabilitation elements, which is recommended for stroke survivors with cognitive impairments. It was, therefore, also anticipated that some of the intervention activities and content may need to be altered accordingly.

The adaptation process and results are reported following the GUIDED checklist (Appendix E), produced to improve reporting of healthcare intervention development studies ⁶¹. The resulting intervention (stroke CST or sCST) is described according to the Template for Intervention Description and Replication (TIDieR) ⁶².

Methods

Study Design

Over the period of June 2023 to August 2024, six phases of intervention development were undertaken in line with steps 1 and 2 from ADAPT guidance ⁴⁹: i) reviewing and mapping the literature for CST and psychological interventions for stroke, ii) consultation with PPI stakeholders, iii) identification of adaptations, iv) drafting of sCST, v) a professional stakeholder review, and vi) finalisation.

Adaptation Team

The research team consisted of two Trainee Clinical Psychologists (SL and MB) with prior experience facilitating CST groups for dementia, a Consultant Clinical Neuropsychologist and a Consultant Clinical Psychologist, both with a specialist interest in stroke (CF and NB), and an Assistant Psychologist with experience in group interventions for stroke survivors (LS). SL and MB led the intervention adaptation, with CF and NB providing consultation on the process and LS assisting with drafting the session plans and materials.

Additional professional stakeholders included a Consultant in Stroke Medicine with an interest in frailty and a Clinical Psychologist specializing in stroke, both from a hospital-based stroke service in Cambridge, UK. A stroke survivor and her husband, who had existing links with the affiliated university and local third-sector organizations, agreed to provide consultation as PPI representatives.

A consultation-based approach to PPI and stakeholder involvement, as outlined by the National Institute of Health and Care Research ⁶³, was utilised in this intervention adaptation. Although the original intervention developers were contacted and were in support of the adaptation (Appendix F), they were not directly involved.

Procedure

Phase i) Reviewing and mapping the literature for CST and psychological interventions for stroke

First, the CST intervention manual ⁴¹, providing an overview of the intervention rationale and aims, detailed descriptions of the 18 principles, and suggested session plans for each of the 14 themed sessions, was reviewed. Literature detailing the original intervention development and evaluation ^{40,64}, proposed mechanisms of the intervention, and systematic reviews of its efficacy were also reviewed. This process helped the researchers understand the proposed theory and mechanisms underpinning CST. This understanding informed the identification of core components of the intervention to retain, even if slight adaptations may be required to best fit the new population ⁵⁷.

Next, the National Institute for Health and Care Excellence guideline for stroke rehabilitation in adults ³⁰ and the National Clinical Guideline for Stroke (NCGS) ²⁹ were reviewed for key recommendations for stroke interventions. Literature relating to existing theories and approaches for cognitive and psychosocial interventions for individuals with stroke and acquired brain injury was also reviewed in order to identify specific approaches and theories identified as particularly helpful or important for stroke or ABI populations. Key theories and evidence relating to CST and psychological interventions in stroke were then compared against one another to identify areas where adaptation was needed.

Phase ii) Consultation with PPI Stakeholders

The PPI stakeholder representatives were asked to review the CST introduction and principles, an overview of the 14 session themes, and three example session plans

from the manual. Three meetings were held to discuss their views on the intervention and possible adaptations.

Phase iii) Identification of Adaptations

Information obtained from the previous two phases was then used to determine which aspects of CST should be retained, adapted or removed and what new stroke-specific elements needed to be introduced. The specific details of the adaptations were decided.

Phase iv) Drafting of sCST

Drafts of the sCST guiding principles and example session plans and materials were produced. For the purpose of this initial development process, and with the knowledge that a pilot trial would be conducted to inform further refinements, eight sessions were selected from the original CST manual for adaptation.

Phase v) Professional Stakeholder Review

The draft session plans and materials were reviewed by the wider research team and professional stakeholders; feedback was sought on the content, use of language, and presentation of materials, with additional feedback also welcomed. This communication took place via email.

Phase vi) Finalisation

Stakeholder feedback was reviewed, and further refinements were made to the session plans and materials accordingly.

Results

Phase i) Mapping CST to Stroke Context

The review of CST literature and the current approaches to cognitive and psychosocial interventions for stroke survivors identified six key areas for further consideration in the adaptation: the format of the intervention; mechanisms and principles for improving cognition; principles of self-efficacy; the mechanisms and principles for improving mood, quality of life and psychosocial well-being; provision of information; and carer involvement.

Format

CST was originally designed to be delivered in a group format but individual CST, or iCST, was later developed one-to-one delivery by a family member or friend ⁶⁸. Although iCST benefits the carer and their relationship with the person with dementia,

it does not provide the same positive benefits to the person with dementia for cognition or quality of life as group-based CST ⁶⁹. This suggests the group context may be key to CST's effectiveness.

Cicerone et al ⁷⁰ acknowledge that some cognitive rehabilitation interventions for stroke may require individual delivery so they can be tailored to specific patient goals. However, they also advocate for group interventions, which provide valuable opportunities for social interaction, using cognitive skills, and supporting psychological adjustment.

Cognition

It has been proposed that the cognitive stimulation provided by CST strengthens neural pathways, resulting in the observable improvements in cognition ^{65,71}. This mechanism draws on the 'use it or lose it' theory of neuronal activation, whereby restoring stimulation to the brain is thought to aid recovery and maintenance of neuronal functioning ^{72,73}. Key CST principles linked to this mechanism are *mental stimulation*, *new ideas*, *thoughts and associations*, *providing triggers and prompts to aid recall and concentration*, *stimulating language*, and *stimulating executive functioning*.

Conversely, neuropsychological rehabilitation for those with brain injuries, such as stroke, typically focuses on teaching compensatory strategies which is grounded in neural plasticity theory ⁷⁴. Indeed, this approach is recommended in the two key clinical guidelines for stroke care in the UK ^{29,30}.

There is no clear evidence to remove any of the above identified CST principles from the adapted intervention because they may still result in cognitive improvement or prevent further decline in new populations. However, there is a rationale for incorporating more compensatory strategy training into the sCST intervention, aligning with recommendations for stroke interventions.

Self-Efficacy

Another proposed mechanism for CST's positive impact on cognition is that its fun, friendly and unconfrontational approach to learning creates positive experiences that reduce negative self-evaluations and, in turn, improve performance on cognitive tests ^{65,71}. It has been proposed that this aligns with "excess disability" ⁷⁵ and "malignant social psychology" ⁷⁶ models ⁷¹, which suggest that poor treatment by society leads to more functional disability in those with dementia than might be expected. It is thought that if individuals receive more positive experiences from their environment, their

functioning will improve. CST principles linked to this mechanism are: *opinions rather* than facts, person-centred, respect, involvement and inclusion, choice, fun, maximising potential and building/strengthening relationships.

This mechanism is similar to that proposed by "self-efficacy theory" ⁷⁷. *Self-efficacy* is a person's belief in their own abilities and is, therefore, a concept strongly associated with confidence and self-esteem ⁷⁷. Interestingly, Bandura ⁷⁸ found that self-efficacy can influence memory performance. According to this theory, self-efficacy is influenced by four factors: experiences of one's own success; experiences of the success of others; positive reinforcement and encouragement from others; and understanding one's own physical and emotional states. Therefore, the fun, unthreatening and sociable learning environment provided by CST lends itself well to the development of self-efficacy.

Self-efficacy has also been linked to improved quality of life, reduced poststroke depression ⁷⁹ and better rehabilitation outcomes ⁸⁰. Indeed, the NCGS ²⁹ considers the development of self-efficacy an important target for interventions.

While CST may already provide good opportunities for the development of self-efficacy, only one of its guiding principles – *maximising potential* – appears to relate directly to the four factors that are thought to influence the development of self-efficacy. Therefore, additional principles could be added to improve the intervention's ability to promote self-efficacy.

Mood, Psychological Well-being and Quality of Life

The mechanism by which CST improves quality of life is not fully understood, but a systematic review showed that this effect is mediated by improvements in cognition ⁶⁷. This might also be understood via self-efficacy theory; if the intervention's fun and sociable environment increases self-efficacy, participants may feel more confident and able to engage in meaningful activity, thus improving their quality of life. Indeed, Gibbor et al's systematic review of qualitative CST research identified that, in addition to increased confidence, both people with dementia and their carers reported increased engagement in activities outside the group ⁸¹.

The NCGS ²⁹ recommends interventions that aim to provide social interaction, psychoeducation and activities that build self-confidence, as well as mind-body interventions like relaxation and mindfulness. A systematic review of interventions for psychosocial well-being post-stroke identified several key components of effective interventions: "mood, recovery, coping, emotions, consequences/problems after stroke,

values and needs, risk factors and secondary prevention, self-management, and medication management" 82(p19).

Incorporating "values and needs" into interventions is regarded as important for adjustment to, and recovery from, perceived changes in identity after an acquired brain injury (ABI), such as a stroke ⁸³. Van Bost et al found that values-based living is important for achieving a good health-related quality of life in those with ABI ⁸⁴. Values also form a key component of Acceptance and Commitment Therapy ⁸⁵ which is a promising therapeutic approach for supporting psychological adjustment post-stroke ^{29,86–88}.

Many of CST's existing guiding principles that likely influence the observed benefits in mood and psychological well-being in those with dementia, such as those relating to social interaction and fun, are likely to be transferable to the stroke population. However, additional aspects, such as psychoeducation about the psychological consequences of stroke and a values-based approach, could provide further benefit to stroke survivors.

Providing Information

CST does not involve the provision of any specific information to patients or their carers. However, clinical guidelines for stroke emphasize the importance of providing information to stroke survivors and their families ^{29,30}. A Cochrane review by Smith et al found that the provision of information improved patient and carer knowledge and reduced depression in stroke survivors ⁸⁹. Stroke carers also expressed a preference for receiving information both verbally and in writing, as they often struggled to remember details and wanted to revisit it later ⁹⁰. The NCGS also highlights further considerations when providing written information, such as ensuring there is a left-sided visual prompt for those with hemispatial neglect ²⁹.

There may be specific recommendations to incorporate into sCST to ensure that patients and carers receive helpful information in an accessible format.

Carer Involvement

Although CST does not specify methods for carer involvement, iCST was developed so that carers can individually deliver the intervention to the person with dementia they care for. This mode of delivery has been found to have positive influence on the caregiver relationship and on the quality of life of caregivers ^{69,91}.

Stroke carers have also expressed that they want to feel more involved in the stroke-survivor's care rather than "left out", as they unfortunately often do 60 . There

may be aspects of iCST's more personal delivery format which could be incorporated into sCST to help stroke carers feel more involved, potentially also providing other benefits.

Phase ii) Consultation with PPI Stakeholders

The first question posed to the PPI stakeholders was to gauge their views on the group song activity in CST. While research, such as Polden et al's systematic review ⁹², has shown the benefits of singing for dementia populations, the researchers leading this adaptation were uncertain how stroke survivors might perceive a singing activity. The stroke survivor felt that the singing would be worth trying but highlighted that some stroke survivors experience changes to their voice, such as reduced power, which could make them feel self-conscious about singing.

The inclusion of physical movement in the intervention was also discussed. The stroke survivor responded that physical activity is helpful but noted that some might, again, feel self-conscious about mobility difficulties within a group setting.

The carer also shared his views, stating that he often felt left out of his wife's care and explained he was rarely asked for his opinion. He felt it would be important to keep carers updated and let them know what has been happening in the sessions so they can feel involved, informed and reassured.

Finally, when asked for any additional thoughts, the stroke survivor expressed uncertainty about the emphasis on reminiscence within the intervention. She explained that the adjustment process after a stroke can be difficult, and reminiscing about past abilities could be painful. Instead, she suggested focusing on the future, coping and current strengths.

Phase iv) Identification of areas for adaptation

All adaptations decided during this phase are presented in Table 2. All other aspects of the original CST were retained to ensure good fidelity and because many aspects and proposed mechanisms of the original program were considered to be appropriately transferable to this new population. Adaptations to materials and delivery were also considered.

Phase v) Drafting of sCST

First, a new set of guiding principles was drafted, based on the theory, guidelines and PPI views already discussed.

For the planned pilot of the adapted intervention, eight sample session plans were selected for initial adaptation. The eight sample session themes were selected from the 14 outlined in the CST manual based on their fit with the newly adapted principles and ability to provide different types of activities and stimulation across a range of cognitive domains. Costs and availability of resources for the pilot study were also considered. The selected sessions are presented in Table 3.

Draft session plans were produced in line with the identified adaptations. For example, for the faces/scenes session, the CST manual suggests an activity whereby attendees are asked to make associations and connections between faces based on subjective qualities such as trustworthiness. Although this was retained, the sCST session plan built on this and allowed for the discussion of challenges with remembering names, sharing compensatory strategies and the introduction of mnemonic techniques to help learn new names.

Table 2sCST Adaptations

Intervention Component	Adapted Element	Adaptation Type	Evidence/Rationale	Description of Adaptation
Principles	Using reminiscence as an aid to the here and now	Removal	PPI stakeholder views: reminiscence may be painful for those still adjusting to their 'new' life	This principle will be removed from the draft version of sCST
	Physical movement	Removal	PPI stakeholder views: emphasis on physical movement in a group setting may trigger insecurities about new disability	This principle will be removed from the draft version of sCST
	Vicarious experiences of success	Addition	Self-efficacy has been found to be associated with positive quality-of-life and depression outcomes post-stroke ⁷⁹ . One of the four key factors for the development of self-efficacy is experiencing the successes of peers ⁷⁷	A new principle will be introduced in sCST encouraging opportunities for group members to share stories of their own successes and achievements since their stroke
	Positive reinforcement and feedback	Addition	See above regarding self-efficacy. One of the four key factors for the development of self-efficacy is receiving encouragement from others ⁷⁷	A new principle will be introduced in sCST encouraging praise to, and between, group members and mutual celebration of achievements
	Values	Addition	Psychosocial interventions that contain components relating to values and needs have been found to be effective ⁸² . Values-based living is associated with better quality-of-life ratings in those with ABI ⁸⁴	A new principle will be introduced in sCST encouraging identification and discussion of values and exploration of how these inform decisions and actions
	Learning new strategies	Addition	Clinical guidelines recommend the provision of psychoeducation, cognitive compensatory strategies and techniques for managing psychological distress, such as relaxation and mindfulness ^{29,30} . Studies have also found that the sharing of coping strategies amongst peers can be very valuable ⁹³	A new principle will be introduced in sCST encouraging the discussion and practicing of compensatory strategies and where relevant to the main activity. Group members will also be encouraged to share their own strategies for managing either cognitive or psychological challenges.

Intervention Component	Adapted Element	Adaptation Type	Evidence/Rationale	Description of Adaptation
Materials	Session handouts	Addition	Clinical guidelines recommend provision of information to stroke survivors and their carers throughout their care journey ^{29,30} . Provision of information improves knowledge and there is some evidence it may help to reduce or prevent post-stroke depression ⁸⁹ . PPI stakeholder views further supported this addition.	In sCST, handouts will be given after each session detailing the theme of the session and the main activity that was completed. There will also be opportunity to provide brief, 'bitesize' psychoeducation regarding common cognitive or psychological consequences of stroke, with details of strategies to help manage these
	Style of handouts	Alteration	Information needs to be presented in an accessible format for stroke survivors, taking into account the sensory, perceptual, cognitive and language difficulties they may be experiencing ²⁹	All written information will be presented in simple terms using large, clear font and with a brightly coloured line on the left-hand side of the page to aid those with left-sided hemispatial neglect. This information can be adapted further if required on an individual basis
Delivery	Group song	Alteration	PPI stakeholder views: some people can experience changes to the quality of their voice after a stroke and singing may feel exposing for these individuals	Backing music will be played during the song so that group members do not feel their voice is too exposed during the singing activity
	Home activities	Addition	Clinical guidelines encourage self-management and self-directed therapeutic activity, with support from family carers where required ^{29,30}	The above-mentioned handouts will suggest an activity that stroke survivors (and their carers) can complete at home to help them practice a strategy to manage common cognitive or psychological consequences of stroke

Table 3Selection of Eight Sample Sessions

CST session	Selected for Adaptation	
Physical games		
Sounds	X	
Childhood		
Food	X	
Current affairs	X	
Faces/scenes	X	
Word association	X	
Being creative		
Categorising objects	X	
Orientation	X	
Using money	X	
Number games		
Word games		
Team quiz		

Phase vi) Professional stakeholder review

Key feedback on the draft session plans from Clinical Psychologists and a Clinical Neuropsychologist specializing in stroke related to the fidelity of the proposed cognitive exercises and strategies to current stroke cognitive rehabilitation practices, along with further recommendations for exercises or strategies to include. For example, it was suggested to introduce a "Stop and think" metacognitive strategy in the word association session, a technique frequently used in the rehabilitation of executive functioning difficulties ⁹⁴. Other feedback suggested consideration of how activities can be scaled up or down to suit the level and needs of the attendees, leading to plans for flexible, in-the-moment adaptations. Finally, feedback regarding the language used and presentation of materials was offered and addressed, such as changing the phrase "only £6" in the *using money* session to be more sensitive to diversity of financial circumstances.

Phase vii) Finalisation of sCST manual, sample sessions and materials

With consideration of the above adaptations, literature and feedback, a full description of the resulting sCST intervention, following TIDieR ⁶² was developed (Appendix G) along with final versions of the guiding principles (Appendix H), and the sample session plans and materials were produced (see Appendix I for two examples).

Discussion

This paper presents the first adaptation of CST for stroke survivors. The process followed the ADAPT framework for adapting existing interventions for new contexts ⁴⁹, which aligns with the broader MRC framework for developing and evaluating complex interventions ⁵⁷. The adaptation process involved mapping and comparing literature on CST and psychological interventions for stroke, as well as consulting with a range of stakeholders, including a stroke survivor and her husband (carer), to identify necessary adaptations at this initial stage. This mapping of literature identified several key areas where adaptations may be required: the general format of the intervention; the mechanisms and principles for improving cognition; principles of self-efficacy; the mechanisms and principles for improving mood, quality of life and psychosocial well-being; carer involvement; and the provision of information. PPI stakeholders highlighted concerns around the 'using reminiscence' and 'physical movement' principles of CST, cautioning that these may trigger painful memories or negative self-evaluations.

New principles were introduced to sCST, based on recommendations from clinical guidelines and other research findings. These were *learning new strategies*, *vicarious experiences of success*, *positive reinforcement and feedback*, and *values*. Due to the importance of providing information highlighted in clinical guidelines by PPI stakeholders and in literature, it was decided that accessible information sheets would accompany each session to provide additional psychoeducation and activities for carers to be involved in at home.

Some uncertainties about the intervention remained, requiring further exploration to inform additional refinements. For example, the proposed length and dosage of the sessions may need to be adjusted, especially in the context of a multicomponent intervention which will involve additional intervention sessions, potentially increasing the burden on stroke survivors and those who support them. Furthermore, despite positive feedback from PPI stakeholders, there were still uncertainties about how a broader stroke-survivor population might perceive some of the activities (such as singing) and themes (such as categorising objects) and whether they may find them patronizing. A small-scale intervention pilot study was conducted to explore the acceptability of the intervention for stroke-survivors and the carers supporting them to attend. The results of this pilot have been reported elsewhere (Chapter 4).

Strengths

A key strength of this intervention adaptation study is its adherence to steps 1 and 2 of the ADAPT guidance ⁴⁹, which involved assessing the rationale for the intervention, considering the fit of the intervention to the new context, and planning and undertaking the adaptations. Many intervention adaptation studies have neglected to identify and follow a framework for adaptation; a 2018 systematic review of such research discovered that less than half of their included studies reported which, if any, adaptation framework had been followed ⁹⁵.

Although CST has previously been adapted for new populations ⁵⁵, to our knowledge, this study is the first that has attempted to adapt CST for stroke survivors. Furthermore, of the few existing adaptations of CST for a new population, this appears to be the first to follow specific guidance for adapting interventions, such as ADAPT ⁴⁹, and to report this work in accordance with guidelines specific to intervention development research, such as GUIDED ⁶¹.

Another strength of this intervention adaptation is the involvement of a range of stakeholders, either as members of the research team or via consultation. Amongst these stakeholders were a stroke survivor and her husband (carer), whose involvement and its impact on the adaptation have been reported thoroughly. This is particularly important given findings from a recent systematic review of PPI in stroke research, which highlighted that family members and carers of stroke survivors are often underrepresented compared to stroke survivors themselves and that the quality of the reporting of PPI involvement is often lacking ⁹⁶.

Finally, this study details the theoretical concepts that informed adaptation decisions. Considering a systematic review found theoretical justifications for stroke interventions have historically been weak⁹⁷, this is a clear strength.

Limitations

The MRC framework ⁵⁷ and ADAPT guidance ⁴⁹ emphasize the importance of involving a diverse range of stakeholders throughout all stages of complex intervention development and evaluation. Although this study involved various stakeholders, the range of professionals consulted could have been broadened further. In particular, it would be useful to involve rehabilitation professionals such as Occupational Therapists, Speech and Language Therapists, or Advanced Clinical Practitioners, who would have valuable ideas and opinions to contribute.

Although stakeholder involvement is strongly encouraged, neither the MRC framework 57 nor the ADAPT guidance 49 makes specific recommendations as to the

methods that should be used. Here, feedback was sought via consultation, but no formal analyses of this feedback were carried out. This differs from other examples of intervention adaptations informed by the same framework and guidance. For example, Blomberg et al ⁹⁸ and Eghøj et al ⁹⁹ conducted interviews with stakeholders and analyzed transcripts to identify key themes to inform their adaptations. Alternatively, Treichler et al ¹⁰⁰ used surveys to capture stakeholders' opinions of the proposed adaptations to a decision-making intervention for veterans. These approaches may offer more rigorous methods for obtaining and interpreting stakeholder views, potentially strengthening the effectiveness and acceptability of resulting interventions.

Implications

The resulting intervention from this adaptation, sCST, has the potential to be a valuable component to include in frailty prevention MCIs after a stroke. This is due to its similarity to interventions already used in such MCIs, its grounding in CST (a widely adopted and effective intervention for another population who experience cognitive and psychosocial difficulties), and the stroke-informed adaptations. A pilot study to assess the acceptability of this intervention has already taken place; the results of this will be used to inform further refinements. It is then hoped that sCST will be adopted into broader post-stroke frailty prevention MCIs for further assessment of feasibility and preliminary effectiveness. Although the development of a *programme theory* is an important step in intervention adaptation and development according to MRC and ADAPT guidance ^{49,57}, this was beyond the scope of the current study; future work should seek to develop a programme theory.

It is possible this intervention may have broader implications for stroke care beyond frailty prevention. The James Lind Alliance's Priority Setting Partnership led by the Stroke Association identified that the top priority in stroke rehabilitation and long-term care research involves determining what interventions "can best prevent psychological difficulties, support adjustment, and improve motivation, well-being and engagement" ¹⁰¹. They highlight the fact that most research has focussed on the first 12 months post-stroke, meaning little is known about the longer-term impacts of stroke and the interventions that could be beneficial beyond 12 months. Given sCST's theoretical potential to improve mood, quality of life, cognition, and self-efficacy, it may be well-placed to support stroke survivors in the later stages of their recovery. Therefore, future research should seek to explore the possible benefits of sCST to stroke survivors and identify the contexts in which it may be most impactful to the population.

Conclusions

Using a theory and evidence-based approach, in line with MRC and ADAPT guidance for developing and adapting interventions, this study presents the adaptation of CST for stroke survivors. The resulting intervention, sCST, maintains many of the original core principles, which were deemed likely to have transferable benefits to a stroke population. However, it also introduces new principles and features informed by stroke literature, clinical guidelines, and a range of stakeholders, including a stroke survivor and her husband. A pilot acceptability study of this new intervention has already been conducted and reported, but further research is necessary to determine the potential benefits of this intervention, primarily in the context of frailty prevention post-stroke but also in broader stroke care.

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Chapter 4 – Empirical Paper

The Acceptability of Cognitive Stimulation Therapy for Stroke: A Single-Arm Pilot with Pre-Frail Stroke Survivors

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The following original research paper was written and formatted following the author guidelines for the journal, *British Journal of Health Psychology* (Appendix J)

Word limit: 6000 words

Abstract word count: 243

Word count: 5,996 (including quotes, whether in the text or in tables, but excluding the abstract, tables, figures, and references).

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Abstract

Objectives: This study aimed to evaluate the acceptability of Cognitive Stimulation Therapy adapted for stroke survivors (sCST) as an intervention for pre-frail stroke survivors and identify required refinements before a larger feasibility trial. It also examines the usefulness of the Theoretical Framework of Acceptability (TFA) in assessing healthcare interventions for this population.

Design: A small-scale, single-arm intervention pilot was conducted to assess intervention acceptability.

Methods: Five adult pre-frail stroke survivors with evidence of cognitive impairment were recruited via Addenbrooke's Hospital stroke services. Participants engaged in eight 45-minute group sCST sessions over four weeks. Interviews were conducted with the four participants who completed the trial intervention to explore their perceptions of acceptability. Interview data were coded deductively, using the seven TFA constructs (Affective attitude, Burden, Ethicality, Intervention coherence, Opportunity costs, Perceived effectiveness, and Self-efficacy), and inductively. Data were analysed using framework analysis.

Results: Twenty-two subthemes emerged across the TFA constructs. Key strengths of acceptability were reflected by the subthemes "general affect", "social interaction", "meeting other stroke survivors", "general effectiveness", and "psychological changes". However, challenges characterised by the subthemes "practicalities", "tolerance of the intervention", "relevance", and "clarity" were identified, highlighting areas for improvement.

Conclusions: The TFA proved a valuable framework for assessing the acceptability of cognitive stimulation-based interventions for pre-frail stroke survivors. The sCST intervention is largely acceptable, though refinements are recommended to reduce burden of the intervention and improve intervention coherence. These findings offer insights for broader research and clinical applications within this population.

Keywords: Stroke, Frailty, Cognitive Stimulation Therapy, Intervention, Acceptability, Pilot

Introduction

Frailty is an issue for the health, well-being, and recovery of stroke survivors. Approximately 21% of stroke patients meet the criteria for frailty, and another 48% meet the criteria for pre-frailty - roughly double the rates of those without stroke (Palmer et al., 2019). Research indicates that frail stroke survivors have an increased risk of adverse outcomes, including mortality, longer hospital stays, and disability, (Burton et al., 2022; Evans et al., 2020, 2022; Li et al., 2024) and that the severity of their frailty increases over time (Lee et al., 2014; Trevisan et al., 2017).

Multicomponent interventions (MCIs), which combine two or more interventions, each targeting different aspects of frailty, such as exercise (strength and balance), nutrition, and cognition, are effective for the prevention and reversal of frailty in older adult populations (Apóstolo et al., 2018; Dedeyne et al., 2017; Tam et al., 2022). MCIs have also proven useful for preventing and reversing frailty in specific clinical populations, such as those with acute cardiac conditions (Ahmad et al., 2023) or diabetes (Rodriguez-Mañas et al., 2019). However, to our knowledge, multicomponent frailty interventions have not yet been trialled within the stroke survivor population.

Given the high prevalence of cognitive difficulties post-stroke (Nys et al., 2007; Sun et al., 2014), depression and anxiety (Barker-Collo, 2007; Hibbard et al., 1992; Schöttke & Giabbiconi, 2015), it is important that an MCI for stroke survivors addresses these difficulties via the inclusion of a cognitive and psychosocial component intervention. Cognitive Stimulation Therapy (CST; Spector et al., 2020) is a National Institute of Health and Care Excellence (NICE) recommended intervention for people with dementia (NICE, 2018) that aims to improve both cognitive and social functioning (Clare & Woods, 2004). CST has also been successfully adopted into MCIs for frail older adults (Tan et al., 2023). With this in mind, we adapted CST for a stroke-survivor population so that the resulting intervention (stroke CST or sCST) can be adopted into an MCI for frailty post-stroke. The adaptation process has been reported separately (see Chapter 3).

The Medical Research Council (MRC) guidance for developing and evaluating complex interventions highlights the importance of understanding intervention acceptability (Skivington et al., 2021); *acceptability* is the extent to which people consider an intervention to be appropriate (Sekhon et al., 2017). The Theoretical Framework of Acceptability (TFA; Table 1; Sekhon et al. 2017) proposes that acceptability can be understood in terms of seven underpinning constructs: Affective Attitude, Burden, Ethicality, Intervention Coherence, Opportunity Costs, Perceived

Effectiveness and Self-Efficacy. The TFA has been used successfully to assess the acceptability of many interventions, including a swallowing intervention for cancer patients (Manduchi et al., 2024), a suicide prevention psychological therapy (Harris et al., 2023), and an exercise intervention for pre-frail memory clinic patients (Western et al., 2023).

Table 1The Seven Constructs of the Theoretical Framework of Acceptability (Adapted from Sekhon et al., 2017)

TFA Constructs	Definition
Affective attitude	How an individual feels about the intervention
Burden	The perceived amount of effort that is required to participate in the
	intervention
Ethicality	The extent to which the intervention had a good fit with an individual's
	value system
Intervention coherence	The extent to which the participant understands the intervention and
	how it works
Opportunity costs	The extent to which benefits, profits or values must be given up to engage
	in the intervention
Perceived effectiveness	The extent to which the intervention is perceived as likely to achieve its
	purpose
Self-efficacy	The participant's confidence that they can perform the behaviours
	required to participate in the intervention

This study investigated the acceptability of sCST for pre-frail stroke survivors to determine its suitability as a psychological component of an MCI for frailty reversal or prevention post-stroke. By understanding the strengths and areas for improvement of sCST from the perspectives of pre-frail stroke survivors, we aimed to inform additional development before further evaluation of its effectiveness, both as a standalone intervention and as part of an MCI. We also aimed to determine the usefulness of the TFA as a framework for assessing the acceptability of group cognitive stimulation-based interventions.

Methods

This research is reported following the CONSORT guidelines extension for randomised pilot and feasibility studies (Eldridge et al., 2016, Appendix K) and guidance on the use of qualitative methods in feasibility studies (O'Cathain et al., 2015).

Ethics

Ethical approval for this research (in conjunction with a connected study; Bramley, 2025) was obtained from the Bradford Leeds Research Ethics Committee and Health Research Authority (Appendix L). Cambridge University Hospitals NHS Foundation Trust (CUHT) acted as the host research site, assisted with recruitment, and provided a location for the pilot intervention within Addenbrooke's hospital. The study was registered with ClincalTrials.gov (Identifier: NCT06733103). No funding was sought.

Before participating in this research, participants read a participant information sheet (Appendix M) and signed a consent form (Appendix N). Participants' GPs were informed of their participation (Appendix O) and, after participation was complete, participants and their carers (who participated in a connected study) were sent a joint debrief letter (Appendix P). Participants received a £10 shopping voucher in appreciation of their involvement and were reimbursed for parking fees upon request. Data were as stored in line with UK General Data Protection Regulation (2016) and University of East Anglia policy.

Patient and Public Involvement

A stroke survivor and her husband provided consultation and feedback on the participant information sheets, leading to revisions in how the term 'frailty' was approached and explained. They felt some stroke survivors with a new disability might find this term confronting, deterring participation; indeed, it does have negative connotations (Shafiq et al., 2023). These negative connotations were important to consider as they could exacerbate the difficulties with identity and adjustment that stroke survivors and their family members often experience (Gracey et al., 2017). They also suggested changes in visual presentation to facilitate information processing.

Design

This pilot acceptability study adopted a single-arm, mixed-methods design. Semi-structured interviews were used to explore the acceptability of the intervention to pre-frail stroke survivors and determine potential improvements. Descriptive quantitative data were collected via a questionnaire based on the TFA (Sekhon et al.,

2022) to highlight areas of strength or weakness. Data relating to recruitment success, group retention rates, and other aspects of feasibility were collected but are reported separately (Bramley, 2025).

The philosophical paradigm adopted was *pragmatism*, which permits that reality may be socially constructed and, as such, can unlikely be wholly understood. However, knowledge can be generated by understanding what is practical or useful within a specific context (Kaushik & Walsh, 2019). This paradigm is helpful for research questions that aim to inform changes or actions rather than understand a phenomenon (Heeks et al., 2025), aligning well with acceptability research.

Participants

Participants were recruited via the Addenbrooke's Hospital stroke service (CUHT). The eligibility criteria were as follows:

- Within 12-months post-stroke
- Living at home
- Pre-frail (3-5 on the Clinical Frailty Scale [CFS; Rockwood et al., 2005], which defines frailty on a scale from 1 to 9 based on the individual's levels of activity and dependence)
- Cognitive impairment (evidence of impairment in any domain of cognition, such as processing speed or language, on a standardised assessment such as the Oxford Cognitive Screen [Demeyere et al., 2015], the Mini-Mental State Examination [Kurlowicz & Wallace, 1999], or the Montreal Cognitive Assessment [Nasreddine et al., 2005])
- A friend or family member to support (who participated in a connected research study on carer perspectives of acceptability [Bramley, 2025])

Individuals with a dementia diagnosis, language difficulties that would significantly impact their ability to take part, or who were unable to provide informed consent were not eligible to take part.

Potentially suitable individuals were identified by clinicians working in the Addenbrooke's Hospital stroke service and checked for eligibility against inclusion and exclusion criteria. Clinicians then contacted these individuals to ask if they might be interested in receiving more information. Those interested were sent a participant information sheet and were visited by researchers, where the details were discussed and informed consent was sought.

We aimed to recruit 10 participants based on the recommended group size of 5-8 for the original CST (Spector et al., 2020) and an expectation of 20% attrition, based on the expected and reported attrition in other CST intervention trials (Ali et al., 2018; Spector et al., 2024).

Procedure

Participation in this research involved completing a demographics questionnaire, attending eight sample sessions of sCST, completing an online questionnaire based on the TFA, and participating in a semi-structured interview.

Demographics Questionnaire

After informed consent was obtained, participants completed a brief demographics questionnaire (Appendix Q) covering age, gender, ethnicity, and level of education.

Pilot Stroke Cognitive Stimulation Therapy Intervention

The pilot sCST intervention consisted of eight 45-minute sessions. Pairs of sessions were delivered consecutively, each separated by a 20-30 minute comfort break, once a week for four weeks. Each session had a specific theme: current affairs, sounds, using money, faces, categorising objects, orientation, word association, and food. The sessions were designed to stimulate discussion, build and strengthen relationships, improve self-efficacy and activate cognitive domains (such as language, attention and executive functioning) via discussions and activities (see Appendices G-I for more information). Each session followed a consistent structure, detailed in Table 2.

Sessions were accompanied by two take-home sheets: one summarising the session activity and its purpose (why and how the activity is relevant for stroke survivors) and another for carers, providing stroke-related psychoeducation and a suggested home activity.

 Table 2

 Structure of sCST Sessions

Section	Time Allocation	Content
Introduction	~10 mins	 Welcome Orientation (discussion of location, weather, recent events/holidays/birthdays, etc.) Sing group song Discuss recent news headlines

Main Activity	~25 mins	- A main activity related to the session theme. This activity should provide opportunities for cognitive stimulation, multi-sensory processing, sharing strategies and building self-efficacy. For example, for the 'Sounds' session, sound clips are played and group members are encouraged to search for the picture (among a selection) that matches the sound effect and then share associations or other thoughts/emotions that are evoked by the sound
Closing	~10 mins	 Summary of the session and anything that group members feel they have learned Reminder of the next session date, time and theme Provision of take-home sheets

Acceptability Questionnaire

After the final session, participants were emailed a Microsoft Forms link to complete the acceptability questionnaire, which was adapted from the "generic TFA questionnaire" in the manner intended by its developers (Sekhon et al., 2022; Appendix R). The 10-item questionnaire consisted of one item each for the *Burden*, *Perceived Effectiveness*, *Intervention Coherence*, and *Self-Efficacy* constructs, two items each for the *Affective Attitude* and *Ethicality* constructs, and one final question relating to overall acceptability. Responses are given on a 5-level Likert scale.

Acceptability Interviews

Semi-structured interviews were conducted via Microsoft Teams using a topic guide containing 15 questions with additional prompts and follow-ups, which was based on the seven constructs of the TFA (Appendix S, Sekhon et al., 2017). The interviews took place 6-21 days post-intervention, lasting between 1h 12m and 1h 41m. The first author, who was also one of the two intervention co-facilitators, conducted the interviews. At age 28, they were younger than the participants but had prior experience of co-facilitating dementia CST groups and working clinically with acquired brain injuries, including stroke.

Quantitative Analysis

Mean ratings for each of the seven TFA constructs on the acceptability questionnaire measure were calculated, as well as for the general acceptability item (item 10). A total mean rating of all 10 items was calculated for each participant, followed by an overall mean across all participants.

Framework Analysis

Interviews were transcribed, anonymised and analysed using a framework approach (Ritchie & Spencer, 1994), applying the TFA (Sekhon et al., 2017) as the guiding analytic framework. NVivo 14 qualitative software was used to manage and code the data and create the framework matrix. A deductive approach to coding was followed whereby the first author read all transcripts thoroughly and assigned broad codes (aligned with the seven TFA constructs) to meaningful segments within the first two transcripts. Meaningful data that did not fit within the TFA constructs were inductively coded. Data were then grouped into subthemes within each of the seven TFA construct codes, and a coding framework was developed. This framework was then applied to the next transcript and was updated, as required, according to new data. This step was repeated for the final transcript, resulting in a final coding framework (Table 3). The data were then charted into a framework matrix, by case and TFA construct.

Table 3Coding Framework

Theme/TFA Construct	Subtheme	Coding instructions
Affective Attitude	General affect	Any reference to enjoyment, liking or disliking of the intervention in general
	Social interaction	Any reference to enjoyment, liking or disliking of the social interaction provided by the intervention
	Meeting other stroke survivors	Any reference to enjoyment, liking or disliking of the opportunity to meet or hear from other stroke survivors
	Activities	Any reference to enjoyment, liking or disliking of any specific activity within the intervention
Burden	Practicalities	Any reference to effort or challenges (or lack thereof) relating to travel, support required to get to sessions, or time commitment.
	Tolerance of the intervention	Any reference to effort or challenges (or lack of) relating to the engagement in the intervention activities themselves, such as level of difficulty and demand, fatigue, difficulty concentrating.
Ethicality	Group cohesion	Any reference, positive or negative, relating to the mix of group members and their alignment with one another.
	Autonomy and inclusivity	Any reference, positive or negative, relating to how well the intervention created a sense of inclusivity and provided opportunities for members to decide how they wished to engage in the intervention

Theme/TFA Construct	Subtheme	Coding instructions
	Comfort	Any reference, positive or negative, relating to the sense of comfort, both physical and psychological, during the intervention and its facilitators
	Appropriateness	Any reference, positive or negative, relating to the perceived appropriateness of the intervention content relative to the individuals' unique values, attitudes and beliefs
Intervention Coherence	Relevance	Any reference to the perceived relevance, or lack of, of the intervention to the individual's perceptions of their own difficulties and needs
	Clarity	Any reference to the perceived clarity, or lack of, of any aspect of the intervention such as its aims or the expectations of group members and carers
	Missed opportunities	Any reference to discrepancies between what the participants were expecting or hoping for and what was delivered
Opportunity Costs	Personal Choices	Any reference to choices made between attending/engaging in the intervention and doing something else
	Availability	Any reference to whether participants were available to attend the intervention sessions or not
Perceived Effectiveness	General effectiveness	Any reference to a general perceived benefits or effectiveness without further detail
	Benefits of peer support	Any reference to the perceived benefit as a result of interacting with other group members, either in terms of increased understanding about stroke, feeling 'I'm not alone', or learning how others cope
	Psychological changes	Any reference to perceived change in mood or other psychological aspect such as confidence
	Cognitive stimulation and strategies	Any reference to perceived benefit or sense of usefulness relating to the cognitive stimulation provided by the activities or the cognitive strategies introduced in the sessions
Self-Efficacy	Overcoming apprehension	Any reference to initial feelings of worry, nervousness, anxiety that were relieved after some time engaging in the intervention
	The people	Any reference to the positive impact of other people (group members or facilitators) on an individual's sense of confidence, comfort or willingness to engage
	Barriers	Any reference to a factor that negatively impacted an individual's willingness to engage, or to an individual's negative appraisal of their own engagement in the intervention

Results

Participant flow

Five participants were recruited to the study; participant characteristics are displayed in Table 4. The types of strokes experienced were: a right frontal lobe ischaemic stroke secondary to large artery atherosclerosis, a left basal ganglia ischaemic stroke secondary to large artery atherosclerosis, a right hemisphere lacunar stroke, right middle cerebral artery embolic strokes secondary to larger artery atherosclerosis, and a left middle cerebral artery infarct of unclear aetiology.

Table 4Participant Characteristics

	Characteristics	N (%)	M, SD (Range)
	Demographics		
Age		_	76.8, 9.01 (64-89)
Gender	Male	1 (20)	-
	Female	4 (80)	-
Ethnicity	White English, Scottish, Northern Irish or British	5 (100)	-
Education	Higher education qualification	2 (40)	-
	No formal qualifications	2 (40)	-
	Not disclosed	1 (20)	-
	Frailty		
CFS Score	3	2 (40)	
	4	1 (20)	-
	5	2 (40)	-
	Stroke		
Time since	stroke onset (days)	-	193, 114.35 (86-337)

Note. CFS, Clinical Frailty Scale

One participant was lost to follow-up after the first session. They had been due to stay for the second session, which took place immediately after the first, but they reported they needed to catch their bus. They were reminded of the times of the sessions for the following week. Their carer was contacted to follow-up, but they had been at work and had been unaware the stroke survivor had left early. They stated they would try to make different transport arrangements for the stroke survivor for future sessions, but they did not return. Further follow-up phone calls were attempted but were not successful. As a result, it was not possible to send this participant the online questionnaire link or arrange an interview.

Two participants completed all eight sessions and two completed six sessions (reasons for non-completion were "other commitments" and "illness"). All four were sent the link to the online questionnaire and completed the follow-up interview.

Quantitative Analysis

Unfortunately, this analysis could not be conducted as the number of responses exceeded the number of participants. With consent from all participants, a new questionnaire link was sent, but again, too many responses were received. The number of responses was not large enough to suspect interference from bots, nor was there any financial incentive for fraudulent responses (Goodrich et al., 2023). Due to the anonymous nature of the questionnaire and lack of identical datasets, it was not possible to determine which datasets resulted from repeat or inappropriate submissions.

Framework Matrix

The framework matrix (Table 5) summarises data per participant for the seven main themes from the TFA. Due to the small number of participants, the results are presented to prevent identification; for example, using ambiguous, gender-neutral terms when referring to participants or their carers. Twenty-two subthemes were identified, all fitting within the seven TFA constructs (Figure 1); no additional themes outside TFA constructs were identified.

 Table 5

 Framework Matrix Summarising the Data for Each Key Theme and Participant

	Participant 1 (80-89 years, <6 months post-stroke)	Participant 2 (70-79 years, >6 months post-stroke)	Participant 3 (80-89 years, <6 months post-stroke)	Participant 4 (60-69 years, >6 months post-stroke)	Acceptability Outcome/Summary
Affective attitude	Found it "interesting" and "enjoyable", mainly socialising with others and reminiscing about life. Looked forward to the group each week.	"Enjoyed" the intervention, particularly "meeting people with the same problem" and specific activities. "[Didn't] want it to be over".	"Enjoyed the mental activity" of the sessions and talking to and "having a laugh" with people with "similar experiences". Found it "very sociable, very pleasant".	Found attending the group was "really nice", particularly talking to "people within the same position" and seeing "how they coped". Liked being able to choose the group name and song. Felt it was "something to look forward to each week".	Participants reported enjoying the intervention and the social interaction it provided. The affective attitude construct appears to be a relative strength of the intervention.
Burden	Found the process of getting to the location "a misery" and was concerned about the impact of this on their spouse. Also felt the activities could be made "more challenging".	Found that they were "tired" after the intervention and travelling, but having a break during the session "helped a lot". Was aware that "getting there" may be a challenge for others. Felt the sessions and activities "could have gone into more depth".	Found the "logistics" of getting to the sessions "tiring" and stated they "couldn't have done it" without support from family. Found some activities quite difficult but overall did not find the intervention to be "onerous or a chore". Didn't read take-home information sheets due to being "inundated with information" since their stroke.	Thought doing two sessions back-to-back was "too draining" and found it hard "concentrating for that long". "Couldn't be bothered" to read the take-home sheets because they contained "too much information". Felt the sessions could have been shorter in duration.	The experience of engaging in the intervention appeared to be tiring for participants, with the location and length of sessions and amount of information presented contributing to this. There were differing views on the difficulty level. Burden is a key area for further exploration and improvement. In particular, there is a need to better consider the practicalities such as location and develop

	Participant 1 (80-89 years, <6 months post-stroke)	Participant 2 (70-79 years, >6 months poststroke)	Participant 3 (80-89 years, <6 months poststroke)	Participant 4 (60-69 years, >6 months poststroke)	Acceptability Outcome/Summary
					further guidance for tailoring the difficulty level.
Ethicality	have been "away from to choose their own activities to be "upb stroke unit" and joked group song but felt and "inclusive", wit that the tea was there could be more everybody having "terrible". opportunities for choice. "chance to speak", l	Found the group and activities to be "upbeat" and "inclusive", with everybody having "chance to speak", but "felt a bit sorry" for the	eat" a bigger groupthen we for h wouldn't be able to get a co word in edgeways" and b out it would be harder to or	Participants generally found the intervention content and materials to be inclusive and the mix of group members appropriate and	
	Found some activities felt "embarrassing" as a result of the group mix and felt it might have been better to have a "bigger" and more "homogeneous group of people, education-wise or income-wise".	Thought some activities initially seemed "for children" and wondered if some topics of the discussions that arose may be "difficult to accept" for some people. Was "pleased with the mix" of group members	only man in the group. "Felt like a three-year- old" due to some of the easy activities but stated this was "quite sweet, really"	concentrate. "Didn't feel left out at all". Found it helpful that they "knew the hospital very well" and felt the location was "comfortable". Appreciated the "big writing" on the take-	positive. With no major concerns presented, ethicality is a strength of the interventions' acceptability.
	Felt it was "novel and interesting" that carers were involved.	but thought "maybe two more would have been nice".		home sheets.	
		Was aware that the room was "not very nice" and needed "tidying up".			
Intervention coherence	Felt the intervention was "not directly relevant" to their specific difficulties but recognised that it might be useful for "those that	Felt the intervention was relevant, but some activities were less relevant to their specific difficulties.	Felt that "more physical activity" or "day-to-day tipswith managing your independence" would have made the sessions more useful and relevant.	Had mixed views on the personal relevance of the intervention.	The purpose and relevance of the intervention was often unclear to participants. Intervention coherence appears to be an area of relative weakness for

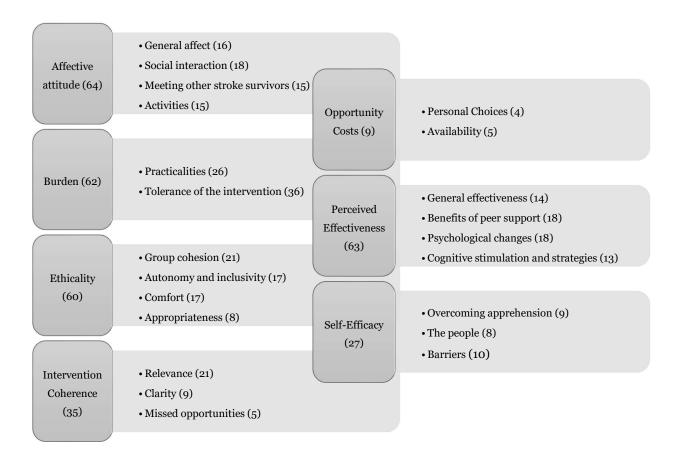
	Participant 1 (80-89 years, <6 months post-stroke) have memory difficulties". Recognised the potential for support from other group members yet felt "it wasn't clear" how the intervention could help mental health.	Participant 2 (70-79 years, >6 months post-stroke) Felt it was clear how the intervention could help with cognition, but not clear how it could help with frailty. Stated "it's got to be made clear that [carers are] not required" at the sessions.	Participant 3 (80-89 years, <6 months post-stroke) Did not feel the cognitive activities were relevant to their difficulties, which were more physical, but recognised that "different parts will be relevant to different people". Felt the sessions could explain more about the psychology behind stroke.	Participant 4 (60-69 years, >6 months post-stroke)	acceptability Outcome/Summary acceptability and requires improvement. In particular, refinements should focus on how to more clearly highlight and demonstrate the intervention's aims, and rationale to participants.
Opportunity costs	Was "pleased to be asked" to the intervention because they weren't doing anything else at the time, but was aware of another stroke group taking place locally. Chose not to attend both.	Stated the group "worked well" for them in terms of availability but noted that if the group had taken place a few weeks later, they would have been busy. Stated that "people will have other things to do and won't be able to make it".	Participant 3 made no references that were coded into this theme.	"Could only go for three [weeks]" and found being "holiday mode" made it harder for them to read through the take-home information afterwards. Unable to fulfil another personal commitment as a result of attending the intervention and had to make alternative arrangements for this.	The opportunity costs construct is a relative strength of the intervention for these participants at that moment time, with the participants being both available and willing to take part. However, this aspect of acceptability may be more variable than others, depending on the participants and timing.
Perceived effectiveness	Felt that they were able to "communicate better" as a result of attending and that it can help with "listening and	Found that the intervention helped them to "think differently" about their situation, and what may	Found it helpful to hear "other people's views and information" and to know "you're not going	Found it helpful to meet and hear from other individuals "in the same boat", "to see how they coped".	Participants perceived there to be predicted and actual positive effects as a result of the intervention including

	Participant 1 (80-89 years, <6 months post-stroke) speaking". They also felt that it could "boost confidence" and make people "more willing to go out", recognising that "you'd get support from the group". Looking through the take-home sheets with their spouse was helpful as it prompted them to "recall what happened and what I did". Identified that the intervention "stimulates people"	Participant 2 (70-79 years, >6 months post-stroke) be helpful. Found it particularly helpful to reduce isolation and realise they were "not the only one" but also that "we're all different". Reported, "It's made me happier" and more confident to go out and do things. However they noted there are certain things they still find difficult.	Participant 3 (80-89 years, <6 months post-stroke) down a rocky path on your own". They also found it helpful because "it was getting me out of the house". They felt it would have been more beneficial if there had been more opportunities to share experiences. Felt it made other group members "more confident and more able to express themselves". Reported a drop in mood after the sessions finished but did not feel this was related to the sessions in any way.	Participant 4 (60-69 years, >6 months post-stroke) Felt the group had a positive impact on their mental health and thought that attending this intervention for a longer period would have been beneficial. They enjoyed the group name and song because "I remember it!but I can't remember what happened yesterday!".	Acceptability Outcome/Summary in communication, confidence and connectedness. Perceived effectiveness appears to be a key strength of the interventions' acceptability.
Self-efficacy	Felt that meeting the facilitators beforehand "increases confidence" and that fact that the group were "genuinely attentive" helped. However, they did "restrict" themselves because they felt they had "a terrible	Had initially been worried about who they would meet and what to expect but found that the other group members made them feel "at home straight away". They also felt they felt more confident because it was "a smaller group".	Initially thought "I'll do one and then I won't bother and I found that I did bother". Didn't feel they "knew all the words or could sing [the group song] with gusto". "Sometimes came away and thought I'd chatted	Initially "didn't know what was going to be expected of me" but felt able to contribute during sessions because it was a small, "friendly" group Found the singing activity "a bit daunting" to begin with.	Participants felt able to engage in the intervention; initial apprehension or concerns about engaging in the intervention or specific activities appeared to be short-lived. The other group members and facilitators were supporting factors.

Participant 1 (80-89 years, <6 months post-stroke)	Participant 2 (70-79 years, >6 months post-stroke)	Participant 3 (80-89 years, <6 months post-stroke)	Participant 4 (60-69 years, >6 months post-stroke)	Acceptability Outcome/Summary
tendency to reminisce and tell stories"	Had initially been worried they were "all gonna drop out" after the fifth participant dropped out and that their "singing [wasn't] up to much".	too much", which led them to feel "a bit guilty".		However, there appeared to be more barriers to engagement in the home-based activities. Self-efficacy was a strength of the acceptability of the
	Left the home activities until the night before the next session and felt more could be done to motivate engagement in these activities at home.			intervention sessions but requires improvement regarding the home-based activities.

Figure 1

Themes and Subthemes



Note. The number of coded data segments within each theme and subtheme are noted in brackets.

Affective Attitude

Four subthemes emerged from the data regarding how participants felt about the sCST intervention. *General affect*, whereby participants described their attitude towards the intervention, was largely positive, with all four participants reporting a sense of enjoyment. Participant 4 summarised, "It was just a nice group, and we were just happy there. It was just nice".

All participants spoke positively of the *social interaction* provided by the intervention. Participant 3 explained:

The sessions... I enjoyed those, yes, because it was sociable, I wasn't getting an opportunity to be sociable with anyone other than immediate family. It was good to hear about other people's lives and what was affecting them as well....

Meeting other stroke survivors was appreciated by all participants, with Participant 2 explaining that they "enjoyed meeting people, with the same problem but slightly different".

Finally, all participants described their opinions of some of the *activities*. All participants mentioned the news headline activity as a highlight. Two participants discussed how the singing activity grew on them over time; for example, Participant 2 said, "It wasn't enjoyable to start with first time, but then we did enjoy it every time". However, Participant 1, highlighted an activity they didn't like: "... the one about the meal planning, with six pounds, I didn't much like that", referring to the fact that this felt irrelevant and "embarrassing" (see *Ethicality*).

Burden

Two subthemes were identified for 'Burden', both of which were discussed by all four participants. Challenges relating to the intervention's *practicalities* were identified, such as the effort and support required to travel to the group sessions, and the time commitment involved. For example, Participant 1 stated, "Addenbrooke's…is only a short drive from here, but it's a misery when we are parking, getting from the car to the lift and finding a…wheelchair and then pushing it". However, some noted these factors weren't an issue in their specific circumstances. Participant 2 explained, "…see its easy for me, the bus is only around the corner and it brings me up right to the hospital".

Tolerance of the intervention was another factor contributing to burden. Participant 4 reported that she found "it drained me for concentrating for that long", but Participant 1 felt "the activities were the lowest level of demand" and could be "made more challenging". Participant 3 also noted having "had a lot of follow up after my stroke, which I think is excellent, but at the end of the day, you're tired and you feel you're just fed up with the whole subject of it".

Ethicality

Four subthemes emerged from the data regarding the fit between sCST and the participants' values systems. *Group cohesion* was identified to have an impact on all participants' experience of the intervention, with some, such as Participant 2, being "really pleased with the mix we had" but others stating they would have preferred a

more "homogenous" group in terms of age or profession (Participant 4) or a "slightly larger" group (Participant 2).

All participants valued the *autonomy and inclusivity* of the intervention. Participant 4 noted that they weren't "left out at all". Participant 1 also appreciated that their spouse "felt all the way along that [they] knew what was going on" and noted that the take-home information was "large enough...to be able to read it", and was "simply expressed".

Three made positive comments about *comfort*; Participant 1 noted that the facilitators "kept the mood very nicely", echoed by Participant 2 who felt that any issues have "got to be handled how you handled them". Participant 3 also noted that the location was big enough for group members to "sit comfortably". In terms of areas for improvement, Participant 1 joked that the "tea was terrible", whereas Participant 2 would have "been happier in a nicer room". Participants also referred to why they felt one participant was lost to follow-up; Participant 1 thought they were "anxious", and Participant 3 felt the session was "too stressful" for them.

Three participants made remarks regarding the *appropriateness* of the intervention or activities. In terms of the location, Participant 1 stated that "ideally it would have been in some separate entity a room, you know... away from stroke unit". Regarding the activities, Participant 2 stated that they initially felt the categorising objects activity was "silly" and "for children" but later realised that it "made me think of different ways of different things and it really was helpful". Similarly, Participant 3 noted that they had "felt like a three-year-old" but clarified this was "quite nice". Participant 1 also highlighted that they had felt the "using money" activity was "embarrassing" and that "more thought needs to go into that", noticing that the range in income amongst the group may have been large and, therefore, money could be a difficult topic. Concerning a discussion that arose amongst group members about remembering the names of people with different ethnicities to your own, Participant 2 felt that some people might have thought, "but hang on, you can't say that…", although they clarified, "I was alright".

Intervention Coherence

Three subthemes described how well the participants understood the intervention and how it works. All participants discussed the *relevance* of the intervention, with some, such as Participant 1, feeling it was "not directly relevant" to their specific difficulties after their stroke. Both Participant 1 and Participant 3 explained that their physical difficulties were their main concern. Others, such as

Participant 3, identified that "different parts will be relevant for different people; it's how it affects you".

Three participants commented on the *clarity* of the intervention and its aims. For example, Participant 2 stated, "It was clear. But I could see that some people might feel differently than, they might feel it wasn't gonna help. It should be explained more at the beginning exactly what you're trying to do…"

Finally, two participants identified *missed opportunities*, things they felt would have made the intervention fit better with their needs and expectations. Participant 3, for example, suggested that "day-to-day tips...with managing your independence" and "a little bit more psychology... how to deal with our moods..." would have been helpful.

Opportunity Costs

Three participants discussed the perceived costs of the sCST intervention, or lack thereof. They discussed making *personal choices*; Participant 1 explained there was a local post-stroke group on a Thursday afternoon but "thought I couldn't really do a Thursday afternoon and a Friday afternoon". Participant 2 also spoke about having to pick the right moment to go through the take-home sheets with their spouse; "as long as [they're] not tired…".

Availability was the other factor discussed. Participant 1 stated they could attend the sCST sessions because "at the moment I'm... really not doing anything". However, Participant 2 identified that might not always be the case and that, on some weeks, people "won't be able to make it", which had been the case for Participant 4, who "could only go for three [weeks]".

Perceived Effectiveness

All four participants discussed their thoughts on the actual or likely effectiveness of the intervention, covering four subthemes. All participants spoke of *general effectiveness*, commenting broadly on the perceived benefits. For example, Participant 2 stated they "...got so much out of it", and Participant 3 "...thought it was very...useful".

All participants also discussed perceived *benefits of peer support*; Participant 3 summarised this well:

Well, it's always beneficial to speak to people who've had a similar experience and hear whether their experiences are the same as yours or it's it's quite heartening because you know you're not going down a rocky path on your own.

Partivipants identified actual or likely *psychological changes*; for example, Participant 2 felt the intervention "made me a happier person" and explained it had given them "confidence to go out and do things...". Three out of the four participants identified confidence as a potential benefit. The participant (Participant 4), who did not speak specifically of confidence, still felt the intervention could benefit mental health, stating, "I'll bet it benefit from mood swings and just something to look forward to actually...". Participant 3 reported feeling "overwhelmed" and "emotional" after the intervention finished but stated, "I don't think it was sadness because I finished the sessions".

Three participants also identified a potential benefit from the *cognitive stimulation and strategies*; Participant 2 reflected that "it made me think of different ways of different things and it was really helpful", and Participant 1 noted that they found the mnemonic strategies "useful".

Self-Efficacy

The participants' perceptions of their ability to engage in the intervention covered four subthemes. Three participants described *overcoming apprehension* with Participant 2 explaining:

I wondered what we would talk about or what we would discuss and what have you and it was nothing like I'd imagined. I thought, 'Oh, it's gonna be awful, we're gonna do this, we're gonna do that'. There was nothing, we even chose our own song. It was lovely.

Three participants described how *the people* helped them to feel more confident and comfortable engaging in the intervention, describing "familiar faces" and the fact that the group members were "genuinely attentive". Participant 2 explained, "everyone was really nice and and I felt comfortable... talking to other people who were strangers, really".

However, three participants also identified barriers to engagement.

Participants 1 and 3 spoke were aware of their contributions in a potentially negative way; for example, Participant 3 stated, "I sometimes came away and thought I'd chatted too much...I should have kept my mouth shut, let other people chat". Participant 4 explained how they "couldn't be bothered" with the take-home sheets. Similarly, Participant 2 felt that more could have been done to motivate engagement with the

take-home sheets, suggesting it "would be better if we could have, say like a question sheet and discuss the questions... 'cause it would have made us sit down and say right, how do we feel about this today..?".

Discussion

This study evaluated the acceptability of a novel adaptation of CST for stroke survivors using a small-scale pilot with five pre-frail stroke survivors. Deductive qualitative analysis using a framework approach revealed key subthemes across the seven constructs of the TFA. Several strengths of acceptability were identified. In terms of affective attitude, participants found the intervention enjoyable. Social interaction and opportunity to meet other stroke survivors, was thought to help participants learn how others cope and feel less alone. These findings align with sCST's guiding principles of 'fun', 'involvement and inclusion' and 'building/strengthening relationships', which were retained from CST (Spector et al., 2020), and suggests these principles have been implemented effectively. These findings support literature on the benefits of peer support (e.g., Clark et al., 2020; Morris & Morris, 2012; Wan et al., 2021) and the role of social participation in reducing isolation for stroke survivors (Hewetson et al., 2018).

Perceived effectiveness was noted for confidence, with one participant reporting they felt more confident to engage in previously avoided activities. Confidence relates to self-efficacy, which is defined one's belief in their ability to perform behaviours required for a desired outcome (Bandura, 1977). Self-efficacy is associated with better physical and psychosocial functioning post-stroke (Korpershoek et al., 2011); for this reason, self-efficacy theory informed some of the sCST adaptations. The potential improvements in confidence reported here provide promising evidence that sCST may support the development of self-efficacy, which could, in turn, aid broader stroke recovery.

The above findings echo the positive experiences identified by those who have attended original CST; "being with others", "enjoyment", "confidence" and "mental stimulation" were themes identified in a systematic review of qualitative experiences of CST for people with dementia (Gibbor et al., 2021). These promising similarities suggest that sCST could provide similar benefits to stroke survivors to those CST provides to people with dementia.

Additionally, three participants reported finding the cognitive stimulation and strategies helpful. Original CST aimed to stimulate various domains of cognition, such as language and executive functioning, via discussions and activities. This was retained in the development of sCST, but, sCST also aimed to incorporate explicit cognitive and

psychological strategies, based on recommendations in stroke guidelines (ISWP, 2023; NICE, 2023). These positive reports suggest the successful implementation of these guiding principles and that the addition of cognitive strategies was beneficial.

However, the data also highlighted areas for improvement, such as Intervention coherence, with some participants feeling the intervention lacked relevance. One participant suggested that more discussion and activities relating to physical and practical difficulties would have better met their needs. This finding may support ideas that stroke patients are less concerned about (Ellis et al., 2013) or lack awareness or acknowledgement of their cognitive and psychological difficulties compared to their physical difficulties (Hartman-Maeir et al., 2003). Since sCST is intended to be part of a broader MCI, other components may address physical needs and, therefore, improve overall intervention coherence. However, it must be noted that the original CST included "physical movement" as a guiding principle, which was omitted sCST; this feedback suggests the omission should be reconsidered.

Additionally, some participants suggested it was unclear how the intervention would support cognition, mood and, particularly, frailty. The aims of the intervention were explained both in the participant information sheets and during an in-person visit with each participant, however, it is true that there was not as much discussion about *how* the intervention might achieve these aims. This echoes findings that stroke patients are more motivated to engage actively in an intervention when it appears meaningful, and they are provided with clear rationale (MacDonald et al., 2013). Therefore, more clarification of the reasoning behind sCST may need to be provided.

Regarding burden, one participant felt sessions were "too much" at times but another recommended making exercises "a little bit more challenging". Similarly, regarding ethicality, two participants referenced how some activities felt like they were for children, potentially raising concerns that the activities were not suitably adapted for this population. However, a systematic review of qualitative findings from CST research also identified "difficulty of sessions" as a key theme, with very similar feedback reported (Gibbor et al., 2021). Therefore, it seems this issue is not unique to sCST but is rather an ongoing challenge in CST-based interventions.

Other issues of burden and ethicality highlighted were more practical issues relating to the location of the sessions and the group size and heterogeneity. Indeed, transport and access have previously been cited as barriers to engagement in stroke rehabilitation (Koh et al., 2014) and the ideal group size would be larger, in line with the 5-8 recommended for CST (Spector et al., 2020). However, one participant felt a

larger group would have increased the burden, making it harder to concentrate and contribute.

Strengths

This is the first study to evaluate the acceptability of sCST, a novel adaptation of CST for stroke survivors. MRC guidelines for developing and evaluating complex interventions recommend that newly developed or adapted interventions be evaluated for feasibility, with an important aspect of this being acceptability (Skivington et al., 2021). The findings of this acceptability study will help to inform refinements to the sCST intervention before it is adopted into a broader MCI for pre-frail stroke survivors, at which point further evaluation can and should take place.

To the authors' knowledge, this is the first study that uses the TFA as a framework for assessing the acceptability of a cognitive stimulation-based intervention and an intervention for a pre-frail stroke survivor population. Furthermore, the fact that no additional themes were identified outside of the seven constructs outlined by the TFA demonstrates that this framework is useful and appears to capture all key aspects of acceptability for this population and intervention. This study, therefore, contributes and supports the broader evidence base demonstrating the usefulness of the TFA in healthcare intervention research.

Limitations

Despite aiming to recruit 10 participants, only five consented, with one lost to follow-up early on. This small sample limited the range of opinions on acceptability obtained, particularly as all the participants identified as White-British, affecting the generalisability of findings. Furthermore, data saturation, as defined by Guest et al.' (2006), was not reached as the coding framework was still being adjusted throughout the analysis of the final transcript. Although data saturation is considered a key quality marker in qualitative research (Braun & Clarke, 2021), the concept has been critiqued. *Information power* (Malterud et al., 2016), an alternative to data saturation, instead suggests that the narrow aim of this study, the specificity of the sample and the use of an established theory all contribute to a higher information power, whereby a smaller sample can adequately answer the research question.

Recruitment challenges and other aspects of feasibility have been reported elsewhere (Bramley, 2025). However, Sekhon et al. (2021) found that prospective acceptability perceptions influence decisions to participate in research trials; this may have been one possible barrier to recruitment in this study. In future research,

collecting data on prospective acceptability based on a description of the intervention before optional participation in the pilot intervention and follow-up would be helpful. This would help to identify key factors of acceptability that influence acceptance and refusal of the intervention and how perceptions change after experiencing the intervention. This would also help to inform refinements in how the intervention is presented to stroke survivors and may address the above-mentioned issues with perceived intervention coherence.

Another limitation was the inability to calculate numeric descriptive statistics from the TFA questionnaire data due to unexpected additional responses being received. It is unclear exactly why these additional datasets were received from the online questionnaire, but this highlights the potential challenges of using technology for data collection, particularly for older adults. Gitlow (2014) found that although older adults are comfortable with familiar digital activities such as emailing and using smartphones and e-readers, they may still require support for novel digital activities or interfaces. Therefore, the online questionnaire platform may have been too unfamiliar and traditional pen-and-paper data collection methods could have been a more reliable and feasible alternative.

Clinical and Research Implications

This study provides promising evidence for the acceptability of sCST, with participants reporting enjoyment and potential benefits to communication skills, confidence, and cognitive stimulation. However, refinements are needed before sCST is adopted into an MCI for frailty post-stroke. Clearer explanations of the intervention's aims and rationale could improve participants' understanding of its relevance to the improvement of frailty and the cognitive and psychosocial consequences of stroke. Furthermore, activities may need to be more adaptable to best suit the level of ability; grouping participants based on cognitive ability or other needs might help to facilitate this adaptability. A repeat acceptability pilot should be conducted after these refinements have been made to evaluate their effectiveness before sCST is adopted into an MCI; prospective acceptability should also be evaluated in order to understand how to improve uptake of the intervention and consider how the acceptability of the intervention changes with experience.

Although this acceptability pilot was carried out within the context of developing a cognitive and psychosocial component intervention to be used within an MCI for frailty, the promising findings suggest sCST also has potential as a stand-alone intervention. Many of the positive aspects identified map closely to those identified by

people with dementia who have engaged in CST; this is encouraging, as CST has consistently been found to benefit cognition, mood, and quality of life (Aguirre et al., 2013; Lobbia et al., 2019; Saragih et al., 2022). There is a need for further evaluation of sCST to determine if it can replicate the benefits of CST for a stroke-survivor population.

Conclusions

This study piloted the first adaptation of CST for stroke survivors, particularly those who are pre-frail. It also demonstrated the usefulness of the TFA in assessing the acceptability of cognitive-stimulation-based interventions and interventions for this population. Overall, participants found sCST acceptable, providing a rationale for further refinement and evaluation of its potential impact, both as a standalone intervention and as part of an MCI. Refinements should aim to a) enhance intervention coherence by clarifying its aims and rationale, b) reduce burden by tailoring the difficulty of activities to different levels and needs, and c) reduce burden and increase ethicality via carefully considering practicalities such as the location and size of the group. These findings also have implications for researchers and healthcare providers developing other interventions for pre-frail stroke survivors and for researchers involved in researching MCI for frailty post-stroke.

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Chapter 5 – General Discussion, Reflection and Critical Appraisal

Word Count: 5,604

This thesis portfolio aimed to support the development of a psychological intervention for stroke survivors with the potential for adoption into a multi-component intervention to reduce frailty after stroke.

Three research papers are presented in this thesis portfolio to address the overall aim. First, a systematic review was conducted to determine the cognitive and psychological outcomes of MCIs in frail, older adult populations and identify which component interventions result in better psychological outcomes. Then, informed by the systematic review findings, Cognitive Stimulation Therapy (CST) was identified as a promising psychological intervention for use within MCIs for frailty prevention and adapted for a stroke-survivor population. This adapted intervention, sCST, was then piloted with a small sample of pre-frail stroke-survivors. Interviews conducted to explore the acceptability of this intervention in this population were analysed using a framework analysis, according to the seven constructs of the Theoretical Framework of Acceptability (TFA). It is hoped the findings of this research will contribute to i) understanding of the potential role for Clinical Psychology in the development and implementation of interventions for frailty prevention and reversal, in stroke and more widely and ii) the evidence-base for psychological interventions post-stroke.

This chapter presents a general discussion and critical appraisal of the research. First, I provide a reflexivity statement (guided by Braund et al., 2024) considering what drew me to this research, what I brought to it, and what I gained from it. I then summarise the findings of this portfolio of work before discussing its strengths and limitations. The implications of the work, for both clinical practice and research, are considered, with further directions for research suggested. Finally, I will outline the main conclusions.

Reflexivity Statement

When working in Older Adult, Stroke, and Neuropsychology services as an Assistant Psychologist or Trainee Clinical Psychologist, I noticed how changes in cognitive and physical abilities appeared to significantly impact confidence and selfesteem in my patients. This often triggered a cycle of reduced activity, avoidance, low mood, anxiety, and further physical and cognitive decline. This highlighted to me the role of clinical psychology in the prevention of physical as well as psychological decline, particularly in neurological conditions such as stroke. It was this observation that motivated this research into psychological interventions for frailty prevention.

MCIs for frailty instantly appealed to me due to their holistic, multi-disciplinary approach, aligning with my interest in the intersection of physical and mental health

and collaborative working with other professionals and disciplines. Reading the descriptions of the cognitive and psychosocial interventions previously included in MCIs, I was reminded of my experiences facilitating CST groups for individuals with dementia, where I witnessed extraordinary transformations in confidence in the group members. I believe this appreciation of, and confidence in, CST made me a good person to undertake the intervention adaptation for a new population as I understood the potential benefit and importance of retaining several of the original features. However, I was aware I might bring some bias because of my strong affinity to the intervention; I was sure to keep this in mind, remaining critical and open-minded.

Although I was different from the pre-frail stroke survivor population in terms of age, ability and health status, I brought both clinical experience and personal understanding of the population and the challenges they face. After my grandmother was diagnosed with vascular dementia, the COVID-19 lockdown exacerbated her decline in health, and she rapidly became frail. She had always been an incredibly sociable and active woman, but the combination of her cognitive difficulties and the restriction of her social activity was a significant catalyst to her decline and, ultimately, her death. I, therefore, have an appreciation of the power of cognitive and social stimulation, or lack thereof, on frailty in those affected by cerebrovascular disease.

I was supported in this research by a Consultant Clinical Neuropsychologist and Consultant Clinical Psychologist with extensive experience working with stroke survivors both clinically in and research, and a Consultant in Stroke Medicine with knowledge of the impact of frailty in stroke survivors. Paired with my personal and clinical experiences and interests, this support made me confident that I was the right person to undertake this research.

I was aware of the importance of Patient and Public Involvement (PPI) in research and keen to ensure involvement was not tokenistic; it was important to me to take the time to develop a good working relationship with the PPI representatives and to genuinely take on board their perspectives. I remember feeling very moved by the surprised response of the husband (carer) of the stroke survivor upon finding out we were interested in his opinions, as this was a novel occurrence for him. It was a pleasure to witness his increasing confidence and willingness to share his thoughts, experiences, and ideas from this point forward; this highlighted the importance of involving carers in research.

The participants recruited were all of White British Ethnicity and lived in an affluent middle-to-upper class area of the UK, like me. This similarity likely helped me

to connect with the participants despite our differences in age and ability. However, because I had co-facilitated the intervention that participants were being asked to share their views on, I knew there was potential for bias from social desirability and demand characteristics. On the other hand, co-facilitating the intervention allowed me to develop a positive rapport with the participants, making it easier for me to discuss these challenges openly and emphasise the importance of their honesty. The prior knowledge of the participants that I had developed also allowed me to better understand their needs and signs of fatigue, helping me to be able to respond flexibly to them during the interviews. My flexibility also improved across the four interviews as I became more relaxed, confident and familiar with the process. However, at times, I was aware I felt conflicted; I wanted to obtain as much helpful data as possible, yet I also did not want to overburden participants when they were beginning to show signs of fatigue.

Due to my passion for CST and my sense of ownership and pride in sCST, it was sometimes difficult and disappointing to hear the more negative aspects of the participants' feedback. However, this did provide some reassurance regarding the possibility of social desirability bias. On the other hand, it was so rewarding to hear the positive comments; one participant discussed how she had booked a trip with her daughter after the intervention, which she said she wouldn't have done a few weeks prior. This felt really important, and I felt truly privileged to have been able to be a part of her recovery journey.

Completing this thesis portfolio developed my skills and confidence in various aspects of research. I had initially felt very daunted and overwhelmed about the prospect of undertaking a systematic review, something I had not done before. However, as soon as I immersed myself in the process, all these worries disappeared, and I enjoyed it. Similarly, adapting CST felt like a big undertaking within the relatively brief timeline available, and I was unfamiliar with how to report this research style. The ADAPT guidance (Moore et al., 2021) and GUIDED reporting guidelines (Duncan et al., 2020) were particularly helpful, and I also referred to other examples of intervention development papers (e.g. Eghøj et al., 2024; Scheibl et al., 2024) to get a sense of the structure. It was ultimately a rewarding experience; I feel proud to have produced something I believe in. The empirical research allowed me to develop my skills and confidence in conducting qualitative research. Being relatively inexperienced in qualitative research, I found using a framework analysis approach, applying the TFA, provided helpful structure to the process.

Summary of Findings

The systematic review found evidence that MCIs, both with and without a cognitive component, benefit cognitive functioning, with improvements observed on measures of global cognition. Of the studies that assessed specific cognitive domains, Van de Rest et al. (2014) reported improvement in information processing speed from an MCI without a cognitive component; however, other studies found the inclusion of a cognitive component intervention resulted in additional improvements in visuospatial skills and verbal fluency (Belleville et al., 2023; Liang et al., 2021; Ng et al., 2018; Romera-Liebana et al., 2018; Yu et al., 2020).

In terms of psychosocial outcomes, the main outcomes assessed were depression and quality of life, with only one study considering anxiety- or self-efficacy-related outcomes. The inclusion of a psychosocial component within the MCI appeared to increase the likelihood of achieving a significant reduction in symptoms of depression. Significant improvements in quality-of-life ratings were reported less frequently; these improvements were not linked to psychological components interventions within the MCIs.

Only one previous systematic review has focussed on the psychological outcomes of frailty MCIs. In the review by Dedeyne et al. (2017) only one of the 12 included studies reported cognitive outcomes (Van De Rest et al., 2014; also included in present systematic review) and only four reported psychosocial outcomes, which demonstrated inconsistent effects. Dedeyne et al. reported that the results for both sets of outcomes were inconclusive. The presented review, however, included 10 studies that assessed cognitive outcomes and 12 that assessed psychosocial outcomes, from which enough data could be extracted to draw conclusions on the effects. Thus, this review presents a new understanding of the cognitive and psychosocial outcomes of MCIs and contributes significantly to the understanding of the effects of MCIs for frail and pre-frail individuals.

Given the apparent benefits of including both cognitive and psychosocial component interventions within MCIs for frailty, CST was identified as a promising candidate for inclusion in MCIs as it aims to target both cognitive and psychosocial functioning (Clare & Woods, 2004) and is known as an efficacious, cost-effective and intervention for people with dementia, recommended by the National Institute for Health and Care Excellence (NICE; Aguirre et al., 2013; Comas-Herrera & Knapp, 2016; NICE, 2018). Before its adoption into an MCI for stroke survivors, CST first needed to be adapted to better suit a stroke survivor population. It is recommended that interventions undergo adaptations before they are used within a new context

(Moore et al., 2021), and there are significant differences between stroke survivors and those with dementia, for whom CST was originally developed, which required attention (Caplan, 2006; Dickerson & Atri, 2014). For example, stroke has a sudden and acute onset, requiring emergency medical intervention and can affect a wide range of individuals in terms of age. Stroke survivors may experience impairments in various abilities (sensory, motor, perceptual and cognitive) with varying degrees of severity, and although some of these difficulties may persist, others may improve over time with appropriate rehabilitation. Dementia, on the other hand, has a more gradual onset of difficulties and typically affects older adults. Cognitive and behavioural difficulties usually emerge first and progressively worsen over time in relatively predictable patterns depending on the type of dementia. These difficulties will not improve with intervention, but deterioration can be slowed.

The adaptation process reported in Chapter 3 identified new elements (emphasis on learning new strategies, opportunities for vicarious experiences of success, positive reinforcement and consideration of values) to introduce into CST for stroke (sCST). PPI representatives also suggested that some of the original elements of CST (use of reminiscence and physical movement) should not be carried into sCST. However, many core elements regarded as key for CST were retained.

There remained uncertainties about how stroke survivors would receive the intervention, so a small-scale acceptability pilot was conducted. Two participants attended six sample sessions of sCST, and two more completed all eight sessions. These four participants completed the follow-up interview. Several sub-themes within each of the seven constructs of the TFA were identified from the data. Key strengths of the intervention's acceptability were that it was found to be enjoyable, and the social interaction it provided was not only liked but also identified as beneficial, as it provided opportunities to learn more about the consequences of stroke, how others cope, and to feel less alone in their recovery. Encouragingly, many of the positives highlighted by participants (such as the social interaction and improvements to mood and confidence) mirror those reported by people with dementia who attended the original CST programme (Gibbor et al., 2021). This supports the fidelity of sCST to the original intervention and suggests it has retained elements critical to its effectiveness.

Areas for improvement that were identified included careful consideration of the location of the intervention, the size and mix of group members, and the level of difficulty provided by the activities. Again, the concerns raised about the level of difficulty bear similarity to concerns raised about the original CST for dementia (Gibbor et al., 2021). This provides some reassurance that this issue did not arise due to a poor

fit to the new population but instead as a reflection of an ongoing challenge in delivering CST-informed interventions.

Based on both the findings and the experience of delivering the intervention, some further refinements may be beneficial before further evaluation takes place. Firstly, in the interviews, the participants did not refer much to the efforts to identify values within the sessions in line with the new values principle that was introduced to sCST. This might suggest that further work is needed to develop this principle and guidance for how it can be incorporated into each session. Secondly, not many participants reported reading the take-home information sheets provided or completing the optional activities at home, with one participant suggesting more could be done to motivate engagement with these. This suggestion should be taken forward; more PPI work may be useful in determining how to better understand the barriers and, therefore, better encourage engagement with the take-home information and activities. Finally, for those delivering the intervention with prior experience of CST, it may be helpful to develop further guidance about the differences in delivering CST and sCST. For example, during one session, a participant discussed a recent holiday they had been on. In a CST session, this might be used as a prompt to discuss people's favourite holidays from their lives to encourage reminiscence. In sCST, however, this discussion was used to prompt conversation about how participants feel about going on holiday and how they might practically cope with or adapt their holidays in light of their stroke.

Strengths and Limitations

A key strength of this thesis portfolio is that it aligns with the Medical Research Council (MRC) framework for developing and evaluating complex interventions and followed the ADAPT guidance for adapting interventions for a new context. In line with the *core elements* of the MRC framework, this portfolio carefully considers the context of the interventionand engages stakeholders. Clear and detailed reporting of the intervention development process is important, particularly in stroke care, where the quality of such reporting is lacking (Redfern et al., 2006; Walker et al., 2017). This newly adapted intervention was then evaluated, as suggested by the MRC framework and ADAPT guidance. Acceptability is a key aspect of feasibility that should be evaluated in these early stages of intervention development (Skivington et al., 2021).

Another strength is the meaningful use of PPI. A stroke survivor and her husband were involved in this work from an early stage. The PPI involvement in the intervention development process has been described in detail (Chapter 3). However, these representatives also provided consultation on other aspects of this research such

as providing feedback on the language and presentation of study materials (e.g. the research advertisement poster and participant information sheet). PPI is recommended by the National Institute for Health and Care Research (NIHR; 2024) and aligns with the *nothing about us without us* movement (Charlton, 1998). However, PPI in stroke research is not taking place regularly enough and, when it does, it is not always well-reported (Da Cruz Peniche et al., 2024). A further strength of the PPI in this work is that the husband of a stroke survivor was consulted; unfortunately, family members and carers of stroke survivors are particularly underutilised in stroke PPI (Da Cruz Peniche et al., 2024).

Further strengths and limitations within the systematic review, intervention development and empirical research papers are considered below.

Systematic Review

Although it is not the first to explore cognitive and psychosocial outcomes of MCIs for frail individuals, this systematic review it is the first, to our knowledge, that has been able to draw conclusions on these outcomes. This review, therefore, contributes significantly to frailty research as it fills a previous gap in the knowledge. To our knowledge, the last systematic review to consider these outcomes following MCIs for frailty took place eight years ago (Dedeyne et al., 2017); since then, more MCI research has occurred, and more researchers have evaluated cognitive and psychosocial outcomes. This is encouraging progress, and the current systematic review will further strengthen the rationale for including psychological outcomes and psychological interventions within future frailty research.

Although five databases were searched to identify papers for inclusion within this systematic review, it must be noted that these searches took place in May 2024. Additional studies meeting inclusion criteria have been published since then (e.g. Murukesu et al., 2024). However, it was not possible to re-run the search and include new papers in the review within the time frame available to complete this thesis portfolio. Murukesu et al. (2024) found that their MCI consisting of cognitive stimulation, exercise, dietary counselling and psychosocial support resulted in significantly greater improvements than their usual care control group in global cognition (assessed via the Mini-Mental State Examination), attention (Digit Span and Trail Making Test A) and verbal memory (Rey Auditory Verbal Learning Test). The inclusion of this study would have added more evidence to support the benefits of MCIs in memory and attention domains. However, when taken alongside the data already included in the systematic review, evidence for these domains remains inconsistent, so

it is unlikely that the inclusion of this paper would have affected the overall conclusions.

Another possible limitation of the searches concerns the fact that there is no clear consensus in the language used to describe MCIs; other terms that have been used are 'multi-domain intervention' and 'combined intervention'. Therefore, it is possible that the search terms used were not broad enough to capture all relevant studies. To help account for this, it would have been helpful to identify studies for inclusion via additional methods, such as reviewing reference lists of included studies or other systematic reviews of MCIs.

Finally, it is important to emphasise that five of the 17 papers were deemed to have a high risk of bias. This means the results from these papers should be interpreted with caution. The key area of weakness was the blinding of participants and those delivering the interventions; for at least one of these groups, all included papers either did not report their blinding procedures (or lack thereof) or reported that blinding was not possible. This aligns with research findings that blinding is often poorly reported in randomised controlled trials (RCTs) for non-pharmacological interventions (Boutron et al., 2007). It has been suggested that this may be due to limited awareness of the possible methods of blinding, or economic barriers to implementing such methods, but it has also been considered that blinding in non-pharmacological RCTS may be more difficult than pharmacological RCTs.

Intervention Adaptation

This paper presents a novel adaptation of CST for stroke survivors; to the authors' knowledge, CST has never before been adapted for this population. This adaptation followed a theory- and evidenced-based approach and, as a result, has presented the theoretical justifications for the adaptations made and proposed mechanisms for change. This is something which has been lacking in previous stroke intervention development studies (Redfern et al., 2006). However, this paper could have been strengthened further by collecting and analysing feedback from stakeholders more formally, such as via interviews or questionnaires and qualitative data analysis. Indeed, this has been recommended in some intervention development guidance (O'Cathain et al., 2019). Limitations in time and budget made this unfeasible. Nevertheless, a broad range of stakeholders were involved in the intervention adaptation: a stroke survivor and carer; an Assistant Psychologist who facilitated group interventions for stroke survivors as part of their role; Clinical Psychologists and Neuropsychologists specialising in stroke; and a Consultant in Stroke Medicine with

published research relating to frailty in stroke survivors. In future work, involving and seeking additional opinions from Occupational Therapists, Speech and Language Therapists, service leads and commissioners would be beneficial.

Empirical Research

This paper focused on understanding the acceptability of the newly developed sCST intervention. Acceptability is an important aspect of feasibility (Skivington et al., 2021) and is thought to be associated with treatment adherence and outcomes (Nastasi et al., 2000; Sekhon et al., 2017). The focus on acceptability can be considered a strength in and of itself, however, an additional strength is the application of the TFA (Sekhon et al., 2017) as a model for evaluating acceptability. There has previously been inconsistency in how acceptability has been conceptualised and operationalised, but this framework provides a clear theoretical understanding of acceptability and a systematic approach to its assessment.

Another strength of this research is the framework approach to qualitative data analysis. This approach facilitated the application of the TFA. Gale et al (2013) highlight the benefits of the framework approach. For example, the flexibility of using both deductive and inductive coding allows this approach to provide a consistent framework of themes to facilitate the comparison of acceptability results between studies whilst still allowing new themes or subthemes to emerge. This approach also facilitates the identification of patterns in the data (both within and between participants) and of areas of diversity in opinions. It can also be used to group together meaningful clusters of participants (such as by age, type of stroke or time since stroke). However, due to the small sample size, grouping the participants in this was unnecessary, as it was feasible to present each participant's data individually within the framework matrix.

The small sample may be considered a weakness of this research; data saturation was not achieved during the qualitative analysis as changes to the codebook were still being made during the coding of the fourth and final transcript (Guest et al., 2006). However, Francis et al. (2010) noted that theory-based interview research, which uses pre-defined constructs for coding (e.g. deductive coding according to the TFA) may require more specific principles for determining data saturation. They recommend that a minimum of 10 interviews be conducted initially, then multiples of three more until no new themes emerge. However, it is not possible to apply this method in a small-scale pilot intervention study such as this, and we were unable to recruit more participants within the available timeframe.

However, the concept and importance of data saturation has been criticised (Braun & Clarke, 2021). An alternative model of assessing sample size sufficiency has been proposed; *information power* (Malterud et al., 2016). *Information power* relates to the amount and relevance of the information provided by the sample concerning the specific research question, and it depends on five factors: the aim of the study, sample specificity, use of established theory, quality of dialogue and analysis strategy. This study's narrow research question, recruitment of participants with highly specific characteristics relevant to the research question, and application of the TFA all contribute to higher information power, reducing the requirement for a larger sample. Similarly, this study's research question, methods and data analysis were informed by the philosophical paradigm of *pragmatism*, which emphasises identifying participants who are likely to provide useful, relevant and practical information (Kelly & Cordeiro, 2020). The participants recruited were members of the target population for this intervention (should it be adopted into clinical practice), making their opinions highly relevant.

Beets et al. (2021) also discuss sample size in their commentary on pilot and feasibility studies. They note clear benefits to using small samples in preliminary pilots of new interventions, of which the potential ethical challenges are unknown; smaller-scale pilots require fewer resources, pose less potential risk and inform modifications that may be required before larger-scale trials occur. In this commentary, Beets et al. also address the issue of pilot interventions being delivered by those who developed them, which is another potential limitation of this research. Although they explain that having the developer of an intervention deliver the pilot could potentially bias findings relating to feasibility and acceptability, there are also benefits. Intervention developers are better placed to adapt and respond flexibly in the moment during a pilot, and this experience helps them to understand what further adaptations are required prior to a larger-scale pilot.

Another potential limitation of the sample relates to the potential for a broad range in cognitive ability. Cognitive impairment was operationalised within the inclusion criteria as evidence of impairment in one or more cognitive domain on a standardised cognitive screening or assessment tool. This means that individuals with difficulty in only one cognitive domain and individuals with several difficulties across multiple domains were eligible to participate. Although this may explain the differences in the perceived difficulty of activities by different participants, it must be noted that no participants commented directly on the different levels of ability among the group members. All participants commented on the perceived benefits of meeting other

stroke survivors, with some explaining it had been interesting to learn how stroke affects everyone differently. Interestingly, research in adult learners has demonstrated that mixed-ability learning groups are perceived more positively than more homogenous groups (Faris, 2009). Perhaps a similar study should be replicated in to determine stroke survivors' views on being part of mixed ability group interventions.

Another key limitation of this research is that it only considers retrospective acceptability. The TFA proposes that acceptability can be assessed both prospectively and retrospectively (Sekhon et al., 2017) and it is recommended that 'acceptability can and should be assessed prior to engaging in an intervention' (Sekhon et al., 2017, p. 9). It has been found that prospective acceptability of an intervention contributes to individuals refusing to participate in research trials (Sekhon et al., 2021); it could, therefore, be reasonably assumed that prospective acceptability might contribute to intervention refusal in clinical contexts, too. That said, retrospective assessment is beneficial for providing an understanding of what the participants' experience was like and whether they might want to continue if given the option (Sekhon et al., 2017). This small-scale pilot aimed to gain an understanding of how this intervention may need to be adapted based on participants' experience of completing the sample sessions; retrospective acceptability was, therefore, deemed most relevant for these specific aims. Future, larger-scale pilots should certainly seek to evaluate both prospective and retrospective acceptability. This is likely more feasible using the quantitative "TFA Questionnaire" measure rather than qualitative methods.

The TFA questionnaire was used in this study to support qualitative findings, but it must be acknowledged that the online, digital format did not work well; the responses received outnumbered the participants — not just once, but twice. Some participants may have completed the questionnaire more than once, either not remembering they had already completed it or due to other challenges with the usability of the online platform. In hindsight, it may have been helpful to have piloted the questionnaire with the PPI representatives, as this may have shed light on some of these issues earlier. There may have been alternative, more user-friendly platforms, or paper and pen questionnaires could have been used instead.

Implications and Future Research Directions

The systematic review found that multicomponent interventions for frailty improve cognitive and psychosocial functioning. This suggests a rationale for using such interventions within clinical settings and that there may be a role for Clinical Psychologists within frailty management. Clinical Psychologists could assess and monitor cognitive and psychosocial functioning in the context of frailty and contribute

to decisions about appropriate interventions. This review also suggests that there should be more emphasis on the involvement of psychologists in frailty research to design and develop interventions, particularly the cognitive and psychosocial components of MCIs found to boost psychological benefits. Psychologists also have an important role in frailty research to better establish the associations between frailty, cognition and psychosocial functioning. Notably, there has been a relative lack of consideration of the association between frailty and anxiety; this needs to be explored further. Furthermore, other psychological theories or concepts, such as self-efficacy, may be important in understanding how to advance frailty management.

Self-efficacy (Bandura, 1977) is a significant predictor of frailty status in older adults (Ageez et al., 2024; Hladek et al., 2020, 2021; X. Li et al., 2022), including in stroke survivors (Aminu et al., 2021). It is surprising, therefore, that researchers exploring the utility of MCI interventions for frailty are not more routinely considering this in the design or selection of their interventions and outcome measures. Self-efficacy is already known to be important in stroke rehabilitation, and is a recommended target for interventions. (Intercollegiate Stroke Working Party, 2023). Therefore, it may be that frailty management researchers could learn from stroke rehabilitation practices. Nonetheless, self-efficacy is a concept that requires further attention in frailty prevention and management, with more research required to understand how it can be most effectively targeted. Again, Clinical Psychologists are well placed to assist with, if not lead, this research. It should also be noted that loneliness, another psychosocial concept, is a possible mediator of the effect of self-efficacy on frailty (X. Li et al., 2022), further supporting the need for more psychological involvement within this field of research.

Some of the new elements introduced into sCST were selected to improve self-efficacy in intervention recipients, and there was promising feedback suggesting this aim was realised. However, more research is required to establish the effectiveness of this intervention, not only concerning self-efficacy, but also cognition, quality of life, depression and anxiety. It will also be helpful for sCST be adopted into a broader frailty prevention MCI, the outcomes of which should also be evaluated. Although this intervention was developed with frailty prevention post-stroke in mind, there might also be broader clinical applications within stroke care. Most research into interventions post-stroke has focused on the first 12 months of recovery (Allida et al., 2020), leaving a gap in the understanding about the types of interventions that could be beneficial beyond this period. The James Lind Alliance's number one priority for research in stroke rehabilitation and long-term care involves determining effective

psychological interventions (James Lind Alliance, 2025a). Given that CST is widely considered effective in those with dementia (a progressive condition), sCST might be a suitable candidate intervention for those in the chronic phase of stroke recovery, six months post-stroke and beyond (Bushnell et al., 2015).

Finally, the acceptability pilot study added to the existing literature that demonstrates the TFA to be a useful approach to evaluating acceptability (e.g., Gerards et al., 2022; Keyworth et al., 2022; Murphy & Gardner, 2019; Musanje et al., 2023; O'Connor et al., 2023). Here, although inductive coding was carried out in addition to deductive coding, no outlying themes were identified. Future researchers exploring the acceptability of healthcare interventions, such as those for frailty or stroke rehabilitation, should consider using the TFA. This framework has the potential to increase the consistency of qualitative acceptability research (Hammarberg et al., 2016; Noble & Smith, 2015) and facilitate the triangulation of acceptability data collected at different time points or from different samples (Arksey & T.Knight, 1999). Using the TFA to inform deductive coding means that it will be easier to compare findings with other studies that have also used this method; this will be helpful if researchers want to evaluate the success of any modifications made to interventions or compare the acceptability of two candidate interventions for a particular purpose and population.

Conclusions

In conclusion, this thesis portfolio found that MCIs for frailty can improve cognitive and psychosocial functioning. MCIs consisting of components such as exercise and nutrition can improve information processing speed and quality of life ratings. However, the addition of cognitive and psychosocial intervention components can lead to further benefits to visuospatial skills, verbal fluency and depression symptoms. Furthermore, it was found that sCST, a newly developed adaptation of CST for stroke survivors, is generally enjoyed and perceived by participants to be beneficial. Some areas for improvement include the location of the intervention, the clarity with which the purpose of the intervention is communicated, and the level of difficulty or challenge provided. Encouragingly, though, much of this feedback was comparable to that received from individuals with dementia who had attended a programme of original CST, which has been adopted internationally due to its beneficial effects. sCST appears to be a promising intervention for adoption into a MCI for preventing frailty in stroke survivors.

There are several implications for this work in clinical practice and research. There is a clear rationale for the involvement of Clinical Psychologists within frailty management research and clinical services; firstly, due to the associations between

frailty and psychological functioning, which have been widely reported. Secondly, due to the need for MCIs to include psychological component interventions. In particular, there is a need to further establish the links between frailty, cognition, depression, anxiety and self-efficacy. Self-efficacy is known to be associated with frailty but may be a key concept in understanding how to make frailty interventions more effective. Self-efficacy is already known to be important in stroke rehabilitation and, as such, informed some of the adaptations made when developing sCST. However, more refinements and further research are required to establish the effectiveness of this intervention on a range of different outcome measures before it can be adopted clinically, either in frailty prevention or broader post-stroke care.

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² This list only contains references from the Introduction and Discussion chapters and the Appendices. For references cited in Chapters 2-4, please refer to the corresponding reference lists.

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Appendices

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Appendix A – Frontiers in Aging Author Guidelines

Article types

Systematic Review

Systematic Review articles present a synthesis of previous research, and use clearly defined methods to identify, categorize, analyze and report aggregated evidence on a specific topic. Included in this article type are meta-syntheses, meta-analyses, mapping reviews, scoping reviews, systematic reviews, and systematic reviews with a metaanalysis. Systematic Review articles are peer-reviewed, have a maximum word count of 12,000 and may contain no more than 15 Figures/Tables. Authors are required to pay a fee (A-type article) to publish a Systematic Review article. Systematic Reviews should: clearly define the research question in terms of population, interventions, comparators, outcomes and study designs (PICOS), and state which reporting guidelines were used in the study. For design and reporting, systematic reviews must conform to the reporting guidelines (e.g., PRISMA, Cochrane, Campbell), and include the PRISMA flow diagram http://prisma-statement.org/prismastatement/flowdiagram.aspx (if applicable), as well as funding information (if no specific funding to carry out the research, please state so). Systematic Reviews should have the following format: 1) Abstract, 2) Introduction, 3) Methods (including study design; participants; interventions; comparators; systematic review protocol; search strategy; data sources; study sections and data extraction; data analysis), 4) Results (including a flow diagram of the studies retrieved for the review; study selection and characteristics; synthesized findings; assessment of risk of bias), 5) Discussion (including summary of main findings; limitations; conclusions). Systematic Reviews must not include unpublished material (unpublished/original data, submitted manuscripts, or personal communications) and may be rejected in review or reclassified, at a significant delay, if found to include such content.

Writing and formatting

Title

The title should be concise, omitting terms that are implicit and, where possible, be a statement of the main result or conclusion presented in the manuscript. Abbreviations should be avoided within the title.

Witty and creative titles are welcome, but only if relevant and within measure. Consider if a title meant to be thought-provoking might be misinterpreted as offensive or

alarming. In extreme cases, the editorial office may veto a title and propose an alternative.

Authors should avoid:

- titles that are a mere question without giving the answer
- unambitious titles, for example starting with 'Towards,' 'A description of,' 'A characterization of or 'Preliminary study on'
- vague titles, for example starting with 'Role of', 'Link between', or 'Effect of' that do not specify the role, link, or effect
- including terms that are out of place, for example the taxonomic affiliation apart from species name.

Abstract

As a primary goal, the abstract should make the general significance and conceptual advance of the work clearly accessible to a broad readership. The abstract should be no longer than a single paragraph and should be structured, for example, according to the IMRAD format. For the specific structure of the abstract, authors should follow the requirements of the article type or journal to which they're submitting. Minimize the use of abbreviations and do not cite references, figures or tables.

For clinical trial articles, please include the unique identifier and the URL of the publicly accessible website on which the trial is registered.

Manuscript length

We encourage you to closely follow the article word count lengths given in the 'Article types' page of the journals. The manuscript length includes only the main body of the text, footnotes, and all citations within it, and excludes the abstract, section titles, figure and table captions, funding statement, acknowledgments, and references in the bibliography. Please indicate the number of words and the number of figures and tables included in your manuscript on the first page.

Sections

The manuscript is organized by headings and subheadings. The section headings should be those appropriate for your field and the research itself. You may insert up to 5 heading levels into your manuscript (i.e.,: 3.2.2.1.2 Heading Title).

For Original Research articles, it is recommended to organize your manuscript in the following sections or their equivalents for your field.

Introduction

Succinct, with no subheadings.

Materials and methods

This section may be divided by subheadings and should contain sufficient detail so that when read in conjunction with cited references, all procedures can be repeated. For experiments reporting results on animal or human subject research, an ethics approval statement should be included in this section (for further information, see the 'Bioethics' section of our policies and publication ethics.)

Results

This section may be divided by subheadings. Footnotes should not be used and must be transferred to the main text.

Discussion

This section may be divided by subheadings. Discussions should cover the key findings of the study: discuss any prior research related to the subject to place the novelty of the discovery in the appropriate context, discuss the potential shortcomings and limitations on their interpretations, discuss their integration into the current understanding of the problem and how this advances the current views, speculate on the future direction of the research, and freely postulate theories that could be tested in the future.

For further information, please check the descriptions defined in the journal's 'Article types' page, in the 'For authors' menu on every journal page.

Language editing

Frontiers requires manuscripts submitted to meet international English language standards to be considered for publication.

For authors who would like their manuscript to receive language editing or proofreading to improve the clarity of the manuscript and help highlight their research, we recommend the language-editing services provided by the following external partners.

Note that sending your manuscript for language editing does not imply or guarantee that it will be accepted for publication by a Frontiers journal. Editorial decisions on the scientific content of a manuscript are independent of whether it has received language editing or proofreading by these partner services or other services.

Editage

We recommend the language-editing service provided by our external partner Editage. These services may be particularly useful for researchers for whom English is not the primary language. They can help to improve the grammar, syntax, and flow of your manuscript prior to submission. Frontiers' authors will receive a 10% discount by visiting the following link: **editage.com/frontiers**

The Charlesworth Group

We recommend the Charlesworth Group's author services, who has a long-standing track record in language editing and proofreading. This is a third-party service for which Frontiers' authors will receive a 10% discount by visiting the following link: www.cwauthors.com/frontiers

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Language style

The default language style at Frontiers is American English. If you prefer your article to be formatted in British English, please specify this on the first page of your manuscript. For any questions regarding style, we recommend authors to consult the **Chicago**Manual of Style

Inclusive language guidelines

Frontiers is an inclusive publisher and we ask that all submissions are in line with our inclusive language policy. When preparing your manuscript for submission, take a mindful approach towards personal biases and a concerted effort to limit their influence. Authors should remove any suggestion or implication of superiority or inferiority of one person over another based on age, gender, race, ethnicity, culture, sexual orientation, disability, religion, or socio-economic class. We ask authors to use inclusive language practices and awareness of diversity, equity, and inclusion into their research and keep it at the forefront during the composition of their findings.

External guidance that may be useful is available at C4DISC's Guidelines on Inclusive Language and Images in Scholarly Communication.

Furthermore, when drafting your work, please take into account the following considerations

In general, seek to avoid

- language that could be deemed insulting, profane, or derogatory.
- descriptors that identify personal attributes such as age, gender, race, ethnicity, culture, sexual orientation, disability, or health conditions, where they are not critically relevant to the discussion.
- any form of language that suggests a particular culture or group as the default or standard.
- And where feasible:
- proactively ask individuals or groups how they would prefer to be referenced.
- adhere to the SAGER guidelines for reference to sex and gender in research.

Remember, the language we use can influence perceptions, evoke emotions, and shape perspectives. Let's work together to nurture an inclusive, respectful, and empowering discourse in science.

Guidelines for artificial intelligence and related technologies

These guidelines cover acceptable uses of generative AI technologies such as Large Language Models (ChatGPT, Jasper) and text-to-image generators (DALL-E 2, Midjourney, Stable Diffusion) in the writing or editing of manuscripts submitted to Frontiers.

Use of AI to create written or visual content

Authors should not list a generative AI technology as a co-author or author of any submitted manuscript. Generative AI technologies cannot be held accountable for all aspects of a manuscript and consequently do not meet the criteria required for authorship.

If the author of a submitted manuscript has used written or visual content produced by or edited using a generative AI technology, this use must follow all Frontiers guidelines and policies. Specifically, the author is responsible for checking the factual accuracy of any content created by the generative AI technology. This includes, but is not limited to, any quotes, citations or references. Figures produced by or edited using a generative AI technology must be checked to ensure they accurately reflect the data presented in the manuscript. Authors must also check that any written or visual content produced by or edited using a generative AI technology is free from plagiarism.

If the author of a submitted manuscript has used written or visual content produced by or edited using a generative AI technology, such use must be acknowledged in the acknowledgements section of the manuscript and the methods section if applicable. This explanation must list the name, version, model, and source of the generative AI technology.

We encourage authors to upload all input prompts provided to a generative AI technology and outputs received from a generative AI technology in the supplementary files for the manuscript.

The entire document should be single-spaced and must contain page and line numbers in order to facilitate the review process. The manuscript should be written using either Word or LaTeX. See above for templates.

Abbreviations and nomenclatures

The use of abbreviations should be kept to a minimum. Non-standard abbreviations should be avoided unless they appear at least four times, and must be defined upon first use in the main text. Consider also giving a list of non-standard abbreviations at the end, immediately before the acknowledgments.

Equations should be inserted in editable format from the equation editor.

Italicize gene symbols and use the approved gene nomenclature where it is available. For human genes, please refer to the HUGO Gene Nomenclature Committee (HGNC). New symbols for human genes should be submitted to the HGNC here. Common alternative gene aliases may also be reported, but should not be used alone in place of the HGNC symbol. Nomenclature committees for other species are listed here. Protein products are not italicized.

We encourage the use of Standard International Units in all manuscripts.

Chemical compounds and biomolecules should be referred to using systematic nomenclature, preferably using the recommendations by the International Union of Pure and Applied Chemistry (IUPAC).

Astronomical objects should be referred to using the nomenclature given by the International Astronomical Union (IAU) provided here

Life Science Identifiers (LSIDs) for ZOOBANK registered names or nomenclatural acts should be listed in the manuscript before the keywords. An LSID is represented as a uniform resource name (URN) with the following format: urn:lsid:<Authority>:<Namespace>:<ObjectID>[:<Version>]

For more information on LSIDs please see the 'Code' section of our policies and publication ethics.

Enhancing search engine optimization (SEO)

There are a few simple ways to maximize your article's discoverability and search results.

- Include a few of your article's keywords in the title of the article
- Do not use long article titles
- Pick 5-8 keywords using a mix of generic and more specific terms on the article subject(s)
- Use the maximum amount of keywords in the first two sentences of the abstract
- Use some of the keywords in level 1 headings

References

Preparing and formatting references

Submissions to Frontiers must be grounded in relevant and up to date peer-reviewed, academic research, and this should be reflected in the accompanying reference lists.

Authors are welcome to use online referencing tools in preparation of their manuscript. Some useful resources include RefMe, Zotero, and Mendeley.

- The citation of non-academic and non-peer-reviewed sources (e.g. blog posts, website content), as well as anonymous sources or commercial websites should be avoided or kept to a minimum
- Authors should avoid citing content that is not directly relevant to the scope of the article and the journal
- Reference lists should reflect the current status of knowledge in the field, avoid bias, and not include a high proportion of citations to the same authors or sources, school of thought, etc.
- The length of the reference list should be appropriate depending on the article type, covering the relevant literature through sufficient referencing
- Authors should ensure that references are accurate, that all links are accessible, and that the citations/references adhere to the reference styles outlined below

Frontiers' journals use one of two reference styles, either Harvard (author-date) or Vancouver (numbered). These formats should be adhered to for the in-text citations

and the reference lists. Please check our help center to find the correct style for the journal to which you're submitting.

- All citations of published works in the text, figures, or tables must be in the reference list and vice-versa.
- The names of the first six authors followed by et al. and the DOI (when available) should be provided.
- Given names of authors should be abbreviated to initials (e.g. Smith, J., Lewis, C.S., etc.).
- The reference list should only include articles that are published or accepted.
- Unpublished data, submitted manuscripts, or personal communications should be cited within the text only, for article types that allow such inclusions. Where additional details are available, these will be included as footnotes.
- For accepted but unpublished works use 'in press' instead of page numbers.
- Data sets that have been deposited to an online repository should be included in the reference list. Include the version and unique identifier when available.
- Personal communications should be documented by a letter of permission.
- Website URLs should be included as footnotes.
- Any inclusion of verbatim text must be contained in quotation marks and should clearly reference the original source.
- Preprints can be cited provided that a DOI or archive URL is available, and the citation clearly mentions that the contribution is a preprint. If a peer-reviewed journal publication for the same preprint exists, the official journal publication is the preferred source. See the preprints section for each reference style below for more information.

Harvard reference style (author-date)

Reference examples for Frontiers' journals using the Harvard referencing system can be found below. For examples of other sources, and for general questions regarding the Harvard reference style, please refer to the **Chicago Manual of Style.**

- References should include the full last name and first name initials of the first six authors, followed by et al. and the year of publication in brackets.
- Alphabetical order is followed for the reference list.

Vancouver reference style (numbered)

Reference examples for Frontiers' journals using the Vancouver referencing system can be found below. For more examples of citing other documents and general questions regarding the Vancouver reference style, please refer to Citing Medicine

- In-text citations in the Vancouver reference style should be numbered consecutively in order of appearance in the text and identified by Arabic numerals in parenthesis.
- Use square brackets for physics and mathematics articles.
- The abbreviation 'Ref' should not be used, e.g.: [e.g., (1)] should NOT read [e.g. Ref. (1)].
- Style for comparing a citation should follow the number format, e.g. [cf. (1)]. The same applies when using 'see', e.g. [see (46)].
- References should be numbered and listed chronologically, according to the order they appear in the text.

Citation of retracted articles

Authors are responsible for ensuring the integrity of the references they cite, including verifying whether any article they intend to cite has been retracted. Citing retracted articles can undermine the credibility of your manuscript and should only occur where it is essential for the context of your discussion.

Guidelines for citing retracted articles:

- 1. **Verification:** Authors are responsible for checking the status of all cited works before submission. Lists of retracted articles can often be found in databases such as PubMed and the Retraction Watch database. Authors can check the version of the record which is expected to include a visible notice of retraction.
- 2. **Disclosure:** If it is necessary to cite a retracted article, authors must clearly indicate the retraction status in the reference list.
- 3. **Justification:** Authors are encouraged to discuss the reasons for citing the retracted article in the manuscript, explaining its relevance and the implications of its retracted status on the discussion.

Adhering to these guidelines is considered best practice as it helps maintain the scientific integrity of the published literature and ensures that all references within the manuscript contribute validly to the scholarly discourse. Ensuring the accuracy and transparency of citations protects authors from inadvertently perpetuating misinformation and supports the overall trustworthiness of research publications.

Acknowledgements

This is a short text to acknowledge the contributions of specific colleagues, institutions, or agencies that aided the efforts of the authors. Should the content of the manuscript have previously appeared online, such as in a thesis or preprint, this should be mentioned here, in addition to listing the source within the reference list.

Acknowledgements are designed to recognize individuals directly involved in the research. We request that authors avoid personal expressions of gratitude toward figures or entities unrelated or indirectly related to the production of the manuscript. While such acknowledgements are understood to be significant to the authors, they are considered indirectly involved in the research unless they pertain to specific research activities. It remains the responsibility of the authors to ensure that these guidelines are adhered to in the final publication.

Templates

If working with Word please use our Word templates. If you wish to submit your article as LaTeX, we recommend our LaTeX templates.

For LaTeX files, please ensure all relevant manuscript files are uploaded: .tex file, PDF, and .bib file (if the bibliography is not already included in the .tex file).

During the interactive review, authors are encouraged to upload versions using track changes. Editors and reviewers can only download the PDF file of the submitted manuscript.

Figures, tables, and images

Figures, tables, and images: rights and permissions

All figures, tables, and images will be published under a Creative Commons CC-BY license, and permission must be obtained for use of copyrighted material from other sources (including re-published/adapted/modified/partial figures and images from the internet). It is the responsibility of the authors to acquire the licenses, follow any citation instructions requested by third-party rights holders, and cover any supplementary charges.

For additional information, please see the 'Image manipulation' section of our policies and publication ethics.

Figures and images: style guidelines

We require figures to be submitted individually, in the same order as they are referred to in the manuscript; the figures will then be automatically embedded at the end of the

submitted manuscript. Ensure that each figure is mentioned in the text and in numerical order.

For figures with more than one panel, panels should be clearly indicated using labels (A), (B), (C), (D), etc. However, do not embed the part labels over any part of the image. These labels will be replaced during typesetting according to Frontiers' journal style. For graphs, there must be a self-explanatory label (including units) along each axis.

For LaTeX files, figures should be included in the provided PDF. In case of acceptance, our production office might require high-resolution files of the figures included in the manuscript in EPS, JPEG or TIF/TIFF format.

To upload more than one figure at a time, save the figures (labeled in order of appearance in the manuscript) in a zip file and upload them as 'Supplementary material presentation.'

Please note that figures not in accordance with the guidelines will cause substantial delay during the production process.

Captions

Captions should be preceded by the appropriate label, for example 'Figure 1.' Figure captions should be placed at the end of the manuscript. Figure panels are referred to by bold capital letters in brackets: (A), (B), (C), (D), etc.

Image size and resolution requirements

Figures should be prepared with the PDF layout in mind. Individual figures should not be longer than one page and with a width that corresponds to one column (85 mm) or two columns (180 mm).

All images must have a resolution of 300 dpi at final size. Check the resolution of your figure by enlarging it to 150%. If the image appears blurry, jagged, or has a stair-stepped effect, the resolution is too low.

The text should be legible and of high quality. The smallest visible text should be no less than eight points in height when viewed at actual size.

Solid lines should not be broken up. Any lines in the graphic should be no smaller than two points wide.

Please note that saving a figure directly as an image file (JPEG, TIF) can greatly affect the resolution of your image. To avoid this, one option is to export the file as PDF, then convert into TIFF or EPS using a graphics software.

Format and color image mode

The following formats are accepted: TIF/TIFF (.tif/.tiff), JPEG (.jpg), and EPS (.eps) (upon acceptance). Images must be submitted in the color mode RGB.

Images of chemical structures

Chemical structures should be prepared using ChemDraw or a similar program. If working with ChemDraw please use our ChemDraw template. If working with another program please follow the guidelines below.

- Drawing settings: chain angle, 120° bond spacing, 18% width; fixed length, 14.4 pt; bold width, 2.0 pt; line width, 0.6 pt; margin width, 1.6 pt; hash spacing, 2.5 pt. Scale 100% Atom Label settings: font, Arial; size, 8 pt
- Assign all chemical compounds a bold, Arabic numeral in the order in which the compounds are presented in the manuscript text.

Table requirements and style guidelines

Tables should be inserted at the end of the manuscript in an editable format. If you use a word processor, build your table in Word. If you use a LaTeX processor, build your table in LaTeX. An empty line should be left before and after the table.

Table captions must be placed immediately before the table. Captions should be preceded by the appropriate label, for example 'Table 1.' Please use only a single paragraph for the caption.

Ensure that each table is mentioned in the text and in numerical order.

Large tables covering several pages cannot be included in the final PDF for formatting reasons. These tables will be published as supplementary material.

Tables which are not according to the above guidelines will cause substantial delay during the production process.

During production, tables will be formatted according to Frontiers' house style. Here is an example of a formatted table.

Accessibility

We encourage authors to make the figures and visual elements of their articles accessible for the visually impaired. Effective use of color can help people with low visual acuity, or color blindness, understand all the content of an article.

These guidelines are easy to implement and are in accordance with the W₃C Web Content Accessibility Guidelines (WCAG 2.1), the standard for web accessibility best practices.

Ensure sufficient contrast between text and its background

People who have low visual acuity or color blindness could find it difficult to read text with low contrast background color. Try using colors that provide maximum contrast.

WC3 recommends the following contrast ratio levels:

- Level AA, contrast ratio of at least 4.5:1
- Level AAA, contrast ratio of at least 7:1

You can verify the contrast ratio of your palette with these online ratio checkers:

- WebAIM
- Color Safe

Avoid using red or green indicators

More than 99% of color-blind people have a red-green color vision deficiency.

Avoid using only color to communicate information

Elements with complex information like charts and graphs can be hard to read when only color is used to distinguish the data. Try to use other visual aspects to communicate information, such as shape, labels, and size. Incorporating patterns into the shape fills also make differences clearer; for an example please see below:

Supplementary material

Selecting supplementary material

Data that are not of primary importance to the text, or which cannot be included in the article because they are too large or the current format does not permit it (such as videos, raw data traces, and PowerPoint presentations), can be uploaded as supplementary material during the submission procedure and will be displayed along with the published article. All supplementary files are deposited to figshare for permanent storage and receive a DOI.

Supplementary material is not typeset, so please ensure that all information is clearly presented without tracked changes/highlighted text/line numbers, and the appropriate caption is included in the file. To avoid discrepancies between the published article and

the supplementary material, please do not add the title, author list, affiliations or correspondence in the supplementary files.

File type requirements

The supplementary material can be uploaded as:

- data sheet (Word, Excel, CSV, CDX, FASTA, PDF or Zip files)
- presentation (PowerPoint, PDF or Zip files)
- image (CDX, EPS, JPEG, PDF, PNG or TIF/TIFF),
- table (Word, Excel, CSV or PDF)
- audio (MP3, WAV or WMA)
- video (AVI, DIVX, FLV, MOV, MP4, MPEG, MPG or WMV).

Technical requirements for supplementary images:

- 300 DPIs
- RGB color mode.

For supplementary material templates (LaTeX and Word), see our supplementary material templates.

Submitting information

Choosing where to submit

Open access and copyright

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Article type

We require authors to select the appropriate article type for their manuscript and to comply with the article type descriptions defined in the journal's 'Article types' page, which can be found under the 'About journal' menu in 'For authors' on every Frontiers journal page. Please pay close attention to the word count limits.

Keywords

All article types require a minimum of five and a maximum of eight keywords.

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CrossMark is a multi-publisher initiative to provide a standard way for readers to locate the current version of a piece of content. By applying the CrossMark logo Frontiers is committed to maintaining the content it publishes and to alerting readers to changes if and when they occur.

Clicking on the CrossMark logo will tell you the current status of a document and may also give you additional publication record information about the document.

For Corrigenda, General Commentaries, and Editorials, the title of your manuscript should have the following format.

- 'Corrigendum: [Title of original article]'
- General Commentaries:
- 'Commentary: [Title of original article]'
- 'Response: Commentary: [Title of original article]'
- 'Editorial: [Title of Research Topic]'

Authors and affiliations

All names are listed together and separated by commas. Provide exact and correct author names as these will be indexed in official archives. Affiliations should be keyed to the author's name with superscript numbers and be listed as follows:

- Laboratory, Institute, Department, Organization, City, State abbreviation (only for United States, Canada, and Australia), and Country (without detailed address information such as city zip codes or street names).

Example: Max Maximus1

1 Department of Excellence, International University of Science, New York, NY, United States.

Correspondence

The corresponding author(s) should be marked with an asterisk in the author list. Provide the exact contact email address of the corresponding author(s) in a separate section.

Example: Max Maximus*

maximus@iuscience.edu

If any authors wish to include a change of address, list the present address(es) below the correspondence details using a unique superscript symbol keyed to the author(s) in the author list.

Equal contributions

The authors who have contributed equally should be marked with a symbol (†) in the author list of the doc/latex and pdf files of the manuscript uploaded at submission.

Please use the appropriate standard statement(s) to indicate equal contributions:

- **Equal contribution:** These authors contributed equally to this work
- **First authorship:** These authors share first authorship
- **Senior authorship:** These authors share senior authorship
- **Last authorship:** These authors share last authorship
- **Equal contribution and first authorship:** These authors contributed equally to this work and share first authorship
- **Equal contribution and senior authorship:** These authors contributed equally to this work and share senior authorship
- **Equal contribution and last authorship: These** authors contributed equally to this work and share last authorship

Example: Max Maximus 1[†], John Smith2[†] and Barbara Smith1

†These authors contributed equally to this work and share first authorship

Consortium/group and collaborative authors

Consortium/group authorship should be listed in the manuscript with the other author(s).

In cases where authorship is retained by the consortium/group, the consortium/group should be listed as an author separated by a comma or 'and'. The consortium/group name will appear in the author list, in the citation, and in the copyright. If provided, the consortium/group members will be listed in a separate section at the end of the article.

For the collaborators of the consortium/group to be indexed in PubMed, they do not have to be inserted in the Frontiers submission system individually. However, in the manuscript itself, provide a section with the name of the consortium/group as the heading followed by the list of collaborators, so they can be tagged accordingly and indexed properly.

Example: John Smith, Barbara Smith and The Collaborative Working Group.

In cases where work is presented by the author(s) on behalf of a consortium/group, it should be included in the author list separated with the wording 'for' or 'on behalf of.'

The consortium/group will not retain authorship and will only appear in the author list.

Example: John Smith and Barbara Smith on behalf of The Collaborative Working Group.

These guidelines cover acceptable uses of generative AI technologies such as Large Language Models (ChatGPT, Jasper) and text-to-image generators (DALL-E 2, Midjourney, Stable Diffusion) in the writing or editing of manuscripts submitted to Frontiers.

Scope statement

When you submit your manuscript, you will be required to summarize in 200 words your manuscript's scope and its relevance to the journal and/or specialty section you're submitting to. The aim is to convey to editors and reviewers how the contents of your manuscript fit within the selected journal's scope.

This statement will not be published with your article if it is accepted for publication. The information will be used during the initial validation and review processes to assess whether the manuscript is a suitable fit for the chosen journal and specialty.

We encourage you to consider carefully where to submit your manuscript, as submissions to an unsuitable journal or specialty will result in delays and increase the likelihood of manuscript rejection.

If you are submitting to a Research Topic, please also clarify how your submission is suited to the specific topic

Appendix B – PRISMA Checklist

Section and Topic	Item # Checklist item		Location where item is reported	
TITLE				
Title 1 Identify the report as a systematic review.				
ABSTRACT				
Abstract	Abstract 2 See the PRISMA 2020 for Abstracts checklist.			
INTRODUCTIO	N			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Pg. 16-17	
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Pg. 17	
METHODS				
Eligibility criteria			Pg. 18-19	
Information sources	1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -		Pg. 18	
Search strategy			App. C, Pg. 177	
Selection process			Pg. 19	
Data collection process	9 Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.		Pg. 20	
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	Pg. 20	
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Pg. 20	
Study risk of bias assessment	bias reviewers assessed each study and whether they worked independently, and if applicable, details of automation to		Pg. 19-20	
Effect measures 12 Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation results.		Pg. 20		

Section and Topic	π If $m\pi$ C indevited from		Location where item is reported	
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).		
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	-	
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Pg. 20	
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Pg. 20	
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	-	
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	-	
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).		
Certainty assessment	15	5 Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.		
RESULTS				
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Pg. 20-22	
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Pg. 21-22	
Study characteristics	17	Cite each included study and present its characteristics.	Pg. 26, 29	
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Pg. 22-24	
Results of individual studies	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.		Pg. 39-45, Pg. 50-54	
Results of	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.		
syntheses	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Pg. 38-57	
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	-	

Section and Topic	The transfer of the transfer o		Location where item is reported
	20d Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.		-
Reporting biases	21	21 Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	-
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Pg. 57-60
	23b	Discuss any limitations of the evidence included in the review.	Pg. 57-60
	23c	Discuss any limitations of the review processes used.	Pg. 38
	23d	Discuss implications of the results for practice, policy, and future research.	Pg. 60-62
OTHER INFOR	OTHER INFORMATION		
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	Pg. 18
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Pg. 18
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	Pg. 18
Support 25 Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.		Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	Pg. 18
Competing interests			-
Availability of data, code and other materials Report which of the following are publicly available and where they can be found: template data collection forms; data code and other materials Report which of the following are publicly available and where they can be found: template data collection forms; data code and other materials used in the review.		-	

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71. This work is licensed under CC BY 4.0.

Appendix C – Search Strategy

CINAHL and MEDLINE

#	Query		
S21	S5 AND S12 AND S20		
S20 S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19			
S19	depression		
S18	anxiety		
S17	psycho*		
S16	cogniti*		
S15	(MH "Psychosocial Functioning")		
S14	(MH "Cognition+")		
S13	(MH "Affect")		
S12 S6 OR S7 OR S8 OR S9 OR S10 OR S11			
S11 AB rct			
S10	AB randomised control trial		
S9	AB randomized control trial		
S8	AB randomized controlled trial		
S7	AB randomised controlled trial		
S6	(MH "Randomized Controlled Trials+")		
S ₅	S1 OR S2 OR S3 OR S4		
S4	AB pre-frail*		
S ₃	AB frail*		
S2	(MH "Frailty Syndrome")		
S1 (MH "Frail Elderly")			

PsychINFO

#	Query		
S20	S4 AND S11 AND S19		
S19	S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18		
S18	depression		
S17	anxiety		
S16	psycho*		
S15	cogniti*		
S14	DE "Psychosocial Outcomes"		
S13	DE "Cognitive Ability" OR DE "Brain Training" OR		
	DE "Cognitive Impairment" OR DE "Intelligence" OR DE "Mathematical		
	Ability" OR DE "Reading Ability" OR		
	DE "Spatial Ability" OR DE "Verbal Ability"		
S12	DE "Emotional States" OR DE "Affection" OR DE "Agitation" OR DE		
	"Alienation" OR DE "Ambivalence" OR DE "Anger" OR DE "Anxiety" OR		
	DE "Apathy" OR DE "Aversion" OR DE "Belonging" OR DE "Bereavement"		
	OR DE "Boredom" OR DE		
	"Catastrophizing" OR DE "Compassion" OR DE "Contempt" OR DE		
	"Contentment" OR DE "Depression (Emotion)" OR DE "Desire" OR DE		
	"Disappointment" OR DE		
	"Disgust" OR DE "Dissatisfaction" OR DE "Distress" OR DE "Doubt" OR		
	DE "Embarrassment" OR DE "Emotional Exhaustion" OR DE "Emotional		

	Trauma" OR DE "Empathy" OR DE "Enthusiasm" OR DE "Euphoria" OR		
	DE "Euthymia" OR DE "Fear" OR DE "Forgiveness" OR DE "Frustration"		
	OR DE		
	"Gratitude" OR DE "Greed" OR DE "Grief" OR DE "Guilt" OR DE		
	"Happiness" OR DE "Hate" OR DE "Helplessness" OR DE "Homesickness		
	OR DE "Hope" OR DE "Hopelessness" OR DE "Jealousy" OR DE		
	"Loneliness" OR DE "Love" OR DE "Mania" OR DE "Mental Confusion"		
	OR DE "Moral Emotions" OR DE		
	"Morale" OR DE "Negative Emotions" OR DE "Optimism" OR DE "Panic"		
	OR DE "Passion" OR DE "Pessimism" OR DE "Pleasure" OR DE "Positive		
	Emotions" OR DE "Pride" OR DE "Psychological		
Engagement" OR DE "Regret" OR DE "Restlessness" OR DE "Sadness"			
	DE "Shame" OR DE "Solidarity" OR DE "Suffering" OR DE "Suspicion" OR		
DE "Sympathy"			
S11 S5 OR S6 OR S7 OR S8			
Cia	OR S9 OR S10		
S10	AB rct		
S9	AB randomised control trial		
S8	AB randomized control trial		
S7	AB randomized controlled trial		
S6	AB randomised controlled trial		
S ₅	DE "Randomized Controlled Trials" OR DE "Randomized Clinical Trials"		
S4	S1 OR S2 OR S3		
S ₃	AB pre-frail*		
S2	AB frail*		
S1	DE "Health Impairments"		
	OR DE "Homebound"		

Web of Science

#	Query		
15	#3 AND #9 AND #14		
14	#10 OR #11 OR #12 OR #13		
13	depression		
12	anxiety		
11	psycho*		
10	cogniti*		
9	#4 OR #5 OR #6 OR #7 OR #8		
8	rct		
7	randomised control trial		
6	randomized control trial		
5	randomized controlled trial		
4	randomised controlled trial		
3	#1 OR #2		
2	pre-frail*		
1	frail*		

EMBASE

"	0
#	Query
19	4 and 11 and 18
18	12 or 13 or 14 or 15 or 16 or 17
17	depression.mp
16	anxiety.mp
15	psycho*.mp
14	cogniti*.mp
13	exp cognition assessment/ or exp cognition/
12	exp "mood and anxiety symptom questionnaire"/ or exp mood change/ or
	exp mood/
11	5 or 6 or 7 or 8 or 9 or 10
10	rct.mp
9	randomized control trial.mp
8	randomised control trial.mp
7	randomized controlled trial.mp
6	randomised controlled trial.mp
5	exp randomized controlled trial/
4	1 or 2 or 3
3	pre-frail*.mp
2	frail*.mp
1	exp frail elderly/

[mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword heading word, floating subheading word, candidate term word]

Appendix D – Clinical Interventions in Aging Author Instructions

Manuscript preparation

- While the editors fully understand the extra challenges posed to authors whose native language is not English, we must ask that all manuscripts be reviewed and edited by a native speaker of English with expertise in that area prior to submission
- Double-spacing
- 3-cm margins
- Page numbers
- Line numbers
- Clear concise language
- American spelling (all components of a manuscript must be in English)
- Ensure tables and figures are cited
- Manuscripts should be submitted in Microsoft Word format
- Use International Systems of Units (SI) symbols and recognized abbreviations for units of measurement
- Do not punctuate abbreviations eg, et al, ie
- Spell out acronyms in the first instance in the abstract and paper
- Word counts are not specified. In general, shorter items range from 1000 to 3000 words and reviews from 3000 to 7,500
- Generic drug names are used in title, text, tables, and figures
- Suppliers of drugs, equipment, and other brand-name material are credited in parentheses (company, name, city, state, country)
- If molecular sequences are used, provide a statement that the data have been deposited in a publicly accessible database, eg, GenBank, and indicate the database accession number
- Depositing laboratory protocols on iois encouraged, where a DOI can be assigned to the protocol. To include a link to a protocol in your manuscript:
- 1) Describe your step-by-step protocol on protocols.io
 - 2) Select "Get DOI" to issue your protocol with a unique DOI (digital object identifier)
 - 3) Include the DOI link in the Methods section of your manuscript using the format provided by protocols.io:

http://dx.doi.org.uea.idm.oclc.org/10.17504/protocols.io.xxxxxx (where xxxxxxx is the unique DOI)

At this stage, your protocol is only visible to those with the link. This allows editors and reviewers to consult your protocol when evaluating the manuscript. You can make your protocols public at any time by selecting "Publish" on the protocols.io website. Any referenced protocols will automatically be made public when your article is published.

Updated 28 September 2021

Manuscript template

We have prepared a manuscript template to help authors when submitting their manuscript to one of our journals.

Please click on the link below and 'Save As' the Word document onto your local computer.

Template for all journals

When you are ready to submit your paper please go to our online submission form, which is designed to be as quick and easy as possible.

If you have any questions about submitting your manuscript please email our Editorial team or use the green/red 'Live Support' button on the website.

Updated 6 December 2021

Manuscript structure

Title page

- First name/given name(s) and last name/family name of authors (see Authorship section below)
- Author affiliations: department, institution, city, state, country
- ORCID number(s) for all authors whenever available
- If 2 or more authors on a paper contributed equally, please use the following format:

Author name1*

Author name2*

Author name3*

*These authors contributed equally to this work

Abstract

There are two types of abstracts - structured and unstructured. Original research papers require a structured abstract. Both types of abstracts should be no more than 300 words.

Plain Language Summary (optional)

It is useful for researchers to write plain language summaries of their articles to make them accessible to a wider audience but also to make research accessible to professionals in nearby disciplines. Crucially, plain language summaries are beneficial to improve public engagement with science and medical research. By helping the public to understand biomedical research, researchers can contribute to raising awareness of its value and attracting further public support and involvement.

As an author, promoting your work in an engaging way to a wider audience can help you:

- Attract more readers
- Potentially increase the number of citations to your articles
- Get noticed
- Build a strong reputation
- Connect with patients, carers, politicians, policy-makers and other decisionmakers
- Attract more funding opportunities
- Expand your professional network

The plain language summary has no minimum word length, but should be no more than 250 words, be written in plain English, and be placed after the Abstract and before the Introduction. The plain language summary should be distinct from the abstract and should be written in an accessible, interesting way without spinning or exaggerating the story.

- The plain language summary should not be a "dumbed down" version of your work. You must not treat your audience as stupid or patronise the reader.
- Provide answers to the questions: Why was the study done, What did the researchers do and find, What do these results mean?
- Communicate the facts in an interesting way and put them in the appropriate context.

- Use short, clear sentences broken up into paragraphs for readability. You may use bullet points.
- Use the active voice rather than the passive voice (for example, "Dr Smith's team report several improvements" rather than "Several improvements were reported by Dr Smith's team").
- Avoid jargon, complex grammatical structures or abbreviations. You should use everyday English words rather than complex words. If you need to use a technical term or abbreviation, please explain it the first time you use it.
- Phrase sentences in a positive manner rather than negatively.
- Use person-centred language rather than focussing on the condition/illness or disability.
- Ask someone, who doesn't have any knowledge of the subject, to read your plain language summary and provide feedback. They should find it interesting and they should be able to understand what your study was, what the conclusions are and what the impact of the research may be.

Keywords

3-6 keywords

Corresponding author

Name, physical address, phone, fax, email

Introduction

Material and Methods

Results

Discussion

Conclusions

Abbreviations (if any)

Ethics approval and informed consent

All research studies on humans (individuals, samples or data) or animals must include a statement on ethics approval and, when human research is involved, consent. A statement confirming the name of the Institutional Review Board (IRB) or other appropriate ethics committee that approved the study must be included within the manuscript. The relevant reference/permit numbers should also be included. Please see our editorial policies for more information.

Consent for publication

Consent to publish statements must confirm that the details of any images, videos, recordings, etc can be published, and that the person(s) providing consent have been shown the article contents to be published. Authors must be prepared to provide copies of signed consent forms to the journal editorial office if requested. Please see our editorial policies for more information.

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Please declare all the sources of funding including financial support. Please describe the role of the sponsor(s), if any, in any of the stages from study design to submission of the paper for publication. Please state if the sponsor(s) had no such involvement.

Please ensure that this information is accurate and in accordance with your funder's requirement.

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Your relationship with other people or organisations may influence the way you interpret data or present the information in your study. This is known as a competing interest and all authors of a paper submitted to any Dove Medical Press journal are required to complete a declaration of competing interests. This includes all financial or non-financial competing interests which can include employment with the study sponsor, stock holdings or options, patents, royalties, personal fees, holding a board position, or any political, religious, or academic interest relevant to the published content. All competing interests will be listed in the declarations at the end of the article.

Please consider the following when completing your competing interest declaration:

- Financial competing interests

In the past three years have you received any funding from an organization that may have a financial interest in the manuscript? If so, please specify.

Do you hold any stock holdings or options in an organization that may have financial interest in the publication of this manuscript? If so, please specify.

Does the content of the manuscript relate to any patents you hold or are you currently applying for? If so, please specify.

Have you received any funding or salary from an organization that holds or has applied for patents relating to the content of the manuscript? If so, please specify.

Do you have any other financial competing interests? If so, please specify.

- Non-financial competing interests

Have you received any drugs or equipment from an entity that might benefit or be at an advantage financially or reputationally from the published findings? If so, please specify.

Have you held a position on an industry board or private company that might benefit or be at an advantage financially or reputationally from the published findings? If so, please specify.

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If you are unsure whether you, or one your co-authors, has a competing interest please discuss this with the editor.

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- 2. Have drafted or written, or substantially revised or critically reviewed the article.
- 3. Have agreed on the journal to which the article will be submitted.
- 4. Reviewed and agreed on all versions of the article before submission, during revision, the final version accepted for publication, and any significant changes introduced at the proofing stage.
- 5. Agree to take responsibility and be accountable for the contents of the article.

All authors must meet conditions 1, 2, 3, 4 and 5 and appropriate credit for each author's contribution should be given.

Acquisition of funding, data collection, or general team supervision alone does not constitute authorship.

Increasingly, authorship of multicentre trials is attributed to a group. All members of the group who are named as authors should fully meet the above criteria for authorship/contributorship.

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Acknowledgments

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- Place between Author Contributions and Acknowledgments
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References

See Reference Style Guidelines

Updated 29 April 2024

Figures and tables

Figures

Checklist

Before you submit any figures, please check this list to ensure your files meet our criteria:

- Files are provided in our required file formats, .jpg, .tif or .pdf (see the 'Preparation' section below)
- If your figure is not in .jpg, .tif or .pdf, please convert to the accepted file type that allows the highest quality
- Artwork is of high quality (correct resolution, not blurred, stretched or pixelated)
- One file provided per figure
- All figures have white space and unnecessary elements removed
- All text is in English and contains no spelling or grammar errors
- All fonts used are embedded and are the journal's standard font style Arial or Symbol
- Font size is consistent
- Lines are a minimum of 0.3pt
- Images do not contain any layers, or transparent objects
- Files are named using the naming convention ([manuscript ID] Figure [number])
- Figures are provided separate from the manuscript
- All multi-panel figure parts are labelled (eg, A, B, C, D)
- All copyrights and permissions for use of third-party content have been obtained. Graphics downloaded from web pages are not acceptable.

Preparation and Submission

Recommended image resolutions:

- Colour photographic images: minimum 300 dpi
- Grayscale photographic images: minimum 600 dpi
- Line art or monochrome images: minimum 1200 dpi
- Combination images (photographs and labelling): minimum 600 dpi

The manuscript should not contain any pasted figures. Please provide figures as high quality .jpg, .tif or .pdf files separate from the manuscript. Please ensure that any files in .pdf format are not 'locked' files, as these are incompatible with our workflow software. Image colour should be RGB.

File naming conventions

Name figure files as Figure 1, 2, 3... etc. according to the order they appear in the text. In multi-part figures, each part should be labelled (eg Figure 1a, Figure 1b). Check and ensure all figures have been cited in the text of the manuscript.

Size

Figures should be supplied in the highest resolution (highest quality) possible. Files should not exceed 50MB. Remove any elements that are not intended for publication, including any excess space around the image. Make sure that the image files do not contain any layers, or transparent objects.

Fonts

Use the journals standard font, Arial, and Symbol (Roman). If providing a .pdf file, ensure your fonts are embedded. Keep the font size consistent throughout your work. Do not use effects such as outlining and shadows on any lettering.

Figure legends

Figure legends must begin with the number of the figure being described (eg 'Figure 1: '). If subfigures are present, each subfigure must be labelled and described in the figure legend.

Captions should be succinct but descriptive. Explanatory notes or a key should be present if the figure contains patterns, colours, symbols, or other formatting that indicates significant data. If symbol or alphabetical indicators have been used (e.g. *, **, #, ##, a, b, etc) a key should be included in the figure legend.

If the figure, or a subfigure, is copyrighted and you have obtained permission for use, please ensure that the necessary credit line or acknowledgments are included in the figure legend. If the image is the property of the author, then this should be

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*Please read and follow the section 'Images and figures' under Editorial Policies. Please note that there are specific instructions and considerations for research images.

Tables

Tables should present new information rather than duplicating what is in the text.

Readers should be able to interpret the table even if presented separately from the text.

Ensure that each table is cited within the text of the manuscript.

- Provide tables in their original, editable format (eg in Microsoft Word or Excel). Our production team cannot accept tables as images (eg tables in .jpg, .tif or other image format).
- Tables may be provided within the manuscript, or as separate files (one file per table).
- Present table legends above each table, rather than including these as the first row of the table. Table footnotes should be separate from the titles, and included beneath the table to which they apply.
- Explanatory notes or a key should be present if the table includes indicators, symbols, abbreviations, bolding or other formatting that indicates significant data.
- If using indicators for footnotes, please use superscript letters (a, b, c).

 These letters should follow alphabetical order from the top left of the table to the bottom right.
- All reference citations included in a table must have the relevant reference list number included (in superscript Arabic numeral). Please ensure these numbers align with the reference list included in the manuscript.
- When submitting multiple tables, consistency in presentation is advised.
- When representing information numerically, use as many decimal places as is appropriate for your purposes. This number should be consistent throughout the column, or table, if possible.
- All text in the tables should be in English.
- Tables must not contain images.

Consider the size of each table and whether it will fit on a single journal page. If the table is cramped in a Microsoft Word document, where the default setting represents an A4 page ($210 \times 297 \text{ mm}$), it will be difficult to represent it clearly on a B5 journal

page (176 x 250 mm). If this is the case, please consider splitting the data into two or more tables.

Updated 14 June 2022

Equations

Equations are to be created using MathType Equation Editor or Microsoft Equation Editor Version 3.0 (older versions are not compatible). Equations must not be inserted into the manuscript as images (such as jpeg) as this is not compatible with our proof creation tools.

Updated 28 January 2020

Supplementary data

If you have included supplementary materials Dove Medical Press will upload the unedited supplementary materials to the https://www.dovepress.com/ website and provide a link in your paper. Supplementary figures and tables should be submitted following our guidelines. We welcome video files either as supplementary data or as part of the actual manuscript to show operations, procedures, etc.

Updated 26 August 2019

Use of Brand Names in submitted manuscripts

We require that non-proprietary names are used in submissions. When proprietary brands are used in research, use the non-proprietary name throughout the text. You may include the proprietary name(s) with the non-proprietary name(s) in parentheses immediately after the first mention then use only the non-proprietary name thereafter (once in the Abstract and once in the body of the manuscript is acceptable).

Updated 31 March 2021

Clinical trials

Registration

We require the registration of all clinical trials in a public trials registry at or before the time of first patient enrolment.

To be considered for publication, all authors submitting clinical trials involving human subjects must have prospectively registered the trial in a public trials registry. This is in accordance with the Declaration of Helsinki. We can only accept trial registrations from registries approved by WHO and ICMJE as these have met mandatory requirements

and are found to be trustworthy, give sufficient details, accessible and provide adequate version controls. Authors must include the Clinical Trial Registration number in the manuscript.

Dove Medical Press defines a clinical trial as:

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may or may not include a placebo or control group) to evaluate the effects of those interventions on a health-related biomedical or behavioural outcome.

Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc.

Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.

Full details of clinical trial registration and the necessary requirements can be found on the ICJME website.

Please note: The Clinical Trial Registration guidelines were adapted from information provided by the International Committee of Medical Journal Editors (ICMJE) and the World Health Organization (WHO).

Data Sharing Statement

Manuscripts submitted to Dove Medical Press journals from July 1st, 2018, reporting on clinical trial data must contain a data sharing statement indicating:

- Whether the authors intend to share individual deidentified participant data;
- What specific data they intend to share;
- What other study-related documents will be made available;
- How the data will be accessible:
- When and for how long they will be made available.

See the ICMJE guidelines on data sharing and example given in the Table.

Clinical trials that begin enrolling participants on or after 1 January 2019 must include a data sharing plan in the trial's registration. Any deviations from this plan must be disclosed in the data sharing statement when published.

Updated 22 March 2022

Reference Style Guidelines

https://files-taylorandfrancis-com.uea.idm.oclc.org/dove-reference-style-guidelines.pdf

Article type definitions

https://files-taylorandfrancis-com.uea.idm.oclc.org/dove-article-type-definitions.pdf Updated 23 September 2021

Invited reviews

We operate a programme that commissions reviews from leading authors around the world and across a range of subjects. We invite the submission of reviews on a particular topic and, in some instances, will even suggest a structure for the review that the authors should follow when writing their review.

Publication processing fee

These invited reviews are submitted in the normal way via our website and are exempted from paying any publication processing fee.

Editorial decision-making

Our long-standing policy has been not to let editorial decision-makers know which papers are invited and which are submitted spontaneously. Our view has always been that editorial decision-makers should not have their view clouded either for or against a paper simply because it has been invited. Good papers should be accepted and bad papers rejected irrespective of their source. As a result some invited reviews will be rejected.

Manuscripts are subject to same checks as all other manuscripts

All invited reviews that come to us are subject to all the same checks that every paper goes through. These are:

- Authors and their affiliations are checked;
- Conflicts of Interest information is sought for all authors;
- CrossCheck antiplagiarism software is used to check for re-use of materials;
- Most journals do not consider meta-analyses for publication any longer, so
 please check before preparing this type of paper for submission as it will
 likely be turned away;

- External peer-review with a minimum of two comprehensive sets of narrative comments and two numerical scores are required;
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- Dove Medical Press works hard to ensure the integrity of all published articles. To prevent bias, our policy is for editorial decision-makers to be unaware if a paper is an invited review or not. The decision will be based solely on the outcome of peer review, and we cannot guarantee acceptance of any article.

After first editorial review

Many manuscripts will require to be modified in order to address points raised by peerreviewers or suggested by editorial decision-makers. It is not a case of having to address all the points raised. Rather we require that the author provide us with a revised manuscript and a point-by-point response to the points raised. If authors disagree with individual points or feel that they are misguided they should detail this in their point-by-point response.

The editorial decision-maker who reviewed the submission at first editorial review will subsequently receive the revised manuscript and the point-by-point covering letter and make a decision. This may be to reject the paper, return it to peer-reviewers for further consideration, or return it to the author directly for further points to be addressed. They may also make the decision to accept the paper for publication.

Updated 20 January 2021

Graphical Abstracts

Graphical Abstracts should be representative of the content of the text Abstract. Just as the Abstract must not introduce information not contained in the body of the paper, the Graphical Abstract should not contain new information or data not included in the body of the paper.

Graphical abstracts should not be a duplication of any figure already included in the paper.

Graphical Abstracts do not have a title, a caption or a note section, so should be completely self-explanatory.

Graphical Abstracts should take up no more than one third of an A4 page.

Before you submit any figures for the Graphical Abstract, please check this list to ensure your files meet our criteria:

- Files are provided in our required file formats, .jpg or .tif (see the 'Preparation' section)
- If your file is not in .jpg or .tif or please convert to the accepted file type that allows the highest quality
- Artwork is of high quality (correct resolution, not blurred, stretched or pixelated)
- Image size: width should be 2500px or less
- One file provided per Graphical Abstract
- White space and unnecessary elements removed
- All text is in English and contains no spelling or grammar errors
- All fonts used are embedded and are the journal's standard font style Arial or Symbol
- Font size is consistent
- Lines are a minimum of 0.3pt
- Images do not contain any layers, or transparent objects
- Files are named using the naming convention ([manuscript ID] Graphical Abstract [number])
- Files are provided separate from the manuscript file
- Graphics downloaded from web pages are not acceptable.
- No copyrighted material can be used for Graphical Abstracts

Updated 11 August 2023

Video abstracts

https://files-taylorandfrancis-com.uea.idm.oclc.org/dove-video-abstracts-guidelines.pdf

Pre-submissions

Authors are welcome to send an abstract of their manuscript to obtain a view from the Editor about the suitability of their paper. Please complete the pre-submission check form on our DovePress site here. Our Editors will do a quick review (not peer review) of your paper and advise if they believe it is appropriate for submission to their journal. It will not be a full review of your manuscript.

Please note that we currently only accept pre-submission enquiries for meta-analyses, which require a pre-submission check prior to submitting

Updated 22 June 2024

Submission process

- All manuscripts should be submitted via our website(in English)
- By doing so you agree to the terms and conditions of submission
- Keep a backup and hard copies of the material submitted

Some of the key research and integrity checks that are performed at DovePress prior to publication can be viewed here.

An outline of the manuscript lifecycle, from submission to publication, can be viewed here

Updated 22 March 2022

Guide to submission status indicators

https://files-taylorandfrancis-com.uea.idm.oclc.org/dove-guide-to-submission-status-indicators.pdf

Proofs

- You will receive a link to your paper in the online correction tool (OCT). To access the OCT you will need to use one of the following browsers: for Windows, Chrome (latest version) or Firefox (below 64); for Mac, Safari (latest version) or Chrome (latest version).
- Please check amendments made during the editing and proof typesetting process have not rendered the material inaccurate
- Check and respond to all author queries
- Keep corrections and amendments minimal, and only to correct errors
- Make corrections directly in the OCT in a similar way to a Word document
- Submit your corrections within 72 hours to ensure speedy publication of your paper
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- You will receive an email confirmation that your corrections have been received if you request a new proof

For more detailed instructions on using the online correction tool view the Video user manual for authors

Updated 30 December 2019

Does your manuscript need to have its English improved?

Manuscript Language Assessment

All manuscripts are subject to a standard Manuscript Language Assessment when first submitted to a Dove Medical Press journal, prior to undergoing any Editorial checks. This is to ensure that the Editor and peer reviewers receive a clear and well-presented manuscript, allowing for a quicker and more accurate review process.

The Manuscript Language Assessment utilizes artificial intelligence screening to identify English language errors including missing articles, the misuse of prepositions, subject-verb agreement errors, verb tenses, noun numbers, and spelling. The language quality of the manuscript is then determined based on the number of errors detected.

After completing the Manuscript Language Assessment, we may require that a manuscript undergoes English editing before it can proceed to peer review. In these cases, the contact author will be notified to advise that English editing is required. At this time, we will also provide a copy of the Manuscript Language Assessment report, which will highlight the errors identified.

The Manuscript Language Assessment report categorizes language errors into two broad categories, which are highlighted in different colors. These categories are spelling errors (highlighted in yellow) and grammatical errors/missing words (highlighted in blue).

A full list of the types of errors identified, including examples of errors and how to correct them, can be found at the bottom of this page.

Please note that the Manuscript Language Assessment report is automatically generated, and thus some errors may not have been identified. As such, while any identified errors will be highlighted for your reference, we still recommend that your full manuscript undergoes a complete copy-edit to ensure that all language errors are addressed. This generally provides better results compared to individually addressing highlighted errors.

Further, please note that Manuscript Language Assessment reports are only sent out in cases where we have determined that a manuscript requires English language revision. If you have not received a report, then your manuscript has passed this assessment and has moved to the next stage in the editorial process.

Professional English Language Editing Services:

For professional English language copy-editing services, we recommend the use of The Charlesworth Group.

The service checks and corrects English language grammar and style. When the editing is complete you will be sent a sample page to approve. When you have approved the sample you will then be asked for payment and the full, edited paper will be made available to you.

Please contact The Charlesworth Group for details of this service and to request a quote.

If you require funding, you may wish to contact Author Aid.

Note that use of this editing service does not guarantee your manuscript will be accepted for publication in a Dove Press journal.

Frequently Asked Questions:

Is the Manuscript Language Assessment Report sent to Peer Reviewers and/or the Editor?

No, the Manuscript Language Assessment Report is not sent to Peer Reviewers or the Editor.

Does Dove Medical Press offer in-house copy-editing services?

No, Dove Medical Press does not offer full in-house English language copy-editing services. For professional copy-editing services, we recommend The Charlesworth Group.

Can I correct the identified English language errors after peer review?

No. While minor corrections can be made later in the process, we require that major English language errors are corrected prior to being sent to peer review. This ensures that the Editor and peer reviewers receive a clear and well-presented manuscript, allowing for a quicker and more accurate review process.

My manuscript has failed the Manuscript Language Assessment, but I have already paid for professional editing services. What should I do?

It is a fair expectation that paying for a copy editor to polish your paper will result in the paper passing assessment for English language with a publisher. Unfortunately, in some cases, a paper may not have been sufficiently improved to pass our language assessment. In these cases, we would recommend that you request a refund for the service and use another copy editor.

Is professional English editing required for Dove Medical Press to consider my manuscript?

No, professional English editing is not a requirement for consideration of a manuscript; however, it is recommended in cases where manuscripts have failed the Manuscript Language Assessment. As an alternative to professional English editing, we would recommend seeking the assistance of a colleague who is a native English speaker.

The Manuscript Language Assessment Report is highlighting medical terminology/brand names/proper nouns as spelling errors – how do I proceed?

We apologize for the inconvenience. The artificial intelligence tool that is used to generate the Manuscript Language Assessment report is a relatively new tool, and we are still optimizing the algorithm to accurately identify areas where improvements are needed. The artificial intelligence tool has a particularly hard time identifying medical terminology, brand names, and proper nouns. Please be reassured that these terms do not need to be corrected for spelling.

The Manuscript Language Assessment report has highlighted a word as containing a grammatical error; however, the word highlighted is grammatically correct – how do I proceed?

Please double check to ensure that no words are missing from the sentence containing the highlighted word. The Manuscript Language Assessment report highlights missing words in the same manner as grammatical errors. In the case of a missing word, the word after the missing word will be highlighted. Please see the "Commonly Identified Errors" table below for an example of how an identified missing word error appears in the Manuscript Language Assessment report.

Should I use American English or British English? Will I be penalized if I use one over the other?

The Manuscript Language Assessment does not discriminate between American English or British English (e.g., "utilize" vs "utilise"). You will not be penalized for using one language style over the other.

What happens if my manuscript fails the Manuscript Language Assessment more than once?

Manuscripts can fail the Manuscript Language Assessment up to three times. If the manuscript subsequently fails the Manuscript Language Assessment for a fourth time, it will be withdrawn so that you may amend your manuscript further.

Please note that, if your manuscript is withdrawn for failing the Manuscript Language Assessment, this does not preclude resubmission once the English language errors have been corrected.

Why was my manuscript rejected after correcting for English language?

The Manuscript Language Assessment is the first step in our Editorial policy, and manuscripts must pass this assessment before they can be sent to our Consulting Editor team for review. Upon receiving your manuscript, the Consulting Editor team may determine that your manuscript cannot be accepted based on a range of separate criteria, such as the scope of the journal, research ethics, novelty, or research integrity.

Does the Manuscript Language Assessment check for plagiarism?

No, the Manuscript Language Assessment does not check for plagiarism. All manuscripts are subjected to a separate plagiarism check using the iThenticate software. Passing the Manuscript Language Assessment does not mean that plagiarism or recycled text will not be detected.

This guide: Commonly Identified Errors displays examples with common errors identified in the Manuscript Language Assessment report and how to correct these types of errors.)

Updated 5 December 202

Appendix E – GUIDED Checklist (Duncan et al., 2020)

Item description	Explanation	Page in manuscript where item is located
Report the context for which the intervention was developed.	Understanding the context in which an intervention was developed informs readers about the suitability and transferability of the intervention to the context in which they are considering evaluating, adapting or using the intervention. Context here can include place, organisational and wider sociopolitical factors that may influence the development and/or delivery of the intervention (15).	74-79
2. Report the purpose of the intervention development process.	Clearly describing the purpose of the intervention specifies what it sets out to achieve. The purpose may be informed by research priorities, for example those identified in systematic reviews, evidence gaps set out in practice guidance such as The National Institute for Health and Care Excellence or specific prioritisation exercises such as those undertaken with patients and practitioners through the James Lind Alliance.	79
3. Report the target population for the intervention development process.	The target population is the population that will potentially benefit from the intervention – this may include patients, clinicians, and/or members of the public. If the target population is clearly described then readers will be able to understand the relevance of the intervention to their own research or practice. Health inequalities, gender and ethnicity are features of the target population that may be relevant to intervention development processes.	77
4. Report how any published intervention development approach contributed to the development process	Many formal intervention development approaches exist and are used to guide the intervention development process (e.g. 6Squid (16) or The Person Based Approach to Intervention Development (17)). Where a formal intervention development approach is used, it is helpful to describe the process that was followed, including any deviations. More general approaches to intervention development also exist and have been categorised as follows (3):- Target Population-centred intervention development; evidence and theory-based intervention development; partnership intervention development; implementation-based intervention development; efficacybased intervention development; step or phased-based intervention development; and intervention-specific intervention development (3). These approaches do not always have specific guidance that describe their use. Nevertheless, it is helpful to give a rich description of how any published approach was operationalised	77-79
5. Report how evidence from different sources informed the intervention development process.	Intervention development is often based on published evidence and/or primary data that has been collected to inform the intervention development process. It is useful to describe and reference all forms of evidence and data that have informed the development of the intervention because evidence bases can change rapidly, and to explain the manner in which the evidence and/or data was used. Understanding what evidence was and was not available at the time of intervention development can help readers to assess transferability to their current situation.	80-81
 Report how/if published theory informed the intervention development process. 	Reporting whether and how theory informed the intervention development process aids the reader's understanding of the theoretical rationale that underpins the intervention. Though not mentioned in the e-Delphi or consensus meeting, it became increasingly apparent through the development of our guidance that this theory item could relate to either existing published theory or programme theory	81-85, 92
7. Report any use of components from an existing intervention in the current intervention development process.	Some interventions are developed with components that have been adopted from existing interventions. Clearly identifying components that have been adopted or adapted and acknowledging their original source helps the reader to understand and distinguish between the novel and adopted components of the new intervention.	81-89

	8. Report any guiding principles, people or factors that were prioritised when making decisions during the intervention development process.	Reporting any guiding principles that governed the development of the application helps the reader to understand the authors' reasoning behind the decisions that were made. These could include the examples of particular populations who views are being considered when designing the intervention, the modality that is viewed as being most appropriate, design features considered important for the target population, or the potential for the intervention to be scaled up.	81-85
	9. Report how stakeholders contributed to the intervention development process.	Potential stakeholders can include patient and community representatives, local and national policy makers, health care providers and those paying for or commissioning health care. Each of these groups may influence the intervention development process in different ways. Specifying how differing groups of stakeholders contributed to the intervention development process helps the reader to understand how stakeholders were involved and the degree of influence they had on the overall process. Further detail on how to integrate stakeholder contributions within intervention reporting are available (19).	70-81
	10. Report how the intervention changed in content and format from the start of the intervention development process.	Intervention development is frequently an iterative process. The conclusion of the initial phase of intervention development does not necessarily mean that all uncertainties have been addressed. It is helpful to list remaining uncertainties such as the intervention intensity, mode of delivery, materials, procedures, or type of location that the intervention is most suitable for. This can guide other researchers to potential future areas of research and practitioners about uncertainties relevant to their healthcare context.	90
	11. Report any changes to interventions required or likely to be required for subgroups.	Specifying any changes that the intervention development team perceive are required for the intervention to be delivered or tailored to specific subgroups enables readers to understand the applicability of the intervention to their target population or context. These changes could include changes to personnel delivering the intervention, to the content of the intervention, or to the mode of delivery of the intervention.	90, Appendix G (208)
	12. Report important uncertainties at the end of the intervention development process.	Intervention development is frequently an iterative process. The conclusion of the initial phase of intervention development does not necessarily mean that all uncertainties have been addressed. It is helpful to list remaining uncertainties such as the intervention intensity, mode of delivery, materials, procedures, or type of location that the intervention is most suitable for. This can guide other researchers to potential future areas of research and practitioners about uncertainties relevant to their healthcare context.	90
	13. Follow TIDieR guidance when describing the developed intervention.	Interventions have been poorly reported for a number of years. In response to this, internationally recognized guidance has been published to support the high-quality reporting of health care? interventions ⁵ and public health interventions ¹⁴ . This guidance should therefore be followed when describing a developed intervention.	Appendix G (208)
k.	14. Report the intervention development process in an open access format.	Unless reports of intervention development are available people considering using an intervention cannot understand the process that was undertaken and make a judgement about its appropriateness to their context. It also limits cumulative learning about intervention development methodology and observed consequences at later evaluation, translation and implementation stages. Reporting intervention development in an open access (Gold or Green) publishing format increases the accessibility and visibility of intervention development research and makes it more likely to be read and used. Potential platforms for open access publication of intervention development include open access journal publications, freely accessible funder reports or a study web-page that details the intervention development process.	72 – Clinical Interventions in Aging is an open access journal

^{*}e.g. if item is reported elsewhere, then the location of this information can be stated here.

From: Duncan E, O'Cathain A, Rousseau N, Croot L, Sworn K, Turner KM, Yardley L, Hoddinott P. Guidance for reporting intervention development studies in health research (GUIDED): an evidence-based consensus study. BMJ Open. 2020 Apr 8;10(4):e033516. This work is licensed under CC BY 4.0

Appendix F – Consent for Adaptation from Cognitive Stimulation Therapy (CST) Creators

Sophie Livsey (MED - Postgraduate Researcher)

From: Bob Woods (Staff)

Sent: 12 June 2023 14:23

To: Sophie Livsey (MED - Postgraduate Researcher); Spector, Aimee;

Cc: Maximilian Bramley (MED - Postgraduate Researcher)

Subject: RE: CST enquiry

Hi Sophie and Max,

Good luck with your thesis projects – as Aimee indicates, we are always happy to see the work on CST taken forward and adapted appropriately for different populations, and take a keen interest in the findings.

Just a small note of caution – the manuals are copyrighted, so if your completed theses will be available electronically or in a library, you should avoid the reproduction of pages or sections from the manual. Also, if your work was to prove successful and you wished eventually to publish an adapted manual for the pre-frail stroke population, this would require further permission from the publisher of the manuals. That is a long way down the track, of course!

Best wishes

Bob Woods

From: Sophie Livsey (MED - Postgraduate Researcher) <S.Livsey@uea.ac.uk>

Sent: Friday, June 9, 2023 5:09 PM

To: Spector, Aime ; Bob Woods (Staff)

Cc: Maximilian Bramley (MED - Postgraduate Researcher) < M.Bramley@uea.ac.uk>

Subject: RE: CST enquiry

Dear Aimee,

Thanks for getting back to me so quickly!

That's great to hear, thank you, and yes, we will be sure to keep you posted!

Very best wishes,

Sophie

Sophie Livsey

First Year Trainee Clinical Psychologist (ClinPsyD)

University of East Anglia

From: Spector, Aimee

Sent: Monday, June 5, 2023 9:41 AM

To: Sophie Livsey (MED - Postgraduate Researcher)

Cc: Maximilian Bramley (MED - Postgraduate Researcher)

Subject: RE: CST enquiry

Warning: This email is from outside the UEA system. Do not click on links or attachments unless you expect them from the sender and know the content is safe.

Dear Sophie,

Many thanks for your email. I see no issues with this myself and would be keen to hear what you find - do keep us posted and good luck!

Kind regards,

Aimee

Aimee Spector

Professor of Clinical Psychology of Aging

T: +44 7679 5925

Dept of Clinical, Educational & Health Psychology | University College London

International lead, Doctorate of Clinical Psychology (DClinPsy) https://www.ucl.ac.uk/clinical-psychology-doctorate/international
Director, International Cognitive Stimulation Therapy Centre www.ucl.ac.uk/international-cognitive-stimulation-therapy

From: Sophie Livsey (MED - Postgraduate Researcher)

Sent: 03 June 2023 17:01

To: Spector, Aimee

Cc: Maximilian Bramley (MED - Postgraduate Researcher)

Subject: CST enquiry

▲ Caution: External sender

Good morning,

My colleague, Max Bramley (cc'd), and I are first year Trainee Clinical Psychologists at the University of East Anglia. We are currently planning our joint thesis projects, in which we are hoping to adapt some sessions of Cognitive Stimulation Therapy for a pre-frail stroke population as part of a feasibility and acceptability study. We are hoping to use the Making a Difference 1 book as a guide for this and therefore may need to reproduce some of the materials within our thesis portfolios and possibly use some of the adapted materials within the brief intervention we will carry out as part of the research.

We were wondering if you might be happy to grant us permission to use the materials in this way? If you have any questions or concerns about this please do not hesitate to get in touch; we would be happy to provide more information if required.

Best wishes,

Sophie Livsey

First Year Trainee Clinical Psychologist (ClinPsyD)

University of East Anglia

Appendix G - Template for Intervention Description and Replication (TIDieR; Hoffmann et al., 2014) Checklist

Checklist	Item	sCST Intervention Description
Brief Name	e	Stroke Cognitive Stimulation Therapy, or sCST
Why		This intervention aims to improve cognitive and social functioning via fun and stimulating activities and discussions (Clare & Woods, 2004). It retains many of the elements of the original CST, for which the rationale and goals have already been documented (Spector et al., 2020). This adaptation introduces new principles based on recommendations and evidence relevant to a stroke survivor population: self-efficacy, values and learning new strategies.
		'Vicarious experiences of success' and 'positive reinforcement and feedback' are two key factors thought to contribute to self-efficacy (Bandura & Adams, 1977). Self-efficacy has been found to have a positive influence on quality of life and post-stroke depression (Korpershoek et al., 2011) and importance of increasing self-efficacy is clearly documented in the National Clinical Guideline for Stroke (ISWP, 2023). 'Values' has been identified as a common component of successful psychosocial interventions for stroke (Van Nimwegen et al., 2023) and values-based living is considered helpful for improving quality of life (Van Bost et al., 2017) and adjusting to identity changes (Gracey et al., 2017) after an acquired brain injury, such as a stroke. Psychoeducational interventions and training in cognitive compensatory strategies and distress management skills such as relaxation and mindfulness are all recommended in stroke guidelines (ISWP, 2023; NICE, 2023). In addition to learning new strategies via intervention facilitators, stroke survivors have also reported finding it valuable to learn coping strategies from their peers within group interventions (e.g. (Morris & Morris, 2012). This intervention also considers the importance of providing information and supporting self-directed therapeutic activity which is recommended in evidence-based stroke rehabilitation guidelines (ISWP, 2023; NICE, 2023). Materials in the intervention are to be presented with consideration of common language and attentional difficulties that result from stroke, such as using simple language and a visual attentional cue on the left-hand side for those with hemispatial neglect.
What	Materials	The programme principles act as training materials for intervention facilitators, explaining the core concepts that should be incorporated as much as possible into all sessions. Further training materials may be produced at a later date, once refinements to the intervention have been made. In the sessions, song lyrics of the group's chosen song will be provided, images and brief text relating to a recent news headline will be shared with the group and resources required for each session's main activity will be provided. Materials for the session activities will be multi-sensory where possible. Examples include sound clips of day-to-day sounds and pictures that match them.

Checklist Item

sCST Intervention Description

Handouts are provided for group members to take home in order to help group members recall what activity they completed in the session and prompt discussion and recall with family members at home.

Additional information sheets provide brief psychoeducation about a common cognitive or psychological consequence of stroke and a compensatory strategy or technique that can help to manage this. Activities that can be completed at home are suggested so that the stroke survivor can practice the new strategy.

Procedures

Each session will contain three sections, consistent with the original CST approach.

The first section (10 mins) is an introduction whereby implicit orientation is facilitated by discussions of how attendees' weeks have been and any key events that took place. Following this, a brief section of the group's chosen song is sung and a recent news headline discussed.

The second section (25 mins) involves the main activity associated with the session theme. This activity should incorporate as many of the programme principles as possible, providing an opportunity for cognitive stimulation and multisensory processing and allowing opportunities to discuss and identify values and share helpful strategies.

The final section (10 mins) involves a summary of the session and any strategies discussed, and a reminder of the theme and date of the next session.

Who provided

As with CST, this intervention can be facilitated by practitioner psychologists (including Assistant and Trainee Psychologists with appropriate supervision), Occupational Therapists, Speech and Language Therapists or other adequately trained healthcare professionals with an understanding of stroke. Two facilitators are recommended so that individual support can be provided by one facilitator where required.

Where

The intervention could take place at any convenient healthcare or community location that can accommodate up to 12 individuals (including intervention facilitators). Ideally there will be a table to facilitate engagement in activities and accessibility should be carefully considered when identifying a location due to the prevalence of physical disability in the stroke population.

When and how much

In line with original CST, the intervention sessions will last approximately 45 minutes and will be delivered twice a week. For now, eight sessions have been developed meaning the intervention will be delivered over a 4-week period however this may be increased to match or exceed the 14 sessions of original CST.

Tailoring

The intervention is designed to be delivered in a group format, but there is scope for the activities to be adapted to suit the needs and abilities of each individual group, either on a flexible or planned basis. The activities outlined in the session plans are suggestions and do not have to be followed exactly, but any new activities should aim to continue to incoporate as many of the principles as possible. This means activities can be made

Checklist Item		sCST Intervention Description	
		easier or more challenging and materials can be adapted to suit additional needs such as visual impairments or language difficulties.	
Modifications		sCST is an adaptation of CST, originally designed for people with dementia. This paper outlines the process and details of the adaptation process.	
many of the core principles and e been retained in order to increase		Adherence or fidelity has not been formally assessed however many of the core principles and elements of original CST have been retained in order to increase fidelity of the adapted intervention to the original version.	
	Actual	An acceptability pilot of this intervention has been reported separately (Chapter 4).	

Appendix H – Stroke CST (sCST) Guiding Principles

Adapted from Spector et al. (2020)

	comp · · · ·	D (° •1•	** . 1'
	sCST Principle	Definition	How to achieve
1	Mental stimulation	Improving cognition and communication through mentally stimulating discussion	Activities should be pitched so that group members have to make an effort but are not too difficult
2	New ideas, thoughts and associations	Encouraging new ideas and opinions by making new semantic connections	Rather than testing people's existing knowledge and memory, ask questions that might elicit new thought processes.
3	Using orientation, sensitively and implicitly	Integrating orientation information into general discussion	Rehearsal of orientation information or asking directly can put people on the spot; instead, ask questions or open conversations that will prompt orientation indirectly. For example, rather than asking about what month it is, ask 'Do you think this weather is normal for October?'
4	Opinions rather than facts	Using topics to generate opinions rather than testing facts	Don't focus too much on facts; instead, ask about peoples' opinions as these cannot be right or wrong. Rather than asking 'Where did you go on holiday as a child?', ask 'Where is your favourite place to go on holiday?'
5	Providing triggers and prompts to aid recall and concentration	Supporting learning through multisensory cues and an information board	Use an orientation board with the group name, date and other key information. Use various senses, such as smells and sounds, to prompt memories and ideas.
6	Continuity and consistency between sessions	Using consistency of sessions to help continuity and familiarity	Run the groups in the same way each time – use the same room and use the same activities and group song to start each session
7	Implicit (rather than explicit) learning	Let learning and remembering happen naturally	Ask direct questions about their knowledge or ideas can put people on the spot or expose difficulties, instead learning should happen via indirect questions and discussions around a topic
8	Stimulating language	Promoting communication and conversation	Incorporate activities that stimulate language abilities such as naming and word associations
9	Stimulating executive functioning	Using activities to support planning and organising thoughts	Incorporate activities that require planning or drawing new connections between objects, ideas or concepts
10	Person-centred	Seeing the person and their uniqueness	Consider and embrace the strengths, preferences and interests of each group member
11	Respect	Respect and dignity for all	Facilitators must make sure all group members are respected and that no one feels vulnerable or exposed
12	Involvement and inclusion	Keep everyone involved	The facilitator should not be doing most of the talking, group members should be encouraged to respond to one another

	sCST Principle	Definition	How to achieve
13	Choice	Activities are flexible and should be adapted for the participants	Activities are flexible and choices should be made available to group members to allow them the chance to make the group their own
14	Fun	Make it fun and enjoyable	The intervention should provide a fun and enjoyable environment for, and approach to, learning
15	Maximising potential	Optimise the learning environment to support people's potential	Provide the right amount of encouragement for each individual group member to facilitate more experiences of success
16	Building / strengthening Relationships	Becoming friends	The intervention aims to strengthen relationships between group members and between members and facilitators
17	Vicarious experiences of success	Promote the sharing of positive stories of coping and progress	Encourage participants to share with the group their own experiences of success and reflect on what they have found helpful in their recovery
18	Positive reinforcement and feedback	Openly acknowledge achievements	Provide acknowledgement and feedback to group members when they demonstrate success, ensuring this is fair and equal between group members
19	Values	Encourage identification and discussion of values	Encourage group members to discuss their personal preferences and explore why certain activities, memories, skills etc. are important to them to bring awareness to the benefits of meaningful activity
20	Learning new strategies	Introduce and discuss compensatory strategies	Introduce compensatory strategies for common cognitive and psychological consequences of stroke and encourage group members to share their experiences of using strategies

Appendix I – sCST Example Session Plans and Materials

Session 2 - Sounds

Materials needed: Audio files of sounds and pictures to match

- Introduction
 - Welcome all members to the group, using their names.
 - o Reminder of group rules
 - Reminder of group name
 - o Sing group song
 - o Discuss the day, month, year, season, weather, time, location
 - Discuss something currently in the news (use newspapers or photographs).
 - o Offer refreshments.
- Introduce theme
 - o What are peoples' favourite music? Why?
- Main Activity
 - Play sound effects and match to pictures
 - Identifying how sounds make us feel, what emotions, memories and associations do they evoke?
- Summarise session: what the group have learnt, what surprised them and what they want to remember
- Take-home activity sheet
 - o Make a playlist for when feeling:
 - Sad
 - Happy
 - Unmotivated

sCST activity Session 2 - Sounds



Today's Activity

To begin, we are going to talk about our favourite music and what this means to us.

Then we are going to listen to some sounds clips and talk about we we can hear. We can try and match the sounds to pictures.

We may find that different people hear different things!

This is not about being right or wrong, instead using our skills and other information to come up with different ideas.

Purpose

After a stroke. some people might find it harder to concentrate on certain things and filter out the unimportant information. This activity is hoped to help you practise your 'selective attention' skills - listening carefully to sounds and then searching through the images to find the one that matches, ignoring the others.

Sounds, when in the form of music, can also be helpful. Research has found that listening to music every day can help to improve memory and attention after a stroke, in addition to helping to improve mood and reduce depression.

sCST take-home sheet Session 2 - Sounds



Today we had our second session. We sang our group song and discussed a recent news headline.

In today's session on Sounds, we discussed our favourite music and sounds we like and dislike. We also practised out attention skills by listening to some sound clips, trying to identify the sounds and finding the matching picture amongst a selection.

Top tip:

Music can hold a powerful place in our lives, many people, following having a stroke can find music more meaningful or helpful. Research has found that when we listen to music, it lights up key areas in our brain that are used to process emotion, the limbic system.

Because of this, it can be useful to know what songs make you feel different emotions. We know that having a stroke and the difficulties many people face after this, can bring up hard emotions. Knowing songs that can influence how happy you feel or how energised you feel can support when adjusting to your stroke can bring up difficult feelings.



Activity:

At home, make a playlist for when you are feeling different emotions. Have a go at making a playlist for when you are feeling: **sad**, **happy**, or **unmotivated**. You can do this together, or you can do one each. This isn't about making sure you have good songs, it's about noticing how they make you feel.

Session 4 – Faces

Materials needed: Image cards of faces with names below them

- Introduction
 - Welcome all members to the group, using their names.
 - o Reminder of group rules
 - o Reminder of group name
 - o Sing group song
 - o Discuss the day, month, year, season, weather, time, location
 - Discuss something currently in the news (use newspapers or photographs).
 - o Offer refreshments
- Introduce theme
 - o Do people find it easy to recall names?
 - Does anyone have any strategies to help?
- Main Activity
 - o Present pictures of faces with names paired with them
 - Discuss the faces and discuss similarities or qualities, such as "who looks most trustworthy?"
 - o Introduce mnemonic strategies briefly
 - As a group, come up with some mnemonic strategies to help learn the face-name pairs
- Summarise session: what the group have learnt, what surprised them and what they want to remember
- Take-home activity sheet
 - Watch the news or a new TV programme or find a news story with an image of a person. Practice using information you learn about someone to create a mnemonic to remember their name

sCST activity Session 4 - Faces



Today's Activity

Have a go at coming up with a mnemonic that helps you to remember the name of the one of the people in the pictures.

For example, if a person has glasses and their name is Greg, you migh use the first letters of 'Greg' and 'glasses' to help you remember:

"Greg with glasses!"

You can use any feature of the name or person to help you remember, you could also create a short story about the person if that helps too.

We will share mnemonics as a group and, if we have time, we will discuss other things about these people. Such as, which one we would trust the most, and why.

Purpose

After a stroke, some people can have more difficulty with their memory. We are more likely to remember things that make sense to us and less likely to remember things that seem random or abstract.

Names often have little to no meaning, and the pairing of a particular name with a particular face has even less. This makes names one of the most difficult things to remember.

However, we can use strategies to help create more meaning and help us to remember things better (mnemonics).

sCST take-home sheet Session 4 - Faces



Today we had our fourth session. We sang our group song and discussed a recent news headline.

In today's session on Faces, we practised coming up with mnemonics to help us remember the names for new people, using images of faces.

We also used our thinking skills and attention to look at specifc features of the faces and decide whether or not the people might be friendly, unfriendly, trustworthy, funny, serious etc.

Top tip:

Use any feature of people's names or faces when creating a mnemonic. The more creative the better, this is as our brain will help us to remember information that is special or meaningful to us. Having a few things to look out for on people's faces e.g., glasses; eye colour; facial hair etc. can be a good start (Greg with the glasses; blue-eyes Beth; Mark with the mustache).

Activity:

At home, you might watch the news, you might start watching a new TV program, or you might read the news paper. Pick a person from the news / TV program and practice using the information you learn about them to come up with a mnemonic. You could do this together as a two, or you could come up with a mnemonic each.

Appendix J – British Journal of Health Psychology Author Guidelines

1. SUBMISSION

Authors should kindly note that submission implies that the content has not been published or submitted for publication elsewhere except as a brief abstract in the proceedings of a scientific meeting or symposium.

New submissions should be made via the Research Exchange submission portal. Should your manuscript proceed to the revision stage, you will be directed to make your revisions via the same submission portal. You may check the status of your submission at anytime by logging on to submission.wiley.com and clicking the "My Submissions" button. For technical help with the submission system, please review our FAQs or contact submissionhelp@wiley.com.

All papers published in the British Journal of Health Psychology are eligible for Panel A: Psychology, Psychiatry and Neuroscience in the Research Excellence Framework (REF).

Data protection:

By submitting a manuscript to or reviewing for this publication, your name, email address, and affiliation, and other contact details the publication might require, will be used for the regular operations of the publication, including, when necessary, sharing with the publisher (Wiley) and partners for production and publication. The publication and the publisher recognize the importance of protecting the personal information collected from users in the operation of these services, and have practices in place to ensure that steps are taken to maintain the security, integrity, and privacy of the personal data collected and processed. You can learn more at https://authorservices-wiley-com.uea.idm.oclc.org/statements/data-protection-policy.html.

Preprint policy:

This journal will consider for review articles previously available as preprints. Authors may also post the submitted version of a manuscript to a preprint server at any time. Authors are requested to update any pre-publication versions with a link to the final published article.

2. AIMS AND SCOPE

The British Journal of Health Psychology publishes original research on all aspects of psychology related to health, health-related behaviour and illness across the lifespan, including:

- experimental and clinical research on psychological factors aetiology;
- experiential and lived experience of health and illness;
- psychological and behavioural management of acute and chronic illness;
- health-related behaviour change and maintenance;
- psychological factors in screening and medical procedures;
- positive psychological approaches to health and illness;
- psychosocial factors in health-related behaviours;
- influence of emotion on health and health-related behaviours;
- psychosocial processes relevant to disease outcomes;
- psychological interventions in health and disease;
- psychological aspects of prevention and public health.

Papers must make a clear potential contribution to health psychology theory, knowledge and/or practice and employ rigorous research design and methodology.

We do not publish studies where the main focus is on mental health or psychopathology. In addition, we typically do not publish cross-sectional studies or those using only student populations unless there is a strong rationale for doing so.

Papers describing intervention development (without also presenting an analysis of the outcomes of the intervention) will usually only be considered if they make a contribution to health psychology theory, knowledge and/or practice beyond the specific intervention context.

The journal encourages submissions of papers reporting experimental, theoretical and applied studies using quantitative, qualitative and mixed-methods approaches. Research carried out at the individual, group and community levels is welcome. It also welcomes systematic reviews and meta-analyses. Submissions concerning clinical applications of Health Psychology principles and interventions with relevance for Health Psychology outcomes and populations are particularly encouraged.

3. MANUSCRIPT CATEGORIES

The types of paper invited are:

- papers reporting original empirical investigations, using quantitative, qualitative or mixed methods;
- theoretical papers which report analyses of theories in health psychology;
- review papers, which should provide systematic overviews, evaluations and interpretations of research in a given field of health psychology (narrative reviews will only be considered for editorials or important theoretical discourses);
- methodological papers dealing with methodological issues of particular relevance to health psychology;
- we particularly welcome papers reporting effectiveness (for example,
 Randomised Controlled Trials) and process evaluations of interventions in clinical and non-clinical populations.

Authors who are interested in submitting papers that do not fit into these categories are advised to contact the editors who would be very happy to discuss the potential submission.

Papers describing single study quantitative research (including reviews with quantitative analyses) should be no more than 5000 words (excluding the abstract, reference list, tables and figures). For papers describing 2 or more quantitative studies, the word limit is 6000 words (excluding the abstract, reference list, tables and figures). Papers describing qualitative or mixed methods research (including reviews with qualitative analyses) should be no more than 6000 words (including quotes, whether in the text or in tables, but excluding the abstract, tables, figures and references).

All systematic reviews must be pre-registered and an anonymous link to the preregistration must be provided in the main document, so that it is available to reviewers. Systematic reviews without pre-registration details will be returned to the authors at submission.

Please refer to the separate guidelines for Registered Reports.

4. PREPARING THE SUBMISSION

Open Research initiatives.

Recognizing the importance of research transparency and data sharing to cumulative research, British Journal of Health Psychology encourages the following Open Research practices.

Sharing of data, materials, research instruments and their accessibility. British Journal of Health Psychology encourages authors to share the data, materials, research

instruments, and other artifacts supporting the results in their study by archiving them in an appropriate public repository. Qualifying public, open-access repositories are committed to preserving data, materials, and/or registered analysis plans and keeping them publicly accessible via the web into perpetuity. Examples include the Open Science Framework (OSF) and the various Dataverse networks. Hundreds of other qualifying data/materials repositories are listed at the Registry of Research Data Repositories (http://www.re3data.org). Personal websites and most departmental websites do not qualify as repositories.

Free Format Submission

British Journal of Health Psychology now offers free format submission for a simplified and streamlined submission process.

Before you submit, you will need:

- Your manuscript: this can be a single file including text, figures, and tables, or separate files whichever you prefer (if you do submit separate files, we encourage you to also include your figures within the main document to make it easier for editors and reviewers to read your manuscript, but this is not compulsory). All required sections should be contained in your manuscript, including abstract, introduction, methods, results, and conclusions. Figures and tables should have legends. References may be submitted in any style or format, as long as it is consistent throughout the manuscript. If the manuscript, figures or tables are difficult for you to read, they will also be difficult for the editors and reviewers. If your manuscript is difficult to read, the editorial office may send it back to you for revision.
- The title page of the manuscript, including a data availability statement and your co-author details with affiliations. (Why is this important? We need to keep all co-authors informed of the outcome of the peer review process.) You may like to use this template for your title page.
- Important: the journal operates a double-anonymous peer review policy. Please anonymise your manuscript and prepare a separate title page containing author details. (Why is this important? We need to uphold rigorous ethical standards for the research we consider for publication.)
- An ORCID ID, freely available at https://orcid.org. (Why is this important?
 Your article, if accepted and published, will be attached to your ORCID profile.
 Institutions and funders are increasingly requiring authors to have ORCID IDs.)

To submit, login at https://wiley.atyponrex.com/journal/BJHP and create a new submission. Follow the submission steps as required and submit the manuscript.

If you are invited to revise your manuscript after peer review, the journal will also request the revised manuscript to be formatted according to journal requirements as described below.

Revised Manuscript Submission

Contributions must be typed in double spacing. All sheets must be numbered.

Cover letters are not mandatory; however, they may be supplied at the author's discretion.

Parts of the Manuscript

The manuscript should be submitted in separate files: title page; statement of contribution; main text file; figures/tables; supporting information.

Title Page

You may like to use this template for your title page. The title page should contain:

- A short informative title containing the major key words. The title should not contain abbreviations (see Wiley's best practice SEO tips);
- A short running title of less than 40 characters;
- The full names of the authors;
- The author's institutional affiliations where the work was conducted, with a
 footnote for the author's present address if different from where the work was
 conducted;
- Abstract;
- Keywords;
- Data availability statement (see Data Sharing and Data Accessibility Policy);
- Acknowledgments.

Author Contributions

For all articles, the journal mandates the CRediT (Contribution Roles Taxonomy)—more information is available on our Author Services site.

Abstract

For articles containing original scientific research, a structured abstract of up to 250 words should be included with the headings: Objectives, Design, Methods, Results,

Conclusions. Review articles should use these headings: Purpose, Methods, Results, Conclusions. As the abstract is often the most widely visible part of your paper, it is important that it conveys succinctly all the most important features of your study. You can save words by writing short, direct sentences. Helpful hints about writing the conclusions to abstracts can be found here.

Keywords

Please provide appropriate keywords.

Acknowledgements

Contributions from anyone who does not meet the criteria for authorship should be listed, with permission from the contributor, in an Acknowledgments section. Financial and material support should also be mentioned. Thanks to anonymous reviewers are not appropriate.

Statement of Contribution

All authors are required to provide a clear summary of 'what is already known on this subject?' and 'what does this study add?'. Authors should identify existing research knowledge relating to the specific research question and give a summary of the new knowledge added by your study. Under each of these headings, please provide 2-3 (maximum) clear outcome statements (not process statements of what the paper does); the statements for 'what does this study add?' should be presented as bullet points of no more than 100 characters each.

Main Text File

As papers are double-anonymous peer reviewed, the main text file should not include any information that might identify the authors.

Manuscripts can be uploaded either as a single document (containing the main text, tables and figures), or with figures and tables provided as separate files. Should your manuscript reach revision stage, figures and tables must be provided as separate files. The main manuscript file can be submitted in Microsoft Word (.doc or .docx) or LaTex (.tex) format.

If submitting your manuscript file in LaTex format via Research Exchange, select the file designation "Main Document – LaTeX .tex File" on upload. When submitting a LaTex Main Document, you must also provide a PDF version of the manuscript for Peer Review. Please upload this file as "Main Document - LaTeX PDF." All supporting files

that are referred to in the LaTex Main Document should be uploaded as a "LaTeX Supplementary File."

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Please check that you have supplied the following files for typesetting post-acceptance:

- PDF of the finalized source manuscript files compiled without any errors.
- The LaTeX source code files (text, figure captions, and tables, preferably in a single file), BibTex files (if used), any associated packages/files along with all other files needed for compiling without any errors. This is particularly important if authors have used any LaTeX style or class files, bibliography files (.bbl, .bst. .blg) or packages apart from those used in the NJD LaTex Template class file.
- Electronic graphics files for the illustrations in Encapsulated PostScript (EPS),
 PDF or TIFF format. Authors are requested not to create figures using LaTeX codes.

Your main document file should include:

- A short informative title containing the major key words. The title should not contain abbreviations;
- Abstract structured (intro/methods/results/conclusion);
- Up to seven keywords;
- Main body: formatted as introduction, materials & methods, results, discussion, conclusion;
- References:
- Tables (each table complete with title and footnotes);
- Figure legends: Legends should be supplied as a complete list in the text. Figures should be uploaded as separate files (see below)
- Statement of contribution

Supporting information should be supplied as separate files. Tables and figures can be included at the end of the main document or attached as separate files but they must be mentioned in the text.

- The main text file should not include any information that might identify the authors. Please do not mention the authors' names or affiliations and always refer to any previous work in the third person.

 The journal uses British spelling; however, authors may submit using either option, as spelling of accepted papers is converted during the production process.

References

This journal uses APA reference style; as the journal offers Free Format submission, however, this is for information only and you do not need to format the references in your article. This will instead be taken care of by the typesetter.

Tables

Tables should be self-contained and complement, not duplicate, information contained in the text. They should be supplied as editable files, not pasted as images. Legends should be concise but comprehensive – the table, legend, and footnotes must be understandable without reference to the text. All abbreviations must be defined in footnotes. Footnote symbols: †, ‡, §, ¶, should be used (in that order) and *, **, *** should be reserved for P-values. Statistical measures such as SD or SEM should be identified in the headings.

Figures

Although authors are encouraged to send the highest-quality figures possible, for peer-review purposes, a wide variety of formats, sizes, and resolutions are accepted.

Click here for the basic figure requirements for figures submitted with manuscripts for initial peer review, as well as the more detailed post-acceptance figure requirements.

Legends should be concise but comprehensive – the figure and its legend must be understandable without reference to the text. Include definitions of any symbols used and define/explain all abbreviations and units of measurement.

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Supporting information is information that is not essential to the article, but provides greater depth and background. It is hosted online and appears without editing or typesetting. It may include tables, figures, videos, datasets, etc.

Click here for Wiley's FAQs on supporting information.

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- Units of measurement: Measurements should be given in SI or SI-derived units.
 Visit the Bureau International des Poids et Mesures (BIPM) website for more information about SI units.
- Effect size: In normal circumstances, effect size should be incorporated.
- Numbers: numbers under 10 are spelt out, except for: measurements with a unit (8mmol/l); age (6 weeks old), or lists with other numbers (11 dogs, 9 cats, 4 gerbils).

Wiley Author Resources

Manuscript Preparation Tips: Wiley has a range of resources for authors preparing manuscripts for submission available here. In particular, we encourage authors to consult Wiley's best practice tips on Writing for Search Engine Optimization.

Article Preparation Support: Wiley Editing Services offers expert help with English Language Editing, as well as translation, manuscript formatting, figure illustration, figure formatting, and graphical abstract design – so you can submit your manuscript with confidence.

Also, check out our resources for Preparing Your Article for general guidance and the BPS Publish with Impact infographic for advice on optimizing your article for search engines.

ECR Best Paper Award

The BPS Early Career Researcher Best Paper Award is open to researchers and practitioners who completed their highest degree no more than five years ago. Please read full terms and criteria before applying. Those who wish to apply can opt-in to the question when submitting their manuscript for peer review.

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Except where otherwise stated, the journal operates a policy of anonymous (double-anonymous) peer review. Please ensure that any information which may reveal author identity is anonymized in your submission, such as institutional affiliations, geographical location or references to unpublished research. We also operate a triage process in which submissions that are out of scope or otherwise inappropriate will be rejected by the editors without external peer review. Before submitting, please read the terms and conditions of submission and the declaration of competing interests.

The Journal receives a large volume of papers to review each year, and in order to make the process as efficient as possible for authors and editors alike, all papers are initially examined by the Editors to ascertain whether the article is suitable for full peer review. In order to qualify for full review, papers must meet the following criteria:

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- research with student populations is appropriately justified
- the word count is within the stated limit for the Journal (i.e. 5000 words, or 6,000 words for qualitative papers)

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Randomised trials: CONSORTSystematic reviews: PRISMA

- Interventions: TIDieR

We encourage authors to adhere to the APA Style Journal Article Reporting Standards for:

- Manuscripts that report primary qualitative research
- Manuscripts that report the collection and integration of qualitative and quantitative data
- Manuscripts that report new data collections regardless of research design

We also encourage authors to refer to and follow guidelines from:

- Future of Research Communications and e-Scholarship (FORCE11)
- The Gold Standard Publication Checklist from Hooijmans and colleagues
- FAIRsharing website

Conflict of Interest

The journal requires that all authors disclose any potential sources of conflict of interest. Any interest or relationship, financial or otherwise that might be perceived as influencing an author's objectivity is considered a potential source of conflict of interest. These must be disclosed when directly relevant or directly related to the work that the authors describe in their manuscript. Potential sources of conflict of interest include, but are not limited to: patent or stock ownership, membership of a company board of directors, membership of an advisory board or committee for a company, and consultancy for or receipt of speaker's fees from a company. The existence of a conflict of interest does not preclude publication. If the authors have no conflict of interest to declare, they must also state this at submission. It is the responsibility of the corresponding author to review this policy with all authors and collectively to disclose with the submission ALL pertinent commercial and other relationships.

Funding

Authors should list all funding sources in the Acknowledgments section. Authors are responsible for the accuracy of their funder designation. If in doubt, please check the Open Funder Registry for the correct nomenclature:

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Data Sharing and Data Accessibility Policy

The British Journal of Health Psychology recognizes the many benefits of archiving data for scientific progress. Archived data provides an indispensable resource for the scientific community, making possible future replications and secondary analyses, in

addition to the importance of verifying the dependability of published research findings.

The journal expects that where possible all data supporting the results in papers published are archived in an appropriate public archive offering open access and guaranteed preservation. The archived data must allow each result in the published paper to be recreated and the analyses reported in the paper to be replicated in full to support the conclusions made. Authors are welcome to archive more than this, but not less.

All papers need to be supported by a data archiving statement and the data set must be cited in the Methods section. Where relevant, the paper must include a link to the repository in order that the statement can be published.

It is not necessary to make data publicly available at the point of submission, but an active link must be included in the final accepted manuscript. For authors who have pre-registered studies, please use the Registered Report link in the Author Guidelines.

In some cases, despite the authors' best efforts, some or all data or materials cannot be shared for legal or ethical reasons, including issues of author consent, third party rights, institutional or national regulations or laws, or the nature of data gathered. In such cases, authors must inform the editors at the time of submission. It is understood that in some cases access will be provided under restrictions to protect confidential or proprietary information. Editors may grant exceptions to data access requirements provided authors explain the restrictions on the data set and how they preclude public access, and, if possible, describe the steps others should follow to gain access to the data.

If the authors cannot or do not intend to make the data publicly available, a statement to this effect, along with the reasons that the data is not shared, must be included in the manuscript.

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Authors are reminded that the British Journal of Health Psychology adheres to the ethics of scientific publication as detailed in the Ethical principles of psychologists and code of conduct (American Psychological Association, 2010). The Journal generally conforms to the Uniform Requirements for Manuscripts of the International Committee of Medical Journal Editors (ICJME) and is also a member and subscribes to

the principles of the Committee on Publication Ethics (COPE). Authors must ensure that all research meets these ethical guidelines and affirm that the research has received permission from a stated Research Ethics Committee (REC) or Institutional Review Board (IRB), including adherence to the legal requirements of the study county.

Note this journal uses iThenticate's CrossCheck software to detect instances of overlapping and similar text in submitted manuscripts. Read Wiley's Top 10 Publishing Ethics Tips for Authors here. Wiley's Publication Ethics Guidelines can be found here.

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Once the paper is typeset, the author will receive an email notification with full instructions on how to provide proof corrections.

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8. POST PUBLICATION

Access and Sharing

When the article is published online:

- The author receives an email alert (if requested).
- The link to the published article can be shared through social media.
- The author will have free access to the paper (after accepting the Terms & Conditions of use, they can view the article).
- For non-open access articles, the corresponding author and co-authors can nominate up to ten colleagues to receive a publication alert and free online access to the article.

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For help with submissions, please contact the Editorial Assistant at bjhp@wiley.com.

Appendix K - CONSORT Guidelines Extension for Randomised Pilot and Feasibility Studies (Eldridge et al., 2010)

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract	110	Shookiist item	110
	1a	Identification as a pilot or feasibility randomised trial in the title	105
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	106
Introduction	1		1
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	
	2b	Specific objectives or research questions for pilot trial	108
Methods	1		1
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	109-110
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	110
	4b	Settings and locations where the data were collected	111-112
	4c	How participants were identified and consented	109-111
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	111-112

Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	111-112
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	NA
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	NA
Sample size	7a	Rationale for numbers in the pilot trial	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence	8a	Method used to generate the random allocation sequence	
generation 8b		Type of randomisation(s); details of any restriction (such as blocking and block size)	
Allocation 9 concealment mechanism		Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	NA
Implementation 10 Who generated the random allocation seques who assigned participants to interventions		Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	NA
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	NA
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods 12 Methods used to address each pilot trial objective whether qualitative or quantitative		111-112	

Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	-
	13b	For each group, losses and exclusions after randomisation, together with reasons	115-116
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the pilot trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	115
Numbers analysed	umbers analysed 16 For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group		116
Outcomes and estimation			NA
Ancillary analyses	ncillary analyses 18 Results of any other analyses performed that could be used to inform the future definitive trial		NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
	19a	If relevant, other important unintended consequences	NA
Discussion		•	I
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	129-130
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	127-129

Interpretation	Interpretation 22 Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence		127-129
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	130-131
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	109
Protocol	Protocol 24 Where the pilot trial protocol can be accessed, if available		N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	109
	26	Ethical approval or approval by research review committee, confirmed with reference number	109

From: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, Lancaster GA; on behalf of the PAFS consensus group. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. This work is licensed under CC BY 4.0.

Appendix L – Research Ethics Committee and Health Research Authority Approval



Yorkshire & The Humber - Bradford Leeds Research Ethics Committee

NHSBT Newcastle Blood Donor Centre Holland Drive Newcastle upon Tyne NE2 4NQ

Telephone: 02071048083

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

27 March 2024

Miss Sophie Livsey



Dear Miss Livsey

Study title: Adapted Cognitive Stimulation Therapy (CST) for

Pre-frail Stroke Survivors: A Non-randomised,

Acceptability and Feasibility Pilot Study

REC reference: 24/YH/0075 IRAS project ID: 335493

Thank you for your letter recent correspondence, responding to the Research Ethics Committee's (REC) request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Vice-Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Good practice principles and responsibilities

The <u>UK Policy Framework for Health and Social Care Research</u> sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

- 1. registering research studies
- 2. reporting results
- 3. informing participants
- 4. sharing study data and tissue

Conditions of the favourable opinion

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

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a public registry before the first participant is recruited and no later than six weeks after. For this purpose, 'clinical trials' are defined as:

- · clinical trial of an investigational medicinal product
- · clinical investigation or other study of a medical device
- combined trial of an investigational medicinal product and an investigational medical device
- other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

A 'public registry' means any registry on the WHO list of primary registries or the ICMJE list of registries provided the registry facilitates public access to information about the UK trial.

Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by the HRA (for more information on registration and requesting a deferral see: Research registration and research project identifiers).

Where a deferral is agreed we expect the sponsor to publish a <u>minimal record</u> on a publicly accessible registry. When the deferral period ends, the sponsor should publish the full record on the same registry, to fulfil the condition of the REC favourable opinion.

If you have not already included registration details in your IRAS application form you should notify the REC of the registration details as soon as possible.

Where the study is registered on ClinicalTrials.gov, please inform <u>deferrals@hra.nhs.uk</u> and the Research Ethics Committee (REC) which issued the final ethical opinion so that our records can be updated.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter. Where a deferral is agreed, <u>a minimum research summary</u> will still be published in <u>the research summaries database</u>. At the end of the deferral period, we will publish the <u>full research summary</u>.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: Research summaries - Health Research Authority (hra.nhs.uk)

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- · Notifying substantial amendments
- Adding new sites and investigators
- · Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- · Reporting results

The latest guidance on these topics can be found at <u>Managing your approval - Health Research</u> Authority (hra.nhs.uk)

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

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

Deciment					
Document Control of the United States of the United	Version	Date 0004			
Copies of materials calling attention of potential participants to the research [Research Poster]	2	22 March 2024			
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UEA Insurance Evidence - all]	1	01 August 2023			
GP/consultant information sheets or letters [Letter to Stroke Survivors' GP]	1	05 November 2023			
IRAS Application Form [IRAS_Form_29022024]		29 February 2024			
Letter from sponsor [UEA Sponsor Letter]	1	23 February 2024			
Letters of invitation to participant [Cover letter for PIS]	2	12 February 2024			
Non-validated questionnaire [Theoretical Framework of Acceptability Questionnaire]	1	08 December 2023			
Non-validated questionnaire [Demographics questionnaire]	1	08 December 2023			
Non-validated questionnaire [Research Interest Form]	1	08 December 2023			
Participant consent form [Consent form for stroke survivor participants]	2	11 June 2023			
Participant consent form [Consent to contact about research form]	1	29 November 2023			
Participant consent form [Carer Clean/Tracked]	3	22 March 2024			
Participant consent form [Stroke survivor Clean/Tracked]	3	22 March 2024			
Participant information sheet (PIS) [Carers Clean/tracked]	3	22 March 2024			
Participant information sheet (PIS) [Stroke Survivor (Clean/Tracked)]	5	22 March 2024			
Protocol [Clean/Tracked]	0.3	26 March 2024			
Response to Additional Conditions Met					
Response to Request for Further Information					
Summary CV for Chief Investigator (CI) [SLivsey CV]	1	23 February 2024			
Summary CV for student [SLivsey CV]	1	23 February 2024			
Summary CV for student [MBramley CV]	1	18 November 2023			
Summary CV for supervisor (student research) [CFord CV]	1	07 December 2023			
Summary CV for supervisor (student research) [NBroomfield CV]	1	07 December 2023			

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

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

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities—see details at: <u>Learning - Health Research Authority (hra.nhs.uk)</u>

IRAS project ID: 335493 Please quote this number on all correspondence

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

Yours sincerely

Pn

Dr Sheila MacLennan Vice Chair

H Hendr

Email:bradfordleeds.rec@hra.nhs.uk

Copy to: Ms Sarah Ruthven, Sponsor Contact

Appendix M - Participant Information Sheet





Form version: 7 Date created: 02/07/2024 REC Ref: 24/YH/0075 IRAS Project ID: 335493

Chief Investigator: Sophie Livsey, Trainee Clinical Psychologist

Sponsor: University of East Anglia

Adapted Cognitive Stimulation Therapy (CST) for Pre-frail Stroke Survivors: A Non-randomised, Acceptability and Feasibility Pilot Study

Stroke Survivor Participant Information Sheet

Summary

We are recruiting participants who have recently had a stroke to take part in our research study.

The lead researcher of this study, Sophie Livsey, is a Trainee Clinical Psychologist completing their Doctorate in Clinical Psychology at the University of East Anglia. This research project is being conducted as part of their studies.

In this pilot study, we are hoping to test the acceptability of a therapy group that is designed to help people practise and develop their memory and thinking skills. 'Acceptability' is the degree to which the intervention seems ethical, relevant, helpful, manageable and likeable.

In order to do this, you are invited to take part by attending a few sample sessions of an intervention and then giving feedback about your experience.

In this research study we will use information from you. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study, we will save some of the data in case we need to check it. We will make sure no-one can work out who you are from the reports we write.

The information pack tells you more about this.

Why have I been given this information sheet?

You have received this information sheet because you have had a stroke within the past twelve months and have been identified by members of your clinical team as possibly meeting criteria to take part in this research.





Background and further information

Individuals who have had a stroke are twice as likely to experience frailty than the general population. Frailty can lead to negative health outcomes, such as disability, poorer recovery and lower quality of life.

Some people may not be frail after a stroke but may have lost some of their physical resilience. This is sometimes known as 'pre-frailty' because it can be a sign that frailty is more likely to develop later on.

Some research has shown that frailty can be prevented by offering 'multi-component interventions' – this is when two or more different therapies that aim to help with different aspects of health, happen at the same time. Usually, the combination is physical exercise therapy, memory and thinking skills therapy, and diet education.

The memory and thinking skills therapies that have been used in stroke and frailty research vary greatly—there is no agreement yet on what they should include or how they should be done.

One well-known therapy for memory and thinking is called Cognitive Stimulation Therapy (CST). This was originally designed for dementia and is usually run in groups. It has been found to improve memory and thinking ability, as well as quality of life.

This study hopes to find out whether an adapted version of CST would be an acceptable intervention for people who have had a stroke. Specifically, whether it seems relevant, helpful, manageable and likeable. This will help to inform further research on the prevention of frailty after stroke.

Who can take part?

You can take part if you:

- ✓ Are 18+ years old
- ✓ Had a stroke 12 months ago, or less
- ✓ Are due to be discharged back home before the adapted CST group starts
- ✓ Are experiencing a loss of physical resilience as a result of your stroke
- ✓ Are experiencing some difficulty with your memory or thinking as a result of your stroke
- ✓ Have a family member or friend who regularly supports you and is willing to take part in a connected research study
- ✓ Have the ability to speak and read the English language to participate fully in the adapted CST group and online interview

You cannot take part if you:

- Have significant difficulties with language, memory or thinking that would make taking part too difficult
- Are not able to independently make the decision about whether you would like to take part
- Have a diagnosis of dementia
- Do not have access to a computer, laptop or tablet from which you can access an online interview





What is involved?

Before the group

A member of the research team will arrange a visit to your home or to the ward to talk through this sheet further and answer questions.

You will be asked to complete a brief demographic information questionnaire.

During the group

Attend **eight sample sessions of the adapted CST group intervention**. You will be invited to Addenbrooke's Hospital **once a week for four weeks**. During each visit, two 45-minute sessions will take place back-to-back with a short break in between. **Each 'visit' to the hospital will therefore last up to 2 hours**.

There will be up to twelve people in the sessions: ten stroke survivors and two researchers who will lead the group. The group sessions will start in a few weeks' time, we will be in touch nearer the time to confirm exact dates if you agree to take part.

In the group sessions, you will be asked to participate in activities (discussions, games, etc.) that are designed to get your brain active. Each session will have a theme and will be structured as follows:

- 1. Introduction welcome, group song, discussion of recent news stories
- 2. Main activity for example, in the 'Faces' session, we will ask you to think about different, fun ways to help you remember the names of new people.
- 3. Summary of session and handing out 'take-home activity sheets

After the group

You will be asked to complete a brief online questionnaire about what you thought of the group sessions. This should take no more than a few minutes to complete.

Then, a week or two after the group CST sessions finish, you will be asked to attend an online interview, via Microsoft Teams, for up to two hours. During this, you will be asked a series of questions about the sessions you attended, which will be discussed as a group. The interview will be recorded using the built-in video and audio recording in Microsoft Teams so that the interview can be transcribed.

Possible advantages of taking part

We cannot guarantee any health benefits to taking part in this research, but:

- Your participation in this study may lead to further research into the development of new treatments after stroke.
- You may find it beneficial to get to know other like-minded stroke survivors
 who take part in the study and, possibly, develop valuable friendships
- You will be able to receive a follow-up appointment with one of the Consultants in Stroke Medicine up to 6 months after the research study has finished, if needed
- You will receive a £10 shopping voucher as a thank you for taking part





Possible disadvantages of taking part

- This study will require approximately 11 hours of your time
- Unfortunately, travel costs to and from Addenbrooke's cannot be reimbursed, but discounted parking at the hospital can be arranged at a rate of £4.80 per day, which can be reimbursed by researchers upon request.
- There is a possibility that taking part in this study could cause adverse effects (such as increased fatigue) or exacerbate existing difficulties (such as anxiety)
- There is also a chance that you will not get on with all other group members, although researchers will make efforts to minimise the impact of this

Other Important Information-Q&A

Q: If I have been given this information sheet, do I have to take part?

A: No, participation in this study is voluntary, Please consider all the information in this leaflet and discuss any questions with the researcher before you make your decision

Q: What will happen in relation to my care if I do not wish to take part?

A: If you do not wish to take part, the medical care you receive will not be affected. However, if you think that taking part will interfere with your other medical appointments, please discuss this with the researchers and/or your medical team.

Q: What can I expect during the consent process?

A: You will have at least 24 hours after receiving this information sheet to consider whether you would like to take part in the study. One of the researchers will visit you again soon and you will have the opportunity to ask any questions you may have. If you are willing to take part, then you will be guided through the consent form.

Q: How will you use information about me?

A: We will need to use information from you and your medical records for this research project. This information will include:

- Your full name
- Contact Details
- Other Demographic Information (age, gender, education, ethnicity)

Researchers will use this information to do the research and check your records to obtain information about your stroke and the impact it has had on your health and physical resilience. This is explained further on the next page. Your name and contact details are only required for communication between the researcher and yourself and will be destroyed after communication is no longer needed. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no one can work out that you took part in the study.





We will keep all information about you safe and secure. Your information will be assigned an anonymous participant code, data we collect from you within the study will not be linked to you by name or any other identifying information. Data and other information we collect from you will be held in a secure online server.

Due to the group setting of the CST sessions, you will be expected to share your first name or a preferred nickname with fellow participants. You have a choice in what other information you choose to share with other participants.

Some direct quotes may be published from the interview, however, these will be anonymised and care will be taken to not publish any quotes that may identify you.

There may be some situations in which researchers may wish to share information about you with other appropriate agencies. for example, if there is a revelation of harm or potential harm to you or another person. If possible, researchers will let you know if they feel this is necessary.

As part of the consent process, you will also be asked if you consent to researchers sending a letter to your GP to let them know about the study and that you have decided to take part.

Demographic information will be anonymously reported in the write-up of the study, in order to describe the characteristics of the participant sample.

Q: Will any of my medical data be accessed, and for what purpose?

A: Yes, medical data that is relevant to your stroke and the impact it has had on your health will be collected (e.g. what type of stroke you had, when you had it, score on memory and thinking tests). This information will be anonymously reported in the write-up of this study, in order to describe characteristics of the participant sample. We will write this in a way that no one can work out that you took part in the study.

Q: What are my choices about how my information is used?

A: You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Q: Where can I find out more about how my information is used?

A: You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/, or by contacting one of the research team members. Our contact details are on the first page of this information sheet.

Q: What will happen if I don't want to carry on with the study?

A: You are free to withdraw from the study at any point if you wish to do so. If you withdraw part way through the research, we will retain the information about you we already have but we will not obtain any new information from or about you from that point onwards. If the reason for withdrawal is due to a medical or health reason, you will





be offered a review appointment with a physician or psychologist within the Addenbrooke's stroke services. You are encouraged to contact a member of the research teams if you have any concerns about the study and your participation.

If you decide that you would not like to continue attending the group CST sessions, you will be given the option to withdraw from the study completely or drop out of the group but remain in the study so that you can still attend an interview to give your feedback. It is important we hear both positive and negative feedback about the CST therapy group to help us develop it further.

If your ability to fully understand, retain and balance information about participating in the study changes, researchers will speak to you about the possibility of withdrawing from the study.

Q: What if something goes wrong?

A: If something happens, such as increased fatigue or distress, you will have the option to discuss your concerns with the researcher to see if adaptations can be made for you or if you need to withdraw. If you, or the researchers, develop any concerns about your health or wellbeing throughout the study we will discuss this with you a follow-up appointment with a physician or psychologist within the stroke services can be arranged. A physician will also be in the room during the group sessions at Addenbrooke's and will be able to assist you should any health events occur.

Q: What will happen to the results of this study?

A: This study will form part of the researcher's thesis for the award of a Doctorate in Clinical Psychology. The results of this study will be shared with researchers within the field and hopefully be published for wider access. Results can also be shared directly with you, the participant, via email or other preferred contact method if you so wish.

0: Who is organising and funding this study?

A: The lead researcher is Sophie Livsey, a Trainee Clinical Psychologist on the doctoral programme in clinical psychology at the University of East Anglia. The research is funded by the University of East Anglia.

Q: How have patients and the public been involved in this study?

A: An advisory group made of a stroke survivor and their carer was formed for the purpose of this study, they assisted with the design of research, research materials (such as this information sheet) and the adaptation of the intervention.

Q: Who has reviewed this study?

A: This research study has received a favourable opinion by the NHS Health Research Authority, the University of East Anglia and the Cambridge University Hospitals NHS Trust.





Thank You!

Thank you for taking the time to read this information sheet. Please, now take some time to consider the information in this sheet and think carefully about whether or not you are willing and happy to take part. Please do discuss or share the information here with others who can help you make a decision, such as trusted family members, friends or health professionals.

If you have any questions or concerns about the information in this document, please contact the researcher or their supervisors at the University of East Anglia, using the following contact information.

Lead researcher: Sophie Livsey (S.Livsey@uea.ac.uk)

Research supervisors: Dr Catherine Ford (<u>Catherine.Ford@uea.ac.uk</u>) and Professor Niall Broomfield (<u>N.Broomfield@uea.ac.uk</u>)

If you wish to make a complaint about this research or the researcher, please contact Professor Sian Coker, Programme Director for the Clinical Psychology Doctorate at the University of East Anglia: s.coker@uea.ac.uk

Appendix N - Consent Form

IRAS ID: 335493 Participant Identification Number for this trial:

Version 5 - 02/07/2024



STROKE SURVIVOR CONSENT FORM

Title of Project: Acceptability of Adapted Cognitive Stimulation Therapy (CST) for Pre-frail Stroke Survivors

Name of Researcher: Sophie Livsey	
Please in	nitial in box
 I confirm that I have read the information sheet dated 02/07/2024 (version 7) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. 	
 I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected, however, data already gathered with consent will be retained for the study. 	
 I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the University of East Anglia, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. 	
 I consent to the storage and processing of personal information and data for the purpose of this study. 	
 I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers. 	
I agree to my General Practitioner being informed of my participation in the study.	
 I agree to information about my participation in this study being shared with other health professionals involved in my care, where necessary and appropriate 	
I agree to take part in the above study. When completed: 1 for participant: 1 for researcher site file: 1 to be uploaded to medical records.	

Version 5 – 02/07/2024 Page 1 of 2

Name of Person taking consent	Date	Signature	
Name of Participant	Date	Signature	
	•	arch once these are available and, therefore, ain my personal contact information until this time.	
Optional			
	tudy change, researche	nderstand, retain and balance information about ers will speak to me about the possibility of	
to keep myself and		t this information will be shared with the relevant bodies	
However, if there is	a sign that either I or the	neral Data Protection Regulations 2018. e person who I care for may come to serious	
		during the study will be treated as strictly confidential	

Appendix O - GP Letter

IRAS Number: 335493



Clinical Psychology Doctorate Programme
Norwich Medical School
University of East Anglia
Norwich Research Park
Norwich
Norfolk
NR4 7JT

[Date]

[Name of Dr] [Address of Dr]

Dear Dr

RE: Adapted Cognitive Stimulation Therapy (CST) for Pre-Frail Stroke Survivors: a non-randomised, mixed methods pilot study

[IRAS Reference Number]

[Patient Name], [Address], [D.O.B].

The above patient has kindly agreed to take part in the above-named research study. This is a brief feasibility study where we are piloting the use of a cognitive intervention to assess its acceptability for Pre-Frail Stroke Survivors. CST is an intervention usually used in those with a diagnosis of dementia, but research has shown that similar cognitive-based psycho-social interventions can reverse frailty in some patient populations when used as part of multi-component interventions (Apóstolo et al., 2018; Dedeyne et al., 2017; Tam et al., 2022). We are therefore interested to find out if an adapted version of CST would be acceptable to pre-frail stroke survivors and their carers, before further research into the potential use of this intervention in the management of frailty in stroke patients. The results of this feasibility study will form part of a larger feasibility study led by Dr Nicholas Evans, Stroke Association Senior Clinical Lecturer at the University of Cambridge, and Honorary Consultant in Stroke Medicine at Addenbrooke's Hospital.

Letter to GP V2 02/07/2024

IRAS Number: 335493



Pre-frail stroke survivors will be asked to attend CST sessions across the course of four weeks at Addenbrookes Hospital. Each week, two of the eight 45-minute-long sessions will be delivered on the same day, separated by a fatigue break. Once all eight sessions have been delivered, individual interviews will take place via Microsoft Teams, each lasting a maximum of two hours, to gain participants' perspectives of the acceptability of the intervention. A brief Likert-scale questionnaire will also be administered to supplement the qualitative data.

The above patient has been recruited into this study as a part of a dyad, their informal carer (**insert relationship**) will support them throughout the duration of the intervention. Their carer will not attend the group but will have the opportunity to share their feedback on the intervention as part of a connected study.

A copy of the participant information sheets are enclosed for your information. Should you have any questions regarding these studies, please do not hesitate to contact either lead researcher by email [m.bramley@uea.ac.uk] or s.livsey@uea.ac.uk].

Yours sincerely,

Sophie Livsey and Max Bramley

Trainee Clinical Psychologists, University of East Anglia

Supervised by:

Dr Catherine Ford

Clinical Associate Professor, University of East Anglia

Professor Niall Broomfield

Professor of Clinical Psychology, University of East Anglia

Encl. Participant information sheet for stroke survivor Participant information sheet for carer

Appendix P - Debrief Letter

IRAS Number: 335493

University of East Anglia

Clinical Psychology Doctorate Programme
Norwich Medical School
University of East Anglia
Norwich Research Park
Norwich
Norfolk
NR4 7JT

Dear .

RE: Acceptability of Adapted Cognitive Stimulation Therapy (CST) for Pre-frail Stroke Survivors

Thank you for your participation in the above research study, we recognize that you have donated a considerable amount of your own time to this research so as a token of gratitude, please find enclosed a £10 shopping voucher each.

By participating in this study, you have helped us to understand whether an adapted version of Cognitive Stimulation Therapy is an acceptable treatment for people who have had a stroke and their carers. The findings of this study will inform and guide further research into treatments and therapies to prevent frailty after stroke.

Research findings

If you would like to receive a copy of the final report once the study is complete, please contact one of the researchers via email (s.livsey@uea.ac.uk or m.bramley@uea.ac.uk)

Withdrawal of data

As we explained before the study began, we need to manage the information we keep about you in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. Therefore, unfortunately you are not able to withdraw your data.

Questions

If you have any questions about the research or your participation, you may contact the lead researchers, Sophie Livsey (lead researcher for stroke survivors) or Max Bramley (lead researcher for informal carers) via email (s.livsey@uea.ac.uk or m.bramley@uea.ac.uk).

Alternatively, you can contact the primary research supervisor, Dr Catherine Ford, Clinical Associate Professor at the University of East Anglia, via email (Catherine.ford@uea.ac.uk).

Any complaints about the research or researchers can be directed to Professor Sian Coker, the Clinical Psychology Doctorate Programme Director (<u>s.coker@uea.ac.uk</u>).

If you have any further questions about your healthcare treatments, your stroke or concerns regarding frailty, please contact your GP or other medical professionals involved in your care. If you would like more support following your stroke, you may find the following organisations helpful:

Stroke Association

o Website: www.stroke.org.uk

Email: helpline@stroke.org.uk

o Tel: 0303 3033 100

Cambridge Stroke Group

Website: www.cambridgestrokegroup.co.uk
 Email: info@cambridgestrokegroup.co.uk

Headway

Website: www.headway.org.ukEmail: enquiries@headway.org.uk

o Tel: 0115 924 0800

Thank you again and we wish you all the best for the future,

Sophie Livsey and Max Bramley

Trainee Clinical Psychologists, University of East Anglia

Supervised by:

Dr Catherine Ford

Clinical Associate Professor, University of East Anglia

Professor Niall Broomfield

Professor of Clinical Psychology, University of East Anglia

Encl. £10 Shopping voucher for stroke survivor £10 Shopping voucher for informal carer

Appendix Q - Demographics Questionnaire

Personal Information and Demographics



Pilot of Cognitive Stimulation Therapy for Pre-frail Stroke Survivors

Thank you for agreeing to take part in this research study.

Please take the time to complete the following questions which ask about your contact information and demographic details.

Why do we need this information?

We ask for your contact information so that we can remain in contact with you throughout the course of this research (for example, if we need to cancel a group session due to researcher sickness, and to send you instructions about how to join the online focus group). This information will be destroyed as soon as we no longer need to remain in contact with you.

We ask for your demographic information so that we can anonymously report information about the participants in the write up of the research study. We will write this in a way that no-one will be able to tell that you took part. This might look something like this: "of the 12 participants in the study, nine (75%) were White British, two (17%) were Pakistani and one (8%) was Black British". We will write this in a way that no-one will be able to tell that you took part.

Personal i	nformation	
Name		DoB
Address		
Email		
Phone		
Demograp	hic information	
	Please tick	Please tick
Gender	Female Highest level of Male Other Prefer not to say	of education O-Level/GCSE Apprenticeship A-Level Higher education (e.g. BA/BSc, diploma or above) Prefer not to say
Ethnicity	Please tick Asian or Asian British Indian Pakistani Bangladeshi Chinese Any other Asian background	Black, Black British, Caribbean or African Caribbean African African Any other Black, Black British, or Caribbean background
V1 - 08/12/	Mixed or multiple ethnic groups White and Black Caribbean White and Black African White and Asian Any other Mixed or multiple ethnic background	White English, Welsh, Scottish, Northern Irish or British Irish Gypsy or Irish Traveller Roma Any other White background

Appendix R - Theoretical Framework of Acceptability (TFA) Questionnaire

Acceptability Questionnaire

Pilot of Cognitive Stimulation Therapy for Pre-frail Stroke Survivors IRAS Project ID: 335493 V1 - 08/12/2023

Thank you for taking part in the adapted Cognitive Stimulation Therapy (CST) group sessions.

The aim of this research is to find out if the CST group is 'acceptable' to the stroke survivors who attend. In other words, whether people like the group and whether they think it is manageable, ethical, and possibly helpful.

Please take the time to answer the following questions about the group, it should not take more than a few minutes to complete.

It is important that you are honest. If you did not like the group, it is helpful for the researchers to know so that changes can be made before more research is carried out.

Your responses will be anonymous, so the researcher will not be able link you to the responses you submit.

You can ask a family member or friend to help you use this form, but try to answer the questions on your own. If you still have difficulties using this form or answering the questions, please contact the researcher, Sophie Livsey, at s.livsey@uea.ac.uk for more support.

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NEGU	III CU	

1. Did you like or dislike the adapted CST group? *

1 2 3 4 5

Strongly disliked Strongly liked

2.	How comfortal	ole did you feel	attending the	adapted CST gr	oup? *
	1	2	3	4	5
	Very uncomfortal	ole			Very comfortable
3.	How much effo	ort did it take to	engage with t	he adapted CS1	group? *
	1	2	3	4	5
	No effort at all				Huge effort
4.	How fair is the stroke? *	adapted CST gi	roup for people	e who have had	a recent
	1	2	3	4	5
	Very unfair				Very fair
5.		you agree or di al or ethical con	_		e adapted
	1	2	3	4	5
	Strongly disagree				Strongly agree
6.		you agree or di CST group has h ng" *	3		ealth
	1	2	3	4	5
	Strongly disagree				Strongly agree

1	2	3	4	5
Strongly disagree				Strongly agree
. How confident di group? *	d you feel ab	oout engaging i	n the adapted	CST
1	2	3	4	5
Very unconfident				Very confiden
"Attending the ac	•	-	s statement? I with my other	priorities"
The state of the s	•	-		priorities"
*	dapted CST g	roup interfered	I with my other	5
* 1 Strongly disagree	dapted CST g	roup interfered	I with my other	5
* 1 Strongly disagree	dapted CST g	roup interfered	I with my other	5
t 1 Strongly disagree How acceptable v	dapted CST g	roup interfered 3 vention to you?	with my other	5 Strongly agre

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Appendix S – TFA-Informed Topic Guide

Topic Guide

Research goals of the interview:

- How would pre-frail stroke survivors feel about adapted CST as an treatment?
- What do pre-frail stroke survivors think about the amount of effort that would be required to participate in an adapted CST treatment?
- What, if any, ethical consequences did pre-frail stroke survivors feel there might be to engaging in an adapted CST treatment?
- What did pre-frail stroke survivors see as the potential costs of engaging in an adapted CST treatment?
- How effective do pre-frail stroke survivors think an adapted CST treatment could be?
- How confident do pre-frail stroke survivors feel about engaging in an adapted CST treatment?
- How well do pre-frail survivors understand the adapted CST treatment and how it works?

Introduction – approximately 10 minutes:

- Welcome, introduction of the interview: "Thank you so much for attending the interview and X sessions. It is so great to be able to try an new treatment. Psychological aspects of stroke, including mood, memory and thinking have not been researched as much as other aspects so it is really important to do more research on this and so helpful to have people get involved"
- Instructions regarding the interview: "throughout this interview I will use the term 'treatment' as an umbrella term to refer to the group sessions you attended AND the take home sheets that provided additional information and activities."
- "In this interview I will ask you questions about your experience of

the memory and thinking skills treatment and how you felt about it"

- "Your views are important to us please feel free to be honest because your comments will help us to know what works well and what we might need to change in order to make it better. We will take a break half way through so you can go to the loo or get a drink, but if you need to step out at any point before or after this break please just let me know"

Main questions – up to 90 minutes with 10 minute break somewhere in the middle:

- "You attended X sessions, the themes of these were.... I will put these in the chat, along with a brief description of the activity we completed, in case this helps you to remember the sessions better"
- "You were also given some take home sheets with some additional optional activities on"
- "To start us off, could you please tell me one word that you feel summarises what you thought of the treatment?"
- "Thank you, let's talk a bit more about how you felt about the treatment
 - What did you like about the treatment? What did you dislike about it? (AA) (prompt for group sessions and or take home sheets/activities)
 - Did you find the treatment enjoyable? Why/why not? (AA)
 (prompt for group sessions and or take home sheets/activities)
 - Were there any other benefits to you as a result of the treatment? (AA/PE) (prompt for group sessions and or take home sheets/activities) (prompt for the process of attending)
 - Do you think that the treatment helped you in any way?(PE)
 - What did you find difficult about the sessions or the process of attending the sessions? (B/OC) (prompt for group sessions and or take home sheets/activities)
 - Practical challenges? (B)
 - Did you have to make any sacrifices to be able to attend?

(OC)

- Did anything about the treatment make you feel uncomfortable or distressed? (E) (prompt for group sessions and or take home sheets/activities) (prompt for the process of attending)
 - Was the treatment fair? Was there anything that didn't feel fair? (E)
- Did you feel confident and able to take part in the treatment? (prompt for group sessions and or take home sheets/activities) (prompt for the process of attending) Why/why not? (SE)
- Thinking back, how did you feel before attending the first session? (SE) Why? (prompt for the process of attending)
- Did the treatment feel relevant to you and the difficulties you experience after your stroke? (IC)
- Was it clear how the treatment might be helpful? (IC)
 - Memory and thinking
 - Mental wellbeing
 - General wellbeing and functioning/frailty
- In this trial, you attended two back-to-back sessions for 4 weeks. Now I'm going to ask some questions about the idea of a longer course of this treatment, such as one weekly session for 14 weeks.
 - If you were to be offered a longer course of sessions, say one session a week for 14 weeks, instead of two sessions a week for 4 weeks, how would you feel about that?
 - Why?
 - Do you think there would be any benefits to attending a full course of this intervention? If so what do you think the benefits could be? (if not mentioned – do you think this intervention would have any effect on your ability to complete your usual day-to-day tasks/your mood/your memory and thinking skills?)
 - Do you think a full course of this intervention would help you to achieve your goals?
 - What would be the barriers or challenges involved in attending a full course of this intervention?

- Finally, are there any changes or improvements that you would recommend?
- (refer back to previous downsides mentioned if possible)
 - o Format and structure?
 - o Length?
 - o Content?
 - Activities?
 - o Take home sheets?
 - o Anything missing?

Conclusion – approximately 10 minutes:

- Sum up what has been discussed, mention the positive aspects, compliment and thank the participants
 - o "Is there anything important to you we haven't mentioned?"
 - o "If you want to follow any issues you have talked about, you can contact myself or my supervisor via email"
 - "We will shortly send you a debrief letter which will explain your options about withdrawing from the study, raising concerns, and how you can be updated on the results of the study. You will also receive a £10 shopping youcher."