PROTOCOL

FULL/LONG TITLE OF THE STUDY
Adapted Cognitive Stimulation Therapy (CST) for Pre-frail Stroke Survivors: A Non-Randomised, Acceptability and Feasibility Pilot Study

SHORT STUDY TITLE / ACRONYM

Pilot of Cognitive Stimulation Therapy for Pre-frail Stroke Survivors

PROTOCOL VERSION NUMBER AND DATE

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Aims

This study aims to establish whether an adapted version of Cognitive Simulation Therapy (CST) is an acceptable treatment for stroke survivors meeting criteria for pre-frailty (an intermediate stage of frailty where some, but not all, signs of frailty are present) and their informal carers. This will inform further research on the application and efficacy of an adapted CST intervention within stroke rehabilitation. This is of relevance to the field of clinical psychology as it would constitute the first stage of development of a psychosocial intervention for use in rehabilitation pathways for frail and pre-frail stroke survivors and potentially suggest a role for clinical psychology within frailty treatment.

Background and Introduction

Stroke

There are around 100,000 strokes every year in the UK and, in 2021, approximately 1.3 million people were living with stroke (Stroke Association, n.d.) There are several adverse

outcomes and additional difficulties which are common after a stroke, such as depression, anxiety, dementia and possibly death (Craig et al., 2020; Ivan et al., 2004; Knapp et al., 2020; Medeiros et al., 2020).

Compared with other long-term conditions, stroke causes a greater range of disability (Adamson et al., 2004). Survivors often rely on informal carers in their day-to-day lives (Han & Hayley, 1999), with an Australian survey finding that 65% of stroke survivors need assistance with activities of daily living, with most spending over 40 hours per week supporting the survivor (Deloitte Access Economics, 2020). In the UK, the value of care by informal carers is estimated at £15.8 billion, almost double the £8.6 billion in NHS and care home and professional carer costs (Patel et al., 2020). Caring can give informal carers a sense of responsibility and value (Gok Metin et al., 2019). However, caring can also cause potential risk for strain, leading to financial, physical and psychosocial burdens, something more pronounced in caring for those who are frail due to associated morbidity (Garlo et al., 2010).

Frailty is another significant 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 those who develop frailty post-stroke have an increased risk of adverse outcomes (Burton et al., 2022; Evans et al., 2020, 2022) and that the severity of their frailty increases over time (Lee et al., 2014; Trevisan et al., 2017).

Frailty

Frailty is a state of vulnerability characterised by a multi-system decline in physiological reserves needed to maintain homeostasis following a stressor e.g., cold weather or bronchitis (Morley et al., 2013; Fried et al., 2001; Campbell & Buchner, 1997). 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. An alternative perspective on frailty was proposed by Mitnitski et al. (2001) suggesting that frailty refers to the number of health deficits an individual has accumulated.

Individuals assessed as 'pre-frail' have an increased risk of becoming frail in the following few years and those assessed as frail are 3-5 times more likely to die than those who are not frail or pre-frail (Gill et al., 2006). Frailty and pre-frailty are independently associated with many adverse outcomes, including psychosocial outcomes such as dementia, loneliness, cognitive decline, depression and lower quality of life (Chu et al., 2021; Hoogendijk et al., 2016; Soysal et al., 2017). However, Gill et al. (2006) identified that frailty is potentially reversible at the pre-frail stage, making pre-frailty an important target for intervention.

Multicomponent interventions are recommended as a first-line therapy for the management of frailty (Dent et al., 2019); these typically consist of weight-based training, provision of caloric supplements, and other physical interventions. Cognitive training interventions have also been found to reduce frailty scores, including as standalone interventions (Ng et al., 2015). Short-term memory, orientation, attention and concentration, speed of information processing, visuospatial processing, linguistic ability, and areas of executive function are targeted in cognitive interventions for frailty. These domains are targeted through a variety of games, including “spot the difference” tasks, maze activities, sorting activities, colouring tasks, memory games, matrix reasoning tasks, and in one study, virtual reality orientation tasks (Murukesu et al., 2020; Dent et al., 2019; Kwan et al., 2021). Cognitive interventions thus show the potential to prevent progression to frailty and associated adverse outcomes of frailty for individuals and informal carers, indicating a potential role for clinical psychology and psychologically informed interventions in the field of frailty management. Given

the prevalence of post-stroke frailty, there is a clear need for interventions to prevent or reverse frailty and reduce the risk of associated adverse outcomes; the above research indicates that multi-component interventions might be the way forward.

The FIESTO Project

Dr Nicholas Evans, Honorary Consultant in Stroke Medicine at Addenbrooke's Hospital and Senior Clinical Lecturer at the University of Cambridge, is leading the 'Frailty and Its Effects on Stroke Treatments and Outcomes' (FIESTO) project. This is hoped to lead to a feasibility randomised controlled trial (RCT) of a multicomponent intervention consisting of physical, cognitive and nutritional components for pre-frail stroke survivors. Initial work is required to develop each component, or 'strand', of the overall multicomponent intervention.

The development of a cognitive training intervention as part of this project will inform wider stroke rehabilitation research on psychological interventions for stroke survivors and their carers, identified as a research priority by the James Lind Alliance (2021) and the National Institute of Health and Care Excellence (NICE; 2013). This research also has the potential to be a valuable contribution to the growing understanding of interventions for frailty and identifying a role for clinical psychology within frailty management.

Cognitive Stimulation Therapy

Currently, there is limited consistency across multi-component interventions for pre-frail individuals regarding the mode of delivery, content, and duration of the cognitive training component (e.g. Apóstolo et al., 2019; Chen et al., 2020; Murukesu et al., 2020; Ng et al., 2015). However, some formats of the cognitive training used in these interventions share similarities with Cognitive Stimulation Therapy (CST; Spector et al., 2003) a NICE-recommended intervention with clearly defined principles for individuals with mild to moderate dementia (NICE, 2018). CST for dementia has been researched globally and found to improve

cognition, quality of life, well-being, activities of daily living, and mood (Aguirre et al., 2013; Lobbia et al., 2019). It does so in an environment promoting fun, learning, and the strengthening of abilities and social relationships among group members and facilitators, while maintaining cognitive skills - such as memory and orientation - in the context of dementia (Spector et al., 2006; Hall et al., 2013).

Aguirre et al. (2014) hypothesise informal carers may also benefit from CST due to an improvement in cognitive skills in those for whom they provide care. There is a small but promising qualitative literature supporting the benefits of CST for informal carers (Lauritzen et al., 2022, Rai et al., 2021), particularly when informal carers are involved in the delivery (Bailey et al., 2017., Leung et al., 2017; Orrell et al., 2017; Rai et al., 2021). Individuals with dementia attending CST interventions with informal carers were found to become more able to communicate socially and interact with others, leading to more positive relationships with informal carers (Bailey et al., 2017; Orrell et al., 2017).

Studies analysing the indirect benefit of CST for carers who did not attend CST reported greater equality in communication between the group member and carer due to improved verbal skills from the group member (Lauritzen et al., 2022; Spector et al., 2011). In these instances, the carer perceived the group as a possible source of happiness leading to carer enrichment and a sense of mutual growth in their relationship (Lauritzen et al., 2022). Positive interactions and bonding during the group generated and modelled feelings of positivity at home (Murray et al., 2016). A multicomponent intervention consisting of CST, exercise, and psychoeducation was beneficial for carers, reported the groups were meaningful for them (Skov et al., 2022). Psychoeducation about CST and the clinical contexts in which it is used may increase the acceptability for family carers, due to being reassured CST is a meaningful activity.

There is promising qualitative research supporting the benefits of CST for carers both when they were involved with the CST intervention in some form and when they were not

(Lauritzen et al., 2022; Skov et al., 2022; Orrell et al., 2017). Little research has analysed quantitative data for caregiver well-being regardless of whether they attend the group. However, in the two studies that do, the results were inconsistent (Aguirre et al., 2014; Rai et al., 2021) suggesting a need for further research in this area.

CST might, therefore, provide a good basis for the cognitive training strand of a multicomponent frailty intervention, including within stroke. CST has not yet been trialled in individuals with a primary diagnosis of stroke, but 25%-30% of ischemic stroke survivors go on to develop delayed vascular cognitive impairment or vascular dementia (Kalaria et al., 2016) and therefore may receive CST at a later stage. Two connected doctoral thesis projects are being proposed to test whether CST is a feasible and acceptable intervention for pre-frail stroke survivors. Although the majority of the recruitment will be conducted jointly, one project (led by Sophie Livsey) will invite stroke survivors to provide feedback about their experience and opinions of the intervention via an online acceptability questionnaire and a focus group and the other (led by Max Bramley) will invite their informal carers to provide their views on acceptability via separate focus groups. The data will also be analysed separately.

Research questions

The stroke survivor arm of this study will address the primary research question: 'Is an adapted Cognitive Stimulation Therapy intervention acceptable to pre-frail stroke survivors?'. Similarly, the informal carer arm will address the primary research question: 'Is an adapted Cognitive Stimulation Therapy intervention acceptable to the informal carers of pre-frail stroke survivors?'. These questions are important because, if the intervention were deemed unacceptable by either group then further adaptations, or a new intervention, will be required for use in the later feasibility trial of the full multicomponent intervention. Acceptability will be

operationalised in this study according to the Theoretical Framework of Acceptability (TFA) developed by Sekhon et al. (2017) which consists of seven constructs of acceptability (Appendix A).

Secondary research questions are: ‘’How can the intervention be improved?’, this question will help inform the development of the cognitive stimulation intervention adopted in the feasibility RCT; and “Is the intervention feasible to use in further research?”, in particular, we are interested to find out if it is feasible to recruit and retain the required numbers to run the group intervention to inform the protocol of future research hoping to utilise this intervention.

Patient and Public Involvement

Patient and Public Involvement (PPI) was sought from a pre-frail stroke survivor and her IC (husband). Their input has been sought to determine the acceptability of recruitment materials (participant information sheets [PIS] and joint leaflet), as such we have adapted the PIS and joint leaflet to include careful consideration when explaining frailty, to be more friendly and gentle to lay-persons and reduce the use of the term, in an effort to move away from the negative connotations that the PPI members felt the term holds. We continue to discuss how to best adapt CST materials to be acceptable to stroke survivors, this has included a suggestion of music being played in the background to the group song to compensate for difficulties common in projecting one's voice after stroke.

Adaptation of CST Materials

CST was developed by Spector et al. (2003) as a group intervention to help improve the cognition and quality of life in those with a diagnosis of dementia and was based on the theoretical concepts of reality orientation and cognitive stimulation. The intervention consists of 14 45-minute long sessions, recommended to be delivered twice per week for seven weeks. Each session is focused on a theme (e.g. food, sounds, faces and scenes) and contains

activities and discussion points designed to stimulate the use of memory and other cognitive skills (Spector et al., 2001). The CST manual (Spector et al., 2020) provides the theme for each session and suggests a choice of two activities relating to this theme.

Eight sessions of CST will be adapted for use in this pilot study. Adaptations have been, and will continue to be, made based on discussions with the PPI advisors and input from research team member, Dr Huw Green (Principal Clinical Psychologist in Stroke at Addenbrooke's Hospital). Adaptations will consider the types of activities that are included within the sessions and the 'take home sheets' and how the original principles of CST can be maintained as much as possible whilst still allowing for changes that will make the intervention more suited for stroke patients, based on the existing evidence for psychological and cognitive interventions for stroke.

The 'take home sheets', will be sheets that are given out after each session for the stroke survivor to take home and will include some psychoeducation information along with some optional, additional activities that can be completed at home with the informal carer. This is not something suggested in the original CST manual but is instead informed by the later developed Individual Cognitive Simulation Therapy, or iCST. In iCST the intervention sessions are completed in the home setting and led by a carer and have been found to improve the quality of the caregiving relationship between a person with dementia and their carer (Orrell et al., 2017).

Consent has been gained from the developers of CST to adapt the materials for use in this novel context.

For the remainder of this protocol, the adapted CST intervention that is to be used in this research will be referred to as *stroke-adapted cognitive stimulation therapy* or *sCST.* A draft, example session plan for sCST can be found in Appendix B.

Method

Design

This study will gather rich data on the acceptability of sCST for pre-frail stroke survivors to ascertain the suitability of the intervention for incorporation in the FIESTO feasibility RCT. As the study will examine the acceptability of the intervention prior to clinical trial, there will be no randomisation or control group, it is categorised as a non-randomised pilot study: a study in which “all or part of the intervention to be evaluated and other processes to be undertaken in a future trial are carried out without randomisation of participants” (Eldridge et al., 2016, p. 15).

This research will adopt a mixed methods design. Qualitative data will be collected via focus groups to gain a rich understanding of the acceptability of the intervention and how it could be changed and improved to best suit the needs and abilities of pre-frail stroke survivors from the perspective of both stroke survivors themselves and their informal carers. Descriptive quantitative data will also be collected from stroke survivors (not the informal carers) using the Theoretical Framework of Acceptability Questionnaire (Sekhon et al., 2022) to quantify acceptability, helping to highlight areas of strength or weakness in intervention acceptability. Data relating to recruitment success and group retention rates will also be collected and descriptively reported in order to determine the feasibility of recruiting participants to research using this intervention.

The philosophical stance, or paradigm, taken in this piece of research is that of pragmatism, where reality is socially constructed and, as such, it is unlikely that reality can ever be wholly understood. However, knowledge can be generated by understanding what practically works best (or doesn’t work) within the specific context (Kaushik & Walsh, 2019). Due to its balanced position and practical approach, pragmatism is well suited to feasibility research (Johnson & Onwuegbuzie, 2004).

Participants

Participants for this study will be ten dyads of adult pre-frail stroke survivors and their informal carers. The aim will be to recruit ten participants. The CST manual (Spector et al., 2020) suggested that a suitable group size for the intervention is between five and eight, however recruiting ten will allow for the possibility of group drop-out. This number is also thought to provide enough data to make meaningful conclusions about the acceptability of the intervention whilst also being a manageable number for a group intervention with two co-facilitators, thereby meeting the criteria suggested by Thabane et al. (2010). A sample size of 10 dyads is also supported by existing guidelines for qualitative analysis (Braun & Clarke, 2013). It is suggested that ten participants, divided into two focus groups of equal numbers, in line with previous research (Braun & Clarke, 2013; Guest et al., 2017) would be acceptable for this analysis.

It is planned to begin to recruit dyads when the stroke survivors are under the care of Addenbrooke's Hospital stroke services (Acute Stroke Unit and Lewin Rehabilitation Unit), participants will either be due to be discharged home or have recently been discharged home. Potential participant dyads will be identified by Addenbrooke's stroke services clinicians, who will have been fully briefed via a letter about the study and the below inclusion and exclusion criteria. Clinicians will bring the identified patients to the attention of Dr Nicholas Evans or Dr Huw Green, who work within the stroke services as an Honorary Consultant in Stroke Medicine and Principal Clinical Psychologist in Stroke, respectively. As Dr Evans and Dr Green are members of the clinical team, they will access the stroke survivors' medical records to confirm eligibility for the research before asking the identifying clinician to provide a poster about the research and seek consent from the patient to be contacted about research by completing a 'consent to contact' form which will be uploaded onto the patients' records and uploaded to a secure online folder (password-protected and located on the UEA OneDrive for Business). The

research poster will also give potential participants the option to register their interest in the research via an online Microsoft Forms form or to email the lead researchers directly, meaning a completed 'consent to contact' form would not be required.

If a dyad registers their interest in the research (using at least one of the above-mentioned methods), a member of the research team (Sophie Livsey, Max Bramley, Dr Nicholas Evans or Dr Huw Green) will contact the dyad by their preferred means (on the unit, or by phone or email) to discuss the research study and provide the participant information sheets. After a minimum of 24 hours, a member of the research team will visit them (either at home or on the unit, depending on circumstance), answer any questions they may have about the study and, if they agree to take part, complete the informed consent process.

Stroke Survivor Specific Inclusion and Exclusion Criteria

Stroke survivor participants will meet clinical criteria for pre-frailty and emerging frailty according to the Clinical Frailty Scale (CFS, Appendix C; Rockwood et al., 2005) where pre-frailty equates to a score of 3-4, but to include emerging frailty, CFS scores will fall between 3-5 (Flaatten et al., 2017; Muessig et al., 2018). CFS ratings are collected routinely in the Addenbrooke's Hospital stroke services and clinicians will identify potential participants based on these. There may also be potential to corroborate the CFS ratings by calculating a Frailty Index (FI), using information from patients' medical records. FI gives a score between 0 and 1 and is calculated based on the presence of diagnostic variables from a given list and pre-frailty is thought to lie between 0.08 and 0.24 (Song et al., 2010).

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Participants must also demonstrate impairment in at least one domain of the Oxford Cognitive Screen (OCS; Demeyere et al., 2015) which is also conducted routinely by clinicians

working in Addenbrookes' Hospital stroke services. Again, these scores will be reviewed by clinicians to help them determine potential eligibility.

Participants will be within 6 months post-stroke. This is the criteria likely to be used in the later feasibility trial of the full multicomponent intervention. Due to reports of worsening frailty post-stroke, it's important to recruit participants early, before they transition from pre-frail to frail when it might become harder to reverse frailty (Gill et al., 2006). Additionally, six months is the window in which it is thought most recovery can happen, although this idea has been critiqued (Teasell et al., 2012).

Participants will be required to have an informal carer (a family member or friend who is not paid for the care they provide) to support the stroke survivor with participation and take part in the informal carer arm of the research. Please refer to the below informal carer inclusion and exclusion criteria.

In order to be eligible, the potential participants must be due to be discharged home before the commencement of the pilot intervention. They cannot be discharged to a care home or other facility. This follows previous research into multi-component interventions for frailty, where the participants are community-dwelling (e.g. Ng et al., 2015)

Those with an additional diagnosis of dementia will not be eligible to participate as dementia was the original target population for CST and may confound the study findings.

Inclusion and Exclusion Criteria for Both Stroke Survivor and Informal Carer

Participants must be over 18 years of age. Although there is a correlation between frailty and age, we do not want to exclude those who may be younger and also experiencing pre-frailty as their experience may be different and valuable to capture. In terms of informal carers, we do not feel it would be ethical to involve young carers in this study due to the commitment involved.

Individuals with significant cognitive or language difficulties (assessed via clinical judgement as likely to impact their ability to actively participate in the focus group) and those assessed as lacking the capacity to consent to participation will be excluded. These scores will not be used to determine eligibility.

Participants need to be able to access and use Microsoft Teams on a computer or tablet (with support) to attend the focus group. Therefore, those unable to do so will not be eligible to take part.

Measures and Data Collection

Qualitative Data

Qualitative data will be collected via semi-structured focus groups. Focus groups draw on the interaction of participants to generate data often rich with language participants use in life outside of research as discussion occurs between participants, merely facilitated by the researcher (Kitzinger, 1994; Wilkinson, 1998). Four focus groups will be held; two of these groups will involve five informal carers each and two will involve five stroke survivors each. This group size fits the recommended size for groups where there may be more information for each participant to share (Krueger, 1988, as cited in Wong, 2008).

Focus groups will be held via Microsoft Teams and will be recorded using the in-built record function so that they can be later transcribed ready for analysis. The groups will take place in the weeks soon after the last session of the intervention and will each last between one and two hours

The topic guides used for the informal carer and stroke survivor focus groups will each be based on the Theoretical Framework of Acceptability (TFA; Sekhon et al., 2017) and data will be analysed through framework analysis (FA) so that data can be mapped onto this pre-existing theoretical framework. The use of the TFA to inform a topic guide and to structure FA has been

shown an effective way of collecting and analysing qualitative data on pilot interventions for pre-frailty (Western et al., 2023). A draft version of the topic guide for stroke survivor participants can be found in Appendix D. Development of the topic guides is ongoing, as discussions with PPI volunteers continue.

Quantitative Data

Stroke survivor's perspectives of the acceptability of the intervention will also be assessed using a questionnaire measure adapted from the 'generic TFA questionnaire' (Sekhon et al., 2022; Appendix E), which was produced by the team who developed the TFA itself (Sekhon et al., 2017). From this, descriptive data (mean ratings for each acceptability construct) can be collected. This scale has been used in several other studies investigating the acceptability of a new intervention, including with populations of pre-frail older adult memory clinic patients (Western et al., 2023). This questionnaire will be conducted via a pseudonymised online form, using Microsoft Forms, and distributed by email after the last session of the sCST intervention is completed and will need to be completed prior to the focus group discussions. Participants may be prompted by a further email to complete the form if response numbers are lower than expected in the lead-up to the focus groups.

Where possible, researchers will also keep an anonymous record of the number of participants identified as being eligible for the research so that a recruitment success percentage can be calculated. A percentage will also be calculated for stroke survivor participant retention rates; in other words, how many participants remain in the intervention for the full eight sessions. This will help to assess the feasibility of recruiting participants to take part in this research that uses this sCST intervention.

Procedure

Participants for this study will be identified and recruited by clinicians within Addenbrooke's stroke unit, as described in the *Participants* section, above. Once informed consent has been obtained, all participants will be asked to fill in a demographics form asking a range of questions relating to personal information (e.g. date of birth, ethnicity, education level) which will be reported in the write-up of the study to contextualise the participant sample, and contact information (email address, telephone number, address). After informed consent is obtained, a letter will be sent to the GP of the stroke survivor participant to let them know of their involvement in the research and their participation in a pilot intervention. The GP details will be collected from the stroke survivor's medical records along with their Clinical Frailty Scale and Oxford Cognitive Screening scores.

The sCST intervention will run as a weekly group at a location, yet to be specifically confirmed, on the Cambridge Biomedical Campus for four weeks. Each week, two of eight 45-minute sCST sessions will be delivered, separated by a 15-30 minute comfort break. After each weekly session, informal carers will be provided with an information sheet about the sessions provided, their suggested benefits, and optional activities to complete with the stroke survivor at home.

After the final session, stroke survivor participants will be emailed a link to the acceptability measure, via Microsoft Forms, and provided with a date by which this needs to be completed. At the same time, both members of each dyad will be emailed a link to join a focus group. The focus group will take place via Microsoft Teams. This will last up to two hours, with a comfort break if required. Stroke survivor participants will be randomly allocated to one of the two focus groups, and the same will apply for the informal carer participants.

Following the focus groups, the participant dyads will be sent a follow-up pack that will include a debriefing letter, including contact details if they wish to discuss their involvement in

the study or any concerns they may have. This pack will also provide a token of gratitude for both the stroke survivor and the carer; this will be a shopping voucher with a value of £10, each.

The total time of involvement will be approximately 11-11.5 hours, not including the time required for travel to and from Addenbrooke's Hospital. If dyads are required to park their car whilst the stroke survivor attends the four weekly sCST intervention sessions, they will be able to claim the discounted parking rate of £4.80 per day, which they can then request to have reimbursed by the researchers.

If a stroke survivor participant reports that they no longer wish to attend the sCST intervention, they will be given the option to drop out of the intervention but remain a participant in the study so that they can attend a focus group and provide their feedback or withdraw from the study altogether. In either case, the informal carer is able to remain in the study and attend the focus group if they are still keen to do so.

If the carer withdraws from the study, the stroke survivor can remain a participant, providing the carer is still able to support the stroke survivor to attend the interventions sessions and access the focus group. If they are not able to do this, then both members of the dyad will be withdrawn.

These are not necessarily the only options available when one member of the dyad wished to withdraw, there may be other case-specific factors to take into consideration.

In all cases, withdrawal from the study will not be possible after the focus groups have taken place.

It is predicted that the last participant contact will take place on 19th July 2024, however this is subject to chang; if there are unexpected delays then the last contact may take place up to a few weeks after this date. If participants have opted to receive a summary of the results, their contact information will be stored until this has been actioned, no later than one year later.

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Please include a definition of the end of study in the protocol

Ethical Issues

This study will require full NHS ethical approval, due to recruitment and other research activities taking place in an NHS setting. Approval will also be sought from the University of East Anglia Research Sponsor team and the Research and Development department of Cambridge University Hospitals NHS Trust (CUHT) due to recruitment and other research activities taking place on the Addenbrooke's Hospital site. Approval for the lead researchers to work on CUHT premises and to recruit from the service will be sought by completing the NHS proforma to obtain a letter of access as stipulated by CUHT Research Governance.

Authors of the original CST programme have consented to the use and adaptation of the materials and permission has been sought from Hawker Publications to reproduce any materials as part of the final write-up, however, we are yet to receive a response. This will be followed up if necessary.

The NHS HRA guidelines have informed the participant information sheets and consent form.

Ethical issues around informed consent, confidentiality, distress/harm, burden, debriefing, reimbursement, coercion, research bias and debriefing have been considered.

Informed Consent

Participants will be provided with a PIS and will be required to provide informed consent before study enrolment. Stroke services staff will be asked to identify individuals with the capacity to consent to participate in research, though capacity will also be assessed before completion of the consent form. Consent will be sought in person (either on the unit or at home) to facilitate discussion which is thought to be crucial to the decision process (Health Research Authority, 2019). If there are any doubts about capacity, the informed consent process will stop, and the individual will be informed sensitively that they do not meet the eligibility criteria for the

study. Capacity to consent will be monitored during all contact with participants, and any concerns that arise will be discussed with the clinical team.

As part of the informed consent process, participants will be informed of their right to withdraw participation from the study. Withdrawal must be done prior to the focus group. Participants can only be recruited in dyads, if one potential participant from the dyad does not wish to enrol then the other member will not be eligible, this will be explained sensitively by the research team, explaining the rationale and aims of the study.

Anonymity and Confidentiality

Participants will be required to sign to confirm they understand and agree to the confidentiality arrangements as part of the consent form.

All data will be stored securely on a password-protected computer on One Drive for Business, a secure central repository linked to the University of East Anglia (UEA) in line with the UEA Data Management Policy (2022). Data will be deleted when the project is submitted. Participants will be informed how their data will be stored before consenting to the study in accordance with The Data Protection Act (2018).

Sensitive participant data will be anonymized, via the use of participant ID codes, and identifiable participant data will be stored on a separate secure file to ensure these two sets of information are kept separate and unconnected. Participant-identifying data will be redacted from transcripts of the focus groups, and names replaced with participant identification codes,

However, participants will be required to share some personal information (e.g. their first names) with other participants to aid effective communication and rapport within the intervention sessions and the focus group. The intervention sessions may also require the sharing of other personal information, such as biographical anecdotes, although participants will have a choice in what they do or do not choose to share.

Efforts will be made to ensure as much confidentiality as possible (e.g., by not using participant's surnames within groups and reiterating the importance of confidentiality at the beginning of each group session).

As per existing NHS confidentiality policy, confidentiality can be broken if it is felt the individual is likely to come to immediate significant harm or cause significant harm based on disclosures to researchers. In this case, it will be important that concerns are raised with the relevant parties; in the case of psychological distress or concerning physical health presentations, the stroke services team will be informed and follow-up appointments with members of the clinical team can be arranged if needed. Participants will be made aware of this via the PIS and asked to consent to information being shared with their clinical team if/when necessary.

Harm, Burden and Benefits

Researchers will be sensitive to participant distress during focus groups and between sCST intervention group sessions. Distress is relevant to intervention feasibility and acceptability, however, the right to withdraw is preserved.

It is possible that taking part in this research may cause distress, harm or burden to participants. Anticipated risks, such as the burden of time commitment, fatigue, or clashes with fellow participants, will be outlined in the PIS. Risk assessments of the intervention delivery space will take place and Dr Evans will be present during sessions, as a member of Addenbrooke's Hospital staff and as a medic, should any participants require medical assistance during the group. Stroke survivor participants will also have the opportunity to receive ad-hoc follow-up appointments with clinicians within the stroke services if this is deemed necessary throughout the period of participation in this research.

If stroke survivor participants wish to withdraw from the group for any reason, there remains the opportunity to remain enrolled in the study in order to attend the focus group to provide feedback, however, this will not be a requirement, as participants must have the right to withdraw without question.

All participants will be encouraged to speak up should they experience any harm or distress as a result of the study, at which point effort will be made to resolve or reduce issues (e.g., difficult group dynamics may benefit from alternative seating arrangements). Options around full withdrawal from the study or withdrawal from the intervention phase alone will be discussed with them.

No deception will be used in the current study, but attention will be given to managing expectations around the intervention and its effect on frailty. Although participants may experience some benefits from participating in this study (such as improvements to their psychological well-being or day-to-day functioning), benefits are not guaranteed. This has been clearly stated in the information sheets.

Reimbursement and Coercion

If participants withdraw from the study, there remains the opportunity to attend the focus group to provide feedback, however, this will not be a requirement, as participants must have the right to withdraw without question.

Study participation will require participants to donate approximately 10-11 hours of their time, not including travel time. There will be a financial cost of travelling to and from Addenbrooke's for the four, weekly intervention visits but participants will be able to park at Addenbrooke's Hospital at the discounted rate of £4.80 per day which can be reimbursed. Participants will be given a token of appreciation after their participation is complete via a £10 shopping voucher.

Debrief and Communicating Results

A debriefing letter will be sent to participating dyads, thanking them for their involvement in this study and reiterating the invitation to contact the researchers about any questions or concerns that may arise after participation is complete, or if they wish to withdraw their data from the study. This letter will also include information about how the results of the study may be communicated to them.

Analysis

The focus group will be transcribed, supported by the transcription function within Microsoft Teams and reviewed by the researcher for accuracy, making amendments where required.

Qualitative focus group data will be analysed using framework Analysis (FA) (Ritchie & Spencer, 1994), with the Theoretical Framework of Acceptability (TFA) (Sekhon et al., 2017) as the framework guiding analysis. FA seeks to understand an event through five stages of analysis (Green & Thorogood, 2018) and is an increasingly popular approach in medical and health research (Gale et al., 2013). It is described as a systematic way to analyse data in a way that makes it clear how the findings of the research were obtained. This is useful to implement recommendations based on findings to guide further studies (Kiernan & Hill, 2018). This method of analysis will help to identify which theoretical constructs of acceptability are strong for this intervention and which could benefit from further attention and improvement, therefore guiding further development of the intervention.

FA will be applied as described by Green and Thorogood (2018) but using the TFA deductively. Audio data will be transcribed and read until the researcher is familiarised with the broad themes of the data. A coding key will be established using the TFA. The key will be applied to the data systematically, described as indexing. Indexed data will be charted, by

tabularising and rearranging according to thematic content in summary form. The final stage will involve mapping and interpretation to explore the relationships between the concepts connecting the TFA with the charted data; an example of this is found in Western et al.'s (2023) study on an intervention for pre-frail individuals. Some 'open coding' will also be carried out to ensure no important data are missed from the analysis (Gale et al., 2013).

In terms of quantitative data obtained from the stroke survivor participants, the degree of acceptability will be calculated by calculating the mean ratings for responses to each of the seven TFA constructs on the acceptability questionnaire measure, the mean rating for the general acceptability item (item 10), and the total mean rating of all items. For two of the seven constructs, Sekhon et al., (2022) suggest a choice of two questions, whereas all other constructs have only one question. For these two constructs, it has been decided that both of the suggested questions would be included in the acceptability questionnaire used in this study, as it was felt that the questions were different enough from one another that they would both be helpful to ask. For example, the generic TFA questionnaire suggests either 'How fair is [Intervention] for [people/ participants/ recipients] with [condition]?' o*r* 'There are moral or ethical consequences [behaviour *i.e. to engage with*] [intervention]' as questions to measure the construct of ethicality.

To improve the sensitivity to context (Yardley, 2000) the researchers will keep reflective diaries of the data analysis process to ensure that consideration is taken of their role in the research and the analysis and to increase awareness of how this, as well as their existing knowledge, experiences and assumptions, may influence the analysis.

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Appendix A

Theoretical Framework of Acceptability

Theoretical Framework of acceptability (TFA)	Definition
Ethicality	The extent to which the intervention has good fit with an individual's value system
Affective Attitude	Anticipated Affective Attitude: How an individual feels about the intervention, prior to taking part Experienced Affective Attitude: How an individual feels about the intervention, after taking part
Burden	Anticipated burden: The perceived amount of effort that is required to participate in the intervention Experienced burden: the amount of effort that was required to participate in the intervention
Opportunity Costs	Anticipated opportunity cost : The extent to which benefits, profits, or values must be given up to engage in the intervention Experienced opportunity cost: the benefits, profits or values that were given up to engage in the intervention
Perceived effectiveness	Anticipated effectiveness: the extent to which the intervention is perceived to be likely to achieve its purpose Experienced effectiveness: the extent to which the intervention is perceived to have achieved its intended purpose
Self-efficacy	The participant's confidence that they can perform the behaviour(s) required to participate in the intervention
Intervention Coherence	The extent to which the participant understands the intervention and how it works

Note. From "Acceptability of healthcare interventions: An overview of reviews and development of a theoretical framework" [Supplementary File 6] by M, Sekhon, M. Cartwright and J. J. Francis. Sekhon, 2017, *BMC Health Services Research*, *17*(1):88, (https://doi.org/10.1186/s12913-017-2031-8). CC BY 4.0 (http://creativecommons.org/licenses/by/4.0/)

Appendix B

Example draft session plan for sCST

Topic - Current Affairs

- Introduction
  - Welcome all to the group by name, name labels.
  - Group rules – confidentiality and respect. Sometimes we might slip up and make mistakes but that's ok, it is important to discuss that privately.
  - Come up with group name
  - Come up with group song – YouTube backing track
  - Orientation – what is the date? Errorless learning? On this day discussion
  - One key headline/news event discussion
- Main activity
  - What possession do you treasure the most?
  - Boomers, Gen x, Millenials, Gen z
  - Fashion
  - Where would you to visit?
  - Social media? Case study use of twitter for good?
- Closing
  - Psycho-ed about summaries as a memory strategy/ rehearsal of information
  - Bullet points – what have you learned during the session or what surprised you?
- Take-home activity
  - Practise the summarising technique, find a news story you find interesting or enjoyable, discuss it with your carer and practise together summarising key points

Appendix C

Clinical Frailty Scale

Box 1: The CSHA Clinical Frailty Scale

1 *Very fit* — robust, active, energetic, well motivated and fit; these people commonly exercise regularly and are in the most fit group for their age

2 *Well* — without active disease, but less fit than people in category 1

3 *Well, with treated comorbid disease* — disease symptoms are well controlled compared with those in category 4

4 *Apparently vulnerable* — although not frankly dependent, these people commonly complain of being "slowed up" or have disease symptoms

5 *Mildly frail* — with limited dependence on others for instrumental activities of daily living

6 *Moderately frail* — help is needed with both instrumental and non-instrumental activities of daily living

7 *Severely frail* — completely dependent on others for the activities of daily living, or terminally ill

Note: CSHA = Canadian Study of Health and Aging.

Note. From "A global clinical measure of fitness and frailty in elderly people" by K. Rockwood, X. Song, C. MacKnight, H. Bergman, D. B. Hogan, I. McDowell, A. Mitnitski, 2005, *CMAJ*, *173*(5), p. 490 (https://doi.org/10.1503/cmaj.050051) Copyright 2005 by CMA Media Inc. or its licensors

Appendix D

Example Focus Group Topic Guide (Draft)

Please note, this is a draft topic guide for the stroke survivor participants. Development of topic guides is ongoing, with input from PPI volunteers.

Research goals of the focus group:

- How would pre-frail stroke survivors feel about adapted CST as an intervention?
- What do pre-frail stroke survivors think about the amount of effort that would be required to participate in an adapted CST intervention?
- What, if any, ethical consequences did pre-frail stroke survivors feel there might be to engaging in an adapted CST intervention?
- What did pre-frail stroke survivors see as the potential costs of engaging in an adapted CST intervention?
- How effective do pre-frail stroke survivors think an adapted CST intervention could be?
- How confident do pre-frail stroke survivors feel about engaging in an adapted CST intervention?
- How well do pre-frail survivors understand the adapted CST intervention and how it works?

Introduction – approximately 10 minutes:

- *Welcome, introduction of the focus group*

- *Instructions regarding the focus group:* "I am interested in how you felt about the sample sessions of adapted CST that you tried and how you would feel about the idea of attending a full programme of perhaps 14 weekly sessions"

- *Ground rules:* "I will ask a number of questions, and I would like to hear from as many of you as possible for each question. It would be helpful for me if only one person speaks at a time so please wait until one person is finished before the

next person speaks. If you are able to use the ‘hands up’ button, it would be helpful if you can press this when you have something to say and I will then invite you to speak. Please be respectful of one another, every opinion is valid and helpful. Please 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 go ahead – just turn off you camera and microphone and turn them on again when you come back”

Main questions – approximately 90 minutes:

- “To start us off, could you please each tell me one word that you feel summarises what you thought of the eight sample sessions you had?”
- “Thank you, let’s talk a bit more about how you felt about the sessions you tried”

    - What did you like about the sessions?
    - What did you not like?
    - What did you find difficult about the sessions or the process of attending the sessions?
    - Did you find the activities enjoyable?
    - What did you think was the purpose of the activities? And do you think that the activities helped you in any way?
    - Did you gain anything from coming to these sessions?
    - Were there any negatives to coming to these sessions?
    - Did the sessions feel relevant to the difficulties you experience after your stroke?
    - Thinking back to before the sessions, how did you feel about attending the first one?

~Comfort break – 10 minutes~

- Now I would like to ask you a few questions about how you would feel about

attending a full course of sessions like these, perhaps 14 sessions once a week?

  - 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, I want to ask you about any changes or improvements that might be needed
  - Is there anything you would change about the general format of the sessions? (e.g. length, frequency, session structure)
  - Is there anything you would change to the content/themes of the sessions?
  - Is there anything missing that you feel would be helpful?
  - Is there anything you would change about the types of activities included in the sessions?

Conclusion – approximately 10 minutes:

- *Sum up what has been discussed, mention the positive aspects, compliment and thank the participants*
  - “Is there anything important to you we haven't mentioned?”
  - “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 voucher.”

Appendix E

Generic TFA-Q

<table>
<tr><th>TFA construct</th><th>Generic TFA questionnaire items</th><th>Notes</th></tr>
<tr><td>Affective attitude

How an individual feels about the intervention</td><td>Did you like or dislike [intervention]?
<table><tr><td>Strongly dislike</td><td>Dislike</td><td>No opinion</td><td>Like</td><td>Strongly like</td></tr><tr><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr></table>
OR

How comfortable did you feel [behaviour i.e. to engage with] [intervention]?
<table><tr><td>Very uncomfortable</td><td>Uncomfortable</td><td>No opinion</td><td>Comfortable</td><td>Very comfortable</td></tr><tr><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr></table></td><td>Depending on the context of the intervention and behaviours associated with the intervention one of the two items should be used.

In some contexts, ‘like or dislike’ will not be appropriate, thus ‘comfortable’ may be more appropriate.</td></tr>
<tr><td>Burden

The amount of effort required to participate in the intervention</td><td>How much effort did it take [behaviour i.e. to engage with] [intervention]?
<table><tr><td>No effort at all</td><td>A little effort</td><td>No opinion</td><td>A lot of effort</td><td>Huge effort</td></tr><tr><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr></table></td><td></td></tr>
<tr><td>Ethicality

The extent to which the intervention has good fit with an individual’s value system</td><td>How fair is [Intervention] for [people/ participants/ recipients] with [condition]?
<table><tr><td>Very unfair</td><td>Unfair</td><td>No opinion</td><td>Fair</td><td>Very fair</td></tr><tr><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr></table>
OR
There are moral or ethical consequences [behaviour i.e. to engage with] [intervention]
<table><tr><td>Strongly disagree</td><td>Disagree</td><td>No opinion</td><td>Agree</td><td>Strongly agree</td></tr><tr><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr></table></td><td>Depending on the context of the intervention and behaviours associated with the intervention one of the two items should be used.</td></tr>
<tr><td>Perceived effectiveness

The extent to which the intervention is</td><td>The [intervention] has improved [behaviour/ condition/ clinical outcome]:
<table><tr><td>Strongly disagree</td><td>Disagree</td><td>No opinion</td><td>Agree</td><td>Strongly agree</td></tr><tr><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr></table></td><td>This item should relate to the primary outcome variable in the main trial/study, thus the item will be intervention</td></tr>
</table>

<table>
<tr><td>perceived to have achieved its objective</td><td></td><td>specific. E.g. quality of life, walking ability</td></tr>
<tr><td>Intervention coherence

The extent to which the participant understands how the intervention works</td><td>It is clear to me how [intervention] will help [manage/ improve] my [behaviour/ condition/clinical outcome]
<table><tr><td>Strongly disagree</td><td>Disagree</td><td>No opinion</td><td>Agree</td><td>Strongly agree</td></tr><tr><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr></table>*Please tell us more about your views</td><td>*In some studies, researchers may want to include an option for participants to provide more information for this item.

This will depend on the resources of the study for analysing qualitative data and whether having more information will be relevant.</td></tr>
<tr><td>Self -efficacy
A participant's confidence that they can perform behaviour(s) required to participate in the intervention</td><td>How confident did you feel about [behaviour i.e. engaging with] [intervention]?
<table><tr><td>Very unconfident</td><td>Unconfident</td><td>No opinion</td><td>Confident</td><td>Very confident</td></tr><tr><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr></table></td><td></td></tr>
<tr><td>Opportunity costs
The benefits, profits or values that would have to be given up to engage with the intervention</td><td>[Behaviour i.e. engaging in] [intervention] interfered with my other priorities
<table><tr><td>Strongly disagree</td><td>Disagree</td><td>No opinion</td><td>Agree</td><td>Strongly agree</td></tr><tr><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr></table></td><td></td></tr>
<tr><td>General acceptability</td><td>How acceptable was the [intervention] to you?
<table><tr><td>Completely unacceptable</td><td>Unacceptable</td><td>No opinion</td><td>Acceptable</td><td>Completely acceptable</td></tr><tr><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr></table></td><td>The general acceptability item has been included as in some instances, an overall acceptability item may be useful and to allow for researchers to explore which of the 7 TFA constructs influences/ drives participants' general acceptability judgment.</td></tr>
</table>

Note. From "Development of a theory-informed questionnaire to assess the acceptability of healthcare interventions" by M, Sekhon, M. Cartwright and J. J. Francis. Sekhon, 2017, *BMC Health Services Research*, *22*(279), supplementary file 7(https://doi.org/10.1186/s12913-022-07577-3). CC BY 4.0 http://creativecommons.org/licenses/by/4.0/)