CONFIDENTIAL RESEARCH PROTOCOL

Adapted **SO**lution **F**ocused brief therapy **I**n post-stroke **A**phasia (SOFIA Trial): a feasibility study

Short title: Adapted solution focused therapy for people with aphasia (SOFIA Trial)

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Abbreviations

AE	Adverse Event
CI	Chief Investigator
CPIB	Communicative Participation Item Bank
CSRI	Client Service Receipt Inventory
CTU	Clinical Trials Unit
DISCS	Depression Intensity Scale Circles
EQ-5D-5L	European Quality of Life measure (5 dimensions, 5 levels)
FAST	Frenchay Aphasia Screening Test
GHQ-12	General Health Questionnaire-12
GP	General Practitioner
HRA	Health Research Authority
MDT	Multi-Disciplinary Team
NHS	National Health Service
PIN	Patient Identification Number
PSYCHLOPS	Psychological Outcome Profiles Questionnaire
QALY	Quality Adjusted Life Years
RA	Research Assistant
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SFBT	Solution Focused Brief Therapy
SLT	Speech and Language Therapist
SOFIA	SOlution Focused brief therapy In post-stroke Aphasia
SOP	Standard Operating Procedure
SRS	Session Rating Scale
SUSAR	Suspected Unexpected Serious Adverse Reaction
SWEMWBS	Short Warwick Edinburgh Mental Well-Being Scale
TSC	Trial Steering Committee
WEMWBS	Warwick Edinburgh Mental Well-Being Scale

Study personnel and advisory groups

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Dr Northcott will meet with at least one of her supervisors at least once a month throughout the course of the project. She will additionally be in email or phone contact as needed. This supervisory group will review and approve trial documentation including the protocol, information sheets and consent forms. It will also provide overall supervision for the study. Dr Northcott will report to them on the conduct and progress of the trial, including recruitment, adherence to protocol, patient safety and consideration of new information.

Trial Steering Committee

Members

Chair	Professor Jane Marshall, Centre for Language Communication Sciences, City, University of London
Members	Dr Chris Flood, Centre for Mental Health Nursing, City, University of London
	Dr Shashivadan Hirani, Centre for Health Services Research, City, University of London
	Dr Kathleen Mulligan, Centre for Health Services Research and Management, City, University of London
	Dr Sarah Northcott, Centre for Language Communication Sciences, City, University of London
	Dr Carole Pound, Faculty of Health and Social Sciences, University of Bournemouth

The Trial Steering Committee will meet at least three times over the course of the project, and will also be consulted via email and phone as needed. They will review the protocol; oversee the conduct of the study; advise on any ethical issues which may arise including monitoring adverse events and breaches to the protocol; give advice on trial processes such as recruitment; and will monitor the progress of the trial. They will also advise on continuing or stopping the trial. Finally, they will advise on whether to proceed to seek funding for a full trial, and if so, what amendments might be made to the protocol.

Aphasia Advisory Group

This group includes four people with aphasia and one carer. They will meet eight times during the project (four meetings have already been conducted). To date, they have advised on: (1) design of project information, including Participant Information Sheet; (2) recruitment processes; (3) inclusion and exclusion criteria; (4) assessments including choice and presentation of outcome measures; (5) topic guide for in-depth interviews; (6) adaptations to the therapy for people with aphasia; (7) building a 'community' around the project e.g. project blog, newsletter; and (8) how to enhance participant experience of taking part in the research (e.g. how best to manage communicating group allocation). The remaining four meetings will focus on: (9) interpreting findings; (10) dissemination; (11) advising on issues that occur in the trial as they arise (e.g. boosting recruitment rates, any ethical concerns); and (12) considering whether or not to proceed to definitive trial.

Protocol amendments since version 1.0

Version and date	**Sections**	**Edit**
2.0 (24Aug2017)	Front cover 4.1 7.1	ClinicalTrials.gov identifier Randomisation: minimisation rather than random permuted blocks Study adopted by North Thames Clinical Research Network

Summary of study

Background and Aims

Around one third of people who have a stroke will experience aphasia, a language disability that can affect talking, understanding, reading or writing. The psychosocial impact of aphasia is considerable: those living with chronic aphasia are at risk of social isolation and depression. One potential intervention is Solution Focused Brief Therapy (SFBT). SFBT is an approach to building positive change in a person's life. It builds up a picture of a client's preferred future; encourages a person to notice positive signs of change; explores personal resources, skills and resilience; and acknowledges the impact of the stroke on a person's life and identity.

The current project builds on a small-scale proof-of-concept study that explored SFBT with five people who had mild to moderate aphasia, at least two years post stroke. There were improvements in participants' mood and participation and participants found the therapy highly acceptable.

The main aims of the current project are to assess: [1] the acceptability of SFBT to people with varying presentations of aphasia; and [2] the feasibility of conducting a future definitive trial investigating clinical and cost effectiveness.

Methods

The overall study will last for 38 months (November 2016 to December 2019), and comprise a Development Phase (year 1) and a single-blind, randomised, wait-list controlled, feasibility trial with nested qualitative research comparing SFBT plus usual care to usual care alone (years 2 and 3).

During the Development Phase we will develop the therapy manual and fidelity checking processes, train the clinicians, and finalise the protocol. Phase One has been informed through four workshops with the Aphasia Advisory Group, comprised of four people with aphasia and one carer, who advised on the study protocol and trial documentation. We have also conducted a pilot study with four people who have severe expressive and receptive aphasia where we trialled the assessment and therapy protocol, and explored adapting the therapy for people with severe communication difficulties.

For the feasibility trial (commencing October 2017) we will recruit 32 participants with any severity of aphasia, at least six months post stroke. Potential participants will be identified either through community (e.g. stroke groups) or through two NHS sites. Participants will be randomly assigned to the intervention group or wait-list control group. Both groups will be assessed by a Research Assistant blinded to treatment allocation on psychosocial outcome measures at T1 (baseline, prior to randomisation), T2 (three months

post randomisation) and T3 (six months post randomisation). Participants will also take part in in-depth interviews at T3 exploring their experiences of taking part in the project as well as complete a resource use questionnaire. All participants will receive all usual care, and up to six SFBT sessions spaced over three months delivered by Speech and Language Therapists (SLTs). The intervention group will receive the therapy immediately post randomisation, while the wait-list control group will be offered the intervention after T3. The wait-list control will additionally be reassessed at T4 (nine months post randomisation). We will also interview the trial clinicians, and the Local Collaborators at the two NHS sites.

Results

We will assess the feasibility of recruitment and retention of participants (including proportion who consent; rate of consent; attrition rates), and of treatment fidelity. Descriptive statistics for the clinical outcome measures will be presented, for the entire trial population and by trial arm, at each time point, with means and confidence intervals plotted over time. We will also report the proportion of missing data. As part of the economic evaluation, we will present the relevant costs and health gains by trial arm and assess the completeness of our data collection methods and their acceptability. Qualitative data on acceptability of the intervention and study procedures will be analysed using Framework Analysis.

Clinical Implications

This trial has been designed to assess the acceptability of the intervention for people with varying presentations of aphasia, and the feasibility of conducting a successful definitive trial evaluating clinical and cost effectiveness in the future. Given the high levels of distress and isolation experienced by people living with aphasia, and the current poor evidence base, there is a pressing need to investigate effective psychosocial interventions. SFBT is potentially a relatively brief approach deliverable by SLTs.

1. Contents

2. Introduction

2.1 Background and rationale

Following a stroke around one third of people will experience aphasia[1], a language disability that can affect speaking, understanding, reading or writing. For 15% of stroke survivors aphasia will persist as a chronic life-long condition[2]; there are around 350,000 people living with aphasia in the UK[3]. The psychosocial impact of chronic aphasia is considerable. Rates of depression post stroke are estimated at 31%[4], and for people with aphasia this figure rises to 62-70%[5]. Those with aphasia are disproportionately likely to lose contact with friends[6, 7] and have weaker social networks[8]. People with severe aphasia are particularly at risk of social isolation[9].

A 2008 Cochrane review on treating depression found no evidence that psychotherapeutic approaches reduced depressive symptoms post stroke[10]. Since then, intervention trials have reported positive results for a behavioural intervention[11], and motivational interviewing[12] early post stroke. However, both studies included only those with mild aphasia. A recent systematic review of interventions to prevent and treat depression in post-stroke aphasia found limited evidence[13]: the only RCT reporting significant benefit when treating depression in people with aphasia was the Communication and Low Mood (CALM) study[14] where people with aphasia received behavioural activation therapy delivered by assistant psychologists.

The National Clinical Guidelines for Stroke[15] and the NHS Stroke Improvement Programme[16] advocate a stepped care approach offering simpler interventions, such as peer support, for low-level mood problems (level 1), progressing on to more complex interventions requiring input from clinical psychology and psychiatry for persistent and severe mood disorders (level 3). The guidelines stress that 'psychological care for this group [stroke survivors] is as essential as physical rehabilitation' (p5)[16]

It is therefore of concern that the recent 2015 Stroke Association's report 'Feeling Overwhelmed' highlighted that two thirds of stroke survivors felt their emotional needs were not as well looked after as their physical needs[17]. A recent study explored the views of UK stroke-specialist Speech and Language Therapists (SLTs) through focus groups (n=23)[18] and an on-line survey (n=124)[19]. A main theme to emerge was that SLTs considered that people with aphasia, particularly those with more severe aphasia, were often excluded from receiving appropriate psychological support as mental health professionals were perceived as finding it difficult to deliver care due to the communication difficulties, and SLTs, while able to facilitate communication, lacked the necessary support or training to address psychological needs.

Current NICE guidelines suggest that the 'whole multidisciplinary team need to be able to identity psychological issues and know how to manage these issues' (p5)[16], and that level 1 and 2 difficulties (mild/moderate symptoms of depression) may be addressed by non-psychology stroke specialist staff with

support from clinical psychologists. However, there is currently a lack of research evaluating an appropriate level 1/level 2 intervention delivered by SLTs. A psychosocial intervention which could enhance emotional well-being and participation, deliverable by healthcare professionals such as SLTs, could make a valuable contribution to the evidence base. The current study focuses on longer-term psychosocial needs (≥6 months post stroke) as services in this area have been identified as particularly weak[20].

Solution Focused Brief Therapy (SFBT). One potential intervention is SFBT. SFBT builds up a picture of a client's preferred future (or how they would like their life to be); encourages a person to notice positive signs of change; and explores personal resources, skills and resilience. It is a relatively brief therapy, typically only three to five sessions[21]. A recent systematic review of the effectiveness of SFBT reviewed 43 controlled outcome studies and found that 74% reported significant positive results, while 23% reported positive trends[22]. The strongest evidence for its effectiveness was in treating adults with depression. There is a growing evidence base for its effectiveness in managing chronic ill-health, for example, managing fatigue in Crohn's disease[23], and coping with HIV/AIDS[24]. It has not yet been systematically evaluated for people with stroke and aphasia. However, our group has produced preliminary evidence to guide further work.

Preliminary data. The main trial builds on two preliminary studies: a proof-of-concept and a pilot study.

[1] Proof-of-concept study. This study explored whether it was possible to adapt SFBT for people with post-stroke aphasia.[25] It was funded by the Research Sustainability Fund, City, University of London, and took place September 2013 to May 2014. Five participants took part, recruited via the community (e.g. through stroke groups). The three men and two women were 2-14 years post stroke, with *mild* to *moderate* aphasia. Participants received on average four therapy sessions, and were assessed pre and post therapy. There were improvements in participants' communicative participation (Communicative Participation Item Bank, CPIB[26], Cohen's d = 0.81) and mood (General Health Questionnaire-12, GHQ-12[27], Cohen's d = 0.79).

Participants also took part in post-therapy in-depth interviews, analysed using Framework Analysis[28] by two researchers to minimise bias. A common theme was that participants felt more confident to talk in different situations, for example, on the telephone, ordering drinks in a café, or chatting to others in church. Participants also noted improvements in their mood as well as increased confidence to undertake activities of daily living independently. Some of the mechanisms by which they believed change had occurred were also explored. These included: describing their preferred future in the context of coping with aphasia, being able to identify one's own successful strategies for dealing with difficult emotions or situations, feeling acknowledged, and the process of celebrating achievements. Participants reported finding the therapy approach highly acceptable, although considered four sessions to be insufficient.

[2] Pilot study (Development Phase of current study). We recruited four people (two men, two women) with *severe* expressive and receptive language difficulties (i.e. very limited ability to speak, understand, read or write), as defined by their scores on the Frenchay Aphasia Screening Test[29], FAST, (≤7 on both receptive and expressive domains). They were recruited via the community, and were between three and 11 years post stroke, and aged late 40s to early 60s. The aims were to: [1] investigate whether it was feasible to include people with severe communication difficulties in the RCT; and [2] to trial the assessment and therapy protocol. Participants received six therapy sessions spaced over three months, completed before and after outcome measures, and participated in an in-depth interview post therapy (assessments and interview conducted by Research Assistant (RA) not involved with delivery of the therapy). For more information on selected outcome measures please see Section 3.4.2 below.

All participants completed all six therapy sessions. Acceptability was probed during the in-depth interview. All four participants reported finding the therapy valuable, and felt strongly that the approach was suitable for people with severe aphasia. This was picked up in high satisfaction ratings on the Session Rating Scale (SRS)[30] (on average 9/10). A common theme was that the therapy enabled them to feel prouder of themselves. They also reported positive changes since starting the therapy (feeling more confident and optimistic, going out more, starting a voluntary job). The primary outcome measure was the Short Warwick Edinburgh Mental Well-being Scale (SWEMWBS)[31]. Pre-therapy mean (SD) was 24.15 (4.99); post-therapy mean (SD) was 28.50 (1.73), Cohen's *d* was 1.13, indicating a large effect size; there was no missing data, and it was the RA's impression that all participants understood all items. Secondary outcome measures were the Communicative Participation Item Bank (CPIB)[26] and the General Health Questionnaire-12 (GHQ-12)[27]. Again there were no missing items, although the RA reported some participants had difficulty understanding the direction of the response options in the CPIB (see section 3.4.2 for how this will be addressed in the trial). The effect sizes were more modest for the secondary outcome measures (CPIB, Cohen's *d* = 0.41; GHQ-12, Cohen's *d* = 0.17). We also trialled the Psychological Outcome Profiles Questionnaire (PSYCHLOPS)[32]: this contained significant levels of missing data (over 25%), and the EQ5D5L[33] (no missing data, items found to be comprehensible).

Based on the results of this pilot, we intend to include people with severe aphasia in the feasibility RCT.

2.2 Trial objectives

The main aims of this study are to assess the acceptability of the intervention when delivered to people with varying presentations of aphasia, and the feasibility of conducting a future definitive trial investigating clinical and cost effectiveness.

Primary objectives are to assess:

[1] Acceptability of the intervention to participants and trial clinicians

[2] Feasibility of recruitment and retention to the trial

[3] Acceptability of research procedures and outcome measures

[4] Feasibility of delivering the intervention by experienced Speech and Language Therapists, following specialist training and with on-going clinical supervision

Secondary objectives are to assess:

[5] Appropriateness of outcome measures

[6] Estimate sample size

[7] Treatment fidelity processes

[8] Feasibility of documenting usual care and resource use

2.3 Trial Design

The overall study will last for 38 months (November 2016 to December 2019). There will be an initial Development Phase (year 1). In October 2017 we will commence the single blind randomised wait-list controlled feasibility trial, with nested qualitative research, comparing SFBT plus usual care to usual care alone (years 2 and 3). For the feasibility RCT, we will recruit 32 participants with mild to severe aphasia, at least six months post stroke. Participants will be recruited from both the community (e.g. stroke groups) and two NHS sites. They will be randomly assigned to the intervention group or wait-list control group. All participants will receive all usual care. Both groups will be assessed by a Research Assistant blinded to treatment allocation on psychosocial outcome measures at T1 (baseline, prior to randomisation), T2 (three months post randomisation) and T3 (six months post randomisation). The intervention group will receive up to six therapy sessions over three months immediately post randomisation; the wait-list control group will be offered the same intervention after T3, and reassessed three months later at T4.

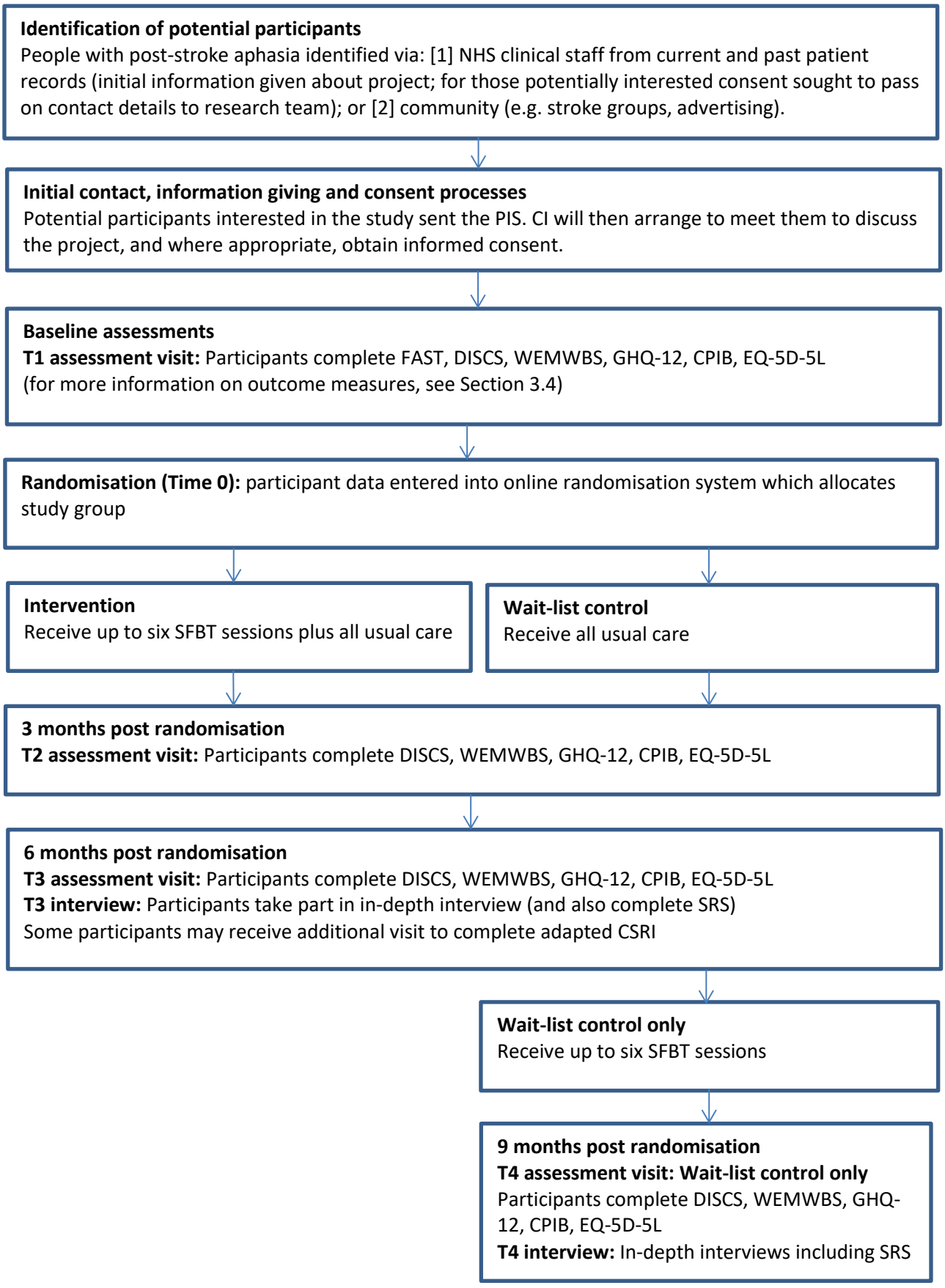
The intervention will be delivered by Speech and Language Therapists (SLTs) experienced at working with this client group. They will receive a minimum of six days training prior to delivering the intervention. This will include four days 'Foundation' training in SFBT (www.brief.org.uk) followed by a minimum of two days training based at City, University of London, on adapting the approach for this client group and research procedures. They will also receive monthly clinical supervision from an experienced clinician.

The study will include nested qualitative research. We will conduct in-depth interviews with all participants at T3, and with wait-list control at T4. The interviews will be conducted by the CI or an unblinded RA and

will explore participants' experiences of taking part in the study, well-being and participation, as well as experiences of the intervention. We will also conduct in-depth interviews with the trial clinicians to explore how they experienced delivering the therapy to this client group, their perception of the training, supervision and on-going support, and the treatment fidelity processes. Finally, we will interview the two Local Collaborators on recruitment processes.

A further strand of the project will be investigating the feasibility of conducting a full economic evaluation of the relative cost-effectiveness of SFBT plus usual care compared to usual care alone in the definitive trial. We will include the European Quality of Life measure (EQ-5D-5L)[33] as part of the assessment protocol. In addition, at T3 we will ask participants to complete a resource use inventory. This will be a version of the Client Service Receipt Inventory[34] (CSRI) adapted for the current project so as to be more relevant and accessible to people with aphasia.

2.4 Trial Flowchart



3. Methods: Participants, Interventions and Outcomes

3.1 Study setting

Potential participants will be recruited through two sources: community (e.g. stroke and voluntary groups) and NHS community stroke teams. Further details of the recruitment process are provided in Section 3.7. The intervention, assessment sessions and in-depth interviews will be conducted in the venue of the participant's choice. In the majority of cases we anticipate that this will be the participant's home or the Roberta Williams Speech and Language Therapy Centre, City, University of London.

3.2 Eligibility criteria

3.2.1 Exclusion and inclusion criteria

Inclusion criteria:

- Have a diagnosis of ischaemic or haemorrhagic stroke
- At least six months post stroke
- 18 years old or over
- Presenting with aphasia as a result of the stroke. For those participants identified via NHS, this will be determined based on Speech and Language Therapist diagnosis. For those recruited via the community, it will be based on their scores on the Frenchay Aphasia Screening Test, FAST[29]. This test covers four major aspects of language: comprehension, expression, reading and writing. Aphasia is determined by published cut-off scores. Where a person has mild aphasia, such that they score as 'normal' on the FAST, but where the participant self-identifies as having aphasia, and this is confirmed by the clinical judgement of the CI, they will be included.

Exclusion criteria:

- Other diagnoses affecting cognition such as dementia or advanced Parkinson's Disease
- Severe uncorrected visual or hearing problems that would impact on their capacity to take part in the intervention
- Severe or potentially terminal co-morbidity on grounds of frailty
- Currently receiving a psychological or psychiatric intervention
- Non-fluent English speaker prior to the stroke based on self/family report
- Do not have mental capacity to consent to take part in the trial

For those participants identified via NHS, the referring NHS clinician will screen potential participants against these eligibility criteria. For those recruited via community, eligibility will be based on self/ family report. Capacity will be further assessed by the CI during the initial information-giving visit.

Use of anti-depressants and rehabilitation therapy (e.g. speech and language therapy) will be recorded although will not be a reason for exclusion.

The trial clinicians will be invited to take part in a qualitative interview about their experience of working on the trial and delivering the intervention. Only those employed to work as trial clinicians will be eligible. The Local Collaborators will also be invited to take part in a qualitative interview: only the named Local Collaborators will be eligible.

3.3 Intervention

3.3.1 Description

All participants will receive SFBT, either immediately (intervention group), or after a delay of six months (wait-list control group). All participants will also receive all usual care, i.e. all health, social care and voluntary services available to them in their borough. Usual care will be documented as part of the project, using the adapted CSRI at T3.

Solution Focused Brief Therapy

Solution focused brief therapy (SFBT) is an approach to building change. It is distinctive from more problem-based therapy approaches. Instead of exploring the causes of the problem or reducing problem behaviour, SFBT explores how a person would like their life to be, and builds on their resources, resilience, and on what is already working. In SFBT the client is considered expert in their own lives, and the therapist does not seek to offer solutions or strategies. The assumption is that the client will have the resources and skills they need to resolve the problem; the therapist's role is to ask questions and listen in such a way that the client begins to notice their own strengths, and can formulate their own way of moving forwards.

SFBT therapy techniques include:

Eliciting 'best hopes'**:** A first therapy session typically begins with asking a client about their 'best hopes' from the work, thus anchoring the conversation around what is important to the client.

Exploring the 'preferred future' : A key aspect of the approach is to enable a person to visualise how they would like their life to be, thus shifting perspective from their problems to visualising an alternative future where their 'best hopes' are realised. In describing their preferred future, a client is typically facilitated to provide as much concrete, observable, small-scale detail as possible, with an emphasis on describing positive features i.e. what is wanted, rather than the absence of negative features.

Scaling questions: A variety of scaling questions are used flexibly within SFBT. The most commonly used scale is where ten represents 'best hopes realised', and zero represents the opposite. Clients are invited to

place themselves somewhere on this scale. The scaling question can be used to elicit instances of success, strengths, resources and resilience, for example, through exploring how the client is not at a zero. It can also be used to explore progress towards a client's preferred future.

Acknowledgement: solution focused work has been described as having one foot in possibility, one foot in acknowledgement[35]. Acknowledgement of the emotional impact of the stroke was found to be a key component of the therapy approach in both the proof-of-concept study[36] and the pilot study.

Adapting SFBT for people with aphasia

SFBT is an abstract psychological 'talking therapy'. An obvious challenge is therefore to adapt it so that it works well for people who have a language disability. A number of strategies were used in the proof-of-concept study. These included: the therapist (CI in current project) modifying her own language e.g. simplifying questions, signposting topics, and 'chunking' language into short simple phrases that are easier to understand; facilitating responses through careful co-construction; and using all communication modalities (writing down key words, gesture, pictures, objects in the environment). In the pilot study with people with severe aphasia, further modifications were explored, including more systematic use of pictorial supports (e.g. to scaffold the conversation around 'best hopes'); further consideration of question forms (e.g. some participants found it difficult to respond to open questions without scaffolding of possible response options from therapist); increased use of 'scaling' questions; and use of smart phone/tablet technology to support conversations.

A further consideration is that less material can be covered within a session due to the language difficulties, yet lengthening a session is often not a feasible option as people with aphasia can become fatigued. Thus although SFBT typically takes between 3 and 5 sessions[21], it is our experience that this is insufficient for people with aphasia. In the proof-of-concept project, participants received four sessions, typically over four weeks: there was consensus that this was too compressed, and too little. The pilot project offered people up to six sessions over three months: although participants would still have preferred additional sessions, this structure allowed for a gradual tailing off of the therapy, and more opportunity to integrate changes into their everyday lives.

3.3.2 Fidelity

An important component of complex behavioural intervention studies is treatment fidelity[37, 38]. If the treatment is well-defined, and the intervention is delivered as intended, it allows for greater confidence in the results.

Therapy manual: in terms of defining the intervention, we will develop a therapy manual during the Development Phase of the project. The manual will draw on established best practice guidelines and

descriptions of the core components of the therapy approach produced by the European Brief Therapy Association, the UK Association for Solution Focused Practice, and also BRIEF, a leading international centre in SFBT. We will seek feedback and expert guidance from leading SFBT experts Evan George and Kidge Burns in writing the manual. In addition, we will draw on the research findings from the two completed studies on how best to adapt the approach for people with aphasia (for example, the emphasis on acknowledgement and empathetic listening to a person's stroke story). Although the manual will form the basis of the training based at City, University of London, (City) and fidelity checklist (see below), it is anticipated that feedback from the trial clinicians, both during and after the trial, will further inform and refine the manual prior to the definitive trial.

Fidelity of training and supervision: trial clinicians will receive a four day 'Foundation training' in the core principles and practices of SFBT at BRIEF (www.brief.org.uk). They will also receive at least 2 days training at City on how to adapt the approach for this client group. A training manual will be developed for the City-based part of the training, so that the essential components can be described and potentially replicated. We will seek feedback from the trial clinicians, both during and after the training, to ensure that it meets their needs and also to improve the training programme prior to the definitive trial.

Following the training, trial clinicians will receive monthly clinical supervision sessions with an experienced SFBT clinician. We will ask both the trial clinicians and clinical supervisors to record topics discussed and brief reflective comments in order to monitor the support provided.

Fidelity of the intervention: we will evaluate to what extent the therapy delivered is consistent with the therapy manual. This will involve checking sessions either live or recorded against a fidelity checklist. There will be an initial phase where the CI will observe the first two sessions delivered by the trial clinician, either live or a recording. The CI will check for compliance with the therapy manual and checklist: where compliance is not observed, feedback and support will be given, and more sessions observed until the trial clinician, the CI, and potentially the clinical supervisor, are confident the therapy is being delivered as intended. A similar approach is being adopted in an ongoing trial, the ASK study, investigating an SLT-delivered intervention for preventing depression in people with aphasia[39].

Once the trial clinician has demonstrated that they are able to deliver the therapy as intended, a further 10% of sessions will be recorded. We will purposively select therapy sessions to represent the range of aphasia severity, and the phase of therapy. Recordings will be scored at regular intervals by an SFBT expert (Diploma level training in SFBT) throughout the period when the intervention is being delivered to assess treatment integrity. If a session fails the checklist, the CI will also listen to the recording in order to provide supportive feedback to the trial clinician and consider arranging for them to have an additional one-to-one supervision with their clinical supervisor. Additional sessions will then be recorded and monitored by either

the CI or clinical supervisor, until they are satisfied that the trial clinician is able to deliver the therapy as intended.

Trial clinicians will complete therapy notes in line with professional standards[40], and also a record form for each session. The record form will quantify the time spent on different therapy components. This will facilitate monitoring the content of the therapy sessions, and assessing variation between therapists and over time.

3.3.3 Adherence/ compliance

Adherence to intervention protocols refers to the degree to which the behaviour of trial participants corresponds to the allocated treatment arm. For participants in the wait-list control arm, we will use the adapted CSRI (collected by unblinded RA or CI) to check whether they have received SFBT prior to T3. For participants in the intervention arm, we will use trial clinician care records to provide us with information. To be compliant, participants need to have received at least two therapy sessions. Various SFBT experts have argued that single session therapy in SFBT can be sufficient to instigate meaningful change[21, 41, 42]. However, based on the proof-of-concept study[36] and pilot study, when someone has aphasia less material can be covered, and in practice the material normally covered in a 'first session' is spaced over two sessions. Therefore, for the purposes of this study, to be compliant a participant needs to have received at least two sessions.

3.4 Outcomes

3.4.1 Primary and secondary endpoints

As a feasibility study the main endpoints relate to the feasibility objectives listed in Section 2.2 above. When the purpose of a study is to investigate the feasibility of proceeding to a definitive trial, it is recommended that researchers specify on what criteria they will base this decision[43]. We outline formal pre-specified criteria to guide the decision as to whether to proceed to a future definitive trial: the extent to which these thresholds have been met will be considered in conjunction with qualitative evidence. The pre-specified criteria are based on published trials investigating complex behavioural interventions with people with aphasia[14, 44] or stroke[11, 12]: reported recruitment, retention and compliance rates have informed what we consider to be realistic progression criteria.

Primary endpoints:

[1] Acceptability of the intervention to participants and trial clinicians: based on in-depth interviews with participants (at T3, T4) and trial clinicians (at end of study); trial clinicians' therapy records (e.g. whether progress was made towards best hopes; acceptability; what challenges were encountered); rates of compliance; scores on the Session Rating Scale.

Pre-specified criteria:

- Proportion of participants who are compliant (attend at least two sessions of SFBT): at least 80%

[2] Feasibility of recruitment and retention to the trial: based on proportion who are eligible of records screened (for those participants identified via NHS prospectively); proportion told about study by direct care team who consent to be contacted by CI; proportion who consent of those who are eligible; rate of participants randomised each month; attrition rates (overall, by stage, and by study arm).

Pre-specified criteria:

- Proportion of eligible participants who consent: at least 60%
- Proportion of participants who are followed up at 6 months post randomisation: at least 70%

[3] Acceptability of research procedures and outcome measures: based on rates of missing data, drop-out rates, length of assessment sessions, and participant interviews.

Pre-specified criteria:

- Proportion of missing data (per scale): less than 15% for people with mild to moderate receptive aphasia (defined as scoring ≥7 on the receptive domains of the FAST). For people with severe receptive aphasia, it is possible that they may be less able to complete measures. For this reason, we have included the DISCS, designed to be accessible to people with more severe linguistic impairment (see description of DISCS in section 3.4.2 below). Proportion of participants who are able to complete the DISCS in full: at least 90%.

[4] Feasibility of delivering the intervention by experienced Speech and Language Therapists: based on interviews with trial clinicians; trial clinicians' therapy notes and session records; clinical supervision records.

Secondary endpoints:

[5] Appropriateness of outcome measures: based on level of variability and missing data; whether scale constructs match any changes described during the in-depth interviews; participant perspective on acceptability.

[6] Estimating sample size: based on standard deviation of probable primary outcome measure (WEMWBS) and retention rates.

[7] Assessing treatment fidelity processes: based on acceptability of processes to the trial clinicians and participants (e.g. perceived burden to trial clinicians and participants); utility and reliability of the fidelity

check-list process (e.g. inter-rater reliability; extent to which checklist scores correspond to therapy and supervision records); extent to which treatment is delivered as intended (e.g. proportion of therapy sessions evaluated as compliant with the therapy manual).

[8] Feasibility of documenting usual care and resource use: based on the acceptability and completeness of data generated by the adapted Client Service Receipt Inventory (CSRI).

3.4.2 Clinical outcomes

Primary and secondary outcomes

Primary clinical outcome measure (probable primary outcome in the definitive trial):

- Warwick Edinburgh Mental Well-being Scale (WEMWBS) (measuring well-being)[45], 14 items, scores range from 14 to 70, with higher scores indicating greater overall mental well-being

Secondary clinical outcome measures:

- General Health Questionnaire-12 (GHQ-12) (measuring psychological distress)[27], 12 items, scores range from 0 to 12, with higher scores indicating greater levels of distress;
- Communicative Participation Item Bank (CPIB) (measuring communicative participation)[26], 10 items, scores range from 0 to 30, with higher scores indicating communication difficulties interfere less with participation;
- Depression Intensity Scale Circles (DISCS) (measuring depression)[46], single item scale, scores range from 0 to 5, with a score 0-1 indicating no/low distress, and 5 high distress; designed to be accessible to people with cognitive or communicative deficits.

As this is a feasibility study, the rationale for collecting clinical outcome data is to assess the acceptability and appropriateness of the outcome measures as described above, rather than to test a hypothesis of effectiveness.

The chosen measures have either been developed specifically for adults with an acquired communication disability (CPIB, DISCS) or have been previously used with people with aphasia with good evidence of accessibility and acceptability (GHQ-12, SWEMWBS), and have sound psychometric properties. The presentation of measures will be modified to make them aphasia-accessible in line with best practice guidelines[47] (participants will be able to point to their preferred response option; they will be able to read items as well as hear them; few items will be presented per page and key words will be emboldened; a practice item will be inserted at the start of questionnaires to familiarise participants with response options). The content, however, will not be changed to avoid affecting the measures' psychometric properties.

The choice of measures has been informed by the views of the Aphasia Advisory Group, who considered the relevance and acceptability of measures. Further, we have trialled measures in the pilot study with participants with severe expressive and receptive aphasia (Development Phase). There was no missing data on the following measures: SWEMWBS, GHQ-12, CPIB and DISCS. However, there were concerns about participants comprehending the direction of the response options in the CPIB, which has led us to change the presentation of this measure: this was strongly approved by the Aphasia Advisory Group. We have also made the decision to use the 14 item WEMWBS rather than the shorter 7 item SWEMWBS, as there is more evidence that it is responsive to change[48]. One potential outcome measure (PSYCHLOPS)[32] contained significant missing data when used in the pilot study, and will therefore not be included in the RCT. It took the RA less than 30 minutes (at both T1 and T2 with all four participants) to complete the following battery of measures: DISCS, SWEMWBS, GHQ-12, CPIB, EQ-5D-5L, and PSYCHLOPS.

Profiling and co-variate outcomes:

- Frenchay Aphasia Screening Test (FAST)[29] (T1 only) – baseline profiling of aphasia
- Session Rating Scale (SRS)[30] – (T3, T4 qualitative interviews) assessing therapeutic alliance as potential explanatory variable. 4 items, total scores ranging from 0 to 40, with higher scores indicating higher levels of satisfaction. The SRS was used in the pilot study, and was found to be acceptable with no missing data.

3.4.3 Economic evaluation outcomes

- European Quality of Life – 5 dimensions, 5 levels[33], EQ-5D-5L, (all assessment time points)
- Adapted Client Service Receipt Inventory, CSRI[34], (T3 only).

We intend to establish the acceptability and utility of the chosen measures: EQ-5D-5L and adapted CSRI.

The EQ-5D-5L was found to be acceptable in the pilot study with people who had severe aphasia, and there was no missing data. It has been successfully used with people who have aphasia in previous research[49, 50].

In terms of collecting information on resource use, we will use a version of the Client Service Receipt Inventory adapted to be more accessible and relevant to people with post-stroke aphasia. Although the adaptations to CSRI are loosely based on a version used in a previous stroke project[51], it has been further modified for the present study to be more accessible to someone with aphasia. It is unclear to what extent people with aphasia will need assistance in completing this form. In order to inform the data collection method in the future definitive trial, we will record the proportion of participants who: [1] elect to have an additional face-to-face visit (with CI), or extend the in-depth interview visit (with CI or unblinded RA); [2] self-complete without assistance; or [3] have a family member complete it on their behalf. We will record whether manner of completion affects completeness of data collected.

3.5 Duration of the study and participant timeline

Study duration: the study is funded for 38 months (November 2016 to December 2019). The initial Development Phase will run for 11 months, from November 2016 to September 2017. The feasibility RCT will run for 29 months, from October 2017 to December 2019. Enrolment to RCT will last for 13 months (October 2017 to November 2018).

Duration of participant involvement: participants allocated to the intervention arm will be in the study for approximately 6 months from recruitment; participants allocated to the wait-list control condition for approximately 9 months. Below is a detailed description of the participant timeline during the feasibility RCT.

Participant Timeline

Purpose	Person responsible	Time	Forms/ Measures	Description	Arm of trial
Identification	SLT (via NHS); Self-identified (via community)	10 minutes	Initial information one-page sheet	Potential participants identified, and asked permission for their contact details to be passed to research team.	All
Information giving	CI	15 minutes	Full Participant Information Sheet	CI to send potential participant PIS at least 24 hours prior to visiting.	All
Information giving and consent	CI	60 minutes	PIS; consent form	CI to visit potential participant (location of participant's choice) and discuss the project, going through the PIS in detail. Written consent to be obtained.	All
T1 Assessment and baseline profiling	RA	50 minutes	FAST; WEMWBS; DISCS; GHQ-12; CPIB; EQ-5D-5L; case history	Outcome measures completed in interview format. FAST at baseline only.	All
Randomisation	CI	10 minutes		Letter, visit or phone call (participant preference) to inform them of group allocation.	All
Intervention	Trial clinicians	6 visits (each visit about 60 minutes)		SFBT therapy sessions	Intervention Arm
T2 Assessment (3 months post randomisation)	Blinded RA	30 minutes	WEMWBS; DISCS; GHQ-12; CPIB; EQ-5D-5L	Face-to-face visit to conduct assessments	All
T3 Assessment (6 months post randomisation)	Blinded RA	30 minutes	WEMWBS; DISCS; GHQ-12; CPIB; EQ-5D-5L	Face-to-face visit to conduct assessments	All
T3 in-depth interview	Unblinded RA or CI	60 minutes	topic guide; SRS	Face-to-face interview	All
T3 resource use questionnaire	CI	20 minutes	Adapted CSRI	Optional additional visit	All
Intervention	Trial clinicians	6 visits (each visit about 60 minutes)		SFBT therapy sessions	Wait-list control arm
T4 Assessment (9 months after randomisation)	Blinded RA	30 minutes	WEMWBS; DISCS; GHQ-12; CPIB; EQ-5D-5L	Face-to-face visit to conduct assessments	Wait-list control arm
T4 in-depth interview	Unblinded RA or CI	30 minutes	Topic guide; SRS	Face-to-face interview	Wait-list control arm

3.6 Sample size

For the feasibility RCT, we will recruit 32 participants in total, 16 participants allocated to each arm of the project. If around 15% are lost to follow up[14], we anticipate that around 28 will be followed up at 6 months. This sample is adequate to inform the parameters of a larger trial, such as recruitment rates, consent rates, completion rates, acceptability, and potentially effect size of outcome measures[52].

3.7 Recruitment

We will assess the feasibility of identifying those with aphasia at least six months post stroke either through the community, or via the NHS. We will work with two community NHS stroke teams: East London NHS Foundation Trust Community Neurology Service (lead site) and also Central London Community Healthcare NHS Trust. At both sites, a lead clinician (Speech and Language Therapist) will act as the Local Collaborator, liaising with the central research team. The process of recruiting will vary depending on the recruitment route.

(1) Participants currently on the active caseload of community NHS stroke teams.

The clinical care teams will screen everyone on their active caseload with stroke and aphasia against the exclusion criteria. For those who are eligible, the care team will discuss the study briefly with them, using the one page summary information sheet. It is anticipated that this will take place during a routine therapy appointment. It will be explained to potential participants that entry into the trial is entirely voluntary and that their treatment and care will not be affected by their decision. For patients who are interested in taking part, the clinician will ask for their permission to pass contact details on to the CI. Since aphasia can often make contact more challenging, we will also collect information on their preferred form of contact (e.g. text, telephone, email, or alternatively to make arrangements via a trusted third party such as a spouse or child). The CI will then contact the potential participant in their preferred modality to tell them more about the research and arrange a home visit to talk through the Participant Information Sheet (PIS). Prior to the visit, the CI will send the potential participant the PIS. Further details about the consent process are provided in Section 7.3.

In situations where a potential participant is about to be discharged from active community rehabilitation, but is not yet six months post stroke, all the above steps will be followed, but the CI will make clear during the initial contact that there will be a delay before they can start in the study. If it is the preference of the potential participant, the CI will arrange to visit again when they are six months post stroke prior to the baseline assessment T1 visit.

(2) NHS community stroke team database

At both sites the clinical teams will send invitation letters to those on the community stroke databases of discharged patients to identify those who may be interested in taking part. Potential participants will be sent a postal pack containing a covering letter, a reply slip and a pre-paid envelope. Return of completed reply slips will be taken as consent to be contacted by the CI, who will then send the potential participant the full PIS, and arrange a time for an initial visit, as above. Where the clinical care team is aware that a person's aphasia means they will have difficulty reading an unsolicited letter, they may also contact the patient by phone, text or email.

(3) Community. In order to include people in the longer-term post stroke, we will also recruit via the community. We will visit stroke and aphasia groups, and work closely with voluntary organisations such as the Stroke Association and Headway, for example, form links with Stroke Association Communication Support Workers who may be able to identify more isolated people who do not attend groups. We will also advertise the project in outlets likely to be read by people living with aphasia (e.g. Stroke News; South London Stroke Register Newsletter), and via social media.

Where an individual expresses interest in the project, the CI will send them the PIS and arrange a home visit to go over the PIS in detail, as well as confirm that they meet eligibility criteria. As with those identified via NHS, it will be explained that entry into the trial is entirely voluntary, that their treatment and care will not be affected by their decision, and that they can change their mind at any time.

Target recruitment rate: two to three participants per month for 13 months. We anticipate that we will recruit at least one participant/ month from each NHS Trust; the remainder we anticipate we will recruit via the community.

4. Methods: assignment of interventions

4.1 Randomisation and blinding

The King's Clinical Trials Unit (KCTU) will provide the randomisation service. Randomisation will use the web-based service hosted at KCTU in accordance with standard operating procedures and held on a secure server. After the baseline assessment T1 visit has been completed, the CI will access the allocation for each participant by logging in to the remote, secure internet-based randomisation system. A unique study

participant identification number (PIN) will be assigned to each participant by the system. Each participant will be randomised in equal proportions to either the intervention group or the wait-list control group.

Randomisation allocation will utilise minimisation based on the following characteristics: site (East London NHS Foundation Trust; Central London Community Healthcare NHS Trust; community) and aphasia severity (moderate to severe vs mild, according to FAST scores). Access to the allocation sequence will be restricted to those with authorisation (named personnel at KCTU only). The sequence of treatment allocations will be concealed until interventions have been assigned and recruitment, data collection, and analyses are complete.

Participants, trial clinicians and the CI will be aware of group allocation. However, RAs who conduct outcome assessments at T2 to T4 will be blinded to group allocation. To reduce the likelihood of the RAs becoming unblinded, we will request that participants do not reveal their group allocation to the RA. To further reduce unblinding RAs will not have access to participant files that reveal treatment allocation. Computer documents with participant details will be password protected. If an RA becomes unblinded they will report this to the CI who will keep a record. If this happens during the T2 assessment point, then the T3 assessment point will be completed by a different RA blind to group allocation. We will also ask the RA to guess the group allocation after the T3 assessment point. T4 assessments will be conducted by an RA with no knowledge of the stage in the study the participant has reached.

5. Methods: Data collection, management and analysis

5.1 Data collection methods

Outcome measures will be collected by RAs. RAs working on the project will either have experience communicating with people with aphasia (e.g. qualified SLT), or will be given appropriate training. Further, each RA will receive an initial training session with the CI to ensure consistency of approach. RAs will be given a data collection pack for each participant at each time point.

Qualitative in-depth interviews will be conducted by the CI or the (unblinded) qualitative RA. Both the qualitative RA and CI are experienced qualitative interviewers with experience of adapting qualitative techniques to facilitate the inclusion of people with aphasia. The CI will discuss the topic guide with the qualitative RA to ensure consistency of approach.

For collecting information about resource use, we will use an adapted version of the CSRI. Although it has been adapted to be more accessible to people with aphasia, it is unclear how much assistance participants will require. At T3 visit, the (blinded) RA will give participants the CSRI and a prepaid envelope. It will be

explained that they can: [1] self-complete without assistance; [2] have a family member complete it on their behalf; or [3] receive face-to-face assistance. If self-completing they will return the completed CSRI by post, or hand it to the CI/ qualitative RA when they are visited for the in-depth interview. Alternatively, they will then have the option of completing the form at the end of the in-depth interview, or the CI returning on a separate visit.

Participants will be contacted by text, telephone or letter (depending on their stated preference) about two weeks prior to each assessment point (e.g. 3 months post randomisation), in order to arrange a mutually convenient time. Where feasible we will aim for all T2-4 visits to be carried out ±1 week of the assessment point. We will also send a reminder text or phone call either on the day or the day before, depending on participant preference. To maximise participant engagement in the project and retention of participants, a quarterly newsletter will be sent to them.

5.2 Data management

5.2.1 Trial databases

The main trial database will be hosted at City, University of London (City), on a secure network drive within the City system, which is regularly backed up. The CI will act as custodian for the trial data. Source data will be entered by authorised staff only (i.e. CI or authorised RA) with full audit trail in which participants will be identified by their unique code, PIN. The main trial database will include feasibility data on people approached, consented, assessment and outcome measures data, and Adverse Event data.

Four further databases will also be hosted at City: intervention details (including number of sessions received; duration of sessions); fidelity data; qualitative data; and health economic data. In all cases, participants will be identified by their unique PIN, and the electronic databases will be on a secure network drive, backed up regularly and password protected.

5.2.2 Database passwords; access to the data

Database access will be restricted through passwords: only Dr Sarah Northcott (CI) and Professor Katerina Hilari (primary supervisor) will have password access to all databases which will be kept on secure network drives. Access will vary according to the database. For the main trial database the CI and an authorised RA will have access in order to input data; Dr Shashivadan Hirani (supervisor overseeing statistical analyses) will also have access to the main trial database. For the qualitative data, the CI and authorised unblinded RA will have password access. The CI and Dr Chris Flood (who will be supporting the CI in analysing the health economics data) will have password access to the spreadsheet detailing health economics data. The intervention database and fidelity database will be accessed by CI and authorised unblinded RA only.

Hard copies of the data will be held in secure filing cabinet at City. Data that contains identifiable information will be secured in a separate filing cabinet accessible to only the CI and Katerina Hilari.

A Trial Delegation Log will be created by the CI, and will detail the members of the research team who have access to the different databases.

5.2.3 Data handling and confidentiality/ format of records

We will adhere to NHS confidentiality practice, and to the Research Governance Framework in monitoring and managing the research. As CI, Dr Sarah Northcott will take overall responsibility for management of the project. Data will be handled, computerised and stored in accordance with the Data Protection Act, 1998. Participants will be identified on the trial and other study databases using their unique PIN. The CI and other research staff will maintain accurate participant records/ results on each participant enrolled.

The qualitative data will be transcribed by an external transcription company, and then saved by the CI in a secure electronic format. Any information which could lead to the identification of a participant will be de-identified through the use of pseudonyms, replacement terms and vaguer descriptors in line with best practice (www.data-archive.ac.uk).

At the end of the study, essential documentation will be archived in accordance with requirements of City, University of London, and destroyed 10 years after study completion. The retention of study data will be the responsibility of the CI.

5.2.4 Identifiable and unblinded data

All participant contact and recruitment data will be stored on spreadsheets at City, which will have restricted access from password-protected secure network drives. Hard copy of identifiable data (e.g. consent forms) will be collated by the CI and stored in locked filing cabinets at City. The qualitative data, the resource use data, as well as the fidelity and intervention databases indicate the arm of the trial a participant has been randomised to. For this reason, only the CI and unblinded and authorised members of the research team will have access to this data.

5.2.5 On-site/central monitoring

The CI will conduct on-site/ central monitoring. This will include regular checks to monitor for completeness and accuracy of data collected and entered on to databases (including range and logic checks) as well as adherence to procedure (e.g. timeliness of visits; e.g. checking that recording procedures at local NHS sites are being followed consistently and accurately; e.g. reporting of and recording adverse events). Variance from procedures and missing or incomplete data will be reported to the Academic Supervisory Group and the TSC.

5.3 Methods of analysis

Trial data will be reported and presented according to the CONSORT 2010 statement: extension to randomised pilot and feasibility trials[43]. As a feasibility study the main analysis will be descriptive rather than formal hypothesis testing, and relate to the eight trial objectives (see Section 2.2), using both qualitative and quantitative methodologies.

We will provide a diagram displaying the flow of participants through the trial. In line with CONSORT Item 13a[43], we will detail the number of participants who were assessed for eligibility; approached; recruited; randomly assigned; received treatment as allocated; complied with treatment as allocated; included in analysis. Additionally, as specified in CONSORT Item 13b[43], we will include for each group the number of people who were excluded, withdrew, or were lost to follow up, at each stage post consent, with reasons why where possible. The primary analysis will be on an intention to treat basis. However, as this is a feasibility study, useful information may also be gained by a per protocol analysis: this will therefore also be conducted for exploratory purposes.

5.3.1 Quantitative analysis

For all descriptive statistics outlined below, we will calculate appropriate 95% confidence intervals.

Study Objective One: acceptability of the intervention. We will provide descriptive statistics for the proportion of participants who comply with the intervention; and the proportion of participants who evaluate the overall intervention (Item 4 of the SRS) at 6/10 or higher, indicating a favourable opinion.

Study Objective Two: feasibility of recruitment and retention. We will analyse: [1] the proportion who are eligible of records screened (for those participants recruited prospectively via NHS only); [2] proportion who consent to have their details passed on to CI; [3] the number who are eligible per month; [4] proportion who consent of those eligible (number who consent/number eligible); [5] rate of consent per month; and [6] rate of recruitment (participants randomised) per month. We will also analyse [7] the frequency and [8] the proportion of participants who withdraw or are lost to follow up overall, by study arm, and by stage including those who do so before and after randomisation will be presented. Finally, we will analyse [9] the baseline characteristics of those missing follow up and those with complete follow up. Secondary analysis of items [3] to [9] will be conducted to see if the rates/ proportions vary according to style of recruitment (i.e. NHS prospective; NHS retrospective; community).

Study Objectives Three and Eight: acceptability of research procedures and outcome measures; feasibility of documenting usual care and resource use. We will analyse the proportion of missing data for each assessment overall and by treatment group (including FAST, SRS, all clinical outcome measures, and the EQ-5D-5L and adapted CSRI). Length of time to conduct T1-T4 visits will also be documented. The adapted

CSRI includes an added Likert item on acceptability; and also an item on time taken to complete. Descriptive statistics for this will be presented.

Study Objectives Five and Six: appropriateness of outcome measures; estimating sample size. All clinical outcome measures will be summarised using summary statistics of measures of central tendency and dispersion, for the entire trial population and by trial arm, at each time point. Means and confidence intervals will be plotted over time. These summary statistics will help inform sample size estimation for the definitive trial. Since the intervention is therapist led, we will also estimate the intra cluster correlation coefficient (ICC) for participants treated by the same therapist for the T3 6-month post-randomisation WEMWBS outcome (probable primary outcome for the definitive trial). The standard deviation of the WEMWBS will be synthesised with standard deviations observed in other published studies and on-going trials (with people with post-stroke aphasia) to provide a robust estimate for use in sample size calculation for the definitive trial.

As part of the feasibility analysis, the effect size for the T3 WEMWBS, the difference in mean scores between the intervention and wait list control groups at 6 months post randomisation, will be estimated, along with its associated 95% confidence interval estimate. This will provide information on the sensitivity of the measures in picking up any change, and also whether the likely effect is within a clinically relevant range which will inform the decision as to whether it is worth progressing with the definitive trial.

Study Objective Seven: assessing treatment fidelity processes. In terms of acceptability of fidelity processes, we will report on: proportion of sessions recorded as planned (as opposed to not recorded due to equipment failure or lack of acceptability); proportion of missing data on therapy records and supervision forms; and the inter-rater reliability for the fidelity check-list. We will also report on the extent to which treatment was delivered as intended. As such, we will report on the proportion of sessions rated that were considered compliant with the therapy manual, and will provide descriptive statistics for the therapy components, based on the therapy record forms. This will enable us to compare the content of the intervention between trial clinicians, and over time.

A detailed statistical analysis plan will be developed and agreed with the Academic Supervisory Group.

5.3.2 Safety outcomes

Please see Section 6.2 on Harms for definitions of the safety outcomes. Adverse events, adverse reactions, serious adverse events, serious adverse reactions and suspected unexpected serious adverse reactions will be summarised overall and by treatment group as counts of events and counts of people who have had events. We will calculate differences in event rates between the two groups and a 95% confidence interval for the difference.

5.3.3 Qualitative analysis

Qualitative data will be reported according to the Standards for Reporting Qualitative Research Guidelines (SRQR). All interviews will be transcribed verbatim.

Analysis of qualitative data will inform Study Objectives One, Three, Four, Five, and Seven. The primary source will be in-depth interviews with all participants, and with therapists and Local Collaborators (at the end of the study). However, we will also refer to therapy and supervision records.

The data will be analysed using Framework Analysis[28]. Initial themes and concepts will be identified through reviewing the data. These will then be used to construct a thematic index. All the interview material will then be indexed so that each phrase or passage can be assigned a label. Thematic charts will be constructed, the chart headings evolving from the indexing process. The labelled raw data will then be summarised and synthesised into the matrices. This matrix-based method of analysis enables systematic exploration of the range of views, and facilitates comparison both between cases and within cases to produce descriptive and explanatory accounts of the data. In order to minimise potential bias a second analyst will independently index a proportion of transcripts and analyse the matrix-based material to ensure all relevant thematic material is represented fairly and is included in the final framework.

5.3.4 Economic evaluation

Given the feasibility status of this project, the aim will be to inform the future design of a more complete economic analysis in a larger trial. In order to achieve this, we will explore the viability of conducting cost-effectiveness analyses through running exploratory analyses with the data gathered in the present project, and assess the completeness of our data collection processes. As part of this, we will present the relevant costs and health outcomes for both the intervention group and the wait-list control group.

For the costs, we will use data collected from the adapted CSRI at 6 months post randomisation. The primary focus will be on health and social care costs. Costs will include service use (health, social and voluntary services), intervention costs (such as speech and language therapist time, clinical supervision and specialist training), as well as considering informal care costs and costs to the individual (e.g. care provided by family members). Unit costs of resources used will be derived from routine sources locally where possible and from national sources such as the NHS reference costs. We will also refer to the unit costs for health and social care compiled by the Personal Social Services Research Unit [53].

Health gains will be obtained from the answers to both the WEMWBS (primary outcome measure assessing well-being) and also the EQ-5D-5L instrument. The gold standard for economic evaluation is to use generic health state outcome measurements because these allow comparability across clinical areas. We will run two types of exploratory economic evaluation analysis. First, we will perform a cost-utility analysis using Quality Adjusted Life Years (QALYs) gained based on the answers to the EQ-5D-5L. Second, we will run

exploratory cost-effectiveness analysis based on the WEMWBS. We will provide an estimate of the relative cost-effectiveness of care received in the intervention group compared to the wait-list control group: this will be exploratory in nature given the feasibility status of the project.

6. Methods: monitoring

6.1 Data monitoring

Monitoring of the data will include confirmation of informed consent; source data verification; data storage procedures; accuracy of database entries. The Academic Supervisory Group will monitor the on-going day-to-day collection of data on a monthly basis, and will advise on data monitoring processes. The TSC will also review evidence of data monitoring.

6.1.1 Stopping guidelines

There are no formal statistical criteria for stopping the trial early. Decisions to stop the trial early on grounds of safety or futility will be made by the TSC.

6.2 Harms

Adverse Events (AE) are any clinical change, disease or disorder experienced by the participant during their participation in the trial, whether or not considered related to the intervention being investigated. Adverse Events associated with participating in the study are considered unlikely. Such adverse events may include participants becoming distressed or anxious during assessment or therapy sessions, or during the in-depth interview.

Adverse events not related to the study may include:

- Participants reveal to RAs or trial clinicians unrelated new medical issues which require an assessment by a healthcare professional (e.g. fits or seizures, worsening visual difficulties, increased frequency or severity of headaches, accidents or injuries such as falls).
- Participant may score as 'distressed' on the GHQ-12 (scoring over 3) indicating low mood at any of the assessment points; or may discuss symptoms of depression or anxiety during therapy sessions or the in-depth interview.
- Risks arising in the home or within the family.

If these adverse events do not lead to any of the outcomes listed a-g below, they will be considered non-serious. Their reporting is covered in the next section. RAs and trial clinicians will be trained on how to respond to such events (see 6.2.2 below).

Serious Adverse Events (SAEs) are considered unlikely in this project, however, they may still occur. Stroke-related events will not be reported as SAEs because these are expected within this population. An AE is considered a SAE if it results in one of the following outcomes:

a) Death
b) Suicide
c) Life-threatening (i.e. with immediate, not hypothetical, risk of death at the time of the event, e.g. further stroke, cardiovascular event, serious infection)
d) Requires in-patient hospitalisation (hospitalisation for elective treatment of a pre-existing condition is not included)
e) Increased severe and persistent disability, where severe indicates significant deterioration in the participant's ability to carry out their activities of daily living; and persistent indicates four weeks continuous duration.
f) Any other important medical condition, which, though not included in the above, may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed.
g) Any episode of deliberate self-harm

A SAE is considered a Serious Adverse Reaction (SAR) if the event is considered related to taking part in the study (e.g. is a consequence of receiving the intervention or taking part in the assessment sessions). A SAE is considered a Suspected Unexpected Serious Adverse Reaction (SUSAR) if the event is deemed as an unexpected reaction to participating in the study. Both SARs and SUSARs are considered highly unlikely in this study. If there is any doubt as to whether the AE is a SAE, SAR or SUSAR, a second opinion will be obtained from members of the Academic Supervisory Group in discussion with the CI.

6.2.1 Reporting AEs, SAEs, SARs and SUSARs

AEs (including SAEs, SARs and SUSARs) may be identified by RAs, the trial clinicians, the qualitative RA or the CI. All research staff will be responsible for reporting of AEs (including SAEs, SARs, and SUSARs) throughout the project.

All adverse events will be recorded on forms, and emailed to the CI within 24-48 hours of occurrence. The SAE form includes the potential outcomes (a-g above) to facilitate research staff choosing between the AE and SAE forms. Research staff will also receive training in completing the forms and handling AEs. The forms will be completed as thoroughly as possible with all available details of the event. In the case of incomplete information at the time of initial reporting, the research staff member will still notify the CI as quickly as possible, and provide subsequent additional information as it becomes available. A record of this notification (including date of notification) will be clearly documented to provide an audit trail.

All AEs (non-serious) will be reported to the Academic Supervisory Group on a monthly basis by the CI. These events will be reported to the TSC on an annual basis (or more frequently if requested) and will be included in the safety reporting of the completed trial.

For all SAEs (including SARs and SUSARs) the CI will notify a member of the Academic Supervisory Group within 24 hours. The relationship of the event to the treatment (SAE or SAR) and expectedness of the event (SAR or SUSAR) may be assessed and indicated on the form by the research staff member. The CI will discuss with at least two members of the Academic Supervisory Group whether the SAE is in fact a SAR or SUSAR.

The CI will also inform the research sponsor of SAEs. The Academic Supervisory Group and the sponsor will decide whether the SAE needs to be reported further to relevant regulatory bodies. If the SAE is considered by the CI and Academic Supervisory Group to be a SUSAR (i.e. related and unexpected), it will be reported to the Research Ethics Committee (REC) which approved the study, as per Health Research Authority (HRA) guidelines, using a modified version of the HRA non-CTIMP SAE report form.

Reporting timelines are as follows:

- SUSARs which are fatal or life-threatening must be reported not later than 7 days after the sponsor is first aware of the reaction. Any additional relevant information must be reported within a further 8 days.
- SUSARs that are not fatal or life-threatening must be reported within 15 days of the sponsor first becoming aware of the reaction.

6.2.2 Follow-up after adverse events

It is likely that a high proportion of participants will score as 'distressed' on the GHQ-12 (i.e. score over 3), at any of the assessment time points. In a comparable population, 45% of participants six months post stroke were classified as 'distressed'[54] on the GHQ-12. RAs administering the GHQ-12 will follow a set protocol in this situation. They will firstly seek permission of the participant for the CI to contact the GP, in order to share this result. They will also advise the participant to visit their GP to consider different therapeutic options for low mood, and will offer to facilitate this (e.g. make initial phone call if requested). The participant will then be given the choice as to whether to remain in the project.

Where an RA, trial clinician, qualitative RA or CI has serious concerns about a participant's mental or physical well-being, they will be trained to respond appropriately. As above, they will encourage the participant to contact their GP, and will additionally explain to the participant that they are concerned for their well-being and will need to discuss it with the CI. They will notify the CI immediately, who will then

discuss appropriate and timely action with at least one member of the Academic Supervisory Group with a view to contacting the participant's GP and any other relevant authorities to state the concerns.

After an SAE, SAR or SUSAR, a decision will be made by the CI, in consultation with the Academic Supervisory Group and other relevant authorities, as to whether the participant should be withdrawn from either their randomised treatment allocation, or from the trial. The CI will make arrangements for further assessment and management as agreed with the relevant authorities (e.g. participant's GP), and participant.

6.3 Auditing

Several mechanisms are in place to monitor and audit trial conduct. The CI will meet with the Academic Supervisory Group at least once a month. At these meetings it is the responsibility of the CI and academic supervisors to discuss trial progress and highlight any issues requiring further input. The TSC will meet three times over the course of the project to oversee the study conduct and management.

7. Ethics and dissemination

7.1 Research ethics approval

The trial will be conducted in compliance with the principles of the Declaration of Helsinki (1996), the principles of Good Clinical Practice and in accordance with all applicable regulatory requirements including but not limited to the Research Governance Framework and the Mental Capacity Act 2005. This protocol and related documents will be submitted for review to the Health Research Authority (HRA) through the Integrated Research Application System. The study has been adopted by the North Thames Clinical Research Network. The CI will submit a final report at conclusion of the trial to the HRA, the Sponsor and Funder.

7.2 Protocol amendments

Any significant amendments to the protocol will be communicated with all relevant parties including the Academic Supervisory Group, the TSC, the sponsor, the funder, HRA and any trial registries that the study is registered with.

7.3 Informed consent

Written informed consent will be obtained from all participants who are able to give it. For participants who are physically unable to sign the form (e.g. due to weakness in dominant hand due to stroke) then

consent will be given using a mark or line in the presence of an independent witness (who has no involvement in the trial) who will then corroborate by signing the consent form.

All our information sheets and consent forms are in line with HRA guidelines. Furthermore, we have developed participant information materials and consent forms that are accessible to people with aphasia. These materials were developed following standard aphasia-friendly principles, such as presenting one idea at a time, using short simple sentences, use of large font and white space, emboldening key words and presenting key ideas with a suitable pictorial image. We based the information sheets and consent forms on templates created by the NIHR CRN for enabling people with aphasia to participate in research (https://www.crn.nihr.ac.uk/stroke/pcpie/enabling-people-with-aphasia-to-participate-in-resaerch-resources-for-stroke-researchers/), which has been specifically designed to facilitate the consent process with people who have aphasia. Additionally, the Aphasia Advisory Group, comprising four people with aphasia and a carer, reviewed and advised on the forms. They were highly supportive of the use of pictures and the presentation of the material. They also made a number of suggestions, which we have incorporated (e.g. how we present the group allocation process). Finally, an earlier version of the Participant Information Sheet was used in the pilot project with people with severe aphasia: their feedback also resulted in further changes (e.g. to consenting to being video recorded).

To facilitate the consent process, each participant will receive the Participant Information Sheet at least 24 hours in advance of meeting with the CI. This will mean they have a chance to discuss the project with friends or family. On the advice of the Aphasia Advisory Group, we will also make a simple video, where the CI explains about the project, and reads out the Participant Information Sheet. Where appropriate (i.e. for those potential participants with an email address; for participants who prefer spoken to written word communication), we will send this via email in advance of meeting up.

For all participants, the CI will meet them for an initial visit to discuss the research study in a location of their choice: we anticipate this will usually be their own home, although some may prefer to meet in the Roberta Williams Speech and Language Therapy Centre, at City, University of London. The CI has extensive experience at facilitating the expression and understanding of people with aphasia, and will use 'total communication' techniques (i.e. all communication modalities, such as writing, gesture, drawing, objects in the environment), as well as modify her own language so that it is more accessible to someone with aphasia. It will be a priority that the information-giving session is a two-way conversation, with the person with aphasia facilitated to take an active role, for example, in asking questions and seeking clarifications. They will be reassured that participating in the study is entirely voluntary, that choosing not to take part will not affect their normal care, and that they can change their mind at any time. It was also the advice of the Aphasia Advisory Group that the potential participant should be listened to holistically and given the

space to consider how the project might fit in with the rest of their lives. As such, we anticipate this initial session is likely to take around an hour.

Only those with capacity are eligible to take part in this project. We consider that those who lack capacity are unlikely to benefit from this particular therapy approach, as it requires actively participating in therapeutic communication, and retaining information between sessions. The Mental Capacity Act (2005) states that there should be an assumption that a person has capacity to make their own decision, unless they are unable to [1] understand the information relevant to the decision; [2] retain that information; [3] use or weigh that information; or [4] communicate their decision. As explained above, we will do all we can to ensure that the person's aphasia does not mask their competence, by facilitating both their comprehension and expression. Once the potential participant has been given the information, and had sufficient time to ask questions and discuss the project, we will make an assessment of a person's capacity to give fully informed consent. We will check that they can remember what the study is about, and can understand the information. We will do this both informally, and also by asking all potential participants three simple yes/no or forced alternative questions after information giving, to confirm they have understood key aspects of the study. These questions will be: Will the researchers visit you once or several times? Can you stop if you wish, yes or no? Is this study about a new drug OR involve talking to a Speech and Language Therapist? If potential participants cannot answer these questions correctly, it will suggest that they are unable to give fully informed consent. These participants will be thanked for their time, but it will be explained to them and their families that they are not eligible for the study, as they are unlikely to benefit from this particular intervention. They will be given information about support options available to them (e.g. local stroke groups) as appropriate.

For those that have capacity, after discussing the PIS, some individuals may wish to give their consent at this point. However, we recognise that others may prefer to have additional time in order to weigh up their options. In this case, we will organise to revisit them at a mutually convenient time. Similarly, potential participants identified by their direct care team will be given as much time as they need before deciding whether to consent to their details being passed on to the research team. It was also the view of the Aphasia Advisory Group that potential participants should have the option of expressing an interest, while stating a preference for the research team to contact them in 3 months rather than immediately.

Written informed consent to participate in in-depth interviews will also be obtained from the trial clinicians and Local Collaborators.

7.4 Progressing to a definitive trial

The decision about whether to seek funding to progress to a future definitive trial, either with or without amendments to the protocol, will be based primarily on the results to our primary objectives (Section 2.2).

The formal pre-specified criteria listed in Section 3.4 will guide the decision, as will information on the acceptability and safety of the intervention and study procedures.

We will draw on the ADePT model (A process for Decision-making after Pilot and feasibility Trials) developed by Bugge *et al.*[55]. This provides a framework which enables: (1) systematic identification and appraisal of problems and potential solutions/ amendments; (2) increased transparency in the decision-making process including clear documentation; (3) a process to make clear any tensions which may exist between pragmatic and explanatory choices about possible amendments (i.e. potential solutions which may work well within the trial, but less well in the real world).

As recommended by both Bugge *et al.*[55] and Eldridge *et al.*[43], we will consult with key stake holders when considering whether to progress to a definitive trial and potential amendments to the protocol. For example, we will discuss possible options with the TSC and lay representatives such as the Aphasia Advisory Group, and will document different perspectives.

7.5 Confidentiality

The Chief Investigator will act as custodian for the trial data. Management of the data will be kept secure, pseudo-anonymised and confidential (see section 5.2) and in accordance with the 1998 Data Protection Act.

7.6 Declarations of interests

The Chief Investigator, Academic Supervisory Group, and TSC have no competing interests to declare for the overall trial and each study site.

7.7 Ancillary and post-trial care

During the trial, if a participant scores within the high emotional distress range of the GHQ-12 (3 or more) at any assessment time point, the protocol for escalating care is described in Section 6.2.2. Information about local support sources will be offered if participants express feelings of loneliness, social isolation or low mood. The Participant Information Sheet also provides contact details of useful organisations such as the helpline numbers of: The Stroke Association; Headway; Age UK; Carers UK; Saneline; The Samaritans; Citizen's Advice Bureau.

7.8 Dissemination policy

It is intended that the results of the study will be reported and disseminated at international conferences and in peer-reviewed scientific journals. Our Aphasia Advisory Group will advise us regarding dissemination to the stroke community, which we anticipate will include publication of the results in stroke and aphasia

voluntary organisations newsletters (e.g. The Stroke Association, Speakability). Aphasia-accessible results leaflet will be created and a dissemination event held to further explain the results to participants and local NHS therapists. We will also consider disseminating results via social media.

8. Insurance/ indemnity

City University has Professional Indemnity and Clinical Trials insurance cover for its liability relating to all of these activities. Professional Indemnity is for £15 million in any one occurrence and insured with Zurich. Insurance for clinical trials is for £10 million in any one occurrence and insured through Arthur J. Gallagher

9. Financial aspects

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10. Signatures

24 August 2017

Chief Investigator Date

Print name

SARAH NORTHCOTT

24 August 2017

Member of the Academic Supervisory Group Date

Print name

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