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SOlution Focused brief therapy In post-stroke Aphasia (SOFIA Trial): protocol for a feasibility randomised controlled trial

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Abstract

Background: Around a quarter of people post stroke will experience aphasia, a language disability. Having aphasia places someone at risk of becoming depressed and isolated. There is limited evidence for effective interventions to enhance psychological well-being for this client group. A potential intervention is Solution Focused Brief Therapy (SFBT), which supports a person to build meaningful, achievable change through focusing on a person's skills and resources rather than their deficits. The SOFIA Trial aims to explore the acceptability of SFBT to people with varying presentations of aphasia, including severe aphasia, and to assess the feasibility of conducting a future definitive trial investigating clinical and cost effectiveness.

Methods: The trial is a single-blind, randomised, wait-list controlled feasibility trial with nested qualitative research and pilot economic evaluation comparing SFBT plus usual care to usual care alone. The study will recruit 32 participants with aphasia who are ≥6 months post stroke. All participants will be assessed on psychosocial outcome measures at baseline, then at three and six months post randomisation by assessors blinded to treatment allocation. Participants will be randomly assigned to intervention group (start intervention immediately post randomisation) or wait-list group (start intervention six months post randomisation). Wait-list group will additionally be assessed nine months post randomisation. The intervention consists of up to six SFBT sessions delivered over three months by speech and language therapists. Participants and therapists will also take part in in-depth interviews exploring their experiences of the study. The pilot economic evaluation will use the EQ-5D-5L measure and an adapted Client Service Receipt Inventory. People with aphasia have been involved in designing and monitoring the trial.

Discussion: Given the high levels of depression and isolation, there is a need to investigate effective interventions that enhance the psychological wellbeing of people with aphasia.

Trial registration: ClinicalTrials.gov NCT03245060. 10/08/2017.

Keywords: Stroke, Aphasia, Solution Focused Brief Therapy, psychological intervention, psychological well-being, feasibility trial

List of Abbreviations

CPIB, Communicative Participation Item Bank; CSRI, Client Service Receipt Inventory; EQ-5D-5L, European Quality of Life, 5 Dimensions, 5 Levels; FAST, Frenchay Aphasia Screening Test; GHQ-12, General Health Questionnaire; GP, General Practitioner (primary care physician); NHS, National Health Service; QALY, quality adjusted life year; SFBT, Solution Focused Brief Therapy; SOFIA, Solution Focused Brief Therapy In post-stroke Aphasia Trial; SRS, Session Rating Scale; TSC, Trial Steering Committee; WEMWBS, Warwick Edinburgh Mental Wellbeing Scale.

Introduction

Aphasia occurs following brain damage and can affect a person's ability to talk, understand, read or write. There are 110,000 strokes each year in England [1]. Around 45% of people will experience aphasia immediately post stroke; by three months, the aphasia persists for 24% of the stroke population [2]. It is estimated that for 15% of people post stroke the aphasia will be a life-long condition [3]. The impact of losing language skills on a person's identity and well-being can be considerable. Those with aphasia are disproportionately likely to lose contact with friends [4, 5], and have weaker social networks [6] than those without aphasia. Further, rates of depression post stroke are high for people with aphasia with one study finding that 70% of people with aphasia at 3 months and 62% at 12 months post stroke fulfilled the DSM-III-R criteria for depression [7]. Expressive communication impairment has also been found to be a significant predictor of depression at one and six months post stroke [8].

There has been increasing recognition of the need to consider the psychological consequences of long-term health conditions [9]. Stroke service guidelines in the UK state that 'psychological care for this group [people post stroke] is as essential as physical rehabilitation' [10]. Yet the UK Stroke Association reported that two thirds of stroke survivors felt their emotional needs were not as well addressed as their physical needs [11]. Services addressing longer-term psychological well-being post stroke have been identified as particularly weak [1]. A study exploring the views of UK speech and language therapists found that people with aphasia were observed to be at risk of not receiving appropriate psychological support. In part this was due to mental health professionals finding it difficult to deliver care due to the communication difficulties. Conversely although speech and language therapists were able to facilitate communication they often lacked the necessary support or training to feel confident addressing psychological needs [12, 13]. There was particular concern about people with more severe aphasia accessing mental health support [13].

Most studies exploring effective psychological interventions post stroke exclude people with aphasia [14], and a systematic review of interventions to prevent and treat depression in post-stroke aphasia found only limited evidence [15]. The only randomised controlled trial reporting significant benefit when treating low mood in people with aphasia was the Communication and Low Mood (CALM) study [16] where behavioural activation therapy was delivered by assistant psychologists.

While severe or persistent mood disorders require specialist input from mental health professionals [17], there has been increasing recognition that psychological care is the concern of the whole healthcare team [18]. UK health service guidelines suggest that mild/moderate symptoms of depression, commonly experienced post stroke, may be addressed by non-psychology stroke specialist staff with support from clinical psychologists [17]. In two surveys of aphasia-specialist Speech and language therapists the vast majority (98% in Australia [19]; 93% in UK [12]) agreed that addressing the psychological needs of their clients was a part of their role. However, only a minority (31% in Australia [19]; 42% in UK [12]) reported that they felt confident to do so. There is currently a lack of research evaluating an intervention for mild/moderate depression which may enhance psychological well-being delivered by Speech and language therapists with appropriate support.

One potential psychological intervention is Solution Focused Brief Therapy (SFBT) which is a client-centred resource-based therapy that aims to enable people to build change in their everyday lives [20, 21]. It explores a person's hopes, how they would like their life to be, and builds on what is already working. The client is considered expert in their own life and takes on expert status within the therapeutic relationship. The assumption is that the client will have the resources and skills they need to resolve the problem; rather than offer advice, the therapist's role is to ask questions and listen in such a way that the client notices their own strengths and can formulate their own way of moving forwards. Acknowledgement of distress, including recognition of the impact of the stroke and aphasia, is also part of the therapy process in this study. The strongest evidence for the effectiveness of SFBT is in treating depression [22]. Further, 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].

A proof-of-concept study exploring SFBT with five people who had mild to moderate post-stroke aphasia reported encouraging trends in terms of improved mood and communicative participation and a main theme from the qualitative interviews was increased confidence [25]. The current study extends this preliminary work in a feasibility trial with the aim of informing the design and feasibility of a full-scale definitive trial. Following consultation work with people with aphasia the project focuses on living with stroke and aphasia in the longer term. We are therefore recruiting participants at least six months post stroke.

Aims

The aim of the study is to assess the feasibility of conducting a future definitive trial investigating the clinical and cost effectiveness of Solution Focused Brief Therapy for people living with chronic post-stroke aphasia. Primary objectives of the trial are to evaluate the acceptability of the intervention to participants with varying severity and presentation of aphasia as well to the trial clinicians; the feasibility of recruitment and retention; the acceptability of research procedures; and the feasibility of delivering the intervention by Speech and language therapists. Secondary objectives are to evaluate the appropriateness of outcome measures; estimate a sample size for the definitive trial; and assess processes for evaluating treatment fidelity and documenting usual care.

Methods

Design

This study is a single-blind, randomised, wait-list controlled feasibility trial comparing Solution Focused Brief Therapy plus usual care to usual care alone for people living with chronic post-stroke aphasia. All participants complete baseline assessment and are then randomised either to receive the intervention immediately or after a delay of six months. Both groups complete assessments at

three months and six months post randomisation; the wait-list group are also assessed nine months post randomisation. All participants are also invited to take part in in-depth interviews six months post randomisation in order to explore their experiences of taking part in the study; the wait-list group take part in an additional in-depth interview nine months post randomisation. Figure 1 illustrates the flow of participants throughout the study.

insert Figure 1 about here

The Consolidated Standards of Reporting Trials (CONSORT) 2010 extension statement to randomised pilot and feasibility trials [26] informed the study design. The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 statement [27] guided the writing of the study protocol. The Template for Intervention Description and Replication (TIDieR) [28] informed the description of the intervention (see Table 1).

Ethical approval

Ethical approval to conduct the study was granted by the NHS Health Research Authority Brighton and Sussex Research Ethics Committee (17/LO/1255). Local NHS Research and Development approvals have also been gained from participating sites. The trial sponsor is City, University of London (Staff/17-18/04), and the study is funded by the Stroke Association (TSA Postdoc 2016/01).

Participants

Setting

Participants will be identified through two National Health Service (NHS) community Speech and Language Therapy services, in East and West London, United Kingdom. We will also recruit via non-NHS community routes, for example, through working with the voluntary sector. All visits will be conducted in the venue of the participant's choice, anticipated to be either the participant's home or the university clinic.

Participants: inclusion and exclusion criteria

Participants will have a diagnosis of ischaemic or haemorrhagic stroke, be at least six months post stroke, 18 years old or over, and presenting with aphasia. Presence of aphasia will be determined by the clinical judgement of a Speech and language therapist. Participants will be excluded if they: have other diagnoses affecting cognition such as dementia or advanced Parkinson's Disease; have severe uncorrected visual or hearing problems; have severe or potentially terminal co-morbidity; are currently receiving a psychological or psychiatric intervention from a mental health professional; were non-fluent English speakers prior to the stroke (based on self or family report); or do not have mental capacity to consent to take part. We are including people with any severity of aphasia, providing they have capacity. Use of anti-depressants or rehabilitation therapy will be recorded but will not be a reason for exclusion.

Recruitment and consent processes

The clinical care teams at the two participating NHS sites will screen people on their caseloads against the eligibility criteria before discussing the study with potential participants during a routine therapy or review appointment using a one-page summary information sheet. Where a person is potentially interested in taking part the clinician will ask permission to pass their contact details to the chief investigator (SN) who will then arrange to meet them to discuss the project further.

Methods of community recruitment are diverse to allow comparison of different strategies. They include: visiting stroke and aphasia groups; accepting self-referrals (e.g. where a potential participant has learnt about the project from the funder's website, twitter, project blog or word of mouth); distributing information about the project to third sector organisations; contacting people known to the University who have given permission for their details to be shared for this purpose. For those participants recruited via the community we will check they meet the eligibility criteria through asking a series of questions and relying on self-report.

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 an independent witness will sign on their behalf. All information sheets and consent forms have been developed using standard aphasia-accessible principles (e.g. presenting one idea at a time, using short simple sentences, presenting key ideas with a suitable pictorial image). They have been based on templates created by the National Institute for Health Research [29] and informed by observations made by the SOFIA Aphasia Advisory Group. The chief investigator (SN), who is an experienced speech and language therapist, will meet with all potential participants to go through the participant information sheet and facilitate the person with aphasia discussing and asking questions about the project. Potential participants will receive the participant information sheet at least 24 hours in advance of this meeting. A person's capacity to give informed consent will be made by SN, both informally and through asking three simple yes/no or forced alternative questions to confirm whether they have understood key aspects of the study.

Participants may withdraw consent to participate in the study at any time and without giving a reason although we will record the reason if known. They may also elect to discontinue with the intervention but continue in the trial in which case we will seek permission to collect outcome data and carry out in-depth interviews with them.

Randomisation

The King's Clinical Trials Unit will provide the randomisation service. After the baseline assessment visit has been completed the chief investigator will access the allocation for each participant by logging into the remote, secure internet-based randomisation system. Participants will be randomised in equal proportions to either the intervention group or the wait-list group. Randomisation allocation will use minimisation with a random component to avoid predictability of allocation. Minimisation will be based on two factors: site (two NHS trusts, community) and aphasia severity. Aphasia severity will be determined according to participants' scores on the Frenchay

Aphasia Screening Test [30]: if a participant scores <7 on either the receptive or expressive domains during baseline assessment they will be classified as having severe aphasia.

Blinding

Participants, trial clinicians, the qualitative researcher, and the chief investigator will be aware of group allocation. However, the research assistants who conduct the psychosocial outcome assessments will be blinded to group allocation. To reduce the likelihood of research assistants becoming unblinded we will request that participants do not reveal their group allocation during assessment visits (both prior to the visit and at the start of the visit); visits will be organised by the chief investigator; and research assistants will have no access to participant files or details that could potentially unblind them. If a researcher becomes unblinded this will be reported and any subsequent visits will be carried out by a different research assistant. Near misses will also be reported. The final visit for the wait-list group (nine months post randomisation) will be conducted by a research assistant blinded to both group allocation and time point. A log will be kept of all instances of unblinding and near misses, as well as the reason for the unblinding.

Intervention

The intervention, therapist training and approach to measuring intervention fidelity are described using the TIDieR checklist (see Table 1) [28]. The wait-list group will receive the same intervention six months post randomisation. Both groups will additionally receive all usual care, including health care, social care and voluntary services. Usual care will be recorded for both groups at six months post randomisation. The choice of study design and comparator was influenced by the SOFIA Aphasia Advisory Group who considered acceptability to potential participants.

insert Table 1 about here

Outcomes

Trial data will be reported and presented according to the CONSORT 2010 statement: extension to randomised pilot and feasibility trials [26]. A CONSORT diagram of recruitment and participation will

be used as shown in Figure 2. We will report participant characteristics, as well as proportion of participants receiving rehabilitation therapy or anti-depressants, overall and by trial arm.

insert Figure 2 about here

As a feasibility study the main endpoints relate to feasibility objectives. We outline four primary and four secondary endpoints. We also state pre-specified criteria for three of the four primary endpoints 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 [16, 31] or stroke [32, 33]: reported recruitment, retention and adherence rates have informed what we consider to be realistic progression criteria. We will consider data from all time points including nine months post randomisation as appropriate. Clinical and economic evaluation outcome measures are listed in Table 2.

Primary endpoints.

[1] Acceptability of the intervention to participants and trial clinicians: evaluation based on rates of adherence to intervention where participants considered to have adhered if they elect to receive at least two therapy sessions; in-depth interviews with participants and trial clinicians; qualitative evaluation of trial clinicians' therapy records e.g. clinician comments on acceptability; scores on the Session Rating Scale [34] assessing therapeutic alliance. **Pre-specified criterion 1:** proportion of participants who adhere (receive at least two therapy sessions) at least 80%.

[2] Feasibility of recruitment and retention to the trial: evaluation based on proportion who give permission for their clinical care team to pass on contact details to the central research team; the proportion who consent; the rate of participants randomised each month; attrition rates (overall, by stage and by study arm) and reasons for attrition if known. **Pre-specified criterion 2**: proportion of eligible participants who consent at least 60%. **Pre-specified criterion 3:** proportion of participants who are followed up at 6 months post randomisation at least 70%.

[3] Acceptability of research procedures and outcome measures: evaluation based on participant interviews exploring their experience of study procedures; drop-out rates; rates of missing data. **Pre-specified criterion 4:** proportion of missing data (per scale for all scales other than the Depression Intensity Scale Circles, DISCS) less than 15% for participants with mild to moderate receptive aphasia, defined as scoring ≥7 on the receptive domains of the Frenchay Aphasia Screening Test (FAST). **Pre-specified criterion 5:** proportion of all participants, including those with severe receptive aphasia, able to complete DISCS at least 90%.

[4] Feasibility of delivering the intervention by experienced speech and language therapists: evaluation based on interviews with trial clinicians at end of the study and qualitative evaluation of the clinical supervisor's records of clinical supervision sessions. In addition, the process of assessing fidelity will provide further insight into the extent to which speech and language therapists were able to deliver the intervention as intended.

Secondary endpoints.

[5] Appropriateness of outcome measures: evaluation based on level of variability of scores; missing data; floor or ceiling effects; whether scale constructs match any changes described during in-depth interviews; participant perspective on acceptability.

[6] Estimating sample size: based on means and standard deviation of proposed primary clinical outcome measure (Warwick Edinburgh Mental Well-Being Scale, [35]) and retention rates.

[7] Assessing treatment fidelity processes: evaluation based on acceptability of fidelity checking processes to trial clinicians and participants; utility and reliability of the fidelity check-list; and extent to which treatment is delivered as intended (i.e. compliant with the therapy manual).

[8] Feasibility of documenting usual care and resource use: evaluation based on the acceptability and completeness of data generated by the adapted version of the Client Service Receipt Inventory (CSRI) [36].

##insert Table 2 about here ##

Patient reported outcome measures

Primary and secondary outcomes: The primary clinical outcome in a future trial is likely to be psychological well-being, measured using the Warwick Edinburgh Mental Well-being Scale (WEMWBS) [35]. Potential secondary clinical outcomes will likely measure mood (General Health Questionnaire-12 item version [37], and Depression Intensity Scale Circles [38]); and communicative participation (Communicative Participation Item Bank, [39]). These measures will be tested in the current trial, and will be completed in face-to-face interview format at baseline, and at three and six months post randomisation, with additional visit nine months post randomisation for the wait-list group. The presentation of measures will be modified to make them accessible to people with aphasia in line with best practice [40]: participants will be able to read items as well as hear them; few items will be presented per page; a large font will be used; and participants will be able to point to their preferred response option. Practice items will be introduced for each scale to ensure participants understand the response formats. The content of the measures will not be changed to avoid affecting their psychometric properties. The visits will be conducted by research assistants who are qualified speech and language therapists able to facilitate responses of people with aphasia as appropriate. The measures chosen have all been successfully used with people with aphasia in previous research projects [25, 41]. The research assistants will receive initial training in completing the outcome measures as well as ongoing support to ensure consistency of approach.

Profiling and co-variate measures: the Frenchay Aphasia Screening Test [30] will be conducted at baseline. Further, a measure of therapeutic alliance, the Session Rating Scale [34], will be completed during the in-depth interview by an unblinded researcher.

Economic evaluation measures: participants will complete the EQ-5D-5L [42] measure at baseline, and all subsequent post-randomisation assessment points. An adapted version of the Client Service Receipt Inventory (CSRI) [36] will be collected by an unblinded research assistant at six months post

randomisation, capturing data for the previous 3 months. Modifications have been made to the CSRI so that it is more relevant and accessible to people with aphasia.

Sample size

We will recruit 32 participants, 16 participants allocated to each arm. This is line with recommendations which suggest a sample size of between 24 and 50 for a feasibility study [43-45]. This is considered sufficient to estimate the parameters of a larger trial, such as recruitment rates, consent rates, completion rates and standard deviation of outcome measures, with acceptable precision. We anticipate at least 24 participants will be followed up at 6 months, the likely endpoint in a future definitive trial. Effect sizes gained from the 6 month data point will be used to inform the sample size calculations of the future definitive trial. A recent aphasia therapy feasibility trial with a similar sample size (n=34) generated sufficiently useful information to enable progression to the definitive Big Cactus trial [31, 46]. In addition to collecting quantitative data, we are also inviting all participants to take part in in-depth interviews. Assuming at least 24 participants complete post therapy interviews, we anticipate this sample will enable us to capture a diverse range of perspectives into how the intervention has been experienced by this client group [47].

Data management and monitoring

The trial databases will be hosted at City, University of London, on a password-protected secure network drive accessed only by named personnel. The datasets will be anonymised with participants being identified by their unique Participant Identification Number. Data will be entered by authorised staff (SN and research assistants) with a full audit trail. Internal auditing of the data collected will occur throughout the trial. Data will be monitored for completeness and accuracy, with range and logic checks conducted and a random selection of at least 20% of the data double checked. The Chief investigator (SN) will meet with four senior academic supervisors every month throughout the project. This Academic Supervisory Group will monitor the progress of the trial including recruitment and adherence to protocol, as well as participant safety. In addition, a Trial

Steering Committee (TSC) will meet three times over the course of the trial to monitor study progress, adverse events, and advise on continuing or stopping the trial. As this is a small low-risk trial, the TSC will also take on the role of a Data Monitoring Committee. There are no planned interim analyses. The decision to stop the trial early on grounds of safety or futility will be made by the TSC, for example, if we fail to recruit, or have very low adherence rates. Any significant amendments to the protocol will be communicated to all relevant authorities including the TSC, the sponsor, the funder, the Health Research Authority, and the relevant trial registry.

Analyses

Quantitative analysis

As a feasibility study the main endpoints relate to the feasibility objectives listed above. Descriptive statistics will be calculated for feasibility outcomes, along with 95% confidence intervals as appropriate.

In terms of clinical outcomes, descriptive statistics will be presented for the primary clinical outcome measure of psychological well-being (WEMWBS) and three secondary outcomes (mood, GHQ-12, DISCS; and participation, CPIB). We will present the GHQ-12 data both as an overall score (range: 0 to 12); and also as categorical data (participants scoring <3 classified as having no or low distress). These measures will be summarised using summary statistics measuring central tendency and dispersion, for the entire trial population and by trial arm, at each time point, including nine months post randomisation for the wait-list group. Means and confidence intervals will be plotted over time. Summary statistics will also be presented for the co-variate outcomes measuring aphasia severity (FAST) and therapeutic alliance (SRS).

Since the intervention is therapist led, we will estimate the intra cluster correlation coefficient (ICC) for participants treated by the same therapist for outcomes six months post randomisation using a random effects model. In addition, we will report on appropriate effect sizes, along with associated 95% confidence intervals, for the clinical outcomes. We will use a random effects model which

adjusts for therapist effect and also includes the baseline outcome as a covariate. We will use this data to estimate the sample size for the definitive trial.

One of the aims of the trial is to explore the acceptability of the intervention and measures for people with severe aphasia (for this trial classified as scoring as <7 on either expressive or receptive domains of the FAST). As secondary analysis, we will additionally present the data for people with severe aphasia separately from people with mild to moderate aphasia for all outcome measures: any noteworthy differences between these two groups will be reported descriptively as group size is small.

We will also conduct missing values analysis at the item level, scale level, and per administration as well as report the number of participants who have complete data for each time point, by treatment group and overall. The aim will be to build a picture of the characteristics of participants with missing data. The nature of the missing data will inform our evaluation of the acceptability of the different measures for this client group.

Qualitative analysis

Qualitative data will be reported according to the Standards for Reporting Qualitative Research Guidelines (SRQR) [48]. The primary source of data will be the in-depth interviews with participants and therapists, although we will also refer to therapy and supervision records. All interviews will be recorded with consent and transcribed verbatim. Data will be analysed using Framework Analysis [49] where raw data is tagged using a thematic index and is then synthesised into thematic matrices enabling between and within case analyses.

Health economics analysis

We will present the relevant costs and health outcomes for both the intervention group and the control group. For the costs, we will use data collected from the adapted CSRI at 6 months post randomisation: it will capture data from the previous 3 months. Costs will be derived from identifying resources used in terms of health and social care service use, intervention costs, as well

as informal care costs and costs to the individual. 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 use the relevant annual costing manual corresponding to the date when the resource use data was collected. We will also refer to the unit costs for health and social care compiled by the Personal Social Services Research Unit [50].

Health gains will be obtained from WEMWBS and the EQ-5D-5L. These measures will inform two types of exploratory economic evaluation analysis, to ascertain the potential cost per unit of change in quality of life using each of the WEMWBS and EQ-5D-5L measures. Additionally, 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 is intended to inform the design of the economic analysis in a larger trial and will be exploratory in nature. We will examine the completeness of the data. We will also explore the acceptability and potential burden of the economic measures to people with aphasia and their family members, for example, in terms of time taken to complete.

Service user involvement

When developing the funding proposal we held a workshop with people who had post-stroke aphasia, both mild and severe, as well as a carer. This workshop influenced the choice of control group, the decision to target people at least six months post stroke, and to include people who had severe aphasia in the trial. In setting up and monitoring the current trial the SOFIA Aphasia Advisory Group is meeting eight times. The group is made up of four people with aphasia and one family member, including two people who have experience of receiving the intervention. The group has already provided advice on: the design of project information including the participant information sheet; recruitment process; presentation of outcome measures; topic guide for the in-depth interviews; ideas to improve the accessibility of the therapy approach; and ways to enhance the participant experience. They have additionally contributed to therapist training. In future meetings

they will advise on issues in the trial as they arise; discuss interpreting findings and dissemination; and consider ways to build a community around the project.

Adverse events, ancillary care and post-trial care

This study is exploring a non-physical non-invasive intervention. As such, adverse events related to participating in the study are considered unlikely. Research assistants and trial clinicians will report all adverse events, both related and unrelated to the study, to the chief investigator. For the purposes of this trial, a participant scoring >3 on the GHQ-12, indicative of moderate psychological distress, is considered an adverse event. In this case, the research assistant will follow a set protocol. They will seek permission for the chief investigator to share the results with their primary care physician (General Practitioner, GP). They will also advise the participant to visit their GP and facilitate this visit as required. The participant will be given the choice as to whether to remain in the project. If a research assistant or trial clinician has serious concerns about a participant's mental or physical well-being a decision will be made with the participant and other relevant authorities about what is in their best interests, for example, escalation of psychological care and potentially withdrawal from the study.

In terms of ancillary care, all research assistants and trial clinicians are also qualified Speech and language therapists who will receive additional training for the trial from the chief investigator, as well as ongoing support. They will be able to listen to participant concerns and will be trained to respond appropriately to participant distress. They will also receive training on the core values of the project which prioritise a positive participant experience during all research visits e.g. participants should feel valued and respected when collecting outcome data; research assistants are encouraged to take an interest in participants as people. In addition, information about local support sources will be offered if participants express feelings of loneliness or low mood. All participants have met the chief investigator during the initial information giving visit. The SOFIA Aphasia Advisory Group advised that the potential participant should be listened to holistically during this visit and that the

process should feel two way. Participants and their families are given the chief investigator's direct work phone line and email address and are encouraged to contact the chief investigator if they have concerns. Further, it is the chief investigator who communicates their group allocation and is in contact with them throughout the trial to confirm or arrange follow up visits, providing continuity. Where possible, we also organise that it is the same research assistant who conducts the first three assessment visits. Participants will not receive any financial incentives to take part in the trial.

In terms of post-trial support, the final visit for all participants is an in-depth interview with a researcher unblinded to treatment allocation and aware of how they have progressed through the trial (e.g. with access to their therapy records and outcome data). This researcher is well placed to talk through different options going forward (e.g. discuss voluntary organisations that offer support and other opportunities within the university), as well as thank them for their contribution and let them know what to expect next.

Dissemination policy

The results of the study will be reported and disseminated at academic and clinical conferences and in peer-reviewed scientific journals, as well as to our funder and the two NHS sites. Our SOFIA Aphasia Advisory Group will advise on how best to disseminate the results to the public and stroke community, for example, writing in the newsletters of stroke and aphasia voluntary organisations, attending stroke events or via social media. We will also work with the SOFIA Aphasia Advisory Group to create an aphasia-accessible results leaflet to explain the results to participants and others involved in the trial, as well as holding a dissemination event.

Study status

The recruitment was scheduled to take 13 months, from 31st October 2017 until 30th November 2018. Recruitment began two weeks earlier than planned on 17th October 2017, and was completed on 5th November 2019. Data collection has not yet been completed and the study is ongoing.

Discussion

This study will evaluate the feasibility of conducting a definitive randomised controlled trial evaluating clinical and cost effectiveness of Solution Focused Brief Therapy for people living with chronic post-stroke aphasia. The aim of the therapy is to enhance the psychological well-being of people with aphasia.

The current study may provide valuable information on ways to adapt a psychological talk-based therapy so that it is accessible to people with a communication difficulty. We decided to include people with severe aphasia. There is evidence that people with severe aphasia have significantly lower health-related quality of life than people with mild to moderate aphasia [51]; have three-fold worse activity limitations in communication than those with moderate aphasia [52]; and are at high risk of social exclusion [53]. Preliminary evidence from a pilot study linked to the current trial suggested that it was possible to modify the approach to make it communicatively accessible to people with severe aphasia, and that they found the therapy approach acceptable [54]. The SOFIA study will provide further information on whether there are particular presentations of aphasia which make the approach less acceptable. A potential challenge of including people with more severe aphasia is exploring how best to capture any change. We took the decision to collect data directly from participants rather than rely on proxy responses, as there are is some evidence that that proxy responses are not commensurable with self-report, particularly for less observable, more subjective constructs. Proxies tend to score people with aphasia as more severely affected than the people with aphasia scores themselves [55, 56]. We have carefully selected measures which have been used successfully with people with aphasia in previous studies, and will monitor closely whether people with more severe aphasia are able to self-report on all the chosen measures in order to inform our choice of measures in the definitive trial.

In conclusion, this study will assist in building the evidence base for potential effective interventions for a client group excluded from most stroke research exploring psychological interventions. The

study may also provide useful information on the viability of speech and language therapists delivering a psychological intervention, including their perspective on support and training needs. Finally, the intervention and the therapist training are both relatively brief suggesting that the approach has the potential to be integrated into routine clinical practice.

This paper reports on protocol version 2 (date: 24th August 2017).

Declarations

Ethics approval and consent to participate

Ethical approval to conduct the study was granted by the NHS Health Research Authority Brighton and Sussex Research Ethics Committee (17/LO/1255) on 14th September 2017. Approvals from all sites to begin recruitment were completed by 5th October 2017. Fully informed, written consent is obtained from all participants.

Consent for publication

Not applicable.

Data availability

Underlying data

No data is associated with this article.

Extended data

Figshare: SOlution Focused brief therapy In post-stroke Aphasia (SOFIA) feasibility trial, **https://doi.org/10.25383/city.c.4491122.v1**

This project contains the following extended data:

- Protocol version 2, dated 24th August 2017
- SOFIA participant information sheet
- SOFIA informed consent form
- SOFIA one page summary information sheet
- SOFIA adapted Client Service Receipt Inventory (based on Beecham and Knapp, 2001)

Reporting guidelines

SPIRIT checklist for 'SOlution Focused brief therapy In post-stroke Aphasia (SOFIA Trial): protocol for a feasibility randomised controlled trial'. **https://doi.org/10.25383/city.8058326.v1**

TIDieR checklist for 'SOlution Focused brief therapy In post-stroke Aphasia (SOFIA Trial): protocol for a feasibility randomised controlled trial'. **https://doi.org/10.25383/city.8058539.v1**

Competing interests

The authors declare no competing interests.

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Authors' contributions

SN led the study and drafted this manuscript. All authors participated in designing the study. KH, AS, ST and SH are members of the academic supervisory group and provide oversight and ongoing advice to the project. SH provides statistical expertise and CF health economics expertise. All authors contributed comments and feedback on this manuscript and approved the final submitted version.

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Table 1. SOFIA Trial: Template for Intervention Description and Replication (TIDieR) checklist

Item	Description
1: Name	**SO**lution **F**ocused Brief Therapy **I**n post-stroke **A**phasia (SOFIA Trial)
2: Rationale, theory or goal of the intervention	The aim of the intervention is to enhance psychological well-being. Solution Focused Brief Therapy (SFBT) hypothesises that in enabling a client to describe their preferred future, as well as notice their competencies, skills, and instances of success, the client can be supported in building positive change [20, 57].
3: Materials for training and delivery	A therapy manual has been developed to guide the training and supervision of trial clinicians, as well as the delivery of the intervention. The manual describes the basic tenets of Solution Focused Brief Therapy, drawing on established descriptions of the approach, for example, provided by the United Kingdom Association for Solution Focused Practice. It follows the model of Solution Focused Brief Therapy developed by Evans, Iveson and Ratner [20]. Trial clinicians will receive a copy of the manual as well as additional resources such as PowerPoint slides and checklists. No specific materials are required for the delivery of the intervention. However, to ensure that the intervention is accessible to people with more severe aphasia, therapists will use pictorial resources including those developed by Talking Mats ©. In addition, therapists will use paper and pen to facilitate total communication, for example, drawing pictures, diagrams or scales, or writing down key words. They will also use objects in the environment and be responsive to modes of communication and materials preferred by the participant e.g. use of paper diary or iPad.
4: The Intervention: Procedures, activities, processes	SFBT is a talk-based psychological intervention. It explores how a person would like their life to be and their hopes for the future. It also seeks to enable people to notice their own resources, resilience, and what is already working. As the participant is considered expert in their own lives, the therapist refrains from offering advice, solutions or strategies, and instead seeks to facilitate the client in finding their own way forward. *Key assumptions:* It is anticipated that the therapist will hold in mind certain key assumptions throughout the therapy process. These include: the participant is expert in their own lives thus will direct the shape of the therapy sessions; that all participants have resources, talents, competencies and strengths, and the therapist's job is to enable the participant to notice them; that a 'solution' may be brought about by small steps, hence a focus on noticing the everyday details of a person's life; that the therapist will hear and validate the participant's stories sufficiently to create a context where change can occur. *Key behaviours:* Two behaviours are expected to be present in all sessions: use of the client's words and frames of reference to guide therapist utterances; and the therapist facilitating the communication of the person with aphasia so that they can participate fully in the intervention. Other key behaviours anticipated to be present in some sessions include: establishing what the participant is hoping for from the therapy; eliciting preferred future descriptions (enabling a participant to describe the everyday details of their life if they achieved their therapy goals); inviting the participant to notice what is

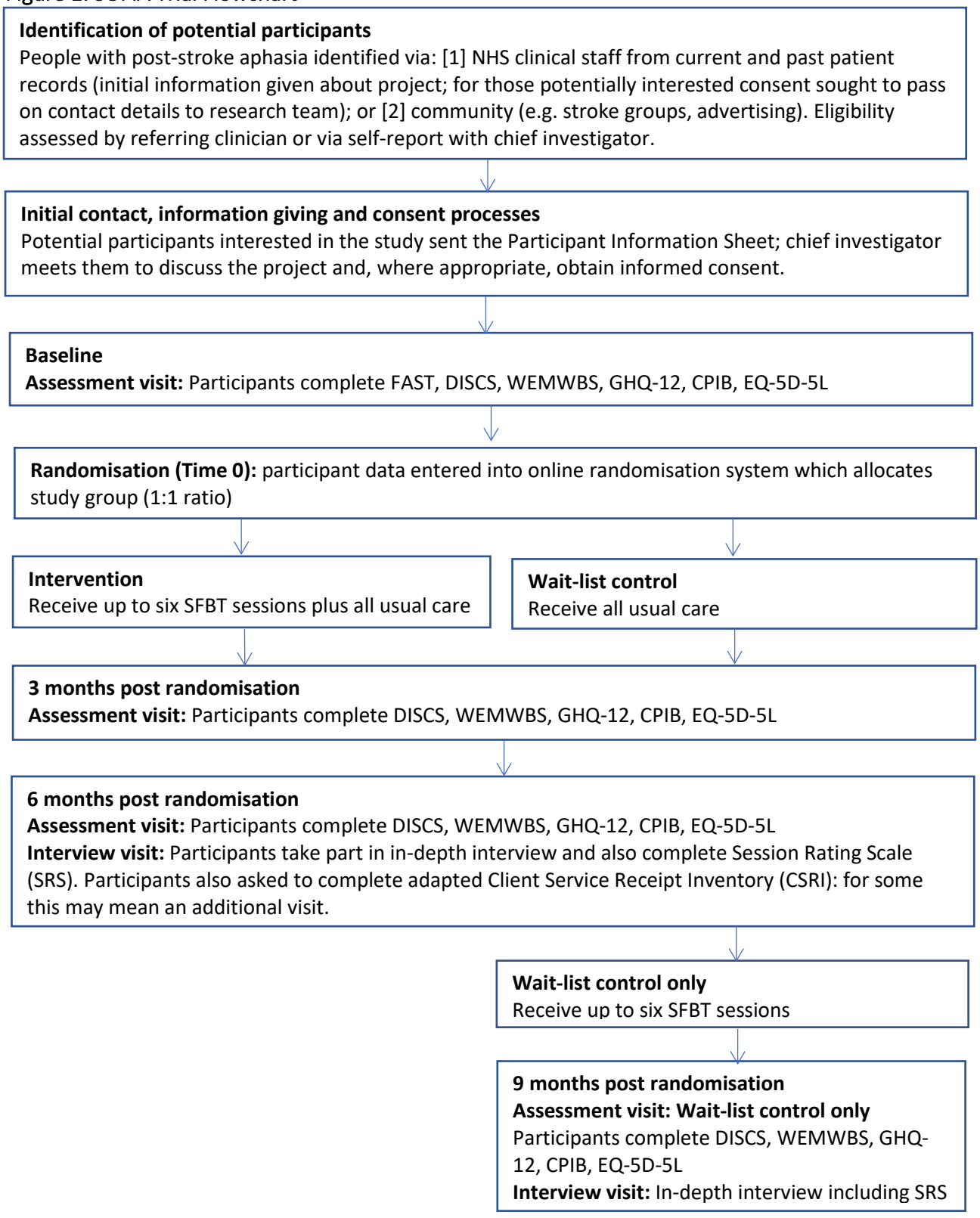
	already working and instances of success, for example, through listing what they've been pleased to notice or using scaling questions; eliciting descriptions of interactional sequences and the perspectives of other people in the participant's life; problem-free talk (noticing the person and what's important to them, what gives them joy); and acknowledgement of the stroke, aphasia, recovery and distress.
5: Intervention providers	The intervention is provided by speech and language therapists with experience of working with people with aphasia. The trial clinicians receive four days 'foundation training' in the core principles and practices of Solution Focused Brief Therapy at the Brief Centre for Solution Focused Practice, London. They additionally receive two days training at City, University of London (led by SN), which focus on adapting the approach for people with aphasia, study procedures, and developing their skills through feedback from members of the SOFIA Aphasia Advisory Group. In addition, they receive training in how to respond to distress and escalate psychological care appropriately (led by mental health nurses, AS and CF). Finally, they receive monthly clinical supervision provided by a speech and language therapist who is also an expert in SFBT.
6: Mode of delivery	The intervention is delivered face to face and provided individually rather than in a group setting. Participants can choose whether to include family members or friends within the therapy sessions.
7: Location	Participants can choose the location of therapy sessions. It is anticipated this will mostly be their own home or the University Clinic. Seeing people in their own home will mean we can include more isolated and housebound participants.
8: When and how much	Participants will be offered up to six sessions spaced over 3 months. The scheduling and number of sessions is led by the participant. Each session will be approximately one hour long. Although SFBT is typically brief (3-5 sessions [20]) people with aphasia are likely to need additional sessions, as less material can be covered in each session due to the language disability [25].
9. Tailoring	The content of SFBT sessions is individualised for each participant. Within any specific session, therapist utterances follow from what the participant says: as such, there is an inherent flexibility. Nonetheless, it is expected that there will be consistency across all sessions in terms of the underlying assumptions that underpin therapist utterances and key therapist behaviours (see Item 4). The sessions are also individualised to enable people with varying presentations of aphasia to participate. It is likely that not all aspects of the approach will be feasible for people with more severe aphasia (e.g. detailed description of the preferred future or describing extended interactional sequences). As such, it is anticipated that for some participants sessions will focus on aspects of the approach less dependent on complex linguistic structures (e.g. celebrating recent successes using photos on the participant's phone).
10: Modifications	If any modifications are made to the intervention during the project they will be reported in full.
11: Adherence and fidelity (planned)	*Adherence:* Adherence is defined as receiving at least two therapy sessions. We will report on the number of sessions participants choose to receive, how they elect to space the sessions, and any complicating factors reported (e.g. sessions cancelled due to participant or therapist illness). We will also analyse participant and therapist views on dosage and spacing of therapy during the in-depth interviews.

	Fidelity: A fidelity checklist has been developed listing the core assumptions expected to be present in therapy sessions, as well as key observable behaviours. Clinicians will self-rate using the checklist after each session. They will bring the completed checklists to clinical supervision for discussion. It is intended that the reflective process of completing the checklist will enhance the likelihood that the intervention is being delivered as intended. It is also anticipated that fidelity will be enhanced by regular clinical supervision with an expert in the SFBT approach. Additionally, a proportion of sessions (at least 15%) will be either audio or video recorded with participant consent. Each therapist will record a diverse sample of sessions including: initial, middle and final sessions; and sessions recorded at all stages of the project (i.e. when therapists are less experienced near the beginning of the trial; mid-trial; and near the end of the trial). The recordings will then be rated by independent raters using the fidelity checklist to determine the extent to which the intervention was delivered as intended.
12: Adherence and fidelity (actual)	Adherence and fidelity results will be reported at the end of trial.

Table 2: Outcome measures used in SOFIA study

Outcome measure	Construct	Modifications made for SOFIA Trial
Clinical Outcomes		
Warwick Edinburgh Mental Wellbeing Scale (WEMWBS) **[35]**	Mental wellbeing	Presentation, not content, adjusted to be more accessible to people with aphasia.
General Health Questionnaire – 12 item version (GHQ) **[37]**	Psychological Distress	Presentation, not content, adjusted to be more accessible to people with aphasia.
Depression Intensity Scale Circles (DISCS) **[38]**	Depression	Presentation, not content, adjusted to be more accessible to people with aphasia.
Communicative Participation Item Bank (CPIB) **[39]**	Communicative Participation	Presentation, not content, adjusted to be more accessible to people with aphasia.
Profiling and co-variate		
Frenchay Aphasia Screening Test (FAST) **[30]**	Language	No modifications
Session Rating Scale (SRS) **[34]**	Therapeutic alliance	Author of SRS has created two versions. Linguistically simpler version used.
Economic Evaluation		
European Quality of Life, 5 Dimension, 5 Levels (EQ-5D-5L) **[42]**	Health-related quality of life	Presentation, not content, adjusted to be more accessible to people with aphasia.
Adapted Client Service Receipt Inventory (CSRI) **[36]**	Service and resource use	Modifications made to both presentation and content so as to be more relevant and accessible to people with aphasia.

Figure 1: SOFIA Trial Flowchart



Key
DISCS: Depression Intensity Scale Circles; CPIB: Communicative Participation Item Bank; CSRI: Client Service Receipt Inventory; EQ-5D-5L: European Quality of Life – 5 Dimensions, 5 Levels; FAST: Frenchay Aphasia Screening Test; GHQ-12: General Health Questionnaire 12 item version; SRS: Session Rating Scale; WEMWBS: Warwick Edinburgh Mental Wellbeing Scale

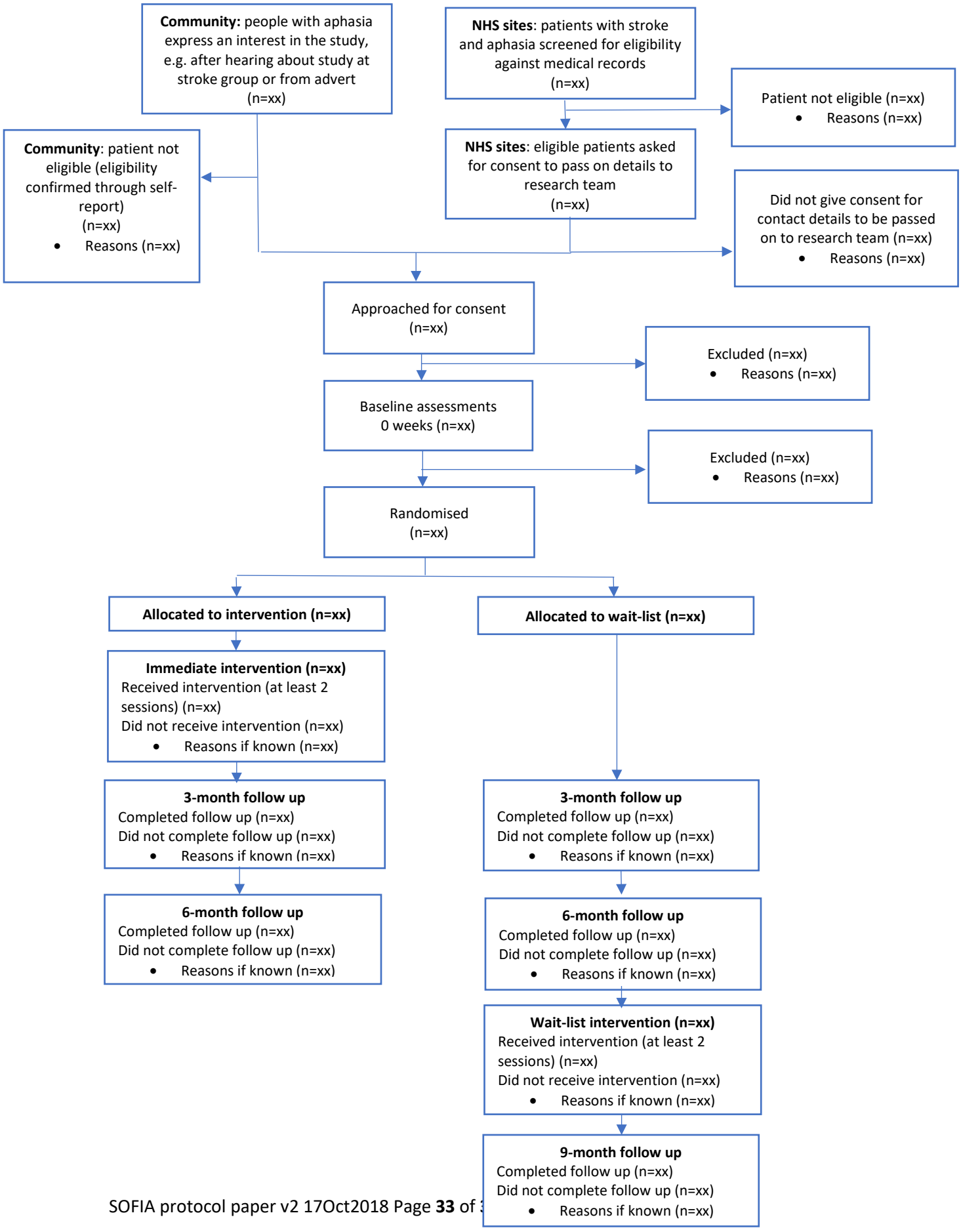



Figure 2: SOFIA CONSORT flow diagram