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PRevention Intervention and Support in Mental health for people with aphasia (Aphasia PRISM): protocol and mixed methods analysis plan for two feasibility studies

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Abstract

Background People with aphasia commonly experience depression and anxiety. The individual therapy program, Aphasia PRevention Intervention and Support in Mental health (Aphasia PRISM) offers low intensity psychotherapeutic interventions using communication supports. Trained stroke clinicians from disciplines other than psychology (e.g., allied health professional, nurse, doctor) can deliver such interventions. The aim of the planned studies is to test the acceptability, feasibility and preliminary effectiveness of Aphasia PRISM for preventing depression and anxiety and supporting wellbeing in people with aphasia after stroke.

Method This protocol describes two feasibility studies of the Aphasia PRISM using parallel, convergent, mixed methods designs. Participants will be adults with aphasia after stroke from a metropolitan healthcare site (Study A, pre-post case series, approximate n = 6) and two regional/rural sites (Study B, randomised controlled trial, n = 30; random allocation to either: treatment arm Aphasia PRISM + usual care; or attention control of secondary stroke prevention information + usual care) in Victoria, Australia. Eligible participants will be offered 7 weekly intervention sessions (via telehealth or in person). Other participant groups include stroke clinicians / site managers and family members. Feasibility will be assessed with treatment acceptability ratings (primary outcome) and secondary outcomes such as recruitment rate and participant clinical response. Participant clinical responses to intervention will be collected pre-intervention (baseline), concurrently (4 week acceptability measure), immediately post (8 weeks), follow-up (3 months) and follow-up at 6 months (Study B only). Descriptive statistics will be used to analyse quantitative data based on the type and distribution of data. Reflexive thematic analysis, an inductive approach will be used to analyse qualitative data.

Discussion Aphasia PRISM offers the potential for trained stroke clinicians to deliver low intensity psychotherapeutic interventions with communication supports to people with aphasia. Studies A and B were registered with the Australian New Zealand Clinical Trials registry under one registration (ACTRN12620000209998) 20th February 2020.

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Keywords Aphasia · Stroke rehabilitation · Psychological therapy · Psychological care · Behavioural activation · Problem solving therapy · Relaxation therapy

1 Introduction

Aphasia is a communication disability caused by damage or changes to the language networks of the brain. It affects a person's ability to speak, understand speech or written words and their ability to read and write. The types of language and communication difficulties can occur in combination and with varying degrees of severity. Approximately 25% of the stroke population have aphasia [1]. People with aphasia are at high risk for serious psychological and mental health conditions after stroke [2]. Depression is the most common mood disorder, with the majority of people with aphasia fulfilling diagnostic criteria at some point within the first year post-stroke [3, 4]. Anxiety is also common, with an estimated prevalence of up to 44% in people with aphasia [5].

Of concern, are the evidence-practice gaps in the consistent provision of psychological care after stroke and aphasia. These gaps include a lack of routine mood screening, assessment and follow-up care utilising psychotherapeutic supports and interventions [6, 7]. Authors of an Australian 2020 national audit of inpatient rehabilitation services for stroke found that approximately 40% of patients with and without aphasia did not have an assessment for depression and anxiety [6]. Furthermore, a third of stroke services did not have access to clinical or neuropsychologists [6]. Access to psychotherapeutic interventions are challenging for people with aphasia due to communication barriers and a dearth of accessible mental health services (e.g., counselling adapted to accommodate communication needs and support) [8].

Stroke clinicians from disciplines other than psychology (e.g., allied health professionals, nurses, doctors) are well placed to initiate 'first line' screening, provide low intensity psychotherapeutic interventions and triage to mental health specialists as required [9]. A lack of formal training in therapies to enhance mood in the context of communication disability may mean that stroke clinicians feel limited in scope of practice or under-skilled to deliver mental health support and intervention [7, 10]. One possible solution to guide interdisciplinary practice is the implementation of level 1, low intensity interventions within a stepped psychological care framework to aphasia rehabilitation [11]. This evidence-based framework can guide stroke clinicians to promptly match the person with aphasia to one of four levels of increasing psychological intervention intensity, depending on the level of severity in symptoms and care needed [11]. Beyond level 1, those with significant depression and/or anxiety symptoms can be triaged to higher intensity psychotherapeutic interventions at levels 2, 3 or 4 (e.g., specialist mental health care facilitated by clinical psychologist and/or medical practitioner). Those without significant depression and/or anxiety remain at level one for low intensity psychotherapeutic interventions to prevent mood problems.

Research evidence in level 1 interventions for aphasia and psychological care informed the development of a new intervention called Aphasia PRevention and Support in Mental health (Aphasia PRISM). It includes adapting psychological therapies for the communication disability associated with aphasia. Participants engaging in the intervention can choose either behavioural activation, problem solving therapy or relaxation therapy informed by a guided decision-making process with their stroke clinician or the primary researcher. These therapies each have emerging evidence to demonstrate acceptability and efficacy in stroke and aphasia clinical populations [12–17], however have not generally been offered as a suite of choices. Advantages to self-selection of psychological therapies include enhanced sense of autonomy and control/agency; engagement in therapy; and tailoring to individual needs and preferences [18, 19].

The aim of the planned studies described in this protocol is to test the acceptability, feasibility and preliminary effectiveness of Aphasia PRevention Intervention and Support in Mental health (Aphasia PRISM) for preventing depression and anxiety and supporting wellbeing in people with aphasia after stroke. The research questions we will address are as follows:

1. Is Aphasia PRISM acceptable to people with aphasia, their family member and stroke clinicians?
2. Is Aphasia PRISM feasible to deliver via telehealth or in person in metropolitan and regional /rural community settings?
3. What is the clinical response of individual participants to the intervention (Aphasia PRISM) (Study A); and to the intervention compared to the attention control arm (health information provision) (Study B).

2 Methods

2.1 Ethics approvals

Multi-site ethics approval to conduct both studies was granted by Monash Health (study number 60654) and research governance granted by all sites (Monash Health, Bendigo Health and Echuca Regional Health). All research in both studies was performed in accordance with the relevant guidelines and regulations. Protocol amendments were submitted and approved following method changes to offer the therapy via telehealth due to COVID-19 restrictions which impacted research activity (2020–2023).

2.2 Study A and B designs

This protocol describes two feasibility studies: Study A (pre-post case series) and Study B (RCT) using parallel, convergent, mixed methods designs based on frameworks of feasibility testing of complex interventions [20–22]. Study A is intended to precede Study B to test the intervention, outcomes, study processes, barriers and facilitators with a small sample (n = 6) to inform the implementation of the pilot RCT with a larger sample size (n = 30).

Study A: is a pre-post case series (one Australian metropolitan site), with all participants with aphasia guided by their clinician or the primary researcher (CB) to self-select one of the three interventions (either behavioural activation, problem solving therapy or relaxation therapy). They will also receive usual care in the community (e.g., General Practitioner (family doctor) appointments, stroke rehabilitation therapy sessions). We will test acceptability, feasibility and evaluate clinical response at individual case-based level.

Study B: is a feasibility randomised control trial (RCT) (two Australian regional sites), with participants randomly allocated to either the intervention group or an attention control group. There are two phases to the RCT:

Phase 1: (pre-implementation) We will convene a reference group of consumers with lived experience, and stroke clinicians/site managers to report preferences for telehealth delivery of Aphasia PRISM in their local regional/rural areas. We will conduct semi-structured focus groups to discuss current telehealth practice, preferences and identified barriers/facilitators.

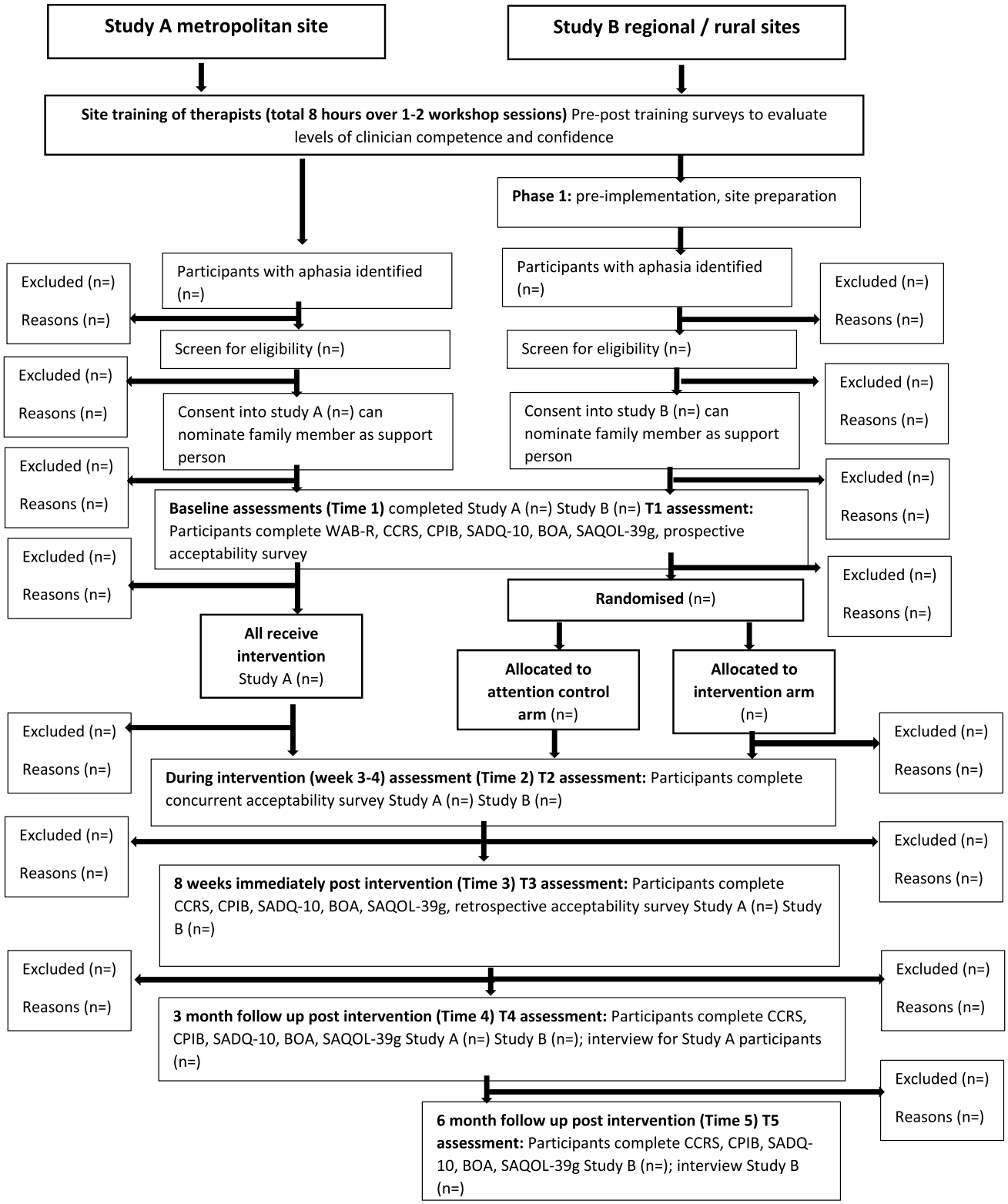
Phase 2: (implementation) We will test the feasibility of Aphasia PRISM via telehealth in terms of acceptability to participants; recruitment capability and sampling; data collection procedures and outcome measures; and evaluation of clinical response for participants in intervention arm compared to attention control arm. We will include eligible participants with aphasia for baseline assessment then random allocation to either the intervention arm (Aphasia PRISM + usual care) or attention control arm (secondary stroke prevention information provision + usual care). All three participant groups (participants with aphasia; family members; and stroke clinicians/site managers) will be offered an interview post-intervention to gain an understanding of their experiences of the intervention.

An overview of the recruitment and study procedure is summarised in Fig. 1. Trial assessments are conducted at baseline (T1); mid-way through intervention at approximately 4 weeks (T2; concurrent acceptability measure only); immediately after completion of the intervention at 8 weeks (T3); follow-up, which is 3 months since completion of the intervention (T4); and an additional follow-up, which is 6 months since completion of the intervention for Study B participants only (T5). We will test acceptability, feasibility and evaluate clinical response by comparing the two groups.

We will adhere to the Template for Intervention Description and Replication (TIDieR) and TIDieR-Telehealth checklist [23, 24], CONSORT reporting guidelines and Medical Research Council frameworks as appropriate [25, 26]. The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 statement was used to structure this protocol [27].

2.3 Study setting

There will be one metropolitan site (Study A) and two regional sites (Study B) in Victoria, Australia. The community health sector of these networks offers stroke rehabilitation services in the community outpatient or home settings and each has a speech pathology department to support the study. Each of the three sites was chosen so that study interventions are implemented in the context of usual healthcare clinical service provision. Healthcare managers and speech pathologists at each site were contacted by the researcher to gain initial expressions of interest in research participation. In an effort



Abbreviations: WAB-R = Western Aphasia Battery- Revised; CCRS = Communication Confidence Rating Scale; CPIB = Communicative Participation Item Bank; SADQ-10 = Stroke Aphasic Depression Questionnaire; BOA = Behavioural Outcome of Anxiety; SAQOL-39g = Stroke and Aphasia Quality of Life Scale.

Fig. 1 Overview of studies with recruitment and participation for participants with aphasia. WAB-R = Western Aphasia Battery- Revised; CCRS = Communication Confidence Rating Scale; CPIB = Communicative Participation Item Bank; SADQ-10 = Stroke Aphasic Depression Questionnaire; BOA = Behavioural Outcome of Anxiety; SAQOL-39g = Stroke and Aphasia Quality of Life Scale

to recruit more participants with aphasia to Study B, an additional three regional/rural community healthcare services in Victoria / New South Wales were identified as potential new sites. Although these healthcare teams were interested in the research, they declined to participate due to limited staff resources to implement the intervention (two sites) or existing commitments to support other research studies (one site).

Participants eligible for delivery of the intervention via telehealth will be in their home setting or other preferred location as required. Those receiving intervention in person will either attend the community clinic or the stroke clinician will provide a home visit as required or appropriate.

Table 1 Inclusion and exclusion criteria for participants

Participants with aphasia	
Inclusion criteria	Exclusion criteria
Adults aged 18 years or over and diagnosed with aphasia due to stroke	Concomitant progressive neurological disorder (e.g. dementia)
Subclinical/low symptoms of depression/anxiety: i.e. Stroke Aphasic Depression Questionnaire-10 (SADQ) score of ≤ 11 (hospital version) and Behavioural Outcomes of Anxiety score of ≤ 17	Severe mental illness or above threshold symptoms of depression/anxiety: i.e. Stroke Aphasic Depression Questionnaire-10 (SADQ) score of ≥ 12 (hospital version) and Behavioural Outcomes of Anxiety score of > 17
Adequate hearing, vision skills and English skills to participate in intervention as judged by stroke clinician	Participant in other aphasia or psychological care/mental health study
Medically stable and living in the community	
Capacity to consent	
For intervention via telehealth:	
Adequate communication skills as per evaluation of stroke health professional/researcher (mild, mild-moderate and moderate severities of aphasia) with or without support of person in the home (preferable to have support person at least for initial sessions)	
Adequate technology equipment self-supplied (internet access, laptop or desktop computer / mobile device / iPad with web-camera) and ability to learn or have basic skills to use (trouble-shooting support and set up provided by stroke clinician /researcher)	
Participant family members	
Inclusion criteria	Exclusion criteria
Adult aged 18 years or over	Progressive neurological conditions (e.g., dementia)
Adequate hearing, vision and English skills to participate in intervention	Severe mental illness
For intervention via telehealth:	
Adequate technology equipment self-supplied (internet access, laptop or desktop computer / mobile device / iPad with web-camera) and ability to learn or have basic skills to use (trouble-shooting support provided by stroke clinician / researcher)	
Participant stroke clinicians	
Inclusion criteria	Exclusion criteria
Qualified health professional working in hospital or community health setting from allied health, nursing or medical background	Students, volunteers
Experience working in aphasia rehabilitation (e.g. at least one person over past 1–2 years). Time to train and deliver therapy	
Participant stroke clinicians	
Inclusion criteria	Exclusion criteria
Qualified health professional working in hospital or community health setting from allied health, nursing or medical background	Students, volunteers
Experience working in aphasia rehabilitation (e.g. at least one person over past 1–2 years). Time to train and deliver therapy	

2.4 Participants

Eligible participants with aphasia, family members and stroke clinicians/site managers will be invited to take part in either Study A or B depending on their location (metropolitan or regional site). Stroke clinicians from disciplines other than psychology (e.g., allied health, nursing, medicine) can deliver the intervention as 'therapists', as long as they have the time to attend training and deliver 7 weekly sessions. Participants with aphasia can nominate a family member to be involved in the study as a support person, however this is not essential and participants without a family member or whose family member does not consent will still be eligible to take part. Table 1 describes the inclusion and exclusion criteria for each type of participant.

2.4.1 Screening and consent process

Potential participants with aphasia will be identified by a stroke clinician (e.g., speech pathologist, occupational therapist, social worker) in the community setting from their current caseload or previous client list. Contact details will be obtained from medical records to seek an expression of interest to participate in Study A or B depending on their location. The treating speech pathologist or researcher will check the potential participant for eligibility based on the inclusion and exclusion criteria for people with aphasia. Those who are ineligible due to depression and anxiety scores in the clinical range (i.e., above sub-clinical and low symptoms) will be provided with information about the mood screening results. These individuals will be provided with mental healthcare support and follow-up as per the local healthcare policy and procedures (e.g., contact General Practitioner (family doctor), triage into local community healthcare supports). They will also be offered information about other aphasia and mental health research opportunities available in the community setting. If ineligible participants are interested in these studies, they will be provided with a "consent to contact form". This consent to contact form will contain only basic personal information.

The speech pathologist will obtain consent from the potential participant to be contacted by the researcher in order to provide information about Study A or B and initiate the consent process if interest is indicated. The consent process can be conducted via telehealth for those who fulfil the inclusion criteria. Each potential participant with aphasia will be provided with an aphasia-friendly verbal explanation of the research study and a written and pictorial participant information sheet and consent form. The participant's capacity to decide whether to participate will be judged by the researcher, a speech pathologist trained in communicating and verifying comprehension with adults with aphasia. Specific processes will be used to determine comprehension of the research as detailed in a previous study investigating a brief speech pathology-led psychosocial intervention [28]. If the family member is interested in participating, the researcher will verbally explain the study as well as provide them with a participant information sheet and obtain their written informed consent.

Potential stroke clinician participants will self-nominate to participate in the project as therapists/assessors/site managers. The eligibility criteria will be checked by a senior clinician, manager or stroke co-ordinator of the relevant rehabilitation team. The researcher will provide information about the study with a verbal explanation and written participant information sheet and consent form.

2.4.2 Sample

We will recruit approximately 6 participants with aphasia in Study A for the pre-post case series design. Previous brief psychological therapies for people with aphasia have recruited similarly small samples to test feasibility [29]. We anticipate this is adequate to evaluate the study processes and evaluate therapy intervention data, barriers and facilitators in a metropolitan setting.

For Study B, the pre-implementation phase at each regional/rural site will be guided by a reference group with an aim to recruit approximately 6 members at each site who represent health service staff and consumers with lived experience of aphasia (at least 1 clinician/health manager from the health service and at least 1 person with aphasia/family member). We anticipate a total of approximately 12 members to be adequate to gain perspectives of current psychological care, telehealth use and potential barriers and facilitators to implementation as found in previous focus group research [30].

For the implementation phase of Study B, we will recruit 30 participants with aphasia (15 in each arm) (20 per health service, 25% predicted attrition rate across 2 health services). This sample size is in accordance with recommendations in the literature for feasibility studies and is not powered to detect significant changes [31, 32].

Purposive sampling will be used for maximum variation across one variable: aphasia severity. The two studies offer variation in participant locations across metropolitan and regional/rural community settings.

2.5 Randomisation (Study B)

Participants will be randomised within 5 days of the baseline assessment being completed. An independent research assistant at La Trobe University will set up the secure web-based computer software (REDCap) for use to randomise participants. Sites will be labelled either site A (Echuca Regional Health) or site B (Bendigo Health) within REDCap. We would like approximately equal numbers of participants allocated to either intervention or attention control group at site A (Echuca Regional Health) and site B (Bendigo Health). This is to ensure that staff at each site gain experience in delivering both Aphasia PRISM intervention and the attention control (secondary stroke prevention information provision) sessions. Randomisation allocation will factor in promotion of balance of allocation to treatment or attention control arms at sites (A or B) and based on the participant's aphasia severity (3 levels) based on Aphasia Severity Rating scale [33] (severe = 0–1; moderate = 2; mild 3–4). On randomisation, a unique participant code will be assigned. Each participant will be randomised to Aphasia PRISM and usual care (Treatment) or attention control and usual care (Control). Please refer to Fig. 1 which shows recruitment and participation for people with aphasia.

2.6 Blinding

In Study A, the assessor collecting quantitative data via surveys and clinical outcome measures will be blinded to the type of therapy chosen by the participant. In Study B, the assessor will be blinded to treatment allocation arm until data collection is complete. The assessors won't have access to participant details and they will be asked to follow the assessment administration instructions provided. The participants will be asked not to provide information to assessors about the intervention they participated in. Assessors will report to the researcher if they become unblinded. This time point of unblinding will be noted and where possible another assessor will complete assessment/s and/or the participant's data will be analysed separately to the main sample. Family members completing the two observer-rated mood measures will be unblinded due to the likelihood of observing and being aware of interventions as a support person during intervention. The research team and site managers will also be unblinded.

2.7 Intervention

2.7.1 Intervention arm–usual care + Aphasia PRISM

The Aphasia PRISM program is a protocolised, individual intervention that offers the person with aphasia a choice of 1 of 3 therapies, either behavioural activation, problem solving therapy or relaxation therapy. These therapies were chosen by the researchers due to emerging support for positive effects on wellbeing and mood outcomes in the research evidence across the field of psychology and specifically for people following aphasia, stroke and other acquired brain injuries [12–17]. The person attends seven weekly therapy sessions of approximately 1 h duration either in person or via telehealth depending on COVID-19 restrictions and preference. The therapy, as detailed in the therapy manual (version 1.1) [34], was developed by the authors, drawing on previous evidence-based research and clinical resources to deliver behavioural activation, problem solving therapy and relaxation therapy after stroke and other types of acquired brain injuries [17, 35]. Principles and guidance for information and communication accessibility for people with aphasia were adhered to in the development of all written and pictorial resources and therapist scripts (e.g., relaxation therapy scripts and audio-visual recordings) [36, 37].

Overall, the principles of the Aphasia PRISM program are: the content and process of delivery are informed by research evidence, both quantitative and qualitative research in aphasia and acquired brain injury studies; offering low intensity therapies delivered by a trained stroke clinician; the person with aphasia can choose preferred therapy type; the in-between session home practice encourages the person to develop independence in self-help skills; and the written information has been adapted for people with aphasia using aphasia-friendly principles for communication accessibility.

Each intervention within the therapy manual details a method for the clinician to monitor mood prior to commencing sessions (administration of the Depression Intensity Scale Circles—DISCs) [38]; an explanation of therapy; rationale for therapy; goal setting; identifying personally meaningful aspects within therapy; action planning; implementation of plan into daily routine; and reviewing progress. Sessions are delivered with family member involvement if nominated

by person with aphasia (i.e., to support communication, support progress and achievement of goals, assist to complete activities).

The final two therapy sessions aim to revisit goals, consider any barriers and provide any additional information or resources where necessary to enable self-help skills. The therapy manual includes modules for the stroke clinicians to guide therapy delivery, and separate aphasia-friendly worksheets for the participants (included in the therapy manual as Appendices). Participants will receive the written materials at each individual session.

Intervention will be provided to all Study A participants, and to Study B participants who are randomly allocated to the intervention arm. Participants will self-select 1 of 3 psychological therapies adapted for communication disability with guided decision-making support by the stroke clinician or researcher. Each therapy will be delivered using the standard format of sessions and modules within the Aphasia PRISM therapy manual. These include (i) behavioural activation, where the participant is supported to increase the frequency and mastery of enjoyable activities to improve mood (e.g., gardening); (ii) problem solving therapy, in which the participant learns and applies steps to effectively solve problems; and (iii) relaxation therapy, where the participant uses techniques to reduce body tension and calm the mind (e.g., progressive muscle relaxation; slow breathing). After each session, the stroke clinician will complete a therapy log sheet which will include details about the session (e.g., session attendance/non-attendance and reason, session duration, goals/activities of session, report of person's communication functioning, whether or not session objectives were met and any additional comments).

Aphasia PRISM can be offered via telehealth for those with adequate technology and communication access to overcome barriers such as distance and during periods of care mandating telehealth, such as during the COVID-19 pandemic [39]. Telehealth delivery is a safe and feasible option for interventions in accordance with health professional policy and practice guidelines [40, 41]. Emerging evidence suggests the efficacy of digital and/or telehealth interventions for individuals with aphasia [42]. However, there is less evidence for telehealth psychological interventions for this population [43]. The intervention and telehealth modifications are described in Table 2 using the TIDieR checklist [23, 24].

2.7.2 Attention control arm–usual care + secondary stroke prevention information provision (Study B)

Participants randomly allocated to the attention control arm in Study B will receive 7 weekly individual sessions of up to 45 min duration supported by a stroke clinician allocated to provide the control arm only. The person will have a choice of 6 out of 9 health topics related to secondary stroke prevention (e.g., role of stroke team, lifestyle, nutrition, risk factors such as high blood pressure). The final session will be a review of content from the previous 6 sessions. These information sheets and videos were developed by the researchers based on information from the Stroke Foundation website (https://strokefoundation.org.au/). The principles and guidance for information and communication access for people with aphasia was adhered to in the development of these resources [36].

2.7.3 Stroke clinician training and treatment fidelity

All intervention sessions will be provided by a qualified stroke clinician (e.g., allied health professional, nurse, doctor) trained in the Aphasia PRISM program. Stroke clinicians are required to have sufficient time for training and intervention delivery throughout the study duration. Stroke clinicians providing Aphasia PRISM will need to:

- be a qualified stroke clinician employed by the health network
- complete the Aphasia PRISM training program.
- provide intervention on a 1:1 basis with the person with aphasia (family member may or may not attend/participate in study)
- not liaise with independent assessor (who will be blinded to type of intervention / type of arm in RCT)
- follow the Aphasia PRISM therapy manual.

The researchers developed training workshop content and resource materials for the intervention providers. The stroke clinicians delivering Aphasia PRISM therapy are required to attend 1 × 8 h in person workshop day; or 2 × 4 h training sessions via telehealth, depending on COVID-19 restrictions. Attention control arm therapists will have a 1 h training session to familiarise themselves with secondary stroke information provision and study procedures. Assessors also have

Table 2 TIDieR checklist describing Aphasia PRISM and telehealth modifications

Item	Telehealth modification
1. Brief name	
Aphasia PRevention Intervention and Support in Mental health (Aphasia PRISM)	
2. Why	
People with aphasia experience difficulty accessing psychological therapies to prevent mood problems and enhance wellbeing. There is a lack of psychological care in stroke and aphasia rehabilitation, particularly in regional and rural settings. Aphasia PRISM uses evidence-based psychological therapies to offer people with aphasia a choice of 1 of 3 preferred therapies: Behavioural Activation, Problem Solving Therapy or Relaxation Therapy. These therapies are briefly described:	
Behavioural activation	
Theory: Behavioural activation therapy is based on the behavioural model of depression, where depression results when the behaviour of a person is not eliciting positive reinforcement or reward. Increasing the frequency of a person's participation in enjoyable activities is rewarding and will improve mood. This therapy is useful after stroke as it is adapted to accommodate communication and cognitive difficulties [12, 17]	
Goal: To identify meaningful, enjoyable activity options and structure and schedule activities into daily routine and promote recognition of the enjoyment and mastery of undertaking the activities. To problem solve barriers to participating in activities	
Problem solving therapy	
Theory: Problem solving helps a person to look at a situation more objectively to enhance the process of decision making. When the person is worried or stressed by a situation they can change, they work through steps to solve the problem in a productive way [35]	
Goal: To understand the steps in effective problem solving and practise these steps routinely	
Relaxation therapy	
Theory: Relaxation exercises combine breathing, progressive muscle relaxation and focused attention to calm the mind and the body. Regular practice can ensure benefits. There is potential benefit for reducing symptoms of depression and anxiety post-stroke [13, 14]	
Goal: To understand relaxation exercise and practice these routinely	
3. What (materials)	
Treatment manual	Materials such as worksheets are provided electronically via email or sharing via shared web-based file or worked on with therapist during session using the screenshare function
Each therapist has access to the treatment manual outlining the treatment objectives, session objectives and content, participant worksheets and resource materials and in between session tasks. The manual provides self-selection of therapy support resource, telehealth use guide, session-by-session details of how to provide therapy including suggested scripts and therapy steps for the therapist to follow and deliver each session	Participants are required to have their own computer or tablet or may borrow a tablet as part of the study. They need to have a reliable internet connection
Participant worksheets and resources are provided in the treatment manual for therapists to copy for participants to use within sessions and for in between session tasks	
Paper and pens For communication support purposes and to support therapy tasks	
Computer / tablet/ smartphone may be used as appropriate to support therapy tasks e.g., recording relaxation therapy session; using audio-visual file of relaxation therapy	

Table 2 (continued)

Item	Telehealth modification
4. What (procedures)	
Each participant self-selects 1 of the 3 psychological therapies offered, the content of the therapy session will depend upon therapy choice and personal goals and progress. They participate in 7 individual therapy sessions. Each session begins with purpose and rationale for the session and review of any previous in between session tasks. The participants focus on the following areas depending on chosen therapy: *Behavioural Activation* • Identifying meaningful activities • Structuring and scheduling activities • Consistent daily activation • Overcoming barriers *Problem Solving Therapy* • Identifying problems • Listing solutions • Potential consequences • Best strategies • Plan actions, implement plan and review results *Relaxation Therapy* • Explaining the relaxation response • How & when to use relaxation exercises • Practice of strategies (e.g., breathing & how to tense and relax muscles throughout the body) • Planning to do relaxation exercises regularly and independently Activities encourage reflection, monitoring of progress and reviewing goals. Weekly between session tasks are discussed and agreed upon to encourage knowledge and skill building and use in everyday activities	
5. Who provided	
Aphasia PRISM is delivered by a qualified stroke clinician (non-psychology background) trained by the research team in supported communication for adults with aphasia and all therapy types (Behavioural Activation; Problem Solving Therapy; Relaxation Therapy). Supervision will be available from senior allied health team members/managers and/or medical staff in the clinical setting as required. The research team will offer regular supervision and support to the intervention providers as required (composed of psychologists and speech pathologists). Quality of intervention delivery is monitored via initial session videorecordings (approximately 2 sessions per participant), therapy log sheets, communication and reflection of sessions and progress between therapist and primary researcher (CB)	
6. How	
Aphasia PRISM is to be delivered in-person or via telehealth on a weekly basis in individual sessions	Following the need for COVID-19 restrictions, the study was further developed to be deliverable via telehealth using local videoconference platforms (e.g., Health Direct or Zoom) and expanded to regional and rural settings (Study B)
7. Where	
The intervention will either be provided onsite at the community rehabilitation centre or in the participant's home, in person or via telehealth	Telehealth occurs at participant's home or agreed upon quiet and private location and the therapist in their workplace
8. When and how much	
The intervention involves 7 weekly sessions, for 1 h duration over a period of 7 to 12 weeks approximately, allowing for any breaks due to public holidays/inability for participant to attend	

Table 2 (continued)

Item	Telehealth modification
9. Tailoring	
The treatment manual is intended to provide flexibility based on the participants goals and progress, communication support needs as long as key objectives are met for the therapy across the 7 sessions. Tailoring of therapy will also occur for differing levels of aphasia severity to ensure the intervention is communicatively accessible (e.g., using communication support strategies)	
10. Modifications	The initial metropolitan site (Study A) was intended to be delivered in person in the person's home or clinic setting. Following COVID-19 the treatment and the manual was modified and redeveloped to include delivery via telehealth and to people in regional and rural areas (Study B). This included understanding local telehealth procedures and use at each health network. Therapists were supported to guide participants in telehealth use (e.g. telehealth checklist of tips and technology testing prior to commencement of therapy)
11. How well (planned)	
The first 2 to 3 therapy sessions will be recorded and evaluated by the primary researcher (CB) for meeting session objectives and following content of treatment manual (checklist—planned components versus components implemented). Intervention fidelity will also be monitored using therapy log sheets (therapist to complete after every session via electronic survey tool (QuestionPro) and monitored by the primary researcher. If deviation of fidelity occurs or there are concerns about delivery of sessions observed by primary researcher then further training support will be offered. Self-reflection of competence will be encouraged with communication of learning and any difficulties in sessions or progress between therapist and the primary researcher during the study	

a 1 h training session to ensure they are familiar with administration of assessments and study procedures. Workshops and training will be facilitated by the researcher using theory, clinical case scenarios, skills practice through role play.

The treatment fidelity of the Aphasia PRISM training and intervention will be monitored by the researcher. Pre-post training surveys developed for the study will assist in the evaluation of competence and confidence of therapists (Supplemental file S1). The survey was constructed by the researchers and included essential knowledge and skill requirements to deliver Aphasia PRISM. These survey items are based on the theory and goals of communication support; and facilitating behavioural activation, problem solving therapy and relaxation therapy. Stroke clinicians will be deemed ready to commence as a therapist if they complete the training, self-report willingness and readiness to start delivering therapy, and score ≥ 85% on the post-training survey.

The therapy log sheets have been created by the researchers for the stroke clinicians to complete following every intervention and attention control arm session. These will be provided via electronic or scanned document to the

Table 3 Strategies for site implementation of intervention

Health network commitment and resources	Allocation of community health resources as per research project agreement (final signed copy included in ethics and site specific authorisations)
Pre-implementation site visits/telehealth consults	Rapport building with health service staff, gaining expressions of interest in participation of health professional intervention providers
Pre-implementation training	Consider developing the training package for stroke clinicians that is tailored to learning needs and builds competency through various approaches during the workshop (e.g., presentation of therapy information, problem-based learning using clinical case scenarios, online quiz)
Ongoing site support	Regular contact with site primary investigator/s via phone/online platform; offer supervision to intervention providers and training support as required

researcher. The researcher will monitor adherence to the therapy manual and session / therapy objectives. Following the participant's consent, approximately 2 therapy sessions will be videotaped and watched against a fidelity checklist (planned versus actual components implemented). This is a feasible number of sessions to videorecord and review based on resources available for this planned study. The researcher will review log sheets and video recordings and follow-up with therapists if there are any concerns about competence or deviations from the intervention. Extra training or supervision will be offered as needed.

2.8 Procedures

2.8.1 Intervention delivery modality, parameters and timing

Weekly Aphasia PRISM sessions will be delivered in person or via telehealth using a secure, web-based platform (e.g., Health Direct, Zoom as per site policy and procedures). Reasons for telehealth use can include physical distance from the health service, transport issues, personal preference and social distancing requirements during the COVID-19 pandemic. For some participants, particularly those with moderate-severe and severe aphasia, sessions via telehealth may not be appropriate due to barriers associated with communication disability. The intervention period will commence up to 14 days after the baseline assessment. The intervention period is defined as the first contact with the therapist up until the 3 month follow-up assessment (Study A) and 6 month follow-up assessment (Study B). During the intervention period, stroke clinicians will provide the intervention protocol as determined by the therapy self-selected by the person with aphasia; or secondary stroke prevention information provision (attention control arm Study B). Intervention will be tailored to the participant's needs and therapy goals, with support from a clinical psychologist from the research team or a site mental health specialist as needed regarding triage to/escalation of mental health care if required. The family member may be involved by providing communication partner support, support with therapy tasks and participation in a post-intervention interview to gather their perspectives of their experience.

2.8.2 Site implementation strategies for intervention delivery

Strategies to implement the intervention in clinical healthcare settings are outlined in Table 3.

2.9 Data collection and outcome measures

The type of measures for Studies A and B are the same and collected across the metropolitan and two regional sites. The time points for data collection are also the same except for an additional 6 month follow-up measure for participants in Study B (RCT).

2.9.1 Demographic/descriptive information

Social demographic information collected at baseline assessment will be consistent with items generated in the DESCRIBE project [44] (e.g., details of stroke, aphasia, language, education). The DESCRIBE study gained international and multidisciplinary consensus on the key characteristics to be reported in aphasia research. The DESCRIBE checklist will be used throughout the study process including report of the study findings [44]. Demographic data will be collected for stroke clinicians/site managers and family members.

Aphasia profile measure: The Western Aphasia Battery-revised [45] administered to participants with aphasia at baseline assessment only.

2.9.2 Feasibility and acceptability

1. Primary outcome: acceptability of intervention to participant with aphasia using:

   a. A self-report survey to measure prospective (baseline), concurrent (during intervention) and retrospective acceptability of intervention and components of telehealth (i.e., technology use/issues). The criterion threshold will be that the majority of participants (> 50%) rate acceptability at ≤ 80% for majority of intervention period. The survey

has been constructed based on the Theoretical Framework of Acceptability described by Sekhon and colleagues [46] using a Likert scale (see Supplemental file S2).
b. Semi-structured qualitative interviews with the person with aphasia to explore acceptability and areas for improvement (e.g., duration of therapy, technology use).

2. Secondary outcome: recruitment capability and sampling using:

a. Recruitment rate per week;
b. Barriers to recruitment;
c. Number of eligible participants (including proportion of eligible participants recruited);
d. Semi-structured qualitative interviews with staff involved in recruitment exploring barriers and facilitators to recruitment (i.e., stroke clinicians, site managers).

3. Secondary outcome: data collection and outcome measures using:

a. Completion rates of outcome measures at each time point;
b. Assessment duration;
c. Semi-structured qualitative interviews across three participant groups (person with aphasia; family member; and assessor) to explore experiences of technology use and issues with telehealth assessments; experiences and preferences of assessments.

4. Secondary outcome: resources and ability to manage and implement interventions using:

a. Semi-structured qualitative interviews with intervention providers (stroke clinicians, site managers) to explore barriers and facilitators to training, content and delivery of intervention including technology use and issues at study completion;
b. Pre-post training survey results for therapists (Supplemental file S1);
c. Fidelity monitoring via review of therapy log sheets and approximately 2 videorecorded therapy sessions per participant by the researcher.

2.9.3 Clinical outcomes

A range of clinical outcome measures will be used with participants with aphasia to evaluate domains of psychological and communication functioning, mood symptoms, wellbeing, communication confidence and social participation. These measures have been chosen as they have been previously used in aphasia research studies with evidence of accessibility, acceptability and/or shown to be sensitive to change pre-post interventions.

5. Secondary outcome: evaluation of participant clinical response to intervention using:

a. Clinical outcome measures: Stroke Aphasic Depression Questionnaire-10 [47]; Behavioural Outcomes of Anxiety [48]; Warwick Edinburgh Wellbeing Scale[49]; Communication Confidence Rating Scale [50]; Communicative Participation Item Bank [51] and the Stroke Aphasia Quality of Life-39 g [52].

2.10 Procedure for collecting outcome measures and conducting interviews

Clinical outcome data will be collected by trained speech pathologist assessors in person and/or via telehealth. The presentation of assessment items will be adapted to ensure they are communicatively accessible and tailored to the person's communication needs (e.g., present one item at a time, use written items in large and clear font with bolded key words) [36]. Assessments and semi-structured interviews will be conducted by speech pathologists not providing the intervention.

Table 4 Pre, concurrent, post and follow-up outcome measurements and within change score for people with aphasia in metropolitan setting (Study A) (n =)

Participants															
Outcome measures	AA					BB					CC				
	Pre	C	Post	FU	Change	Pre	C	Post	FU	Change	Pre	C	Post	FU	Change
Primary outcome															
Acceptability															
Secondary outcomes															
C SADQ															
BOA															
SAQOL-39g															
CPIB															
CCRSA															
WEMWBS															

Change indicators: values bolded indicate improvement

Pre pre-intervention, *C* concurrent treatment acceptability score, *Post* immediately post-intervention (8 weeks), *FU* follow up (3 months), *C SADQ* community Stroke Aphasic Depression Questionnaire, *BOA* Behavioural Outcomes of Anxiety, *SAQOL-39g* Stroke Aphasic Quality of Life scale, *CPIB* Communicative Participation Item Bank, *CCRS* Communication Confidence Rating Scale, *WEMWBS* Warwick Edinburgh Mental Wellbeing Scale

2.11 Data analyses

Quantitative data from each study will be analysed separately due to the difference in study designs. The qualitative data derived from interviews / focus groups in Study A and B will also be analysed separately. Overall, the qualitative and quantitative data will be collected concurrently but analysed separately as per the description of parallel, concurrent, mixed methods design [22].

2.11.1 Quantitative analysis of feasibility outcomes

1. Primary outcome: Acceptability surveys completed by participants with aphasia will be analysed using descriptive statistics (% from possible total score of 40); criterion: scores of ≤ 80% indicate high acceptability.
2. Secondary outcome: Recruitment capability and sampling will be analysed using descriptive statistics of frequency counts / percentages of:
a. Recruitment rate per week;
b. Barriers to recruitment;
c. Number of eligible participants (including proportion of eligible participants recruited).
3. Secondary outcome: Data collection and outcome measures will be analysed using descriptive statistics of frequency counts, average and range of time in minutes/hours:

a) completion rates of outcome measures at time points;
b) assessment duration.

4. Secondary outcome: Resource and ability to manage and implement will be analysed using descriptive statistics/ data visualisation of intervention provider pre-post training survey scores (%); and therapy log sheet completion frequency/counts of non-adherence to intervention procedure (planned versus implemented components of intervention).

2.11.2 Quantitative analysis of clinical outcomes

5. Secondary outcome: Evaluation of participant clinical response to intervention. We will consider clinical response as exploratory in nature. Study A and B are feasibility studies with the acceptability and feasibility outcomes the most

Table 5 Pre, concurrent, post and follow-up outcome measurements and within change score for people with aphasia in regional setting (Study B) allocated to intervention arm (n =)/attention control arm (n =)

Outcome measure	EE						FF						GG					
	Pre	C	Post	FU1	FU2	Change	Pre	C	Post	FU1	FU2	Change	Pre	C	Post	FU1	FU2	Change
Primary outcome																		
Acceptability																		
Secondary outcomes																		
C SADQ																		
BOA																		
SAQOL-39g																		
CPIB																		
CCRSA																		
WEMWBS																		

Change indicator: values bolded indicate improvement

Pre pre-intervention, *C* concurrent treatment acceptability score, *Post* immediately post-intervention (8 weeks), *FU1* follow up (3 months), *FU2* follow up (6 months), *CSADQ* community Stroke Aphasic Depression Questionnaire, *BOA* Behavioural Outcomes of Anxiety, *SAQOL-39g* Stroke Aphasic Quality of Life scale, *CPIB* Communicative Participation Item Bank, *CCRS* Communication Confidence Rating Scale, *WEMWBS* Warwick Edinburgh Mental Wellbeing Scale

important aspects of the research. We will aim to measure the internal consistency (reliability) of the acceptability survey using Cronbach's alpha.

In Study A (pre-post case series), based on approximate sample (n = 6), we will use descriptive statistics of assessment scores over time (%/sub-section and total scores). Data visualisation using graphs/tables will be presented to show change or no change in scores pre-post interventions at individual case-based level (within change scores). We will evaluate changes in individual scores from pre-post intervention (8 weeks) and follow-up (3 months) using an appropriate method such as the Reliable Change Index [53]. A descriptive quantitative summary will be presented in a table (see Table 4 as an example).

In Study B (RCT), based on the target sample size (n = 30), we will analyse the total acceptability score (primary outcome) and other communication and mood parameters (secondary outcomes) using linear mixed models with the 8 week, 3 and 6 months post-randomisation measures as dependent variables. A treatment group by time interaction will be completed to derive comparisons at 8 weeks, 3 and 6 months post-randomisation time points. The models will account for missing data using the maximum likelihood estimation. If the sample size is less than 20 participants, we will use descriptive statistics of assessment scores over time (%/sub-section and total scores) with data visualisation using graphs/tables to show change or no change in scores pre-post interventions at individual case-based level (within change scores). Data will be presented for participants randomly allocated to the intervention and attention control arms. Pre-intervention scores on all outcome measures will be compared with post-intervention (8 weeks) and follow-up (3 months and 6 months) using an appropriate method such as the Reliable Change Index [53]. A descriptive quantitative summary will be presented in a table for each group (see Table 5 as an example).

2.12 Missing quantitative data

The reasons and amount of missing data in both studies and for each intervention group will be reported. The baseline characteristics of those missing follow-up measures and those with complete follow-up will be reported using a descriptive summary.

2.13 Qualitative analysis

Qualitative data derived from Studies A and B will be analysed as two data sets due to the difference in study designs. Data will be analysed using reflexive thematic analysis [54]. Reflexive thematic analysis was chosen for the methods and data analysis as an inductive approach which values the researcher's subjective experience as the primary way to discern

knowledge from the data. The purpose is to make sense of the data from using the researcher's experiences, rather than aiming for objectivity and removal of bias [54]. Codes and themes will be generated from the data. Analysis and interpretation of findings will generate knowledge about understanding experiences, acceptability, feasibility, experience of telehealth, barriers, facilitators and preferences regarding the intervention from the perspective of participants with aphasia, family members and stroke clinicians/site managers. We will adhere to the Consolidated criteria for Reporting Qualitative research (COREQ) [55].

2.14 Data management

Data will be collected and managed using an electronic data spreadsheet (e.g., Microsoft Excel). Electronic data will be stored on a password secure computer at the University site (La Trobe University). Upon completion of the project participant data will be maintained in storage for a period of 7 years after completion of the study.

2.15 Data monitoring and risk management

Once data collection has commenced, the research team will monitor study progress and adverse safety events (meeting regularly every 4 to 6 weeks to provide oversight and guidance and contribute to key decision making). The risk of harms or adverse events to participants is considered unlikely. Data entry will be monitored by the research team. The research team will support the blinded assessor in maintaining accurate data collection and entry to the data spreadsheet. Harm/adverse events will be managed according to the National Statement on Ethical Conduct in Human Research [56].

Stroke clinicians delivering interventions who are concerned about deterioration of mood in participants will triage participants into appropriate mental healthcare. During the study, clinicians can ask about the person's general health and wellbeing:

"How are you feeling?".
"Have you felt unwell or different from usual?"
"Since the last time we spoke have you needed to see a healthcare professional for anything other than a routine check-up?"

Based on the participant responses further probing may be used if necessary to identify the exact nature of the event. Administering of the Depression Intensity Scale Circles [38] prior to each therapy session will be used to monitor mood also.

3 Discussion

There are numerous barriers to psychological care for people with aphasia which may include beliefs about the lack of effectiveness of treatment, clinicians' lack of confidence and limited resources in stroke rehabilitation. Aphasia PRISM has been developed to address some of these barriers through staff training, provision of communication support and tailoring therapy to a person's goals and needs. It is now important to test the feasibility of the intervention as outlined in this protocol. The findings will inform future implementation of Aphasia PRISM in stroke and aphasia rehabilitation.

3.1 Study A and B status

Study A and B commenced in September 2021 following ethics approval and site specific authorisations. Study A was intended to precede Study B, however due to a combination of factors including staff resource shortages, funding requirements and the disruption of COVID-19 on health services and research activity, the studies were conducted concurrently. Following staff training and site preparation, recruitment opened to people with aphasia from June 2022. Recruitment closed at the end of August 2023 with whatever number of participants were enrolled in either Study A or B. Recruitment was limited to this period of time due to resource constraints and funding conditions. The first participant with aphasia was enrolled 24th June 2022. Data collection will be completed in June 2024.

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Data availability The planned studies will report data in the manuscript and/or supplementary tables. Quantitative data will include participant characteristics; clinical outcome measure scores/change. Qualitative data will include examples of data analysis, themes/sub-themes and exemplar quotes from interview transcripts. Raw data for both studies will not be publicly available due to participant privacy and confidentiality regulations as per ethics approvals.

Declarations

Competing interests The authors declare no competing interests.

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