RESEARCH PROTOCOL

Wellbeing After Stroke (WAterS-2): Upskilling a workforce to deliver inclusive, accessible psychological support after stroke

Short title: Wellbeing After Stroke (WAterS-2)

Contents

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2) INTRODUCTION

A brief summary introduction and overview is provided here with more details throughout the protocol:

Stroke survivors face a range of challenges adjusting to life after stroke. There are limited treatment options and a lack of psychologists to provide support. Acceptance and Commitment Therapy (ACT) has successfully improved wellbeing.

An earlier study working with stroke survivors, healthcare professionals and researchers developed WAterS (Wellbeing after stroke). WAterS is informed by ACT, designed specifically for groups of stroke survivors for remote delivery. We also developed a training and supervision programme for staff without ACT expertise to deliver WAterS. Findings were promising (published here / referenced below). Changes are required to make WAterS more inclusive.

The current study is a pilot feasibility and acceptability study. It aims to deliver an adapted intervention (WAterS-2) targeting stroke survivors for support. We will explore:

- factors that may help or hinder future WAterS research (feasibility data);
- if WAterS-2 can be provided as planned for stroke survivor populations of interest that have been historically under-represented in stroke research e.g. people from minoritised ethnic communities and those with communication disabilities;
- patient and staff experiences of WAterS-2 in terms of perceived impact, acceptability and safety.

We will recruit and train up to 16 staff (4 per site) with experience of supporting stroke survivors, to deliver WAterS-2 in this pilot study. We will also recruit up to 40 stroke survivors (10 per site), at least 4 months post-stroke, with self-reported difficulty adjusting. Recruitment will take place over a 3 month period. We will run up to 4 separate courses of WAterS-2 groups (1 per site). Each course will consist of 8 online group sessions lasting up to two hours. If a participant requires support to take part, a supporting individual will also be recruited and will feedback on experience.

To collect information on delivery success, acceptability and feasibility of study processes and procedures, we will use online surveys and feedback questionnaires, and will review recordings of sessions. We will invite a sub-sample of staff and stroke survivor participants to interview with a researcher to understand more about their experiences. Findings will help plan studies looking at the effectiveness of WAterS-2.

3) BACKGROUND

Supporting psychological adjustment and wellbeing is the number one research priority for life after stroke [1] but we lack appropriate interventions as well as workforces to deliver these interventions at scale and to a diverse stroke population [2,3]. There are a number of promising emerging interventions that increase understanding of how to support psychological wellbeing after stroke. For example:

stroke-specific mindfulness based stress reduction such as HEADS:UP (Helping Ease Anxiety and Depression after Stroke) [4], motivational interviewing [5], and supporting wellbeing through peer-befriending (SUPERB) for people with aphasia [6]. These 'new wave' of therapies target mood disorders, with emerging evidence that they may be at least, if not more, effective than traditional cognitive behavioural therapy (CBT) [7] or usual care [8].

Acceptance and Commitment Therapy (ACT) is another promising new-wave therapy model [9]. It is a trans-diagnostic psychotherapy focusing on accepting and adjusting to experiences, and committing to valued and purposeful behaviours, in order to promote psychological well-being. ACT offers support to identify important personal values and set achievable person-centred goals, as well as exercises to connect with the present moment (e.g. breathing and mindfulness). There is a growing evidence base [10-13] and conceptual reviews [14-16] that advocate the use of ACT post-stroke, including trials that suggest it has value in preventing depression after stroke [17], and brain injury [18].

Dr Emma Patchwood's Stroke Association funded Postdoctoral Fellowship (18/100024; funded 2019-2022) co-developed - with stroke survivors, carers and healthcare professionals - the Wellbeing After Stroke (WAterS) intervention, including:
- An ACT-based psychotherapy group to reduce distress and improve adjustment after stroke. Delivered remotely by two trained staff ('lead' and 'assistant') over nine weekly sessions. It is highly structured and script-informed to promote fidelity, consistency and quality of facilitation. It was developed with cognitive and communication difficulties in mind and includes audio visual resources to support accessibility, as well as a client workbook, sent in advance, to improve accessibility and engagement.
- A workforce training and support programme delivered remotely by a Clinical Psychologist with ACT expertise to upskill staff for delivering the intervention. Staff were Stroke Association Recovery Service Coordinators and Emotional Support staff who had no prior training in ACT. WAterS was designed with workforce implementation considerations from the outset as ACT interventions are often the remit of Clinical Psychologists, who are a scarce workforce.

We chose group delivery, as evidence suggests that groups may have added perceived psychological benefits through increasing social interactions [19]. Remote delivery was necessary during the pandemic. There is an increasing post-pandemic push for tele-rehabilitation interventions that may improve reach and deliverability of services and be resilient against future pandemics. Tele-rehabilitation may support people with disabilities and those in rural settings to access a wider range of healthcare services [20].

After development of WAterS we ran a 'proof of principle' study exploring acceptability and feasibility, and the findings were promising. We recruited 17 stroke survivors over 4 staggered months, primarily using online advertising (twitter and Stroke Association). Stroke survivors were at least 4 months post stroke (up to 7 years). Some had mild/moderate aphasia and cognitive difficulties. Eight Stroke Association

staff were trained and six of those successfully delivered three intervention groups to 12 stroke survivors (four per group). We did not recruit through NHS services.

Our findings [21-23] suggested that WAterS was delivered with good fidelity to protocol and in line with the ACT model of facilitation. Attendance by stroke survivors was almost 100%. Online collection of Patient Report Outcome Measures (PROMS) was feasible and acceptable to collect at multiple timepoints.

As an exploratory feasibility study, WAterS was not powered to explore effectiveness, although an encouraging pattern emerged on the HADS Depression subscale, with self-reported depression lower on average by 1.3 points (from 8.5 pre-group to 7.1 at 3 month follow up; 95% CI -0.4 to 3.2). No related serious adverse events occurred, suggesting the intervention did no harm.

In qualitative interviews staff told us they felt well-equipped to deliver the groups and believed groups were enjoyable and beneficial for stroke survivors. During qualitative interviews immediately post-intervention and at six month follow-up, stroke survivors reported the groups as highly acceptable, valuable, and accessible. They reported benefits from WAterS, even when they found sessions challenging or upsetting.
This initial encouraging work has produced rich data that inform improvements for the intervention [21-22]: the client handbook; audio-visual materials; when and how content is introduced to maximise impact. There were similar suggested improvements to the staff training programme to support embedding of the knowledge and improve confidence in session delivery. In addition, we are mindful of two major areas that need attention:

1) Diversity of stroke survivors: 10/12 of the stroke survivors receiving WAterS were White British. Our Patient, Carer and Public Involvement (PCPI) Advisory Group of stroke survivors, who helped develop WAterS, were also primarily white British. In addition, whilst cognitive and communication difficulties were considered in the development - and 2/12 stroke survivor research participants had aphasia – most participants had mild/moderate cognitive difficulties only. We believe we can and should take steps to optimise WAterS as much as possible to meet the needs of these stroke survivors.
2) Wider workforce and delivery considerations: all settings and staff were within the Stroke Association. It is important to consider how the intervention would work in broader settings, including NHS, to have greater potential for wide reach. This would include how staff would be identified and trained, as well as how an intervention like this might be commissioned and implemented within a broader stroke pathway.

The WATERS-2 study is funded by the Stroke Association.

4) STUDY OBJECTIVES

4.1 Primary Question/Objective:

To determine the feasibility of delivering the adapted WAterS intervention (WAterS-2).

4.2 Secondary Question/Objective:

a) To explore the feasibility of delivering "WAterS-2" in varied sites, specifically targeting:
   - stroke survivors with communication disabilities
   - stroke survivors from minoritized communities and ethnic groups

b) To explore acceptability, fidelity, safety and perceived effectiveness from both survivor and staff perspectives.

c) To identify barriers and facilitators to implementing WAterS-2 in different research settings to support the design and delivery of future research into effectiveness.

5) STUDY DESIGN & PROTOCOL

5.1 Participants

There will be three groups of participants:

- Staff: Up to 16 staff (ie up to 4 per site) who will be trained, and will deliver the WAterS-2 intervention
- Stroke survivors: Up to 40 stroke survivors (ie up to 10 per site) will be recruited, to ensure the groups will run at each site with up to 10 stroke survivor participants taking part
- Supporting individuals: There is no recruitment target for supporting individuals. Where a stroke survivor requires support to access or participate in the online groups they may identify a "supporting individual" to assist them with this. Where this is the case the supporting individual will also be recruited.

5.2 Study Intervention and/or Procedures

As above there will be three groups of participants in this study. Recruitment procedures are given in section 6. ALL research procedures, including data collection, are conducted electronically/online. And all research procedures and information that will be given to participants has been reviewed by our collaborators, including patients, carers and members of the public (via our Research Advisory Panel (see section 10)

Figure 1 gives a visual representation of the study process for all participant groups. Figure 2 gives an *idealised* timeline for these processes. We hope these figures give a useful overview of all study processes, which are then broken down with more detail, organised by each of the three different study participant types.

Figure 1: Study process flowchart: simple overview

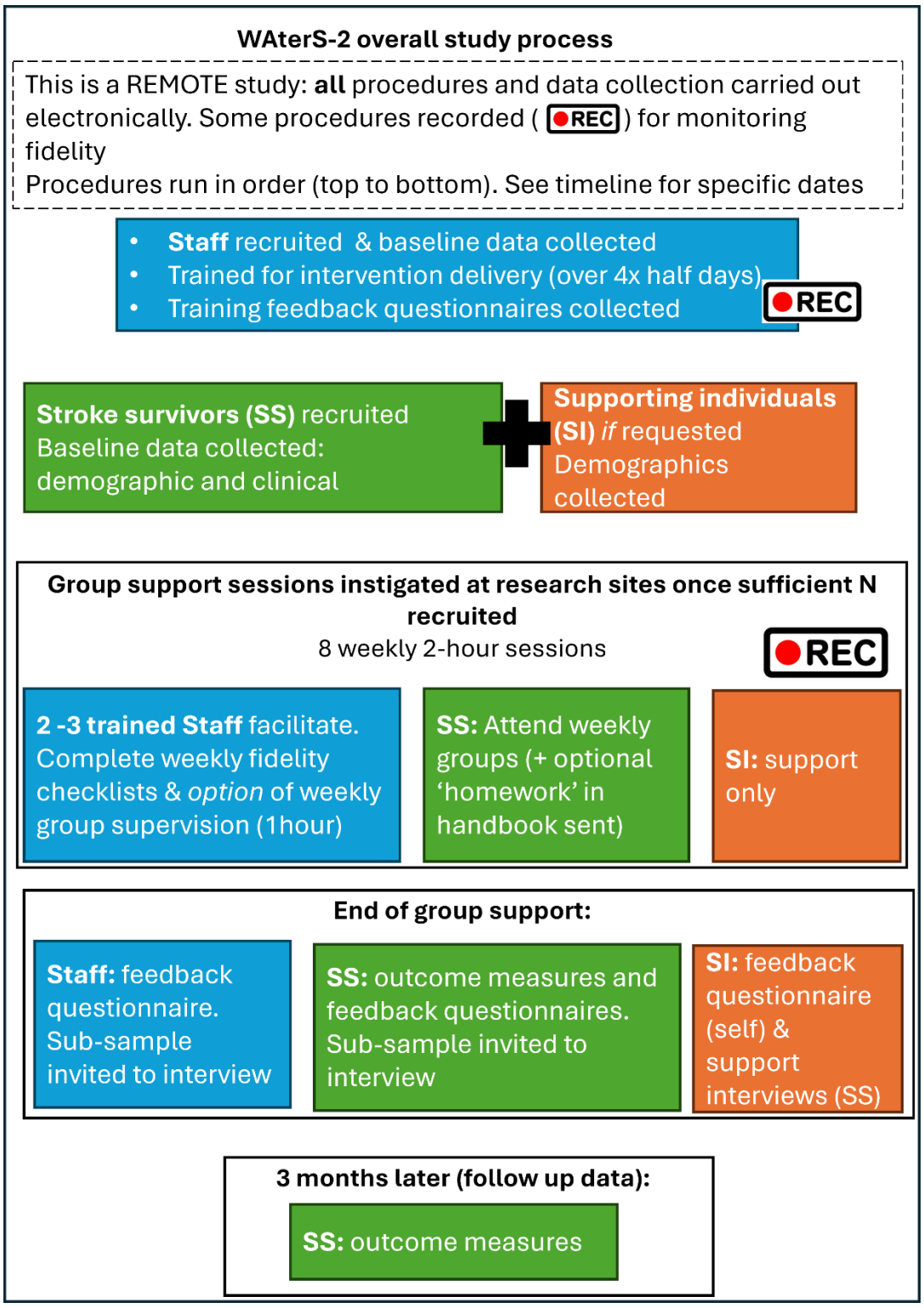
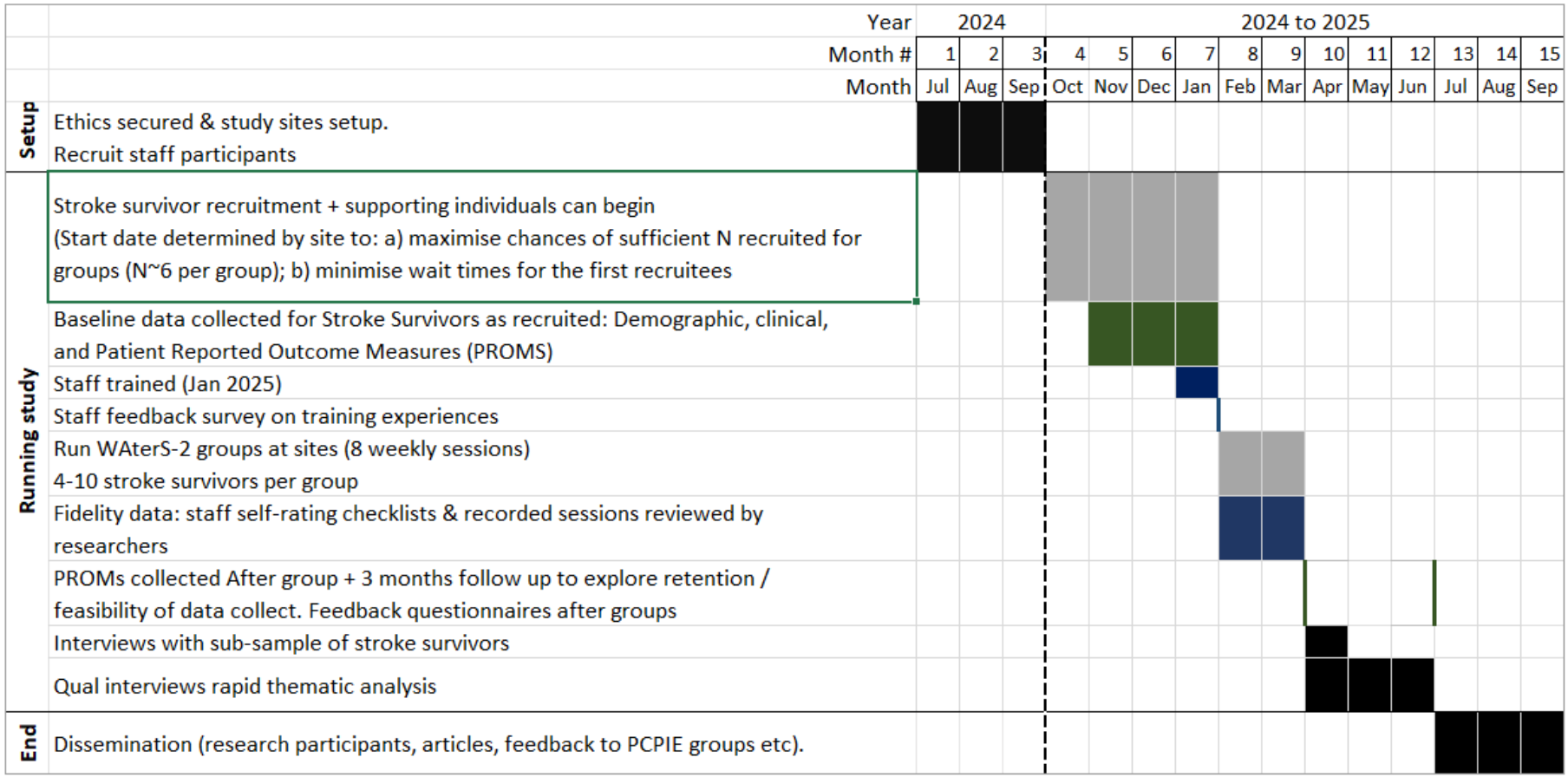


Figure 2: Study timelines of processes with *ideal* months based on 15 month project



We now provide a details breakdown of what happens to each study participant by type.

Staff participants

Baseline and demographic information (staff participants)

Following consent staff will be asked to provide demographic and background information including: age, gender identity, ethnicity qualifications, experience of stroke, experience delivering psychological interventions.

WAterS-2 training + group session delivery (delivered remotely)

Staff are trained to deliver WAterS-2 over 4x half day sessions. Training is provided by the Clinical Collaborators in the research team over University-approved video conference platforms (e.g. Teams), with recordings taken to monitor fidelity of staff delivery (e.g. did we deliver what we planned to deliver?). Video files will be retained for the purpose of review and fidelity monitoring, the files will be deleted once fidelity monitoring is complete / reliably rated.

The WAterS-2 group sessions themselves sessions are facilitated by at least 2 trained staff to groups of stroke survivors (up to 10 per group). They run over eight weeks; up to 2 hours long. They are delivered remotely via a University approved video-calling software and recorded to support monitoring of fidelity. Group sessions will not require transcription. However, video files will be retained for the purpose of review and fidelity monitoring and deleted once fidelity monitoring is complete / reliably rated. Sessions are structured and script-informed to support fidelity and replicability. A clinical protocol of the 8 sessions is included as a supporting document.

Questionnaires / checklists (staff participants)

Staff participants will be invited to complete online data at various timepoints:

- Following training: Feedback Questionnaires to explore experience of the training
- After each session of the WAterS2 group: Fidelity checklists to monitor fidelity of the delivery of the intervention
- At the end of the course of sessions: Feedback questionnaires to provide a final overview of experience of delivering WAterS-2

These will be distributed a University approved online platform (eg: Qualtrics) and should take no longer than 20 minutes each to complete.

Interviews (staff participants)

- A subgroup of staff participants, with at least one from each recruited site, will be invited to take part in a semi-structured qualitative interview. These will be conducted over a University approved video-calling software by a suitably qualified member of the research team and will take up to 45 minutes. Interviews will be recorded with audio extracted for transcription. Video files will be retained until we have an accurate transcription is produced (e.g., often body language can change meaning).

Stroke survivor participants

Baseline data collection (stroke survivor participants)

Following recruitment and consent (see section 6) stroke survivors participants will be asked to provide baseline data and complete baseline assessments. This consists of:

- Demographics (age, gender identity, ethnicity, education, marital status/ home situation)
- Clinical data (self-reported date of stroke, measure of functioning independence)
- Support they have recently or are currently accessing
- Baseline cognitive profile using either the Tele-OCS (Oxford Cognitive Screen) or the Montreal Cognitive assessment (MoCA) (adapted for use online)
- Baseline language profile using the Frenchay Aphasia Screening Test (FAST) (adapted for use online)

This baseline data will be collected, and assessments completed remotely by a suitably qualified member of the research team via a University approved video conferencing software It is anticipated that the collection of baseline data and assessments will take a maximum of 40 minutes. After completion of baseline language and cognitive profiles the researchers will rate participants overall cognition and language using the Therapy Outcome Measures.

On completion of these assessments the participant will be sent a link to a University approved survey platform e.g. Qualtrics to complete the following baseline questionnaires (Patient Reported Outcome Measures, PROMS).

- Personal well-being (ONS4)
- Mood / distress- Patient health questionnaire (HADS)
- Quality of life (EQ-5D-5L)
- Adjustment / acceptance (AAQ-ABI)
- The simplified modified Rankin Scale questionnaire (smRSq)

These questionnaires will take approximately 20 minutes to complete and can be completed by the participant at a time convenient to them. Should they require assistance to complete these a member of the research team can assist by phone.

WAterS-2 group sessions (stroke survivor participants)

Participants will be invited to attend a course of eight group sessions of WAters-2. The sessions will be up to 2 hours long and held weekly, delivered remotely via a University approved video-calling software. The groups will be delivered by two trained members of staff and recorded to support monitoring fidelity. These group sessions will be recorded, with video and audio files retained until satisfactory monitoring/fidelity checks are completed.

At the end of the course of sessions feedback questionnaires will be distributed to stroke survivor participants via a University approved online platform eg: qualtrics. It is anticipated that these will take less than 20 minutes to complete.

Outcome data collection (stroke survivor participants)

Outcome data will be collected using online surveys hosted on a University approved survey site eg: qualtrics. Participants will be offered support over the telephone to

complete if needed/desired. Outcome data will be collected at the end of the 8 sessions and again 3 months (12 weeks) later. Assessments include:

- Personal well-being (ONS4)
- Mood / distress- Hospital Anxiety and Depression (HADS)
- Quality of life (EQ-5D-5L)
- Adjustment / acceptance (AAQ-ABI)
- Valued living questionnaire (VQ)

It is anticipated that these assessments will take a maximum of 30 minutes to complete.

Interviews (stroke survivor participants)

A subgroup of stroke survivor participants who, at consent said that they would be willing to be interviewed, will be invited to take part in a semi-structured qualitative interview. These will be conducted over a University approved video-calling software by a suitably qualified member of the research team and will take up to 45 minutes. Interviews will be recorded with audio extracted for transcription. Video files will be retained until an accurate transcription is produced (sometimes we need to add things about body language that change meaning and aren't picked up with audio transcription).

Supporting individuals

Where a stroke survivor participant requires/ would like support to access the remote technology and/ or to participate in the group sessions, they can nominate a 'supporting individual' to help them. We will aim to recruit those support individuals, collecting some basic data about who they are. The intervention is not 'geared' for supporting individuals.

WAterS-2 group sessions (supporting individual participants)

Participants will be invited to support their stroke survivor participant attend the recorded WAterS-2 sessions (as described above)

Feedback questionnaires

At the end of the course of sessions feedback questionnaires will be distributed to supporting individual participants via a University approved online platform eg: Qualtrics. It is anticipated that these will take less than 20 minutes to complete. These questionnaires will explore how they have found supporting their individuals to participant in WAterS-2

Interviews (supporting individual participants)

Should the stroke survivor agree to take part in a semi-structured qualitative interview the supporting individual may be invited by the stroke survivor to join them. The interview will be conducted over a University approved video-calling software by a suitably qualified member of the research team and will take up to 45 minutes.

6) STUDY PARTICIPANTS

6.1 Inclusion Criteria:

Staff Participants

- Staff who have capacity to participate with clearance and support from their line manager;
- have an understanding of the impact of stroke;
- have experience / knowledge of facilitating groups;
- willing to be trained and adhere to research procedures.

Stroke survivor participants

- Adults in the UK (Over the age of 18)
- At least 4 months post-stroke (no upper limit);
- Who identify as having unmet needs in terms of psychological adjustment to stroke
- Sufficient English language to engage in groups / complete measures
- Access to the internet and ability to engage in remote group intervention

Supporting individual participants

- Adults in the UK (Over the age of 18)
- Supporting a stroke survivor who is a participant in WAterS-2
- Sufficient English language to engage in groups / complete measures

6.2 Exclusion Criteria:

Staff Participants

No additional exclusion criteria although we aim to recruit people without extensive experience of the therapy model (Acceptance and Commitment Therapy, ACT) as one of our goals is to explore whether non-experts can be upskilled to deliver an ACT-informed intervention.

Stroke survivor participants

- Severely anxious or depressed or at risk of harm. In this instance information on referral to more appropriate, services (likely tailored and one-to-one) would be provided
- No capacity to provide informed consent: all recruitment materials have been developed through PCPI to support understanding and accessibility and have been 'pitched' at the same level of comprehension as the intervention itself. If people cannot be supported to provide informed consent, they cannot participate.

Supporting individual participants

No additional exclusion criteria

6.3 Recruitment:

Specific 'routes to recruitment' for each participate type is given below but for all participants who wish to participate: consent will be taken orally by a member of the research team over a telephone call or via a university approved video conferencing software. Transcription will not be required. Any audio files will be extracted from video files if needed (this is relevant for Microsoft Teams; Zoom creates a separate audio file). Video files will be deleted immediately. The member of the research team will complete the appropriate participant-specific consent form electronically. The researcher will read statements aloud with the researcher noting responses (Yes/No) to each statement, adding the participants name to it and then dating it to confirm it has been fully completed before storing in the University of Manchester secured storage systems designed for research data (Research Data Storage; RDS). An electronic copy of the consent form will also be provided to the staff participant. The participant will be offered the option of an audio file copy of their consent.

Staff Participants

Staff will be identified by line manager (typically the PI at research sites) as being eligible to deliver the WAterS-2 intervention, They will be provided with a staff participant information sheet (PIS) electronically and invited to advise the research team if they would like to participate in the study. Participants will typically be given a minimum of 24 hours to consider information and ask questions, however consent may be provided sooner if the participant is clear that they have had sufficient time and information to decide sooner.

Stroke survivor participants

Stroke survivors may be made aware of the study by participating clinical teams who have access to their information via treating and waiting lists. They may also learn of the study through local community groups or through brief study leaflets (posters) in physical locations (e.g. community centres) or online (e.g. social media). They may make direct contact with the research team or – if approached by a member of their care team with appropriate level of access - may complete a "consent to contact" form consenting to the research team making direct contact with them.

Once the potential stroke survivor participant has contacted the research team they will be given stroke survivor participant information sheet. Participants will typically be given a minimum of 24 hours to consider information and ask questions, however consent may be provided sooner if the participant is clear that they have had sufficient time and information to decide sooner. Arrangements will be made to make contact again in order for consent to be provided (as above)

As part of the consenting process participants will be asked if they would like the research team to inform their General Practitioner (GP) of their involvement in the study. Should the participant wish for their GP to be informed, the research team will collect the GP address and store this in a separate secure file to research data.
An electronic copy of the consent form will also be provided to the stroke survivor.
Participants will also be offered the option of an audio copy of their consent.

Supporting individuals
Where a stroke survivor participants requires/ would like support to access the remote technology, to participate in the group sessions and/ or interviews they may invite a supporting individual (eg: carer/ friend/ family member) to support them with this. A consent to contact form and supporting individual PIS will be provided to the stroke survivor for the supporting individual if the individual is not present at the time of discussions with the stroke survivor. The consent to contact form can be returned to the research team, alternatively the supporting individual can contact the research team directly.

Participants will typically be given a minimum of 24 hours to consider information and ask questions, however consent may be provided sooner if the participant is clear that they have had sufficient time and information to decide sooner. Potential participants will then asked to consent orally, as above.

All audio file recordings of consent will be labelled and identified by pseudo-ID only, and stored separately and securely within a password protected folder of the RDS. The pseudo-key to link the participant pseudo-ID to personally identifiable information will be stored separately and securely within the RDS within a legitimate access password protected folder.

6.5 Participants who withdraw consent [or lose capacity to consent]:
Participation in the research is voluntary. Participants can withdraw consent at any time without giving any reason and without their care, employment or legal rights being affected. Participants can withdraw by letting a member of the research team know that they wish to withdraw. Participants will be informed through discussion that if they withdraw we will use any information already collected in our final analysis and that they can discuss withdrawal of their data with us. Withdrawal of data will only be possible prior to full anonymisation, at the end of the study.

Capacity to consent to participate will be re-assessed if the research team have doubts about capacity or if any doubts are reported to the research team (e.g. by the staff running the intervention). If a participant is judged to have lost capacity they will be withdrawn from the study. Data already collected with consent will be retained and used in the study, unless participants asked for the data to be withdrawn. No further data will be collected or any other research procedures carried out in relation to the participant.

7) OUTCOME MEASURES
There is no primary outcome as this is a pilot evaluation of feasibility of delivering the WATerS-2 intervention. Feasibility will be measured through figures of recruitment, treatment fidelity, acceptability (qualitative and quantitative), attrition, completeness of data collection, and variability of the sample. Feasibility and acceptability will also be investigated using questionnaires and semi-structured qualitative interviews with staff and stroke survivors. The results of this study will inform future trials of WAterS-2, including potential choice of primary outcome and secondary measures.

8) DATA COLLECTION, SOURCE DATA AND CONFIDENTIALITY

Data handing

A member of the direct care team will obtain required data to determine potential eligibility of stroke survivors from the medical records and their clinical waiting lists. Email and telephone will be used to liaise with clinical teams, clinicians, and potential participants in the study depending on their preferred method of contact. Only members with legitimate access would view personal data of potentially eligible participants to identify and contact them. The research team will only contact potential participants after they have completed or indicated consent to contact or have expressed an interest in the study after seeing an advert. This will be on an encrypted university/NHS network and emails will be encrypted. Personal data transferred in this way will be encrypted during the transfer.

Questionnaires will not collect personal information. Data will be collected online using a University of Manchester approved survey tool eg: Qualtrics.

Audio recordings will be transcribed by a University of Manchester approved external transcription service. All files will be encrypted and transferred to this service via a secure website. The files will be deleted from this site at the earliest opportunity. The approved service will have signed a confidentiality agreement in line with the University of Manchester SOP.

In line with the University of Manchester standard operating procedure, either a University approved encrypted device will be used to audio record telephone interviews or a secure video conferencing software and cloud space will be used to record online interviews and temporarily store audio recorded data. The data will be uploaded/downloaded onto the university network and stored on the University's secure research data management systems (RDS) until the data has been transcribed. Recordings will be destroyed as soon as the study team is satisfied that that the written transcription has accurately and comprehensively captured the interview data.

Manual files will be stored in a locked filing cabinet in a locked office on the university campus. Responsibility for these files lies with the CI. University computers/Laptop computers: Data will be stored on the university RDS, accessible only by password login and VPN. Only some of the University of Manchester based research team will have access to the data. The University network is encrypted and regularly.

Confidentiality

Personal data will be stored separately to research data. Data will be pseudo-anonymised during collection and thereafter during analysis and publication. Each participant will be issued a unique identifier. The pseudo-anonymisation key linking this identifier to personal information will be kept separately from the research data on a different secure encrypted drive.

Research data will be stored using the University of Manchester's Research Data Storage Service. Access is restricted so that only approved members of the research

team can access this secure, encrypted drive. The drive has regular secure backups. Research data will be archived and retained in accordance with the University of Manchester's data archiving policy and data retention policy. Consent forms and documents containing personal identifiable information will be retained for 7 years. Research data will be retained for 15 years after publication.

Audio recordings will be gathered and stored in line with the University of Manchester "Taking recordings of participants for research" standard operating procedure and processed in line with data protection laws. All recordings will be labelled via pseudo-ID, and not by personal identifiable information. Recordings of consent will not require a transcription. Audio will be extracted from video if needed (this is only relevant for Microsoft Teams; Zoom creates a separate audio file). Video files will be deleted immediately. For recordings of group work, transcription is not required. Video files will be retained for the purpose of review and fidelity monitoring and deleted once fidelity monitoring is complete / reliably rated. For recordings of interviews, audio will be extracted to send for transcription. Video files will be retained until an accurate transcription is produced. We will store and access the data at UoM through encrypted servers and share with University approved transcription services through password protected electronic transfer systems. We will pseudo-anonymise transcripts giving each participant an individual study identification number. The key to identify participants from their study ID will be stored on a separate server such that only some members of the University of Manchester research team will have access to the process to identify them. The key file will be destroyed once the research team is in agreement that a full and accurate transcript is written for each interview. At the point this file is destroyed, all transcripts will be fully anonymised. Study data and material may be looked at by individuals from the University of Manchester, from regulatory authorities or from the NHS Trust, for monitoring and auditing purposes and this may well include access to personal information. Confidentiality will only be breached in the event of a disclosure of information deemed to be a safeguarding, emergency issue, or evidence of bad practice. The CI will be made aware and appropriate course of action taken, dependent on context. The participant will be made aware of a disclosure prior to action being taken.

The study will comply with the Data Protection Act (2018). We are experienced researchers who handle data sensitively and in compliance with regulations.

9) STATISTICAL CONSIDERATIONS

9.1 Statistical Analysis

In keeping with the aims of this feasibility trial, our analyses will be mostly descriptive to establish the recruitment, fidelity and attrition rates and the variability (SD) of the primary participant outcome.

In addition, we will undertake exploratory analysis of participant outcome. We will seek outcome data for all participants regardless of treatment adherence unless consent to follow-up is explicitly withdrawn. We recognise that such analyses are under-powered. Thematic analysis using Rapid Qualitative Analysis (RREAL) of

qualitative data will commence following the first interviews. Data will be anonymised, coded and then organised into themes.

9.2 Sample Size:

This is a feasibility study and as such the power or formal study size calculations are not appropriate and have not been completed. However, up to 56 participants will be recruited (up to 16 staff to deliver the intervention ie maximum of 4 per site; up to 40 stroke survivors ie up to 10 per site, to ensure the groups will run at each site with up to 10 stroke survivor participants taking part)
The project does not have a recruitment target for individuals who may support a stroke survivor to attend. However, it will be the same or fewer than the number of stroke survivors recruited who request this option of receiving support.

10) MONITORING AND QUALITY ASSURANCE

The study will be subject to the audit and monitoring regime of the University of Manchester. In addition oversight is provided by the following.

Study Management group
The research team has formed a dedicated study management group which will meet every two months for the duration of the study or more frequently as required. The Study management group will monitor the management of the study, including the clinical and practical aspects, and will ensure that the study is analysed and reported appropriately. It will consist of:

- Members of the research team + co-investigators
- Clinical co-investigators
- A representative from the research advisory group (RAP)
- Other people may be invited to attend as required

Study steering committee (SSC)
The purpose of the SSC is to provide overall supervision of, and expert independent guidance on, the conduct and progress of the study. It serves to protect the safety and wellbeing of participants as well as the validity and credibility of the study and ensures that it is undertaken in accordance with the principles of Good Clinical Practice. The SSC is an independent, expert group, separate from the WAterS-2 research and management team who have responsibility for the day-to-day running of the study.

Owing to the exploratory and observational nature of the study, a separate data monitoring committee will not be convened. The SSC will assume the roles of the data monitoring committee. The independent members of the steering committee include:

- Janice Mackenzie (Chair), Consultant Clinical Neuropsychologist. Clinical Lead for Psychology for Greater Manchester
- Deb Lowe, Consultant Stroke Physician and National Clinical Director for Stroke NHS-England

- Marney Williams, Stroke Survivor championing Patient Carer and Public Involvement in NHS, public health and social care research
- Katy Rothwell, Head of Experience and Development at the Stroke Association
- Sarah Knowles, Senior health services researcher specialising in mental health
- Charles Kwaku Odoi, Chief Executive of the Caribbean and African Health Network

Patient, carer and public Involvement (PCPI)

The research advisory panel (RAP) is at the heart of the WATERS-2 PCPI model. the RAP includes:

- People affected by stroke: including survivors and people with experience of supporting for stroke survivors
- People from ethnic groups which may not have been well represented previously (including non-stroke survivors / carers)
- People with experience of communication difficulties (as a consequence of stroke or other health condition)

The RAP meets regularly as collaborators every 2 to 3 months (depending on the stage of the project) to help inform, manage, and steer the study.

People with 1st hand experience of stroke are represented on both the steering committee and the management group and RAP activities and feedback are discussed at both.

11) SAFETY CONSIDERATIONS AND ADVERSE EVENTS

Due to the nature of the population being studied a range of Adverse Events (AEs) and Serious AEs (SAEs) may occur which would be unrelated to the intervention e.g. deaths, further strokes, infections, accidental injury linked to the stroke, re-hospitalisation.

We will adhere to research ethics safety reporting for non-CTIMPS, specifically we will report to the REC a serious adverse event (SAE) occurring to a research participant only if the chief investigator believes that the SAE is related to the research and is unexpected. The CI will send details of the SAE to FBMHethics@manchester.ac.uk within one working day of being notified of the SAE (this is the point from the SAE being defined by the CI, not any prior conversation/processed followed that may be had by the site and the CI). Non-serious AEs/ARs will be reported to the sponsor, the CI will send details of the AR to FBMHethics@manchester.ac.uk within 5 working days of being notified of the AE/AR. The CI will maintain a log of adverse events occurring during the study and make this available to the Sponsor upon request.

Any SAEs that are considered related to a study intervention/procedures and unexpected (i.e. an unexpected SAR) will be reported to the REC within 15 days of the CI first becoming aware of the event. This means the REC will be notified based on the initial report, even if the final report is pending.

12) PEER REVIEW

This study was reviewed by the Stroke Association as part of the funding process, all members of the research team, including an expert on methodological issues and statistician. As a feasibility and acceptability study, WAterS-2 is not powered to statistically explore effectiveness and statistical analysis is therefore not likely to feature heavily. Analyses will be mostly descriptive to establish feasibility of implementation of WAterS-2.

13) ETHICAL and REGULATORY CONSIDERATIONS

13.1 Approvals

NHS Research Ethics Committee approval will be obtained before commencing research. The study will be conducted in full conformance with all relevant legal requirements and the principles of the Declaration of Helsinki, Good Clinical Practice (GCP) and the UK Policy Framework for Health and Social Care Research 2017.

13.2 Risks

Whilst WAterS-2 presents limited risks the following potential risks/ burdens to participants have been identified:

Time

Participants will give up their time in order to take part. The training course (staff participants) and intervention (stroke survivor participants) are delivered remotely so there is no burden of travel. Participants can access the training/intervention/ questionnaires from wherever is comfortable/suitable for them. Interviews will be scheduled with individuals, at a time that suits them.

Fatigue

People with stroke may experience fatigue as a result of their stroke. There will be no change to the group therapy sessions, but all patients will be explicitly informed that they can take breaks as needed. Staff delivering the therapy are all experienced in working with patients with stroke and therapy will be scheduled accordingly. There will be regular, scheduled breaks within the therapy sessions.

The members of the research team conducting interviews and outcome measures are experienced in working with people with stroke. They will ensure that participants have breaks if required and may schedule to complete outcome measures/ interviews on separate occasions to reduce fatigue.

Distress

Attending the ACT intervention group may be emotive as it is an intervention targeting psychological distress poststroke. The staff delivering the group will all be trained by an experienced clinical psychologist and will have on-going access to supervision from the clinical psychologist. Stroke survivors will be informed from the outset that they can take a break from the group if they feel distressed. There will be the opportunity for them to speak 1:1 to a trained staff member.

Stroke survivor interviews may be emotive as they involve asking the stroke survivor to recall their experience of the intervention. The research team have experience of supporting stroke survivors. Interviews may be stopped at any time by the participant or if the researcher feels they are struggling. Participants will be reminded that they can stop the interview at any time if they become tired or upset. A distress procedure is in place detailing how to manage a situation with distressed participants. Participants will be informed that they can withdraw consent at any time.

Potential disclosures

Participants may disclose information during assessments, intervention or interviews which indicates that they, or someone else, is at risk of harm. As indicated in the PIS, in this situation the researchers may need to break confidentiality. If this is the case it would be discussed with the participant in the first instance.

Serious adverse events

The intervention does not include investigative medicinal products and all procedures will be conducted remotely e.g. telephone, postal or video conferencing. The following serious adverse events (SAEs) are often related to living with stroke and receiving intervention for well-being:

- New medical problems or deterioration of existing medical problems, including depression.
- Injury e.g. musculoskeletal

It is possible (although rare) that these could lead to hospitalisation, prolongation of existing hospitalisation, disability / incapacity, or death. As such, they are expected SAEs and we will monitor their relationship to the research intervention.

14) STATEMENT OF INDEMNITY

The University has insurance available in respect of research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students. The University also has insurance available that provides compensation for non-negligent harm to research subjects occasioned in circumstances that are under the control of the University.

15) FUNDING and RESOURCES

WAterS-2 is funded by the Stroke Association (Project grant PG22/23_S1100063).

16) PUBLICATION POLICY

Results of the study will be disseminated widely including through peer review journals, conference presentations reports, newsletters, reports to funders, social media and websites. The study will also be on the International Standard Randomised Controlled Trial Number (ISRCTN) register following adoption onto the NIHR Clinical Portfolio.

A lay version of the findings will be provided to all participants who agreed to their details being retained for this purpose. We will also ensure this report on findings is available on our study website: https://sites.manchester.ac.uk/waters2/

We will determine authorship of any publications resulting from this study on the basis of the Uniform Requirement for Manuscripts Submitted to Biomedical Journals, which states:

- Authorship credit should be based on (1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (2) drafting the article or revising it critically for important intellectual content; (3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.
- When a large, multicentre group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript.
- These individuals should fully meet the criteria for authorship defined above.
- Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.
- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
- Each author should have participated sufficiently in the work to take public responsibility for appropriate proportions of the content.

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