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Delivering inclusive, accessible support for psychological adjustment after stroke

Submission date	**Recruitment status**	[X] Prospectively registered
16/08/2024	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/11/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
20/03/2026	Circulatory System	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Stroke survivors face a range of challenges in 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. Researchers also developed a training and supervision programme for staff without ACT expertise to deliver WAterS. The findings were promising. Changes are required to make WAterS more inclusive. This study aims to deliver an adapted therapy (WAterS-2), within the NHS, targeting stroke survivors with communication disabilities and those from minoritized ethnic communities. The study will explore:
1. If WAterS-2 can be provided as planned
2. Patient and staff experiences of WAterS-2 in terms of perceived impact, acceptability and safety
3. Factors that may help or hinder future WAterS research

Who can participate?
Stroke survivors aged 18 years and over, at least 4 months after stroke, with self-reported difficulty adjusting.

What does the study involve?
Participants will be invited to attend the WAterS-2 group course that aims to help people adjust after a life-changing stroke event. Each course will consist of eight online group sessions lasting up to 2 hours. More information on the WAterS2 intervention is available on the study website and in published papers. If a participant requires support to take part, a supporting individual will also be recruited and will feedback on the experience. The researchers will use online surveys and feedback questionnaires and will review recordings of sessions to collect information on delivery success and acceptability. Some people will also be invited to an interview with a researcher to understand more about their experiences

What are the possible benefits and risks of participating?
This is provided in the detailed Information Sheet for stroke survivors who are referred to the

study team for more information. Please note that recruitment will be managed through participating sites.

Where is the study run from?
The University of Manchester (UK)

When is the study starting and how long is it expected to run for?
October 2023 to March 2026

Who is funding the study?
The Stroke Association (UK)

Who is the main contact?
Dr Emma Patchwood, waters@manchester.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Integrated Research Application System (IRAS)
287785

Central Portfolio Management System (CPMS)
63014

Protocol serial number
Stroke Association Grant Codes: PG22/23_S1100063

Study information

Scientific Title

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

Acronym
WAterS-2

Study objectives
In keeping with the aims of this feasibility study, there are no experimental or null hypotheses. The aim is to deliver an adapted therapy (WAterS-2), within the NHS, targeting stroke survivors with communication disabilities and those from minoritized ethnic communities. The researchers will explore:
1. If WAterS-2 can be provided as planned
2. Patient and staff experiences of WAterS-2 in terms of perceived impact, acceptability and safety
3. Factors that may help or hinder future WAterS research

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/08/2024, Wales REC6 (Health and Care Research Wales, Castlebridge 5, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)2922940911, +44 (0)2922 940954, +44 (0) 2922 941090; Wales.REC6@wales.nhs.uk), ref: 24/WA/0238

Study design
Non-randomized; Interventional; Design type: Prevention, Psychological & Behavioural

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Stroke

Interventions
This is a pilot study, exploring the feasibility and acceptability of the WAterS2 remote group intervention to support adjustment after stroke. The group intervention is informed by Acceptance and Commitment Therapy (ACT) and delivered remotely to groups over 8 weekly sessions. More details on the intervention are available via the linked study website and published papers.

There is no comparator/control group. All research procedures, including data collection, are conducted electronically/online.

There are three different 'types' of research participants:
1. Staff: trained and supported to deliver the WAterS-2 intervention
2. Stroke survivors: receive the WAterS-2 intervention
3. 'Supporting individuals' (e.g. family members, carers, friends) who may be recruited to support stroke survivors to participate, if stroke survivors request.

To broadly summarise the overall timeline and procedures of the study:
1. Staff are recruited and trained by research team Clinical Psychologists. Training is conducted over 4x half-day sessions. Training sessions are recorded to monitor fidelity (to explore: did we deliver training as planned?). Staff are asked to give feedback on the training received.
2. Stroke survivors (and any requested 'supporting individuals') are recruited, with baseline demographic and clinical data collected.
3. WAterS-2 groups conducted: 8 x weekly remote group sessions, lasting 2 hours per session. Two trained staff facilitate each group session with up to six recruited stroke survivors + any of their recruited supporting individuals. The sessions are primarily aimed at stroke survivors' psychological adjustment. Supporting individuals are, as named, there to support. Group sessions are recorded for monitoring fidelity (to explore: did we deliver the WAterS-2 intervention as planned?). Staff will also be asked to complete checklists after each session to help monitor fidelity.
4. OPTIONAL weekly group clinical supervision for staff running WAterS-2 groups: staff will have access to a weekly group support session, facilitated by research team Clinical Psychologists, to help improve fidelity and provide support for delivery of the group sessions.
5. Once all eight WAterS-2 group sessions are complete, all stroke survivors are asked to complete measures exploring their wellbeing and the impact of groups. Both stroke survivors and any supporting individuals will be asked to give feedback on their experiences through questionnaires. A sub-sample will be invited to give more feedback in qualitative interviews with the research team. Staff will also be asked to complete questionnaires about their experiences of delivering the group sessions.
6. Three months after groups have completed, stroke survivors will be asked to complete a final 'follow-up' of measures exploring their wellbeing and the perceived impact of groups.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcomes as of 20/03/2026:
The primary aim of this study is to establish the feasibility and acceptability of the intervention and a future definitive trial. As such, most measures will relate to feasibility, collected and summarised by the end of the study period in time for write-up (approx. March 2026), such as:
1. Establishing recruitment pathways and workforce criteria in four test sites
2. Informing the recruitment and retention of a future fully-powered trial by establishing the number of participants identified, approached, consented, randomised and completed.
3. Refining future study procedures by establishing the acceptability and experience of the trial process to participants, including completion of outcome measures.
4. Determining the fidelity of delivery of the intervention through checklists and recordings
5. Determining the optimal primary outcome measure in future work by assessing the performance of selected candidate outcome measures with respect to the level of acceptability to participants (completion rates, perceived burden) and participant-perceived relevance and value.
6. Further assessing the acceptability of the treatment via qualitative interviews and more.

Previous primary outcomes:
The primary aim of this study is to establish the feasibility and acceptability of the intervention and a future definitive trial. As such, most measures will relate to feasibility, collected and summarised by the end of the study period in time for write-up (approx. June 2025), such as:
1. Establishing recruitment pathways and workforce criteria in three test sites
2. Informing the recruitment and retention of a future fully-powered trial by establishing the

number of participants identified, approached, consented, randomised and completed.
3. Refining future study procedures by establishing the acceptability and experience of the trial process to participants, including completion of outcome measures.
4. Determining the fidelity of delivery of the intervention through checklists and recordings
5. Determining the optimal primary outcome measure in future work by assessing the performance of selected candidate outcome measures with respect to the level of acceptability to participants (completion rates, perceived burden) and participant-perceived relevance and value.
6. Further assessing the acceptability of the treatment via qualitative interviews and more.

Key secondary outcome(s))
Some examples of measures that will be taken at timepoints are as follows:
1. At baseline: demographic and self-report clinical information related to the impact of impairments to cognition and language.
2. At baseline: research administered remote assessment of cognition and communication (this will be to establish, post hoc, whom this intervention might be best-suited for. It is not used to determine eligibility)

In addition, the following Patient Reported Outcome Measures (PROMs) are repeated at baseline, after group intervention is completed, and again 3 months later:
3. Mood as recorded by the Hospital Anxiety and Depression Scale (HADS)
4. Wellbeing as recorded by Office of National Statistics 4 (ONS4)
5. Quality of life as recorded by EQ-5D-5L
6. Adjustment and acceptance as recorded by the Acceptance and Action Questionnaire for Acquired Brain Injury (AAQ-ABI)
7. Valued living as recorded by the Valuing Questionnaire (VQ)
8. Feedback questionnaires and qualitative interviews will also be conducted

Completion date
20/03/2026

Eligibility

Key inclusion criteria
Staff inclusion criteria:
1. Can participate with clearance and support from their line manager
2. An understanding of the impact of stroke
3. Experience/knowledge of facilitating groups
4. Willing to be trained and adhere to research procedures

Stroke survivor inclusion criteria:
1. Adults in the UK (at least 18 years old)
2. At least 4 months post-stroke (no upper limit)
3. Who identify as having unmet needs in terms of psychological adjustment to stroke
4. Sufficient English language to engage in groups/complete measures
5. Access to the internet and ability to engage in remote group intervention

Supporting individual inclusion criteria:
1. Adults in the UK (over the age of 18 years)

2. Supporting a stroke survivor who is a participant in WAterS-2
3. Sufficient English language to engage in groups/complete measures
4. Capacity to consent

Participant type(s)
Health professional, Patient

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
40

Key exclusion criteria
Staff exclusion criteria:
1. Not meeting the above inclusion criteria

Stroke survivor exclusion criteria:
1. Lacking the capacity to consent
2. Stroke survivors who identify as severely anxious or depressed, or at risk of harm would be excluded from this research, and information on referral to appropriate expert psychological support will be provided

Supporting Individual exclusion criteria:
1. Not meeting the above inclusion criteria

Date of first enrolment
05/12/2024

Date of final enrolment
01/05/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Manchester
Oxford Road
Manchester
England
M13 9PT

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
Stroke Association

Alternative Name(s)
TheStrokeAssociation, TheStrokeAssoc

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study may be available upon reasonable request from Dr Emma Patchwood (emma.patchwood@manchester.ac.uk) or Prof.

Audrey Bowen (Audrey.bowen@manchester.ac.uk). The type of data available will be subject to case by case analysis but anonymisation will always be ensured.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	A brief video describing the project		20/03/2026	No	No
Plain English results		11/03/2026	20/03/2026	No	Yes
Protocol file	version 4.0	13/05/2025	18/09/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes