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Feasibility study of the Clear Water Protocol in acute stroke

Submission date	**Recruitment status**	[_] Prospectively registered
29/12/2025	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/01/2026	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
13/01/2026	Circulatory System	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

The Free Water Protocol (FWP) gives patients who are at risk of aspiration the option to drink water between meals after thorough mouth care. There is a lack of evidence about the use of the FWP in acute stroke units. The aim of this preliminary feasibility study is to develop and test an implementation strategy for a FWP and explore the feasibility of delivering the FWP to stroke patients with dysphagia in an acute stroke unit setting.

Who can participate?

1. Stroke survivors aged 18 years and over with swallowing difficulties
2. Stroke professionals working in Acute Stroke

What does the study involve?

The research programme has four stages. In Stage 1, the developmental work to inform national stakeholder codesign workshops will include a review of the existing research, a national survey, and interviews with health professionals to inform contextual factors and determinants to implementation of the FWP in an acute stroke unit setting. Collective data about the barriers and enablers to implementation will feed into stakeholder workshops (Stage 2) that will discuss implementation strategies and inform the training to deliver the intervention (Stage 3). Thirty patients will be recruited to participate in the FWP using a pre/post intervention design and will complete a satisfaction questionnaire. Data collection will include level of fluid intake and development of pneumonia. In Stage 4, the process evaluation will involve interviews with clinician and patient participants to identify barriers and facilitators to implementing the FWP. The Consolidated Framework for Implementation Research will underpin implementation science throughout the study and be used to analyse the data. Patients and the public will be involved throughout the research.

What are the possible benefits and risks of participating?

Participants may enjoy drinking water between meals and drink more. The research study will help us to learn, and this may improve recovery for other people after stroke. There is a risk that participants may get a chest infection from water going ‘down the wrong way’. The risk is low if

the mouth is clean. The participants chest will be monitored closely and if there are any concerns we will stop offering water between meals. Participants may experience a small rash from the blood tests.

Where is the study run from?
Sheffield Teaching Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
December 2024 to August 2026

Who is funding the study?
The Stroke Association (UK) - SA PDF 23\100001

Who is the main contact?
Sarah Wilkinson, sarah.wilkinson71@nhs.net

Contact information

Type(s)
Public

Contact name
Dr Sarah Wilkinson

Contact details
Clinical Research & Innovation Office
D Floor
Royal Hallamshire Hospital
Sheffield Teaching Hospitals NHS Foundation Trust
Glossop Road
Sheffield
United Kingdom
S10 2JF
+44 (0)114 271 1658 ext 11658
sarah.wilkinson71@nhs.net

Type(s)
Scientific

Contact name
Ms Sabrina Eltringham

ORCID ID
https://orcid.org/0000-0002-0453-2456

Contact details
Clinical Research & Innovation Office
D Floor
Royal Hallamshire Hospital
Sheffield Teaching Hospitals NHS Foundation Trust
Glossop Road

Sheffield
United Kingdom
S10 2JF
+44 (0)114 271 2533
sabrina.eltringham@nhs.net

Additional identifiers

Integrated Research Application System (IRAS)
343095

Central Portfolio Management System (CPMS)
63018

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SA PDF 23\100001

Study information

Scientific Title
A feasibility study of the implementation of the Clear Water Protocol for stroke survIvors with dysphagia in acute stroke unit setting (RAPIDS)

Acronym
RAPIDS

Study objectives
Is it feasible to develop and test an implementation strategy for a Free Water Protocol intervention and deliver the FWP intervention in an acute stroke unit setting?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/10/2024, Yorkshire and Humber – Leeds East (2 Redman Place, Stratford, London, E20 1JQ, UK; Tel: not available; leedseast.rec@hra.nhs.uk), ref: 24/YH/0165

Primary study design
Interventional

Study design
Non-randomized; Both; Design type: Treatment, Process of Care, Management of Care, Qualitative

Study type(s)
Treatment

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

Interventions

There are four stages of the research project.
Stage 1: Developmental work to inform national stakeholder co-design workshops
The preparatory work will combine quantitative and qualitative methods and include a systematic review of the existing evidence about the barriers and facilitators to implementing a Free Water Protocol in the acute stroke setting, a survey of NHS professionals, and staff focus groups.

Survey
The topics for the survey will be structured using the domains and constructs of the Consolidated Framework for Implementation Research (CFIR) and the questions for the survey will be developed from the findings of the systematic review. The survey will be a web mode survey and the Qualtrics online survey tool will be used to build the survey. Participants would include acute stroke unit practitioner's representative of the different NHS professionals who would be involved directly or indirectly in the delivery of the Free Water Protocol (FWP). A convenience sampling method will be used, and the sample size will be 50 completed questionnaires. The survey will be distributed to stroke professionals through professional networks and groups, professional newsletters, the research team's networks, and social media (e.g., X formerly Twitter, LinkedIn) to gain a broad representation of views and perspectives of the individual and contextual determinants that may influence implementation of the FWP in the acute stroke unit setting. Up to three follow up reminders will be sent to encourage response. Potential participants who are interested in taking part in the survey will access the survey via an electronic link. This link will be included in the social media message or invitation letter. The potential participant will be able to read the participant information sheet which will be included in the survey before deciding whether to take part. By checking the box to indicate they have met the inclusion criteria, consent to participate will be implied by completing and submitting the survey. The Qualtrics online survey tool will be used to collect anonymised respondent data. Data will be exported to SPSS for Windows predictive analysis software for analysis.

Staff focus groups
Four focus groups will be conducted by the Chief Investigator with staff from 5 different NHS hospital sites to ensure the views expressed are representative of different stroke units. Participants would be staff primarily involved in delivering the FWP intervention in the acute stroke unit setting. Sites will be selected based on knowledge from a national survey of dysphagia management in stroke units in England and Wales (Eltringham et al., 2021) including: sites which use the FWP; sites that have identified barriers to its use; and variation in models of dysphagia assessment. A purposeful sampling method will be used. A local gatekeeper will be identified at each site from the research team's clinical networks. The gatekeeper will identify a speech and language therapist, nurse and clinical support worker from each site and will approach them about the study. If the member of staff is interested in taking part a participant information sheet will be emailed to the staff member and they will be given the opportunity to ask further questions about the study. If they are willing to take part, they will be invited to take part in a 30-minute online focus group using Microsoft Teams. The focus groups will be single professional groups to encourage expression of views. A mixed professional group for those unable to attend their designated professional group and interviews ill be offered for pragmatic reasons. The CFIR domains and constructs will underpin the topic guide which will be developed following the systematic review. The CFIR interview guide will be used to select constructs and questions. The focus groups will also provide an opportunity to explore the preliminary findings from the survey in more depth.
The results of these underpinning studies will inform the stakeholder workshops (Stage 2).

Stage 2 Stakeholder workshops
There will be three stakeholder workshops. The duration of the workshops will be between 90 minutes and 2 hours. The remit of the national stakeholder workshops is to co-design the implementation process. This will involve designing the activities and strategies used to implement the Free Water Protocol (FWP) in a hospital stroke unit. The group will design the training to deliver the Free Water Protocol and decide the best ways to record the delivery of the intervention and fluid intake.

Membership of the group will include representation from CFIR 'outer' and 'inner' domains and types of roles involved with implementing, delivering and or receiving the intervention. The outer setting comprises of systems where the inner domain exists. Outer domain communities may include NHS England Stroke Getting it Right First Time (GIRFT), Integrated Stroke Delivery Networks (ISDNs), Intercollegiate Stroke Working Party, NICE Stroke Rehabilitation Guideline and stroke health strategy and workforce development leaders. The hospital is the 'inner' setting where the FWP intervention will be implemented. Some individuals may span both outer and inner domains. Individual domain roles will include transdisciplinary hospital acute stroke unit practitioners with a range of perspectives, skills, and context specific knowledge. Intervention recipients (stroke survivors with dysphagia and their informal caregivers) will be recruited from the study PCPIE group. Individual domain roles applicable to the project include high level leaders; mid-level leaders; opinion leaders; implementation facilitators; implementation leads; implementation team members; other implementation support; intervention deliverers and intervention recipients. Representation will be national to ensure that consideration is given to the broader acute stroke context to address the potential limitation of a single site intervention and include perspectives from people that may present obstacles for implementation as well as facilitators.

Stage 3 – The Free Water Protocol Pre/Post Intervention Study
Study design - A single centre feasibility study using a pre/post intervention design. Participants will be offered diet and fluids in line with their speech and language therapy swallowing recommendations for 3 days from recruitment to gather subject baseline information. This will include a pre intervention patient satisfaction questionnaire, fluid intake and hydration status from a blood test. After this period, participants will continue to be offered diet and fluids as per their speech and language therapy recommendations at mealtimes. On Day 4 participants will start the FWP after the baseline blood test. Providing there are no concerns (see section on Safety Assessment) participants will follow the protocol until Day 21. Two further blood tests will be taken after commencement of the FWP on Day 8 and Day 15. Participants will complete a post intervention satisfaction questionnaire and interview. Discussions about continuation of the FWP beyond the intervention study period will take place on an individual basis by the clinical speech and language therapist. All outcome measures will be collected at the acute stroke unit at the Royal Hallamshire Hospital. Stage 3 will take place in the Acute Stroke Unit, Royal Hallamshire Hospital, Sheffield Teaching Hospitals NHS Foundation Trust. Typical of the stroke patient pathway in the United Kingdom patients are admitted to the regional Hyper Acute Stroke Unit (HASU) for specialist assessment, diagnosis and hyper acute treatment and remain on HASU for up to 72 hours and are then transferred to the acute stroke unit. The average length of stay on the Acute Stroke Unit is 20 days.

A local implementation group will be recruited to facilitate the training and delivery of the intervention at a local level. This will be led by the Principal Investigator with Chief Investigator support. The Principal Investigator is the Speech and Language Therapy Lead for the Acute Stroke Unit setting where the intervention is taking place. The composition of the local implementation group will replicate the 'inner setting' of the national stakeholder group at a local level. Potential participants will be identified following admission to the Acute Stroke Unit

(ASU) and a clinical bedside swallowing assessment by a speech and language therapist. Potential participants will be screened based on the inclusion and exclusion criteria. If a patient does not meet inclusion criteria on admission to ASU they will be monitored by the research team during their stay and will be approached if their eligibility changes. A screening log will be maintained. The screening log will record information about sex, age, ethnicity, language, stroke type, stroke location, stroke severity, days post stroke, dysphagia severity measured by the Therapy Outcome Measures (TOMs), diet and fluid recommendations following the swallowing assessment, and if the person is receiving artificially administered fluids. Reasons for exclusion will be recorded. If the person meets the inclusion criteria the speech and language therapist will discuss the potential participant with their stroke physician to check that they agree for the potential participant to be approached. Any discrepancies regarding suitability will be recorded. If the stroke physician agrees or the person to be approached a member of the research team will approach them in person on the Acute Stroke Unit and they will be given an information sheet about the study. If they are willing to take part in the study informed consent will be obtained. If it is not appropriate to consent the patient directly, for example, due to the patient lacking mental capacity, consent to participate would be sought from the named next of kin or an independent physician via the consultee process. Due to the time sensitive nature of the research, participants will be asked to decide whether they would like to take part on the same day as they are approached. We will continue to recruit until 30 participants have had a blood test on Day 1 and Day 8. The participants swallow will be regularly assessed by the speech and language therapist as per usual clinical care. If the participant is no longer considered to be at risk of aspiration with thin liquids the participation in the study will be complete.

Description of the FWP intervention

The Free Water Protocol (FWP) intervention allows people who are at risk of aspiration with thin liquids (International Dysphagia Diet Standardisation (IDDSI) Level 0 Thin Fluids) the option to drink water between mealtimes, alongside thorough mouthcare. Mouthcare refers to the maintenance of a clean oral cavity including the teeth, gums, cheeks, tongue and palate and includes removal of food debris, dental plaque and excess secretions, and application of lip balm. The expectation is that other recommendations by the speech and language therapist are followed alongside this (e.g., compensatory strategies).

Free Water Protocol Guidelines

Mouthcare should be completed in the morning and the evening and after any dietary intake. Mouthcare should involve brushing of teeth, dentures and cleaning of gums and tongue with a low foaming, fluoride-containing toothpaste. If the person is on modified diet that includes thickened fluids, plain water is allowed up until the first mouthful of food but restricted until 30 minutes after finishing a meal. No water is allowed during the meal and no thin liquids are allowed other than water.

If the person is nil by mouth, they can drink water freely during the day.

If the person is taking medications orally, medications should be taken with food or thickened fluid that was recommended from the swallowing assessment. Medications should not be given with water.

Any other compensatory strategies for safe oral intake should be followed by those receiving and delivering the intervention.

Each person will be considered individually. The programme using the FWP may be modified as the person’s status required, for example plain water offered from a teaspoon if unable to comfortably manage sips.

For the person’s safety, any non-adherence to the FWP guidelines by persons receiving or delivering the FWP will result in the person being withdrawn from the protocol.

Stage 4 - Process Evaluation
Patient post intervention questionnaire
All 30 patient participants will be asked to complete a post intervention patient satisfaction questionnaire (see section 6.7 Justification of measures for further information about the questionnaire). Timing of the questionnaire will be dependent on the participant's duration on the FWP. As part of the process evaluation the results of the pre and post intervention questionnaires will be compared and analysed. The results of the questionnaires will inform the topics for further exploration in the patient carer interviews.

Patient-carer interviews
Ten of the 30 patients who received the intervention will be interviewed about their experiences of the FWP. Interviews will take place in a quiet room on the Acute Stroke Unit and be approximately 15 minutes. The timing of the interview will be flexible to accommodate how the patient is feeling. Potential participants will be purposefully selected to provide a broad representation of experiences based on participant characteristics and using information from the questionnaire. Participants will be asked if they would like a carer or loved one to be present in the interview for support. The timing of the interview will be dependent on the participant's duration on the FWP. Semi-structured interviews will be conducted, recorded and transcribed by the Chief Investigator (see Section 7 Data Management for further information). The interviews will be used to help understand what worked about the intervention and what could be improved (See section 7.3 for further information about analysis of Quantitative Data). The project PCPIE group will be involved in the analysis and interpretation of the data (see section 11 Service Users and Patient and Public Involvement (PPI) for further information).

Staff interviews
Semi structured Interviews will be conducted with clinicians who were directly and indirectly involved in delivering the FWP. Five staff will be purposively selected and will be representative of the different professional groups involved and include speech and language therapists, qualified and unqualified nursing staff from the Acute Stroke Unit, Royal Hallamshire Hospital. The setting and timing for the staff interviews will be flexible to accommodate staff availability. Staff will be given the option of a face to interview on the Acute Stroke Unit or online interviews using Microsoft Teams. The interviews will be approximately 15 minutes and will be recorded. The approach to data analysis and interpretation will be consistent with the patient-carer interviews.

Intervention Type
Other

Primary outcome(s)
1. Acceptability of staff and patients involved in delivering or receiving the FWP measured using a patient participant questionnaire at pre and post intervention and patient and staff interviews

2. Feasibility measured using (i) the number of participants screened as eligible for recruitment ; (ii) proportion of possible participants recruited; (iii) proportion of participants who were eligible for recruitment but declined to take part; (iv) reasons for declining; (v) participant retention; and (vi) reasons for withdrawal from the study at Day 0-Day 21

3. Fidelity measured using (i) proportion of participants treated according to the FWP guidelines measured using fluid intake and oral care documentation at Day 1-21; (ii) how well the protocol was tolerated and reasons for declining will be measured using patient interviews. at post intervention

4. Barriers and facilitators to implementing the FWP measured using staff and patient process evaluation interviews at post intervention

Key secondary outcome(s)
1. Amount of thickened and unthickened fluids consumed daily in millilitres (ml) measured using fluid intake documentation. For patients receiving artificially administered fluids, the amount of ml given will be recorded daily as part of routine care. at Day 1-21

2. Development of pneumonia measured using a new initiation of antibiotics for pneumonia documented on the patient's medical record at Day 1-21

3. Changes in hydration measured using the BUN to creatinine ratio calculated from a blood test at pre and post intervention

Completion date
31/08/2026

Eligibility

Key inclusion criteria
Patients with acute stroke (ischaemic or haemorrhagic) who:
1. Are a patient on the Acute Stroke Unit, Royal Hallamshire, Sheffield Teaching Hospitals NHS Foundation Trust (STHFT).
2. Have had a clinical bedside swallowing evaluation by a Speech and Language Therapist (SLT) or equivalent trained health professional and who are considered at risk of aspiration with thin liquids (Level 0 Thin Fluids).
3. Have been on their swallowing recommendations (thickened fluids or NBM) for 72 hours.
4. Have extreme impulsivity or excessive coughing will have water under supervision.
5. Can sit out in a chair (minimum mobility hoist to chair).
6. Can engage with eating (even if they require assistance).
7. Can give written consent in English, Urdu or Arabic to enter the study or consultee of the patient either a family member or the medical team who gives written consent for the patient to participate on their behalf.
8. Are over 18 years of age.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment

0

Key exclusion criteria
Patients with acute stroke (ischaemic or haemorrhagic) who:
1. Have a pre-existing dysphagia and are recommended to drink thickened fluids pre-stroke.
2. Are fully dependent for feeding.
3. Have an active pneumonia, acute exacerbation of Chronic Obstructive Pulmonary Disease or active asthma with symptoms.
4. Have a degenerative neurological condition (e.g., Parkinson's Disease, Multiple Sclerosis).
5. Have severe kidney disease (CKD 4/ requiring dialysis).
6. Are enrolled in other intervention studies related to dysphagia.
7. Experience extreme coughing to the point of discomfort with thin fluids.
8. Have severe oral stage dysphagia such that the majority of the water bolus is lost anteriorly.
9. Have an oral or dental infection, including lesions associated with head and neck cancer treatment.
10. Have an absent pharyngeal swallow response.
11. Are for imminent discharge i.e. within the next 7 days or for palliation.

Date of first enrolment
02/12/2024

Date of final enrolment
31/08/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
Sheffield
England
S5 7AU

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

ROR

https://ror.org/018hjpz25

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

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3.0	24/09/2025	06/01/2026	No	No