Long title: A feasibility study of the implementation of the F**R**ee W**A**ter **P**rotocol for stroke surv**I**vors with **D**ysphagia in acute **S**troke unit setting (RAPIDS)

Short title: Feasibility study of the Free Water Protocol in acute stroke

Sponsor: Sheffield Teaching Hospitals NHS Foundation Trust

Funded by: The Stroke Association

Chief Investigator: Dr Sabrina A. Eltringham

Principal Investigator: Dr Nicola Martindale

Project Details

Investigator and Supervisory Team Details:

Chief Investigator and Award Holder:
Dr Sabrina A. Eltringham
Role: Chief Investigator
Telephone: 0114 271 3189
Email: sabrina.eltringham@nhs.net

Principal Investigator:
Dr Nicola Martindale
Role: Principal Investigator
Telephone: 0114 271 3822
Email: nicola.martindale@nhs.net

Supervisory Team:
Professor Craig J Smith (Lead Supervisor)
Division of Cardiovascular Sciences
The University of Manchester
Manchester Centre for Clinical Neurosciences
Salford Royal NHS Foundation Trust
Role: Lead Supervisor
Telephone: 0161 206 0623
Email: craig.smith-2@manchester.ac.uk

Professor Sue Pownall (Co-supervisor)
Therapeutics and Palliative Care Directorate
Sheffield Teaching Hospitals NHS Foundation Trust
Role: Co Supervisor
Telephone: 0114 271 3189
Email: sue.pownall2@nhs.net

Professor Elizabeth Lightbody (Co-Supervisor)
University of Central Lancashire
Lancashire Teaching Hospitals NHS Foundation Trust
Role: Co Supervisor
Telephone: 01772 893648
Email: celightbody@uclan.ac.uk

Sponsor Details:
Sheffield Teaching Hospitals NHS Foundation Trust, Royal Hallamshire Hospital, Glossop Road, Sheffield S10 2JF

Project Title:
A feasibility study of the implementation of the Free Water Protocol for stroke survivors with dysphagia in acute stroke unit setting

STH Project Reference Number:
STH 22165

IRAS:
343095

Protocol Version Number and Date:
Version V3.0 Date 24/09/2025

STH Directorate Affiliation:
Therapeutics and Palliative Care

Confidentiality Statement:
This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, HRA, host organisation, and members of the Research Ethics Committee, unless authorised to do so by the Chief Investigator.

Table of Contents

1. Study Synopsis/Profile

Study title	A feasibility study of the implementation of the Free Water Protocol for stroke survivors with dysphagia in acute Stroke unit setting (RAPIDS).
Study short title	Feasibility study of the Free Water Protocol in acute stroke.
Study design	Mixed methods. Pre/post intervention design.
Study participants	**Inclusion criteria:** **Stage 1** – NHS stroke professionals working in Acute Stroke. **Stage 3** - Stroke survivors with dysphagia. **Stage 4** - Stroke survivors with dysphagia, informal caregivers, stroke professionals working in the Acute Stroke Unit, Sheffield Teaching Hospitals NHS Foundation Trust. **Exclusion criteria:** **Stage 1** – NHS stroke professionals working in Rehabilitation settings. **Stage 3** – Stroke survivors with dysphagia who are for imminent discharge or for palliation. **Stage 4** Stroke survivors and NHS professionals in other NHS sites.
Planned sample size	**Stage 1** **15 staff** for multisite staff focus groups. **50 staff** for survey of professional networks. **Stage 3** **30 stroke patients** for pre/post intervention study. **Stage 4** **30 stroke patients** for single site process evaluation for quality of life/satisfaction questionnaire – these will be the ***same patients that participated in Stage 3***

	10 stroke patients +/- informal caregivers for single site process evaluation interviews – patients will be purposively sampled from the ***same patients that participated in Stage 3*** **5 staff** for single site process evaluation interviews – staff will be purposefully sampled from staff delivering the intervention.
Planned study period	01/09/24-30/9/2026
Planned recruitment period	01/09/24-31/8/2026
Study intervention	Deliver the Free Water Protocol for a maximum of 3 weeks
Objectives	1. To determine if the FWP is acceptable to staff and patients involved in delivering or receiving the FWP (acceptability). 2. To establish whether recruitment of people with stroke is feasible in the time scale. To test the ability to collect outcomes measures: Level of fluid intake (thickened fluids, plain water and artificially administered fluids); differences in hydration pre/post FWP intervention; and patient satisfaction of the FWP (feasibility). 3. To find out if the FWP can be administered as intended (fidelity). 4. To identify barriers and facilitators to implementing the FWP.
Outcome measures	**Feasibility outcome measures** 1. **Acceptability** - Acceptability of staff and patients involved in delivering or receiving the FWP. 2. **Feasibility** – (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.

	3. **Fidelity** – (i) Proportion of participants treated according to the Free Water Protocol guidelines (ii) how well the protocol was tolerated and reasons for declining (tolerability). 4. **Barriers and facilitators to implementing the FWP** measured through the process evaluation. **Intervention outcome measures** 1. Amount of thickened and unthickened fluids consumed daily in millilitres (mls). For patients receiving artificially administered fluids, the amount of mls given will be recorded daily as part of routine care. 2. Development of pneumonia and new initiation of antibiotics for pneumonia. 3. Changes in hydration measured using the BUN to creatinine ratio.

2. Research Questions

Main question

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?

Secondary Research Questions:

1. To what extent is the FWP perceived as acceptable to the individuals directly or indirectly involved in delivering or receiving the FWP?
2. To what degree was the FWP administered as it was intended?
3. What are the barriers and facilitators to implementing the FWP in the acute stroke unit setting?

4. Should we proceed to a multi-site feasibility study?

3. Abstract/Summary

Background

The Free Water Protocol (FWP) gives patients 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.

Method

The research programme has four stages. In Stage 1, the developmental work to inform national stakeholder co-design workshops will include a systematic review, 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.

Results

Primary feasibility outcomes will investigate acceptability, feasibility, fidelity, and barriers and facilitators to implementing the FWP. Secondary intervention outcomes will include level of fluid intake, hydration, and development of pneumonia.

Conclusion

The results of the study will inform a larger multi-site feasibility study to determine whether a phase 3 multicentre trial is feasible in NHS acute care.

4. Aims and objectives of the study

Aim

The aim of this preliminary feasibility study is to develop and test an implementation strategy for a Free Water Protocol (FWP) in acute stroke and explore the acceptability, feasibility and fidelity of delivering the FWP to inform a larger multi-site feasibility study to determine whether a Phase 3 multicentre trial is feasible in NHS acute stroke unit care.

Objectives

1. To determine if the FWP is acceptable to patients and staff involved in delivering or receiving the FWP (acceptability).
2. To establish whether recruitment of people with stroke is feasible in the time scale. To test the ability to collect outcomes measures: Level of fluid intake (thickened fluids, plain water and artificially administered fluids); differences in hydration pre/post FWP intervention; and patient satisfaction of the FWP (feasibility).
3. To find out if the FWP can be administered as intended (fidelity).
4. To identify barriers and facilitators to implementing the FWP.

5. Background

Dysphagia affects around half of stroke survivors. It increases the risk of stroke-associated pneumonia (SAP), malnutrition and dehydration, and reduces quality of life (QOL). Research that reduces post stroke complications and improves stroke survivor and carer experiences of the stroke treatment and care pathway have been identified as priority areas for stroke research (Stroke Association, 2021). Treatment of post-stroke dysphagia can involve exercises to reduce the impairment, compensatory strategies and positioning to improve the safety and efficiency of the swallow. Patients are often recommended to drink thickened fluids as they move more slowly in the mouth and pharynx (Dantas et al. 1990, Newman et al., 2016), maintain cohesiveness (Nishinari et al. 2019), and increase the speed and extent of laryngeal movements (Nakao et al., 2022) thereby increasing the safety of the swallow (Newman et al. 2016) and reducing the risk of aspiration pneumonia (Teasell et al. 1996). However, many stroke survivors dislike thickened fluids, comparing it to “sludge” (Eltringham et al. 2019). This can lead to reduced fluid intake and dehydration (Whelan et al., 2001) which increases the risk of complications, such as extension of the presenting stroke or recurrent strokes (Lin et al., 2011, Yasaka et al.,1993), venous thromboembolism (Kelly et al., 2004) and increased mortality (Bhalla et al. 2000).

The Free Water Protocol (FWP) (Panther, 2005) is a method sometimes incorporated into dysphagia treatment as a means of increasing hydration and QOL. Patients who are known to aspirate thin fluids are permitted to drink water between meals provided water is given 30-minutes after meals and after rigorous oral care. The premise supporting the consumption of water is that water is pH neutral, and if aspirated in small amounts will be absorbed into the blood stream via aquaporins and do no harm to the lungs. A meta-analysis of the data from rehabilitation studies which included stroke patients, found no significant increase in lung complications when following a FWP, fluid intake may increase, and a trend for improved QOL (Gillman et al. 2017). There is also a suggestion that giving patients an option to

'practice' drinking thin fluids in the relatively safe form of water may help rehabilitate the swallow in accordance with the principles of experience dependent neuroplasticity (Murray et al. 2016, 2018). In addition, improving dysphagia early may avoid tube feeding. Stroke survivors find nasogastric tube (NGT) insertion 'painful' (Eltringham et al., 2019). NGTs can be accidentally displaced resulting in the need for reinsertion and confirmation of positioning which can in turn impact on sustaining adequate nutrition and hydration. Avoiding percutaneous endoscopic gastrostomy (PEG) would prevent the physical and psychological consequences of living with a PEG, as well as reducing length of hospital stay and economic costs associated with this.

Research about the effectiveness and the safety of the FWP specifically for patients with dysphagia post stroke is promising but limited and further research to investigate its use is recommended (NICE, 2023). Murray et al (2016) have proposed revisiting exclusion criteria and investigating the safety of water protocols for patients in acute settings to determine whether it is an appropriate approach for a wider group of stroke survivors. In an acute stroke unit stroke survivors need more help with eating, drinking and keeping their mouths clean because of physical and cognitive impairments. Nursing staff are primarily responsible for supporting patients to eat and drink and provision of oral care. In developing and evaluating complex interventions such as the FWP, it is important to test feasibility in the acute stroke unit setting to ensure it is appropriate to take the intervention to a full-scale trial.

6. Plan of the Investigation

6.1 Methodology and study design

A feasibility study using mixed methods. The Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2022) will underpin the study design and implementation science methods. The Implementation science research development (ImpRes) tool (Hull, 2019) has been used to consider the different implementation elements to support the design and activities associated with the study. The mixed methods research will draw from the strengths of qualitative and quantitative approaches and creates a richer understanding of phenomena. The incorporation of a process evaluation will ensure we understand the barriers and facilitators to implementing the interventions. These methods will also contextualise the findings of the research.

6.2 Programme of research

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.

(I) **Systematic Review** - A protocol for the systematic review has been written and registered on PROSPERO (Registration number CRD42023470349). The systematic review will use a qualitative evidence synthesis using Best-Fit framework synthesis (Carroll et al. 2013) to integrate evidence from qualitative and quantitative studies. The evidence from the review will be mapped onto the CFIR. It is anticipated that the qualitative data will be the primary source of data. However, evidence from the quantitative studies about the difficulties of implementing the Free Water Protocol may increase understanding about contextual determinants of the implementation of this complex intervention in the acute stroke unit setting and/or provide new insights about barriers and facilitators to intervention. Populating the CFIR will elucidate if there is correspondence between the two sources of data or if the different data sources identify unique challenges. The findings will be synthesised qualitatively in a narrative synthesis.

(II) **Survey** – The topics for the survey will be structured using the domains and constructs of the 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. The survey will take approximately 15 minutes to complete. 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. 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 email. 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.

(III) **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 recorded 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 will 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

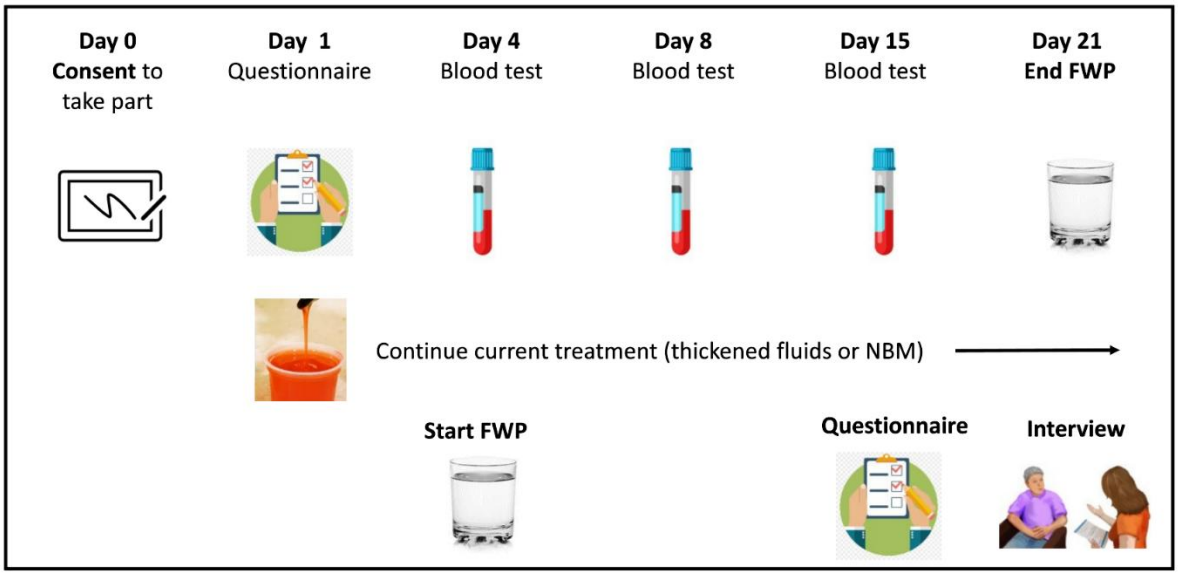
There will be three virtual stakeholder workshops between April-August 2025, with approximately one month between each workshop The duration of the workshops will be between 90 minutes and 2 hours. The remit of the national stakeholder workshops is to co-design the implementation process. This will involve 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 Patient Carer Public Involvement and Engagement (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.

Below is a visual overview of the pre/post intervention design.



Additional information

(1) Timing of the post intervention questionnaire is dependent on participant duration on the FWP.

(2) Third blood test subject to participant duration on the FWP.

(3) Timing of the process evaluation interview is dependent on participation duration on the FWP.

Setting – The study 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 hyperacute treatment and remain on HASU for up to 72 hours and are then transferred to the acute stroke unit (Rodgers et al. 2017). The average length of stay on the Acute Stroke Unit is 20 days.

Participants - Stroke survivors with dysphagia who have been assessed by a speech and language therapist and are at risk of aspiration with Level 0 Thin Fluids. All potential participants will be screened for suitability based on the inclusion and exclusion criteria.

Inclusion Criteria

Patients with acute stroke (ischaemic or haemorrhagic) who:

- Are a patient on the Acute Stroke Unit, Royal Hallamshire, Sheffield Teaching Hospitals NHS Foundation Trust (STHFT).
- 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).
- Have been on their swallowing recommendations (thickened fluids or NBM) for 72 hours.
- Have extreme impulsivity or excessive coughing will have water under supervision.

- Can sit out in a chair (minimum mobility hoist to chair).
- Can engage with eating (even if they require assistance).
- 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.
- Are over 18 years of age.

Exclusion Criteria

Patients with acute stroke (ischaemic or haemorrhagic) who:

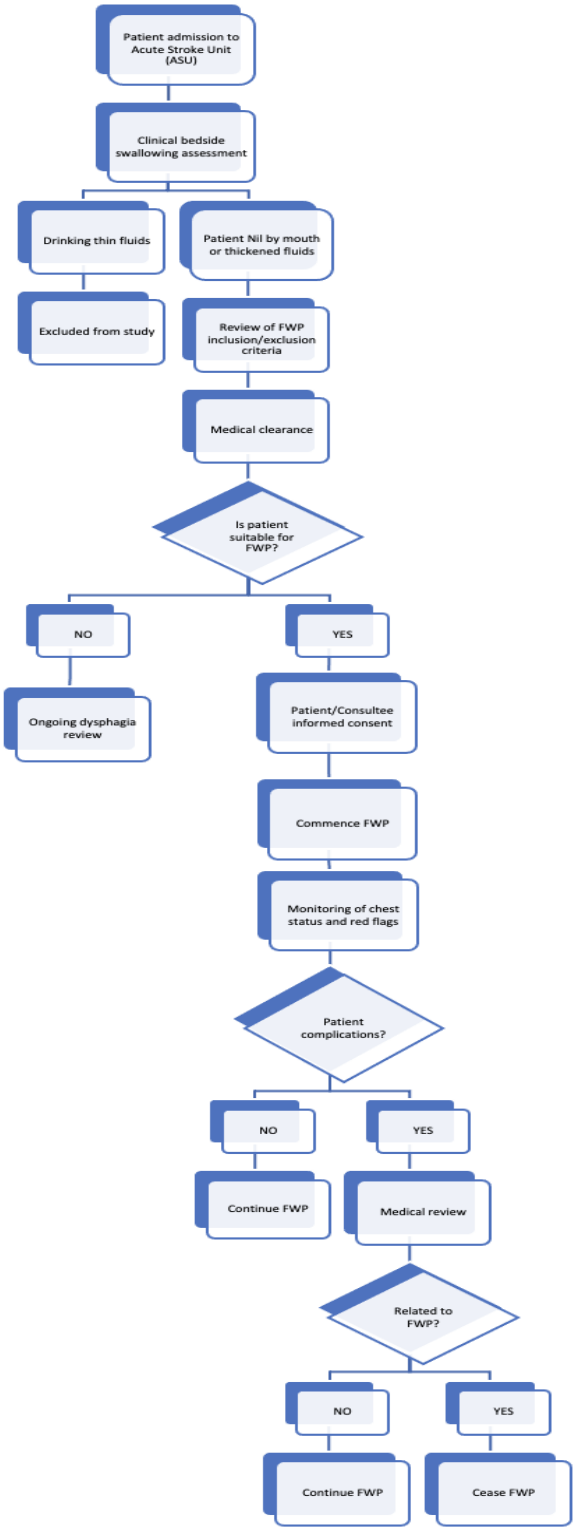
- Have a pre-existing dysphagia and are recommended to drink thickened fluids pre-stroke.
- Are fully dependent for feeding.
- Have an active pneumonia, acute exacerbation of Chronic Obstructive Pulmonary Disease or active asthma with symptoms.
- Have a degenerative neurological condition (e.g., Parkinson's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

Methods - 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) (Enderby and John, 2019), International Dysphagia Diet Standardisation Initiative (IDDSI) (https://www.iddsi.org) 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 for 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.

Flowchart to support decision making for screening, recruitment and monitoring participants.



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 (National Clinical Guideline for Stroke, 2023). 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.

Short Video of the Participant's Perspectives of the Free Water Protocol

The research team will selectively approach participants after they have completed the study and ask if they are happy to be videoed and share their experiences of the Free Water Protocol. The video will be taken either in hospital or the participant's discharge destination. The purpose of this video is to enhance the education and training materials, which are a key primary output of the trial. The video will be embedded into the toolkit of implementation resources we are developing. This will provide valuable insights and real-world perspectives that will greatly benefit the overall effectiveness of our training materials.

Stage 4 - Process Evaluation

(I) 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.

(II) 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 Patient Carer Public Involvement and Engagement (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).

(III) 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. The approach to data analysis and interpretation will be consistent with the patient-carer interviews.

6.3 Outcome Measure(s)

Feasibility outcome measures

1. **Acceptability** - Acceptability of staff and patients involved in delivering or receiving the FWP measured through the process evaluation.
2. **Feasibility** – (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 (iii) reasons for declining (iv) participant retention and (v) reasons for withdrawal from the study.

3. **Fidelity** – (i) Proportion of participants treated according to the Free Water Protocol guidelines (ii) how well the protocol was tolerated and reasons for declining (tolerability).
4. **Barriers and facilitators to implementing the FWP** measured through the process evaluation.

Intervention outcome measures

1. Amount of thickened and unthickened fluids consumed daily in millilitres (mls). For patients receiving artificially administered fluids, the amount of mls given will be recorded daily as part of routine care.
2. Development of pneumonia and new initiation of antibiotics for pneumonia.
3. Changes in hydration measured using the BUN to creatinine ratio.

Figure 1: Study Schedule for Outcome Measures

	Baseline visit Day 0	**Day 1**	**Day 4**	**Day 8**	**Day 15**	**Day 21**
Screening – Inclusion/exclusion	X					
Informed consent	X					
Pre/post intervention questionnaire		X			X	
Blood test			X	X	X	
Process evaluation interview						X

ADDITIONAL DETAILS

(4) Timing of post intervention questionnaire dependent on participant duration on the FWP.

(5) Third blood test subject to participant duration on the FWP.

(6) Timing of the process evaluation interview dependent on participation duration on the FWP.

6.5 Safety Assessment

After screening and identifying suitable participants for the study based on the inclusion/exclusion criteria a member of the research team will agree their suitability for inclusion with their treating physician. If the treating physician agrees the participant is suitable the participant will be approached and provided with the participant information sheet about the study. After commencing on the FWP, the participants chest status will be

closely monitored for any deterioration by the medical team alongside any other red flags (not adverse events) including a spike in temperature, extreme coughing on thin water or medical deterioration. If there are any red flags the research team would discuss these with the medical team and to ask their opinion about whether these red flags were felt to be attributable to the FWP or other factors. The participant's treating physicians would make the decision about whether the participant should be withdrawn from the intervention Development of pneumonia if considered to be attributable to the intervention would be captured as an adverse event.

6.6 Subject Withdrawal

Participants will be advised that they can withdraw from the study at any time without giving a reason and without this affecting their clinical care. Any data already collected will be analysed with permission from the participant.

If a participant loses capacity during the study, the research team will seek consultee consent to retain participant in the study.

6.7 End of Trial Definition

The end of the trial will be when the last patient-carer or staff interview has been completed after the intervention period.

6.8 Justification of Measures

Feasibility outcome measures

Acceptability – Perception that a treatment is agreeable, palatable and acceptable should be assessed based on the stakeholder's knowledge of or direct experience with various dimensions of the treatment to be implemented, such as its content, complexity, or comfort (Procter et al. 2011). Interviews and questionnaires are typical measures of acceptability.

Rated acceptability is considered dynamic and can change with experience and may be different when taken pre and post intervention. The swallow related quality of life (QOL) questionnaire SWAL-QOL is a patient reported outcome measure that is frequently used in dysphagia research studies as a measure of the impact of swallowing disorders on daily activities on QOL. However, studies that have investigated the FWP and used the SWAL-QOL have identified limitations. Limitations have included that the SWAL-QOL is not specifically related to fluid intake, the number of incomplete questionnaires, proxy reporting by family and carers, and accessibility difficulties for people with aphasia and cognitive challenges. This has led to some researchers creating their own questionnaires (Karagiannis and Karagiannis 2014, Karagiannis et al. 2011, Murray et al. 2016) designed to be accessible for people with cognitive and communication difficulties. With the involvement of the Stroke and Aphasia PPI Panel and the study PCPIE group we will create a simple questionnaire with a Likert and visual analogue scale based on Murray et al.'s (2016) questions. There will be no questions of a sensitive or distressing nature. The questionnaire will be accessible for people with aphasia and cognitive communication difficulties and will be available in other languages. If a participant requires support to complete the

questionnaire due to cognitive-communication or physical difficulties a speech and language therapist who is not a member of the research team will provide support.

Feasibility - Recruitment, retention and participation rates are typically used retrospectively as measures to explain the concept of feasibility (Procter et al. 2011).

Fidelity – Adherence to the program protocol, the dose or amount of program delivered, and quality of program delivery of the intervention compared to the original evidence-based intervention are typical measures of fidelity. The literature identifies five implementation fidelity dimensions including adherence, quality of delivery, program component differentiation, exposure to the intervention, and participant responsiveness or involvement (Proctor et al., 2011). Checklists and self report are typical measures of fidelity.

Intervention outcome measures

BUN/Cr ratio – Hydration status will be measured using the blood urea nitrogen/creatinine (BUN/Cr) ratio. The BUN/Cr ratio has been extensively used as an index for hydration in stroke studies (Crary et al. 2016, Murray et al. 2018).

Measurement of fluids – Fluid balance charts will be completed for every day the participant is on the FWP study intervention or until they are upgraded to thin fluids whichever occurs first.

Development of pneumonia will be measured based on the initiation of antibiotics for a newly acquired chest infection. This measurement is consistent with the measure of pneumonia used on Sentinel Stroke National Audit Programme.

7 Data Management

7.1 Statistical Analysis

Survey responses

Survey data will be analysed using descriptive statistics and will include analysis of categorical data. Descriptive statistics of categorical variables will be frequency analysis i.e. percentage of the different categories in each variable.

Intervention outcomes

Descriptive statistics will be performed to analyse trends in the data collection of the secondary outcomes of fluid intake, hydration status and incidence of pneumonia. The purpose of the analysis is to find out if it is possible to collect this data to inform future hypotheses testing for the multi-site feasibility study.

Practical issues around data collection and accuracy of recording in the real world will be explored and potential reasons for missing or inaccurate reporting. Examples of such practical issues may be provision of fluids, accuracy of reporting fluid intake, incomplete recording of paper documentation or clinical laboratories not reporting the blood results.

What happens to participants who only get to a certain number of days in the study will be mapped out. Examples of possible events may include the participant's swallowing improves such that they are no longer considered at risk of aspiration with thin fluids, tolerability of the FWP, or the participant is no longer considered medically suitable.

7.2 Statistical Opinion

As this is a feasibility study, a power analysis and sample size estimation have not been conducted. A sample size of 30 will obtain the data to inform a multi-site feasibility study. The rationale for the intervention sample size is based on Lancaster and Thabane (2019) guidelines for reporting feasibility studies, NIHR RDS resources and local RDS advice and potentially eligible patients based on the inclusion/exclusion criteria.

Further statistical advice would be sought from Dr Ben Bray (Principal in the Health Analytics Practice at Lane Clark and Peacock, LLP).

7.3 Qualitative analysis

Focus group and interview data will be analysed thematically by the Chief Investigator (CI). Participants' statements will be examined and coded for their intended meaning. Relationships between codes will be searched for and like for like codes will be grouped together into categories. The Consolidated Framework for Implementation Research (CFIR) code book will be used to help deductively map the categories onto the CFIR constructs to provide insights into the barriers and facilitators to implementation of the FWP. The Principal Investigator (PI) will check the identified categories and consensus between the CI and PI will be reached before they are mapped onto the CFIR constructs. Anonymised quotations will be used to support interpretations of the data under the different constructs.

7.4 Data Collection, Handling and Storage Record Keeping

Survey data

The Qualtrics online survey tool will be used to collect anonymous respondent data. Data will be exported to SPSS for Windows predictive analysis software for analysis.

Focus groups and interview data

The focus groups will be video recorded using Microsoft Teams. The Chief Investigator will transcribe the audio recording into a Microsoft word document and any potential sources of identification will be anonymised. The video will not be used other than for the purpose of

transcribing what was said, and the Microsoft Teams recording will be deleted after the data has been transcribed. .

The interviews will be audio recorded and transcribed by the Chief Investigator into a Microsoft word document and any potential sources of identification will be anonymised.

The word documents will be stored in a secure electronic database. See paragraph *Confidentiality and data security* in Section 10.1 Ethical considerations for information about how personal information will be kept secure and maintained.

Participant data

Information about the participants characteristics will be collected from the participant's medical record and inputted directly on an electronic Case Report Form (eCRF) which will be secured in a secure electronic database.

Questionnaire data

The completed pre and post questionnaire paper document will be collected after completion by the patient participant and electronically scanned and stored in a secure electronic database.

Intervention outcome data

The amounts of thickened fluids, plain water and artificially administered fluids will be collected and recorded by the nursing staff as per routine care on a paper document which will be stored in the patient's nursing care folder. Data from the source paper documents will be inputted directly into an eCRF by a designated member of the research team and stored in a secure electronic database.

Data from the blood test will be reported as per routine practice on a secure web portal. Data will be transferred onto the eCRF.

Data about the prescription of antibiotics for a newly acquired pneumonia will be reported on the patient's electronic drug record as per routine practice. Data will be transferred onto the eCRF.

The Chief Investigator/Principal Investigator will check all source documents and eCRF input before submitting to minimise the chance of any data errors.

The analysis will take place on a STH computer/laptop.

7.5 Data Storage

Data will be collected and retained in accordance with the Data Protection Act 1998. Paper copies of source data and consent forms will be stored in a locked cupboard in the Acute

Stroke Unit Speech and Language Therapy office at the Royal Hallamshire Hospital. Electronic data collected will be stored on a password protected computer in the STH computer network. The data will be accessible only to the study team and the trust approved research and governance auditors. The data will be stored within the STH archiving facility for 5 years after completion of the study.

7.6 Confidentiality

All personal information collected will be kept secure. This will involve the creation of coded, de-personalised data where the participant's identifying information is replaced with an unrelated sequence of characters. Secure maintenance of the data and linking code will be kept in separate encrypted digital files within password protected files. Access to the research data will be limited within the research team. The data will not be used for anything in addition to what is already specified in the protocol and the participant information sheets.

8. Study Management

8.1 Project Plan

Activity	Time Frame
Protocol Development	September-December 2023
Recruit PCPIE Panel	September-October 2023
Systematic Review	September 2023-August 2024
Ethical Approvals and amendments	March-August 2024
Staff survey	September-October 2024
Staff focus groups	December 2024-January 2025
National Codesign Stakeholder groups	April-August 2025
Development of training delivery and resources for implementation of FWP	June-August 2025
Rolling programme of FWP and oral care training	September 2025-August 2026
Recruitment for FWP intervention	October 2025-August 2026
Patient interviews	October 2025-August 2026

Staff interviews	December 2025-August 2026
Data analyses	September 2026-January 2027
Final Report	June-August 2028

8.2 GANNT chart (see Excel spreadsheet)

8.3 Project Management

The Chief Investigator will have overall responsibility for the study and will supervise, monitor and review any work undertaken by the research team. They will also be responsible for the data collection and analysis of the outcome measures. The Chief Investigator will be supervised by the Supervisory Team who will monitor and review the work undertaken. The Combined Community and Acute Care Group Research Coordinator will assist in with the set up and delivery of the study and monitoring of the performance outputs.

There will also be a Project Steering group which will include stroke researchers, clinical academics and a patient representative. The role of the Project Steering Group will be to reflect on the different contextual factors involved in the implementation process and to sense check the implementation strategy developed by the National Co-design Group.

The Chief Investigator will submit progress reports as required by the Stroke Association and a final report at the end of the grant.

9. Expertise

Three supervisors have been identified who will be able to provide support for different aspects of the Chief Investigator/Award Holder (SE) training and for their clinical and research expertise:

Professor Craig Smith - Professor of Stroke Medicine, Division of Cardiovascular Sciences, Faculty of Biology, Medicine and Health, University of Manchester, Consultant in Stroke Medicine, Manchester Centre for Clinical Neurosciences, Salford Royal Hospitals NHS Foundation Trust

Professor Craig Smith has a breadth of experience in Stroke medicine and research. His research spans experimental stroke, cohort studies, mixed methods, meta-analyses and clinical trials. He is Chief Investigator for the CHOSEN feasibility trial, which is evaluating mouth care intervention in stroke patients with dysphagia to prevent post stroke pneumonia. Professor Smith has extensive knowledge of oral care learning needs, which will be invaluable for designing the training delivery to support the implementation of the FWP.

Professor Sue Pownall - Academic Director, Therapeutics & Palliative Care Directorate, Sheffield Teaching Hospitals NHS Foundation Trust

Professor Pownall is the former Head of Sheffield Adult Speech and Language Therapy Service and the Academic Director for the Therapeutics and Palliative Care Directorate in Sheffield Teaching Hospitals. Professor Pownall is an active researcher with an interest in assessment and treatment interventions for dysphagia, implementation of research into clinical practice and educational approaches to skill sharing across professional boundaries.

Professor Liz Lightbody – Professor of Stroke Care and Improvement, UK's Deputy Director of the NIHR, Global Health Research Group for Improving Stroke Care in India School of Nursing, University of Central Lancashire

Professor Liz Lightbody has research expertise in applied health research, service improvement and implementation with a research focus on acute stroke care and workforce development. She is currently a collaborator on the CHOSEN feasibility trial and oversees all aspects of process evaluation, including nurse training and education. Professor Lightbody will provide insight on the training delivery and measurement of the feasibility criteria.

Dr Sabrina Eltringham – Sheffield Teaching Hospitals NHS Foundation Trust

Dr Sabrina Eltringham is a postdoctoral clinical academic fellow and speech and language therapist who will be undertaking the project as part of her Stroke Association Clinical Academic Postdoctoral Fellowship. Her previous research experience includes working as a Knowledge Translation Research Associate for Collaboration for Leadership in Applied Health Research and Care (CLAHRC), being a hospital Directorate Patient and Public Involvement Coordinator and undertaking her own clinically applied research. Her research interest is preventing post stroke complications and assessment and management of dysphagia.

Dr Nicola Martindale – Sheffield Teaching Hospitals NHS Foundation Trust

Dr Nicola Martindale is the Lead Speech and Language Therapist on the Acute Stroke Unit at the Hallamshire Hospital with a clinical specialism in the assessment and management of patients with swallow and communication impairment after stroke. She is ideally placed to screen participants for eligibility, educate and support staff, patients and relatives to implement the FWP on the unit and liaise with the medical staff regarding the patient's medical status. As part of the integration of training posts into the Fellowship she will be supported by the Chief Investigator to develop her research skills from project set up to dissemination.

10. Ethical Issues

10.1 Ethical Considerations:

Independent Peer Review

This research study has been independently scientifically reviewed by the Stroke Association Award Panel and the Stroke Voices in Research (SViR) PPI Panel and the

application was approved by the Stroke Association Trustees. This study protocol has been reviewed by the Sheffield Teaching Hospitals NHS Foundation Trust Clinical Research Innovation Office and Research Coordinators. Expert review has taken place by the supervisory team. People affected by stroke from the Stroke and Aphasia PPI Panel, the SY ISDN PPI Panel and the study PCPIE group have been involved in the development of the study protocol.

Informed consent

The researcher asking for consent and the Participant Information Sheet (PIS) will inform the potential participants that participation is entirely voluntary, and their medical care will not be affected by their decision. The PIS and Informed Consent Form (ICF) will be given to the potential participant, and they will be given adequate time to read and understand the information and ask any questions prior to consenting. They will be informed that they have the right to withdraw at any time without giving reason and this will not affect their medical care or legal rights. The participants' rights to information and consent, confidentiality and privacy are and will be respected and upheld throughout the duration of this study.

Equity, diversity and inclusion

Patients lacking capacity - Impaired cognition is often an exclusion criterion in studies evaluating the FWP (Gillman et al. 2017). A consultee process will be in place for persons lacking in mental capacity. The consultee will be given a consultee participant information sheet and informed consent form and advise on the participants wishes about taking part.

People with aphasia (PWA) are often excluded from taking part in research that is relevant because of difficulties in informing, consenting and conducting research with people with aphasia (Cruice et al., 2022). Potential bias has been minimised by involving PWA as early as possible in the research planning process so their views can be considered from the outset. Members of the Stroke and Aphasia Group have helped to produce an aphasia friendly version of the participant information leaflet to support PWA to make an informed decision about whether they want to take part. This accessible leaflet will be used to support other patient populations such as patients with cognitive communication disorders. If a participant would like a carer or loved one to be present during the interview, the carer will be provided with a Carer participant information sheet and consent form. If they are willing to take part, they will be asked for their written consent.

To be more inclusive of non-English speaking participants, participant facing materials will be translated into the two most common language of persons admitted to the Acute Stroke Unit. An interpreting or translation service will be offered and used for conducting the interviews and translation of the interview transcripts. We have also consulted with the regional NIHR Ethnic Minority of Research Inclusion Hub Lead about ways to promote inclusion of people from minority ethnic backgrounds in our research.

Based on service user feedback we will record a voice over to accompany our aphasia participant information leaflet. The voice over will be exactly as what is written in the leaflet. Our intention is that the person asking for consent will talk through the participant information leaflet with the potential participant. Having a recording will enable the potential participant to replay the voiceover to help them decide if they want to take part. This was identified as helpful by the SY ISDN PPI Panel for potential participants with visual impairments.

Confidentiality and data security

All personal information collected will be kept secure and maintained. This will involve the creation of coded, de-personalised data where the participant's identifying information is replaced by an unrelated sequence of characters. Secure maintenance of the data and the linking code are kept in separate encrypted digital files within password protected files. Access to the research data will be limited within the research team. The data will not be used for anything in addition to what is already specified in the protocol. Participants will be given pseudonyms for the research write up so that they cannot be identified. All data will be stored on a secure server, which has been approved by Sheffield Teaching Hospitals Information Governance.

Disclosure

Should something be revealed that may be harmful to patients this will be managed according to the hospital work code of conduct. Where appropriate, therefore, confidentiality may have to be breached in the public interest.

What will happen at the end of the study?

As part of the consenting procedure for all participants, the research team will seek consent on the findings of the research being disseminated for the purposes of public engagement, educational and service development. The possible impact on research participants is that their anonymity may be jeopardised or that they feel their contributions are misrepresented within the research findings. Care will be taken when presenting research findings to ensure that those taking part cannot be identified, (for example, by person identifying quotes) while at the same timing balancing an individual's wish to be identified, for example as co-author or co-presenter at a conference or public engagement event.

Risk of pneumonia

Participants will be protected from risk of development of pneumonia by the strict inclusion criteria on screening participants for inclusion, the protocol guidelines, and the provision of education and training about the FWP guidelines and the delivery of oral care.

10.2 Declaration of Helsinki

The CI will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

10.3 Guidelines for Good Clinical Practice

All research active staff will have completed the GCP training or re-fresher training within the last 3 years (in line with STH Trust Requirements).

10.4 Expenses and Benefits

Thickened fluids can discourage stroke survivors from drinking and reduce quality of life. Participants may find that being on the FWP improves their hydration levels and improves their quality of life. There has also been some discussion about whether it may help to rehabilitate the swallow. It is hoped that the research will contribute to the knowledge base about whether the FWP could be a safe approach that maintains and or improves hydration levels while not increasing pneumonia levels. There will be no expenses provided for taking part.

10.5 Other Ethical Considerations

People affected by stroke may struggle to understand what has happened in the first few days after their stroke and experience psychological effects (Eltringham et al. 2019). Any psychological distress the participants may experience because of their stroke will be managed in the usual way that rehabilitation professionals support patients.

11. Service Users and Patient and Public Involvement

This research addresses two of the top priorities in stroke research identified by stroke survivors and stroke professionals (Stroke Association, 2021). As part of the development of the Stroke Association Postdoctoral Application the Chief Investigator and Principal Investigator applied for a National Institute of Health Research Design Service (NIHR RDS) PPI Fund Award. The application for the PPI fund was successful and enabled members from the Sheffield Teaching Hospitals Stroke and Aphasia Panel and the Stroke Association Stroke Voices in Research Network shape the development of the application. Members influenced the Lay Abstract and Title and provided advice on inclusion criteria, recruitment, and design challenges such as delivery and recording of the intervention.

A study PCPIE group of people affected by stroke who have experience of swallowing problems has been recruited. Membership includes people from underserved groups including people with speech, language and cognitive difficulties as well from different socio economic, cultural and ethnic backgrounds. We have also involved the Stroke and Aphasia Panel and the South Yorkshire Integrated Stroke Delivery Network PPI group in the development of the Protocol.

Members of these panels have been asked for their advice from a stroke survivor and carer perspective about what factors need to be considered when implementing the FWP in hospital and for their opinions regarding the degree to which participant materials were clear and easy to understand. The STH Stroke and Aphasia Panel helped to produce an aphasia friendly version of the participant recruitment leaflet and were involved with the PCPIE Panel in designing the patient satisfaction questionnaire.

Going forward the PCPIE group will be involved in developing the topic guide for the patient interviews about their experiences of being on the FWP. The group will be asked about what questions to ask and how best to ask them and be involved in the analysis and interpretation of the interview transcripts. As part of the development work to inform the stakeholder workshops the group will discuss the staff survey and focus group findings before the

workshops happen. The group will be involved in developing and reviewing how we share the research findings from the project.

Two members of PCPIE group will be part of the National Codesign Stakeholder Group. The remit of the National Codesign Stakeholder Group is to codesign the implementation process. This will involve designing the activities and strategies used to implement the FWP in a hospital stroke unit. The group will design the training delivery to deliver the FWP and decide the best ways to record the delivery of the intervention and fluid intake. A member of PCPIE group will be part of the Project Steering Group which will monitor the progress of the research study and to sense check the outputs from the National Codesign Stakeholder Group and to identify anything that may have been overlooked.

12. Dissemination

A lay summary of the results will be disseminated to the participants. The findings of this study will be presented and discussed at local and international meetings, submitted for publication by the award holder to international peer reviewed journals, and disseminated on social media platforms. Annual reports will be submitted to the Stroke Association and on-going progress will be reported to the Combined Community and Acute Care Group Research Team. The study will be included on national registers.

The Research Department may publish details of the research project as part of the Trust's R&D programme.

13. Taking the Work Forward

This study will inform a larger randomised feasibility study to determine whether a Phase 3 Multicentre Trial is feasible in NHS acute stroke care. If feasible the Free Water Protocol (FWP) intervention could have considerable impact on improving patient hydration and experience. It may also help to minimise costs to the NHS by reducing, for example: rates of infection associated with dehydration (Murray et al. 2016); the need for artificial feeding by early rehabilitation of the swallow; and length of hospitalisation. Potential patient benefits include improved hydration and quality of life, reduced dependency and increased participation and improved psychological wellbeing (Eltringham et al., 2019). Potential staff impacts include increased staff awareness of the FWP and confidence about oral care provision for dysphagic patients.

The preliminary feasibility study will be the first step in assessing whether the training delivery required for the implementation of the FWP and the implementation of the FWP is feasible in an acute stroke setting. The next step would be to refine training, participant eligibility, data collection and test in several acute stroke units with differing characteristics and operational approaches. Additional clinical outcome measures would include modified Rankin Scale (mRS) for measuring the degree of disability and dependency, and survival. This study will be a multi-site randomised feasibility study to test the implementation of the FWP across four NHS stroke units which perform differently on the SSNAP registry to reflect

the variation in delivery of care processes and pneumonia rates across stroke units. An application for a NIHR Research for Patient Benefit grant will be submitted, and the estimated duration of the research study would be two years. The purpose of the randomised feasibility study would also be to test the feasibility of randomising, participant willingness to complete the study, and whether feasibility progression criteria are met for a phase 3 trial and whether further piloting is required.

14. Intellectual Property

No Intellectual Property is anticipated from the completion of this study.

15. Costing Schedule

Budget Heading	**Total**
Salaries	
Sabrina Eltringham – Fellowship Award Holder Band 7	£151,433
Nicola Martindale – Research Training Post Band 7	£30,287
Research Training Post Band 3	£2,874
Clinical Trials Assistant Band 4	£1,967
Salaries Total	**£186,561**
Consumables	
Graduated plastic cups and water bottles	£500
Printing	£750
Consumables Total	**£1,250**
Travel	
Conference registration fees, travel and accommodation	£4,675
Travel Total	**£4,675**
Other Expenses	
Patient and Public Involvement Costs	£2,295
Open Access Publishing Costs	£9,684

Interpretation and Translation Costs	£2,000
Research Training Courses for Award Holder	£857
Staff training about the FWP (Excess treatment costs)	£610
Laboratory tests	£661.50
Dissemination of the Research	£500
NHS Archiving Costs	£750
Other Expenses Total	£17,357.50
Grand Total	**£209,843.50**

16. Funding Arrangements

This research has been funded by The Stroke Association. Grant reference – SA PDF23/100001 (£209, 843).

17. References

Barker A, Doeltgen S, Lynch E, Murray J. Perceived barriers and enablers for implementing water protocols in acute stroke care: A qualitative study using the Theoretical Domains Framework. Int J Speech Lang Pathol. 2019 Jun;21(3):286-294. doi: 10.1080/17549507.2019.1595145. PMID: 31213158.

Bhalla A., Sankaralingam S., Dundas S., Swaminathan R., Wolfe C. D. and Rudd A. G. 2000. Influence of raised plasma osmolarity on clinical outcome after acute stroke. Stroke 31 2043- 2048.

Carroll, C., Booth, A., Leaviss, J. et al. “Best fit” framework synthesis: refining the method. BMC Med Res Methodol 13, 37 (2013). https://doi.org/10.1186/1471-2288-13-37

Crary MA, Carnaby GD, Shabbir Y, Miller L, Silliman S. Clinical Variables Associated with Hydration Status in Acute Ischemic Stroke Patients with Dysphagia. Dysphagia. 2016 Feb;31(1):60-5. doi:10.1007/s00455-015-9658-6.

Cruice, M and Dipper, L. (2022) 'Meaningful Collaboration with People with (Stroke) Aphasia in Novel Intervention Development: Illustrations from the LUNA research project in Volkmer, A. and Broomfield, K. (Eds) Seldom Heard Voices in Service User Involvement. Croydon. J&R Press Limited, 151-172.

Damschroder, L.J., Reardon, C.M., Widerquist, M.A.O. et al. The updated Consolidated Framework for Implementation Research based on user feedback. Implementation Sci 17, 75 (2022). https://doi.org/10.1186/s13012-022-01245-0

Dantas RO, Kern MK, Massey BT, Dodds WJ, Kahrilas PJ, Brasseur JG, Cook IJ, Lang IM. Effect of swallowed bolus variables on oral and pharyngeal phases of swallowing. Am J Physiol. 1990 May;258(5 Pt1):G675-81. doi: 10.1152/ajpgi.1990.258.5.G675.

Eldridge S M, Chan C L, Campbell M J, Bond C M, Hopewell S, Thabane L et al. CONSORT 2010 statement:extension to randomised pilot and feasibility trials BMJ 2016; 355 :i5239 doi:10.1136/bmj.i5239

Eltringham S.A., Bray BD, Smith CJ, Pownall S, Sage K. Are Differences in Dysphagia Assessment, Oral Care Provision, or Nasogastric Tube Insertion Associated with Stroke-Associated Pneumonia? A Nationwide Survey Linked to National Stroke Registry Data. Cerebrovasc Dis. 2021 Dec 16:1-8. doi: 10.1159/000519903. Epub ahead of print. PMID: 34915473.

Eltringham, S.A., Pownall, S.; Bray, B.; Smith, C.J.; Piercy, L.; Sage, K. Experiences of Dysphagia after Stroke: An Interview Study of Stroke Survivors and Their Informal Caregivers.Geriatrics, 2019,4, 67. https://doi.org/10.3390/geriatrics4040067

Eltringham, S.A., Smith, C.J.; Pownall, S.; Sage, K.; Bray, B. Variation in Dysphagia Assessment and Management in Acute Stroke: An Interview Study.Geriatrics, 2019,4, 60. https://doi.org/10.3390/geriatrics4040060

Eltringham, S.A., Kilner, K., Gee, M. et al. Factors Associated with Risk of Stroke-Associated Pneumonia in Patients with Dysphagia: A Systematic Review. Dysphagia (2019). https://doi.org/10.1007/s00455-019-10061-6

Eltringham S, A., Kilner K, Gee M, Sage K, Bray B, D, Pownall S, Smith C, J: Impact of Dysphagia Assessment and Management on Risk of Stroke-Associated Pneumonia: A Systematic Review. Cerebrovasc Dis 2018;46:97-105. doi: 10.1159/000492730

Gillman A, Winkler R, Taylor NF. Implementing the Free Water Protocol does not Result in Aspiration Pneumonia in Carefully Selected Patients with Dysphagia: A Systematic Review. Dysphagia. 2017 Jun;32(3):345-361. doi: 10.1007/s00455-016-9761-3.

Karagiannis, M.J., Chivers, L. & Karagiannis, T.C. Effects of oral intake of water in patients with oropharyngeal dysphagia. BMC Geriatr 11, 9 (2011). https://doi.org/10.1186/1471-2318-11-9

Karagiannis M, Karagiannis TC. Oropharyngeal dysphagia, free water protocol and quality of life: an update from a prospective clinical trial. Hell J Nucl Med. 2014 Jan-Apr;17 Suppl 1:26-9. PMID: 24392465.

Kelly J, Hunt BJ, Lewis RR, Swaminathan R, Moody A, Seed PT, Rudd A. Dehydration and venous thromboembolism after acute stroke. QJM. 2004 May;97(5):293-6. doi: 10.1093/qjmed/hch050.

Lancaster, G.A., Thabane, L. Guidelines for reporting non-randomised pilot and feasibility studies. Pilot Feasibility Stud 5, 114 (2019). https://doi.org/10.1186/s40814-019-0499-1

Lin LC, Yang JT, Weng HH, Hsiao CT, Lai SL, Fann WC. Predictors of early clinical deterioration after acute ischemic stroke. Am J Emerg Med. 2011 Jul;29(6):577-81. doi: 10.1016/j.ajem.2009.12.019.

McHorney CA, Robbins J, Lomax K, Rosenbek JC, Chignell K, Kramer AE, Bricker DE. The SWAL-QOL and SWAL-CARE outcomes tool for oropharyngeal dysphagia in adults: III. Documentation of reliability and validity. Dysphagia. 2002 Spring;17(2):97-114. doi: 10.1007/s00455-001-0109-1. PMID: 11956835.

Murray J, Doeltgen S, Miller M, Scholten I. Does a Water Protocol Improve the Hydration and Health Status of Individuals with Thin Liquid Aspiration Following Stroke? A Randomized Controlled Trial. Dysphagia. 2016 Jun;31(3):424-33. doi: 10.1007/s00455-016-9694-x.

Murray J, Scholten I, Doeltgen S. Factors Contributing to Hydration, Fluid Intake and Health Status of Inpatients With and Without Dysphagia Post Stroke. Dysphagia. 2018 Oct;33(5):670-683. doi: 10.1007/s00455-018-9886-7.

Nakao Y, Onishi H, Haji T, Shiromoto O, Saito S, Nanto T, Uchiyama Y, Domen K. Impact of Thickened Liquids on Laryngeal Movement Velocity in Patients with Dysphagia. Dysphagia. 2022 Feb;37(1):207-215. doi: 10.1007/s00455-021-10267-7.

National Clinical Guideline for Stroke for the UK and Ireland. London: Intercollegiate Stroke Working Party; 2023 May 4. Available at: www.strokeguideline.org

Newman R, Vilardell N, Clavé P, Speyer R. Effect of Bolus Viscosity on the Safety and Efficacy of Swallowing and the Kinematics of the Swallow Response in Patients with Oropharyngeal Dysphagia: White Paper by the European Society for Swallowing Disorders (ESSD). Dysphagia. 2016 Apr;31(2):232-49. doi:10.1007/s00455-016-9696-8.

National Institute for Healthcare Excellence guideline [NG236] Stroke rehabilitation in adults. Published: 18 October 2023 Accessed https://www.nice.org.uk/guidance/ng236 on 16/1/2024

Nishinari K, Turcanu M, Nakauma M, Fang Y. Role of fluid cohesiveness in safe swallowing. NPJ Sci Food. 2019 Apr 3;3:5. doi: 10.1038/s41538-019-0038-8. PMID: 31304277; PMCID: PMC6550271.

Panther K. (2005) The Frazier free water protocol. SIG 13 perspectives on swallowing and swallowing disorders. Dysphagia, 14, 4-9.

Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, Griffey R, Hensley M. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Health. 2011 Mar;38(2):65-76. doi: 10.1007/s10488-010-0319-7. PMID: 20957426; PMCID: PMC3068522.

Rodgers H, Price C. Stroke unit care, inpatient rehabilitation and early supported discharge. Clin Med (Lond). 2017 Apr;17(2):173-177. doi: 10.7861/clinmedicine.17-2-173. PMID: 28365632; PMCID: PMC6297619.

Smith, C. J. (2021a) 'CHlorhexidine Or toothpaSte, manual or powered brushing to prEvent pNeumonia complicating stroke (CHOSEN): a 2x2 factorial randomised controlled feasibility trial.' [Online]. [Accessed 24/03/2021] https://fundingawards.nihr.ac.uk/award/NIHR200739.

Stroke Association (2021) Shaping Stroke Research to rebuild lives. The Stroke Priority Setting Partnership results for investment. Accessed via https://stroke-org-prod.codeenigma.net/sites/default/files/research/stroke_priority_setting_partnership_full_report.pdf on 16/1/2024

Teasell RW, McRae M, Marchuk Y, Finestone HM. Pneumonia associated with aspiration following stroke. Arch Phys Med Rehabil. 1996 Jul;77(7):707-9. doi: 10.1016/s0003-9993(96)90012-x.

Whelan K. Inadequate fluid intakes in dysphagic acute stroke. Clin Nutr. 2001 Oct;20(5):423-8. doi:10.1054/clnu.2001.0467. PMID: 11534937.

Yasaka M, Yamaguchi T, Oita J, Sawada T, Shichiri M, Omae T. Clinical features of recurrent embolization in acute cardioembolic stroke. Stroke. 1993 Nov;24(11):1681-5. doi:10.1161/01.str.24.11.1681.

18. Curriculum Vitae

Eltringham CV.docx Smith CV.docx Pownall CV.doc Lightbody CV.docx Martindale CV.docx

19. Contact Details

Chief Investigator and Award Holder: Dr Sabrina Eltringham
Address: Sheffield Teaching Hospitals NHS Foundation Trust, Sheffield
Telephone: 0114 271 3189
Email: sabrina.eltringham@nhs.net