

AQUA: An open label **A**ceptability and feasibility trial of 'Jelly Drops™' for hydration and **Q**UALity of care for people with dementia



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STUDY PROTOCOL

Title: AQUA: An open label Aceptability and feasibility trial of 'Jelly Drops™' for hydration and QUALity of care for people with dementia

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AQUA: An open label Acceptability and feasibility trial of 'Jelly Drops™' for hydration and **QUALITY** of care for people with dementia



1. SUMMARY OF RESEARCH

The research study will explore the acceptability to those living with dementia of consuming Jelly Drops™ in addition to usual care to support hydration. It will also test how feasible it would be to do a larger trial to test whether it can effectively hydrate people. If successful, this research could facilitate improved service provision and patient outcomes related to patient hydration for those living with dementia within Rotherham Doncaster and South Humber NHS Foundation Trust (RDaSH).

Jelly Drops™ are a water-based (95%), sugar free, vegan treat containing electrolytes, which were developed to increase fluid intake for those with dementia. They have been developed by a private company in the UK and are currently on general sale within the UK and other countries. They are suitable for those with diabetes, are listed as an item of confectionary and are not classed as a nutritional supplement.

2. BACKGROUND AND RATIONALE

Issues with water balance in the body and dehydration prevail in those with dementia (Lauriola et al., 2018). This is associated with an increased likelihood for hospitalisation, and a reduced quality of life for those affected (Marshall et al., 2016). It has long been known that people with dementia, hydration can affect their cognitive functioning making them more confused (Seymour et al., 1980). As dementia progresses people may not be able to communicate or experience the sensation of thirst. In dementia the sensation of thirst can become affected and putting a drink in front of someone may not be an adequate prompt to enable them to drink.

Part of effective dementia care is ensuring that people with dementia remain adequately hydrated. People with dementia often don't drink enough for a variety of reasons, such as not recognising that they are thirsty, a lack of co-ordination when trying to drink, or forgetting to drink (NHS, 2024). Poor hydration leads to other difficulties such as constipation, poor kidney functioning and low blood pressure which can all contribute to an underlying delirium and cause increased confusion and more distress for individuals with dementia. Delirium in individuals with dementia can have a poor prognosis and can result in an escalation of acute illness. Inadequate hydration can prevent optimisation which can lead to longer hospital stays which it is well documented is not therapeutic for a person with dementia and can result in poor outcomes.

The burden to support hydration falls on carers (paid and unpaid) by prompting and setting reminders, however this is not always effective. There is an added issue of a lack of valid predictors for dehydration in those with dementia, therefore the need to find strategies to boost hydration is hugely important for this population (Marshall et al., 2016). This acceptability and feasibility study is proposed to explore the feasibility of a novel confectionary: Jelly Drops™, which was specifically designed to support hydration in those with dementia (<https://www.jellydrops.com/>).

2.1. Patient and Stakeholder perspectives

AQUA: An open label Acceptability and feasibility trial of 'Jelly Drops™' for hydration and **QUALITY** of care for people with dementia



The community we serve has the same needs as those described in the national and international literature. There are anxiety-provoking, practical issues described by familial care givers supporting those with hydration to stay hydrated whilst living at home in our community:

"Sometimes she forgets to drink so we have to set regular reminders, which is a worry for us trying to remember and check that we've done it. Strangely, her appetite is still there, and she doesn't forget to eat. Sometimes it's not forgetting to drink but it is a conscious decision not to, due to frailty and the consequences of drinking too much liquid and not being able to get to the toilet in time. It would help her and us if we could find some other options to help with this" (Family member of someone living with Dementia, Doncaster)

There is also support for the potential of a hydrating agent in the form of confectionary, such as Jelly Drops™:

"My relative always had issues with not drinking enough but when she got dementia it became a real concern while she was still living independently. She loved sweets however and I think this would have been something that could have helped her stay hydrated in between family/carer visits" (Family member of someone living with Dementia, Rotherham)

Likewise, there are known issues described by clinicians working within Rotherham Doncaster and South Humber Trust services to the extent that fluid is prescribed for some people living with dementia in our inpatient wards:

"I am aware that for patients with dementia, hydration and nutrition can remain a challenge for an individual and their carers, and families. The impact on nutrition and hydration impacts both ones physical and mental health. This study will help shine light on an area that matters to individuals and families in our communities" (Consultant Psychiatrist, RDaSH NHS Foundation Trust's Older adult services, North Lincs)

"When attempting to improve hydration we use different techniques including different coloured cups and avoiding water in clear cups due to perception difficulties. Adequate hydration can be measured by staff without invasive interventions such as testing skin elasticity. Fluids chart are maintained on the ward to ensure adequate intake. For RDaSH patients we are unable to medically treat poor renal functioning secondary to dehydration, and this can result in admission to the acute ward which can be distressing for individuals with dementia, cause confusion and environmental delirium. 'Availability of the Jelly Drops through this study would enable ward staff to use novel ways of ensuring that patients remain hydrated and the physical health optimised. Use of the drops will divert away from an individual's usual method of hydration which can be complex and difficult to maintain. It can be difficult to encourage someone with dementia to drink if they are actively objecting even with persuasion. The Jelly Drops would provide alternative means of hydration that may be more accepted and accessible for individuals" (Nurse Consultant, RDaSH NHS Foundation Trust's Older adult services, Doncaster)

This piece of work will help build knowledge and skills within individuals and could lead to a larger trial to look at testing the effectiveness of an intervention that may improve the care of those with dementia.

3. AIM AND OBJECTIVES

AQUA: An open label **A**ceptability and feasibility trial of 'Jelly Drops™' for hydration and **Q**uality of care for people with dementia



The aim of conducting this study is to explore whether a) Jelly Drops™ is an acceptable intervention to patients and their families as a means to support hydration and b) it is feasible to collect all the data required to effectively test the intervention as a means of hydration in a future randomised controlled trial. The intervention of Jelly Drops™ would be administered 'open label', where participants will know exactly what they are receiving, with no comparator (known as a placebo). This study will measure both the feasibility and acceptability of giving Jelly Drops™ to patients to boost their hydration levels. This is because it is important to understand patient, carer and professionals' views on providing these to patients, to help design and deliver a definitive trial to measure efficacy of increasing hydration in from a larger sample of patients. Their views will help shape the finer details and design of a future trial.

The acceptability of providing Jelly Drops™ will be measured through:

- i. Calculating the proportion of participants consented from the total screened or approached to take part.
- ii. Calculating the proportion of participants retained throughout the duration of the study (e.g. some participants may ask to be withdrawn after they taste the Jelly Drops™).
- iii. Collecting the views of participants (patients), carers (family members) or professionals on the value and benefits of providing Jelly Drops™. This will be collected through semi-structured interviews with questions on key aspects such as taste, feel, ease of use, ability to incorporate within daily life and service provision.
- iv. Collecting and analysing the data on patient food consumption (photographs pre and post-meal consumption) collected from the point they are recruited to the study for 24-hours post consumption of the Jelly Drops™.

The potential for future testing of the efficacy of Jelly Drops™ as a means of hydration will be measured through the feasibility of collecting data related to effectiveness on hydration, such as kidney function and fluid balance data. Also, the feasibility of accessing the following data collected through routine clinical care:

- i. Physiological measures of hydration status of individuals, assessed via:
 - a) Blood sample analysis, e.g. sodium concentration
 - b) Subjectively measured fluid intake and bowel frequency data (e.g. monitored by members of the clinical or study team in parallel for the time period whilst Jelly Drops™ are being consumed (all participants)).

3.1 Nested qualitative arm

A part of the feasibility and acceptability of the study is to explore whether the proposed intervention to improve hydration improves the quality of care provided to patients with dementia who are dehydrated. The views of key stakeholders, such as familial carers of patients, patients who can provide informed consent and healthcare professionals will be sought on key aspects of providing Jelly Drops™ as a means of hydration, such as ease of use, sensory and taste factors and any benefits or concerns around consuming them.

AQUA: An open label **A**ceptability and feasibility trial of 'Jelly Drops™' for hydration and **Q**UALity of care for people with dementia



Views will be sought via individual semi-structured interviews at a point during the study after the patient has been prescribed the Jelly Drops™. The interviews will be collected with an experienced member of the study team and the data collected will be analysed using reflective thematic analysis (Braun and Clarke, 2019).

4. RESEARCH METHODS

4.1 Study design

This is an open-label single arm trial of a novel intervention in addition to usual care for all patients. The use of a single arm trial is warranted in circumstances where a novel treatment without a matched control is being piloted and/or where it would be unethical to deprive individuals of a treatment that may be beneficial (Wang et al., 2025).

This trial will be conducted as a feasibility and acceptability study and methodologically will be based on the framework conceptualised by Eldridge and colleagues (2016). The framework clarifies that the feasibility study is conducted to shape and inform the main RCT, which will examine the effectiveness of an intervention. Feasibility studies are mostly qualitative, with some descriptive quantitative data and are used to provide the necessary assurance that the protocol for the trial should 'work' (Eldridge et al., 2016).

4.2 Sample

This study is assessing the feasibility of providing Jelly Drops™ to patients on an inpatient ward treating older adults with dementia or other mental health issues. The population where the study sample will be drawn are individuals who receive usual care within an NHS inpatient ward, where dehydration is a known issue. The trial methodology of an open-label single arm trial has been chosen for this study because Jelly Drops™ is a novel product that is being tested in addition to usual care and because it would be unethical to provide a control arm who would not benefit from this intervention where there could be significant benefit to health and wellbeing of the patients who may participate.

As this study has a nested qualitative arm, participants will fall into three categories:

- 1) NHS patients who have capacity, who will receive Jelly Drops™ and can consent to interviews.
- 2) Familial carers or appropriate nominated professionals (in the event that the patient has no family or carers) who can act as consultees for patients who do not have capacity and can take part in interviews.
- 3) Healthcare professionals working with patients who have received Jelly Drops™ who can take part in interviews

Participants for the study will be residing in England and will be recruited purposively via Rotherham, Doncaster and South Humber (RDaSH) NHS Foundation Trust's clinical services.

4.3 Recruitment

AQUA: An open label Acceptability and feasibility trial of 'Jelly Drops™' for hydration and **QUALITY** of care for people with dementia



4.3.1 Overview of the main feasibility study of patients who will receive the Jelly Drops™

Potential participants will be patients within RDaSH NHS Trust's older adult inpatient wards who will be identified by clinical health professionals who provide care for these patients on a daily basis and who are also part of the study team. Healthcare professionals in the clinical team will receive 60 minutes of training on the study protocol and other documents from members of the research team in order to recruit to the study. The health professionals will provide copies of study promotional materials, such as a flyer/poster or study invitation leaflet either to the individuals if they deem them to have capacity, or to a member of their family if they do not.

Any potential participant, or a member of their family, or appropriate nominated professional who could act as a consultee for someone who lacks capacity to provide informed consent, that expresses an interest in the study, will be provided with a copy of the Participant Information Sheet (PIS). The content of the study promotional materials and Participant Information Sheet (PIS) will be explained by a health professional from the clinical service or the Grounded Research Team.

4.3.2. Nested qualitative arm

Recruitment of participants to the qualitative interview phase of the study will take place via direct liaison with the clinical team in the case of patients and carers and from within the team in the case of healthcare professionals. The invitation information will be delivered verbally by a member of the study team or the clinical team. A Participant Information Sheet (PIS) will be issued to anyone expressing an interest on their own behalf or on behalf of their family member for patients that cannot provide informed consent. Separate versions of the consent form will also be developed; one for patients who have capacity to consent for the main study and one for family members who will be consenting on behalf of the patient for the main study, one for participants taking part in the nested qualitative study. The Chief Investigator (KW) and the Principal Investigator (JN) will be listed as points of contact for anyone wishing to know more about the study prior to registering their interest.

4.3.3 Both arms of the study

All interested individuals will be screened against the inclusion/exclusion criteria and will be asked to provide informed consent for their participation, or for the participation of their family member in the case of patients who are lacking the capacity to provide informed consent.

There will be different versions of the consent form produced, as follows:

- 1) Patients to the main feasibility study who can provide informed consent
- 2) Patients to the main feasibility study where consent will be given by a family member
- 3) Patients, carers or healthcare professionals who consent to participate in the nested qualitative interview phase

4.4 Sample size

AQUA: An open label **A**ceptability and feasibility trial of 'Jelly Drops™' for hydration and **Q**UALity of care for people with dementia



The outcome of this trial is not to detect an effect size of the new treatment, as this is a feasibility and acceptability study. The overall participation rate will be dependent upon multiple factors, mostly the admission of patients to clinical services, which is variable.

Smaller sample sizes are sufficient for evaluating feasibility and acceptability of interventions with a median of 30 participants being sufficient (Totton et al., 2023).

We intend to recruit over a period of 6 months. During this time, it is anticipated that up to 50 participants will be screened for eligibility to participate, with all eligible participants being invited to take part in the main study arm. Using a conservative estimate we expect 40% of the people screened to take part in the intervention which equates to 20 participants. Based on the work of Malterud et al 2016 we anticipate approximately 12 people to take part in the interviews. In total we aim to recruit 32 participants across the intervention and interview sections of the study.

4.5 Inclusion and exclusion criteria

Participants will be eligible for inclusion in the intervention arm if they are:

- 1) aged 16 years or older (inclusive) on the day of consent
- 2) Either
 - a. A diagnosis of dementia and be undergoing NHS care on an inpatient ward within the NHS Trust
 - b. A family member of someone with dementia who has been prescribed Jelly Drops™ as part of the study and can act as consultee or an appropriate nominated professional who can act as consultee in the absence of any family or carers.
 - c. A healthcare professional providing care for those with dementia

Participants will be eligible for inclusion in the qualitative interview arm if they are

- 1) aged 16 years or older (inclusive) on the day of consent
- 2) Either
 - a. A diagnosis of dementia and be undergoing NHS care on an inpatient ward within the NHS Trust
 - b. A family member of someone with dementia who has been prescribed Jelly Drops™ as part of the study.
 - c. A healthcare professional providing care for those with dementia

Participants will not be eligible for inclusion in the intervention arm if they are

- 1) Unable to read and understand the consent form in order to provide informed consent to participate in the study. (with the exception of participants who have an appropriate consultee or those for whom translation or interpreter adaptations are available as would be used in usual care)
- 2) Known to have swallowing difficulties
- 3) If there is any other medication or safety issue identified by the clinical team, or due to the potential burden of sample collection

Participants will not be eligible for inclusion in the qualitative interview arm if they are

- 1) Unable to read and understand the consent form in order to provide informed consent to participate in the study. (with the exception of participants who have an appropriate

AQUA: An open label **A**ceptability and feasibility trial of 'Jelly Drops™' for hydration and **Q**uality of care for people with dementia



consultee or those for whom translation or interpreter adaptations are available as would be used in usual care)

A screening record will be developed and maintained for the study to help check potential participants for their eligibility and to provide a record of the proportion of eligible participants from the total sample and the proportion of eligible participants who enrol on the study.

4.6 The Intervention

4.6.1 Provision of Jelly Drops™

4.6.1.1 Prescribed to patients by Nurse Consultant/Principal Investigator (PI)

For the purposes of this study the provision of Jelly Drops™ to patients will be managed through a prescription issued by the Principal Investigator (JN) who is a Nurse Consultant. No healthcare professional will provide Jelly Drops™ on an ad hoc basis. The administration of Jelly Drops™ will only be to patients who are enrolled on the study and only via a prescription.

4.6.1.2. Adjunctive treatment

Jelly Drops™, for the purposes of the study, will not replace any aspect of usual care. Healthcare professionals will continue to advocate and encourage drinking of fluids throughout the duration of the study and fluids will still be prescribed to patients, as part of treatment as usual.

4.6.1.3. Recorded in notes

A note will be put onto the patients care record once a patient has been consented to take part in the study. Likewise, all prescriptions for Jelly Drops™ will also be added to the patient's care record and will be added to their discharge summary. A letter noting their participation will be sent to their General Practitioner (GP).

4.6.2 Facilitation and support for Jelly Drops™ consumption

The intervention (provision of Jelly Drops™) will be prescribed by the Principal Investigator to eligible patients three to four times per day whilst they are staying on the inpatient ward. The PI will have checked the medical notes for eligibility, including any swallowing issues.

Once prescribed, Jelly Drops™ will be dispensed to the patient by an appropriately qualified healthcare professional for 7 days following which a further blood sample will be taken.

Whilst patients are consuming the Jelly Drops™ they will be under the supervision of healthcare professionals who are providing care to the patients who will monitor a) volume of Jelly Drops™ consumed and b) any issues that may arise, such as concerns. Opened Jelly Drops™ will be swapped for fresh ones if not consumed within a set period of time in line with manufacturers

AQUA: An open label **A**ceptability and feasibility trial of 'Jelly Drops™' for hydration and **Q**UALity of care for people with dementia



recommendation and printed on the side of each pot, and as their consumption is continually monitored the study team will be aware of whether any Jelly Drops™ have been left in participant bedrooms, given away or otherwise disposed of by participants.

4.7 Data Collection

This is a feasibility and acceptability study to test how feasible it is to recruit and retain participants to the study and how feasible it is to collect necessary study data. These are outlined as follows:

- 1) Measure the Feasibility and acceptability of the intervention to patients
 - a. Feasibility of recruitment processes for patients
 - i. At the point of admission onto the ward where the clinical team would deem that they are suffering from dehydration and would be instigating a protocol to improve hydration (usual clinical care). This includes prescription of water and fluid balance charts.
 - ii. Experiencing acute dehydration whilst staying on the ward
 - b. Feasibility of collecting the following measures, or for accessing the data for measures collected as part of routine care (which are points i, ii, iii, iv) for patients on the two pathways above:
 - i. Clinical blood sample collection at baseline and one follow up point 7-9 days after the participant began the intervention
 - ii. Measurement of urea and electrolytes
 - iii. Measurement of fluid balance (Urine input v output)
 - iv. Bowel frequency monitoring over 24-hour period
 - v. Dietary intake (photographed plates pre and post consumption) of patients who are consuming Jelly Drops™ in parallel with consumption of Jelly Drops™
 - vi. Nutritional status (calculated using photographs of meals), calculated using appropriate dietary analysis software: Nutritics™
 - vii. Intake and total consumption of Jelly Drops™ as prescribed by the Principal Investigator (followed by Clinical Bloods)
 - viii. The service-level impact on additional hydration support (e.g. variance in admissions to DRI for acute dehydration)
- 2) Feasibility and acceptability of the intervention to familial carers
 - a. Feasibility of recruitment processes for carers of patients engaged in the intervention
 - b. Views of familial carers on
 - i. Their experience of supporting their family member through the intervention
 - ii. Their views on the impact of Jelly Drops™
 - iii. Their views on the potential to administer Jelly Drops™

AQUA: An open label **A**ceptability and feasibility trial of 'Jelly Drops™' for hydration and **Q**uality of care for people with dementia



- 3) Feasibility and acceptability of the intervention to healthcare professionals supporting patients and their families
 - a. Feasibility of recruitment processes for healthcare professionals supporting patients and their families with the Jelly Drops™ intervention
 - b. Views of healthcare professionals on the impact of Jelly Drops™ on patients and their families
- 4) The feasibility of developing a 'prescribing' pathway for the implementation of Jelly Drops™ for patients with
 - a. Acute dehydration
 - b. Chronic dehydration

**Baseline denotes at the point where the intervention is being initiated*

4.7.1 Outcome measurement

The primary outcomes include the acceptability of the proposed intervention, the feasibility of recruitment and measurement and the adherence to the intervention. The secondary outcomes are provided to present some preliminary data on the outcomes of interest for the intervention, e.g. the impact of Jelly Drops™ on hydration status.

A summary of the data collection strategy is provided in Table 1 below.

Measure	Data source	Usual care or Research measure	Primary Outcome(s)	Secondary Outcome
Biological and clinician-assessed measures of hydration	i. Results of venous blood sample; Full blood count, C-Reactive protein, and Urea and Electrolytes which will test for urea, sodium, creatinine and potassium, used to calculate estimated glomerular filtration rate. These will help measure hydration status ii. Results of clinician scored skin integrity test iii. Results of fluid balance measurement chart	Usual care	Access to all relevant data within clinical record	Comparison of Standard result dataset post-baseline including: Kidney function data (from venous blood sample); Skin integrity score; Fluid input and urine output data (ml); Bowel frequency data (number of movements)

AQUA: An open label **A**ceptability and feasibility trial of 'Jelly Drops™' for hydration and **Q**uality of care for people with dementia



	iv.Results of the bowel frequency chart			
Recruitment of potential participants (patients) to the interventional study	Percentage recruitment to the study	Research	Proportion of participants recruited from eligible population	Proportion of participants who withdraw from the study
Consumption of Jelly Drops™	Observed consumption as volume of Jelly Drops™	Research	Volume (grams) of Jelly Drops™ consumed per patient to optimise hydration per dehydration episode	Time taken (number of hours Jelly Drops™ are consumed) to optimise hydration following Jelly Drops™ consumption per dehydration episode
Views on the consumption of Jelly Drops™	Interviews	Research	Qualitative, semi-structured interview data on the consumption of Jelly Drops™	Views of acceptability of Jelly Drops™ to patients, family members and healthcare professionals
Potential impact on diet and nutritional status whilst consuming Jelly Drops™	Diet monitoring by health professionals via analysis of photographs of meals pre and post consumption following the method of (Oldknow et al. 2019)	Research	Ability to ascertain nutritional data for patients whilst consuming Jelly Drops™	Nutrition and diet quality dataset post-baseline of: Total weight of food consumed per day Total weight of different foods consumed per day Nutritional quality of diet
Missing data	All sources	Research	Proportion of data field incomplete	

Table 1: Summary of data sources and data measurement

4.7.1 Access to clinical records

One of the outcomes being assessed is the ability to extract relevant care procedure assessment data conducted during routine care from the clinical record.

4.7.2 Measuring the consumption of Jelly Drops™

AQUA: An open label **A**ceptability and feasibility trial of 'Jelly Drops™' for hydration and **Q**uality of care for people with dementia



The Jelly Drops™ will be provided via a prescription to participants and will be administered and monitored by a member of the healthcare team. They will be consumed by participants under direct supervision by a member of the Healthcare team. A new, sealed pot containing a known weight of Jelly Drops™ will be issued to each patient, which has a known weight (grams) and each pot will be returned at the end of a two-hour period and will be weighed. These weights (grams) will be recorded in the clinical record, alongside a log of the flavour of Jelly Drops™ consumed, who provided it and date and time of the consumption period. This will allow for the calculation of total volume consumed by each participant per dehydration episode.

4.7.3 Measuring the views of participants, participants' families and healthcare workers on the use of Jelly Drops™ for hydration

A series of semi-structured interviews will be conducted to seek the views of study personnel, participants and participants' family members. The discussion will be guided by a topic guide.

4.7.4 Measuring the impact of Jelly Drops™ consumption on diet quality and nutritional status

The measurement of diet quality and nutritional status has previously been reported Oldknow et al. (2019). In summary, all meals, snacks and beverages of each participant will be weighed once plated pre and post consumption, and photographs will be taken pre and post consumption. The analysis of the nutritional content of the foods and beverages consumed will be overseen by a Registered Nutritionist (KW) using dietary analysis software called Nutritics®, which will analyse the dietary data to produce a nutrient profile detailing the nutritional status for each participant.

4.7.5 Study end

The end of the study will be the date that the last interview is conducted. The final interview for the study will not be conducted until all research procedures have been completed with the last participant recruited to receive Jelly Drops.

4.8 Data management Plan

4.8.1 Personally identifiable data

4.8.1.1 Contact details

The only personally identifiable data that will be collected for the purposes of inclusion in the research project will be the participant's contact details (patients, carers and health professionals), e.g. their name, telephone number or email and NHS patient number. This information will be stored securely by the clinical Principal Investigator (JN) on a server located behind the NHS firewall. There will be no paper records of contact details generated.

4.8.1.2 Consent forms

AQUA: An open label **A**ceptability and feasibility trial of 'Jelly Drops™' for hydration and **Q**UALity of care for people with dementia



Paper copies of the consent forms will be scanned, and an electronic copy will be stored securely on an NHS server located behind the NHS firewall and a copy will be uploaded onto the patient's NHS patient record. The paper copies will be stored as part of the patient record and a copy will be saved in the Trial Master File, held by the Research Team.

4.8.2 Medical records

Medical records will be accessed for patients online and will be populated to a) indicate that a person is undertaking the study and b) make clinical notes of relevance related to the study. This will be done by a member of the clinical team who is also a part of the study team. Any professional accessing the medical records will have the delegated authority to do so.

4.8.3 Descriptive data

The research team will create a password protected excel database to record data in, access to this will be limited to clinical and research staff working on the study and noted in the delegation log. This will be stored on the L drive. All data analysis will be conducted from this database by delegated staff, and the database will not be transferred anywhere else. All summary data, e.g. percentage recruitment of sample or percentage attrition rate, will be logged in this database and stored securely on an NHS server.

4.8.4 Interview data collection

All interviews will be conducted face-to-face and will be audio recorded using an encrypted digital recording device or directly via an MS Teams link running on a secure, encrypted laptop in the room, all following informed consent. These audio files will be transferred to an NHS secure server as soon as is possible and deleted from the recorder, where appropriate.

Interview files will be transcribed by a member of the research team or by an approved transcription company, such as 1st Class Secretarial. All participants are likely to consent to the use of audio recording, however if some would rather not be recorded, then the interviewer can make notes.

Participants will not have to give their name as part of the audio recorded interview. Any direct quotation from the interview data will be made with a pseudonym and no trace will be made of their identity. The pseudonymised transcripts will be copied onto the NHS server.

4.9 Data analysis

4.9.1 Descriptive data

The quantitative data will be analysed using excel and will be used to produce descriptive statistics, e.g. percentages.

Clinical measures will be used to present descriptive data and trends; this will allow us to see whether there would be value in including these in a larger trial.

AQUA: An open label Acceptability and feasibility trial of 'Jelly Drops™' for hydration and **QUALITY** of care for people with dementia



The study will not provide enough data to test the effect of the intervention on hydration; however, it will help to inform a future study in terms of dosing. It will also inform the power calculation needed to test the effect in the future.

4.9.2 Interview data

The transcripts produced from the interviews will be analysed using thematic analysis (Braun and Clarke, 2019). A 'theme' is a descriptor that captures something from the data that is relevant to the research question (Braun and Clarke, 2006). In line with Braun and Clarke's recommendation (2006), an inductive approach to coding and analysing the data has been chosen for this study, because there is little prior evidence published on this topic to give the researcher preconceptions to support a theoretical analysis approach.

The process of reflective thematic analysis within each group will be guided by Braun and Clarke's widely cited six step guide (2006). The first step is familiarisation with the data, through repeated reading, to facilitate the search for 'patterns' or 'themes'. The researcher will list the most interesting facets of the data, from which 'codes' will be generated (step 2), which will be counted and collated (step 3) and then refined into 'themes' (step 4). Following this, the themes will be constructed (step 5) ready for reporting and discussing (step 6).

Data analysis may be supported by NVivo, a qualitative data analysis software programme (QSR International Pty Ltd. Version 12, 2018). This programme provides electronic facilitation for data handling and coding, which is useful to large datasets.

Both quantitative and qualitative data findings will be developed into a narrative synthesis.

4.10 Monitoring

The study will be subject to internal monitoring by Rotherham Doncaster and South Humber (RDaSH) NHS Foundation Trust as sponsor.

5. DISSEMINATION AND PROJECTED OUTPUTS

5.1 Local (RDaSH) dissemination

The findings will be written as a report and submitted to the RDaSH NHS Foundation Trust's Research and Innovation Group and via local dementia charities and groups.

5.2. National dissemination (Journals)

The findings will be reported in an academic paper. Authorship guidelines will follow the International Committee of Medical Journal Editors (ICMJE) Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals (2015).

5.3. Dissemination to study participants

AQUA: An open label Acceptability and feasibility trial of 'Jelly Drops™' for hydration and **QUALITY** of care for people with dementia



Participants will be asked in the consent form if they wish to receive the results of the study. If they request this then results will be shared with them once the study is complete.

5.4 Project outcomes and impact

If this study is deemed feasible and acceptable then the outcomes will be used to develop a programme grant award to support delivery of a fully powered Randomised Controlled Trial (RCT).

5.4.1 Progression criteria and plans for a definitive trial

The progression decision for this feasibility study will require consideration of both objective quantifiable measures of feasibility and key subjective qualitative markers of acceptability. The objective progression criteria relating to feasibility will be categorised using a traffic light system, as outlined in Table 2 below.

Criterion	Red	Amber	Green	Comment
Recruitment rate	0-29%	30-49%	50%+	Based on prior experience of engagement with those who have mental ill health, we estimate 50% consented.
Completion of intervention	0-29%	30-49%	50%+	Based on prior experiences of retention to studies focussing on dementia, we aim for 50% who engage in the intervention
Completion of outcome measures	0-29%	30-49%	50%+	Another key milestone for the collection of survey data and success would equate to at least 50% of all outcome measures completed in their entirety.

Table 2: Measures of success of feasibility and acceptability

6. STUDY TIMETABLE

Month	Task
December 2024 to December 2025	Prepare study documents, e.g. protocol, Participant information sheet (PIS) and consent form. Apply for NREC/HRA approval
December 2025 to March 2026	Obtain NREC/HRA approval
March 2026 to August 2026	Recruitment of participants
March 2026 to October 2026	Delivery of Intervention and Data Collection
March 2026 to February 2027	Data analysis
February 2027 to September 2027	Write up results and Prepare journal publication and conference presentation

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December 2025 to February 2028	Prepare and submit further funding application(s)
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7. PROJECT MANAGEMENT

7.1 Personnel

Oversight and responsibility for study will be provided by Dr Kevin Williamson, Chief Investigator and Jo Nicholls, Principal Investigator (PI). The study will be conducted by the study team comprising members of the clinical team and the Grounded Research team.

7.2 Management

The Chief Investigator will be responsible for the overall leadership, management and outputs of the programme. Regular, e.g. monthly research management and supervision meetings will be convened to ensure achievement against specific milestones and compliance with ethics and governance. Day to day responsibility for the study in the clinical ward will be with the Principal Investigator.

8. ETHICS AND GOVERNANCE

8.1 Research ethics committee review

Approval for the study will be sought from the Health Research Authority (HRA) with an ethical opinion from the NREC. This study will be conducted in compliance with the study protocol and University regulatory and monitoring requirements. The team have considerable expertise in conducting ethical research in mental health service settings. The key ethical concerns are confidentiality and the duty to report, informed consent to participate in research, particularly as some patients will not be capacitous to provide informed consent for the study and will require a family member to consent on their behalf and the potential for participant distress. Research governance principles and ethical committee approvals bind all applicants.

8.2 Possible risks and anticipated benefits for research participants and society

8.2.1 Research participants

The potential benefit of this study is that if the findings are positive then this intervention could form a standard part of the treatment of NHS patients with dehydration who have been admitted to NHS inpatient services for dementia or mental health treatment.

There is a risk that some participants may have difficulty swallowing the Jelly Drops™, however this is a very small risk, as all potential participants will be screened for known swallowing difficulties as part of the eligibility and suitability assessment prior to recruitment into the study. The risk to

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patients from a swallowing difficulty will be managed through direct observation of patients by a member of the healthcare team whilst they consume the Jelly Drops™. In the unlikely event that an individual does experience a swallowing difficulty, then the healthcare professional who is monitoring the patient is trained in first aid and will act according to NHS policies and procedures, as required.

There is the risk to the participant of distress caused by questions asked during the interview as it may lead participants to recall memories from their experience of being unwell (see section 8.4 in this document for further information). Interview participants will also be provided with a debrief sheet following the interview which thanks them for their participation and advises them of local support services they can contact if they feel they need further support.

There is the risk that a participant may lose capacity to consent during the study, as the study is ward based staff will be monitoring patients throughout. In accordance with the Mental Capacity Act 2005, in this event a personal consultee will be appointed. If no one is available to be a personal consultee a nominated consultee will be appointed. Staff will then seek advice from the consultee regarding the participant's continued involvement and their likely wishes and feelings moving forwards.

8.2.2 Researchers

No risks have been identified to the researchers associated with involvement in the study.

8.3 Confidentiality and the duty to report

Participants may be concerned about their anonymity and the confidentiality of the information they articulate or discuss within an interview, which may adversely affect the data collected during the interviews. Detailed participant information sheets and a copy of the consent form will therefore be provided to participants prior to interviews.

With any research around healthcare there may be disclosures made that the research team have a duty to report. This is defined by guidance issued by the World Health Organisation (WHO) (Kalra et al., 2013) as information about an imminent error or action that could result in severe and irreversible harm and that intervention from the research team may prevent or limit this harm. Or that if an incident has already occurred, intervention may reverse the effects. This is thought to be a low risk during the proposed interviews, and the Principal Investigator will escalate any such issues to their supervisory team as a matter of urgency. This is covered in the Participant Information Sheet. In the event of an incident detailed contemporaneous notes will be made.

8.4 Participant distress

8.4.1 Consumption of Jelly Drops™

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Participants may experience distress if they have an adverse reaction whilst consuming the Jelly Drops™, however the risk of this will be very low. As participants consuming Jelly Drops™ will be receiving 24-hour care as residents on an inpatient ward. If they do experience distress then a member of the healthcare team, who are present 24 hours per day, will be trained and experienced at supporting patients who are experiencing distress.

8.4.2 Nested qualitative interviews

Many people enjoy being interviewed, although there is also always a risk that people may become distressed when discussing personal experiences. As a result, the research has an interview distress policy to ensure that participants are supported both during and after participation, if this should become necessary. The interviewer is sensitive to these issues and is experienced at supporting people experiencing distress. Interview participants will also be provided with a debrief sheet following the interview which thanks them for their participation and advises them of local support services they can contact if they feel they need further support. Sources of support have also been outlined in the PIS.

8.5 Informing potential participants of possible risks and anticipated benefits

All potential participants will be provided with a participant information sheet (PIS) written to current HRA guidelines prior to the study commencing. The PIS will be given to potential participants when they are invited to take part in the study. It will provide potential participants with information about the study, including the potential benefits and risks of taking part as described above. Researchers contact details are provided so participants can contact them with any queries prior to deciding to take part. Members of the research team will further discuss risks and benefits immediately prior to the interview taking place.

8.6 Declaration of interest

The study team members are employees of RDaSH NHS Foundation Trust (the recruitment site for participants to this study).

Jelly Drops™ have supplied product for the duration of the study free of charge.

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