This protocol has regard for the HRA guidance and order of content

FULL/LONG TITLE OF THE STUDY

A prospective observational study to assess compliance and palatability of fortified porridge compared to standard liquid-based oral nutritional supplementation in hospitalised older adults with malnutrition

SHORT STUDY TITLE / ACRONYM

The RELISH study

PROTOCOL VERSION NUMBER AND DATE

Version 1.1 31/05/24

RESEARCH REFERENCE NUMBERS

IRAS Number: 316234

SPONSORS Number: RHM MED1921

FUNDERS Number: Internally funded via the UHS Commercial Team

ClinicalTrials.Gov Number: Waiting for record to be approved and released

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:

.....

Date:
...../...../.....

Name (please print):

.....

Position:

.....

Chief Investigator:

Signature: 

.....

Date:
31/05/2024

Name: (please print): Dr Stephen Lim

.....

LIST of CONTENTS

KEY STUDY CONTACTS

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STUDY SUMMARY

Study Title	Compliance and palatability of fortified porridge compared to standard liquid-based oral nutritional supplementation in hospitalised older adults with malnutrition
Internal ref. no. (or short title)	ONS Compliance and Palatability
Background	22% of hospitalised older adults are estimated to be in a state of malnutrition. Malnutrition, also known as undernutrition, is a lack of nutritional intake leading to decreased fat free mass and diminished physiological functioning. Malnutrition impairs patient recovery, increasing hospital length of stay and escalating healthcare costs. Therefore, the identification and management of malnutrition is a vital patient-centred outcome to enhance older adult's health and quality of life and to enable cost-effective treatment and care. A key method to support individualised nutritional care of hospital in-patients is the use of oral nutritional supplementation (ONS). ONS are energy and nutrient dense products designed to increase dietary intake when diet alone is insufficient to meet daily nutritional requirements. Overall, research suggests favourable impacts of ONS on nutritional status and healthcare costs, while the impact on functional outcomes and mortality are more controversial. A burgeoning evidence base attests to the importance of considering acceptability and compliance of ONS on adequate intake and thus effectiveness of ONS in practice. Patient compliance to ONS considers the relationship between the amount of ONS prescribed and the amount of ONS ingested and is important to maximise clinical and cost-effectiveness. Palatability refers to the hedonic (i.e., pleasantness) evaluation of sensory factors, such as taste and

	smell, leading to alterations in food or fluid consumption. Supplemental preference may be affected by a multitude of factors such as taste, colour, smell, after taste and texture. Typically, hospital patients are offered liquid based ONS (sip feeds). However, previous research has pinpointed that 56% of older adults on geriatric wards did not like sip feeds. Hence, exploration of compliance to different ONS formats is an important research direction to maximise malnourished older adult's nutritional intake. Malnourished hospitalised older adults should be offered an improved range and provision of ONS to suit patient preferences and maximise intake. For instance, an attractive alternative strategy is the use of energy and protein-dense meals (via fortification) or snacks (supplementation), including fortified bread, protein-enriched main meals and between meal snacks, such as biscuits, yoghurt and ice cream. Yet this is an understudied area, with limited data investigating compliance to alternative ONS products compared to ready-made drinks in hospital, such as powdered ONS and snacks, or their clinical effectiveness. Therefore, the current study aimed to investigate the compliance and palatability of novel fortified porridge compared to traditional sip-feeds in malnourished hospitalised older adults.
Research Question/Aim(s)	1. What are the compliance rates (% intake) of fortified porridge compared to standard liquid based ONS in malnourished hospitalised older adults? 2. What are the palatability ratings (e.g., taste) of fortified porridge compared to standard liquid based ONS in malnourished hospitalised older adults? 3. What is the acceptability of fortified porridge compared to standard liquid based ONS in malnourished hospitalised older adults, including facilitators and barriers to their use on medical wards?
Study Design & Methods	A mixed methods randomised controlled crossover design will be conducted to determine compliance and palatability of fortified porridge in malnourished hospitalised older adults compared to a liquid-based control ONS. The acceptability of products will be assessed through qualitative interviews to explore patients and healthcare professionals' experiences and views of using the nutritional supplements. Participants will be prescribed ONS twice per day for 4 days, in addition to normal meals, in a crossover design. The products will be offered in-between breakfast and lunch, and after dinner to reduce the detrimental long period of calorie absence experienced overnight.
Study Participants	Patients on UHS acute medical wards aged ≥65 years with medium-high risk of malnutrition (MUST score 1-4) and who are able to provide written consent will be invited to participate in the study.

Planned Size of Sample (if applicable)	A sample size of 50 was chosen based upon guidance from previous literature investigating compliance and palatability of ONS. To explore acceptability, 15 interviews will be conducted among patients (N= 9) and health care professionals (N= 6) to share their thoughts on using the ONS products and to capture their views regarding implementation of ONS products on the wards.
Outcomes	Primary Outcome Measures: 1. Compliance to ONS will be assessed by the study team via careful documentation of ONS leftovers at 2 timepoints, including after lunch (for ONS given in the morning) and early morning the following day (for ONS given after dinner), to ensure enough time for consumption. Leftovers will be weighed (g) and documented. Compliance will be calculated as the percentage of the mean ONS consumed per day. Moreover, the mean intake of ONS energy (kcal/day) and protein (g/day) consumed per day will be calculated and an estimation of the percentage ingested. 2. Palatability ratings, including appearance, smell, taste, sweetness, texture, thickness, aftertaste, mouth feel, and overall likability will be assessed with a 7-point hedonic Likert scale (7 = definitely like, 6 = moderately like, 5 = mildly like, 4 = neither like nor dislike, 3 = mildly dislike, 2 = moderately dislike, 1 = definitely dislike). Secondary Outcome Measures: 1. Total energy intake will be assessed through completion of patient food charts, including estimated proportion of meals consumed. 2. Acceptability of ONS products will be explored with semi-structured interviews. The semi-structured interviews will consist of several key open-ended questions that help define the areas explored but allow the interviewer or interviewee to expand and diverge with the aim of pursuing or developing an idea with more depth.
Patient and Public Involvement	9 patients (5 male) aged 71-99 years on geriatric wards at UHS completed a pilot palatability survey to explore Adams Vital Nutrition Build & Restore fortified porridge. The majority of patients chose chocolate porridge over golden syrup (N= 8). Palatability was measured on a 10-point Likert scale (e.g., 0, not tasty at all to 10, very tasty). Patients had a mean taste rating of 7.22, consistency of 7.14 and appearance of 7.33.

	Three patients ate the whole portion, 3 ate half, and 3 ate less than half of the portion. Patients were also asked at what time of day they would prefer to eat the product. Four patients preferred to eat the product for breakfast, 1 as a mid-afternoon snack, 2 preferred the product in the evening, and 2 patients would eat the product at any time of day. This pilot helped to inform patient facing materials, data collection templates, and gave early indication regarding the palatability of the trial product. To help with further development of ONS flavours, a PPI survey was distributed to 25 older adults (age 86.23 ± 5.93 years; 56% female; 92% White British, 8% Indian) on UHS geriatric medical wards. We assessed patients' likability for porridge and porridge flavours using a 7-point Likert scale from 'definitely like' (7) to 'definitely dislike' (1). Analyses showed a median likability rating of 5 'mildly like' (IQR 3-6) for porridge with 60% circling a score in the 'like' section of the scale, 8% neither like nor dislike, and 32% circling scores in the 'dislike' section. Three participants explained they have difficulty swallowing, so even though porridge was not their favourite snack they would eat it as they can only manage soft foods. When asked 'what is your favourite type of snack to eat between meals?' most preferred fruit (n = 7, 28%), or biscuits (n = 6, 24%), and 16% preferred not to eat any snacks. The top three flavours of porridge that participants were most likely to eat were golden syrup (44% like, 8% neither like nor dislike, 48% dislike), strawberries and cream (32% like, 8% neither like nor dislike, 60% dislike), and apple and cinnamon (32% like, 8% neither like nor dislike, 60% dislike). Participants were asked 'when you make porridge for yourself what flavour do you prefer to eat?' Participants preferred neutral porridge with sugar, strawberry jam, or golden syrup added (n = 18, 72%). 1 public contributor provided input into this study proposal. They will be invited to join the study management group and be involved from development to dissemination of study findings.
Dissemination	Results will be shared with commissioning services, NHS staff, and service users, supported by our PPI partners. Results will also be shared via publication and conference presentations.
Planned Study Period	Start Date: 1st April 2024 End Date: 31st October 2024 Years: 0 Months: 7 Days: 0

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	FINANCIAL AND NON FINANCIALSUPPORT GIVEN
University Hospital Southampton NHS Foundation Trust Commercial Team, Southampton General Hospital Southampton SO16 6YD commercial@uhs.nhs.uk asa.thorpe@uhs.nhs.uk	Funding secured: £3,881.28 Duration: 7 months

ROLE OF STUDY SPONSOR AND FUNDER

The sponsor will take overall responsibility for proportionate, effective arrangements being in place to set up, run and report the research project. The study sponsor will review research protocols and study documents to ensure they meet regulatory requirements. The sponsor will also review IRAS forms before submission for ethical review and will monitor the conduct of the study, including any amendments that need to be made. The sponsor will review annual progress reports and will be involved in the 'close out' of the study.

Funding for this study is provided through the University Hospital Southampton NHS FT commercial team. The study funder reviewed the protocol before funding was secured to ensure the proposed project aligned with research portfolios within UHS clinical divisions, and/or the UHS/UoS research infrastructure. The funder has provided funding to cover the costs of the study, detailed below:

Summary of costs

Research Fellow	£3,881.28
Total	£3,881.28

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

The Chief Investigator (CI), Dr Stephen Lim is responsible for the overall conduct of the study. He has the primary responsibilities of planning and managing the project, ensuring that the project progresses according to schedule.

The Principle Investigator (PI), Dr Samantha Jane Meredith, will assist the CI in participant recruitment, data collection and data entry. Weekly meetings will be held with the CI and the research fellow to discuss the day to day running of the study. Monthly project management meetings will be held with the CI, RF and PPI lead to discuss the progress of the study and to monitor the conduct of the study.

Dr Harnish Patel is a Consultant Geriatrician with extensive experience in the clinical management of older people both within the acute and rehabilitation settings. He has a specialist interest in the recognition and management of frailty and is developing pathways within Southampton General

Hospital. His expertise will be key to the delivery of a robust nutrition intervention. His experience in conducting trials will ensure that the study will be conducted to a high standard.

Rebecca Picton is the lead dietitian for medicine for older people at University Hospital Southampton. Her expertise will support the development of a safe and effective ONS trial, including help in the steering of suitable ONS products used in the trial and appropriate for patient needs.

Pamela Holloway is the lead PPI representative involved in the management of the study from development to dissemination of study findings.

PROTOCOL CONTRIBUTORS

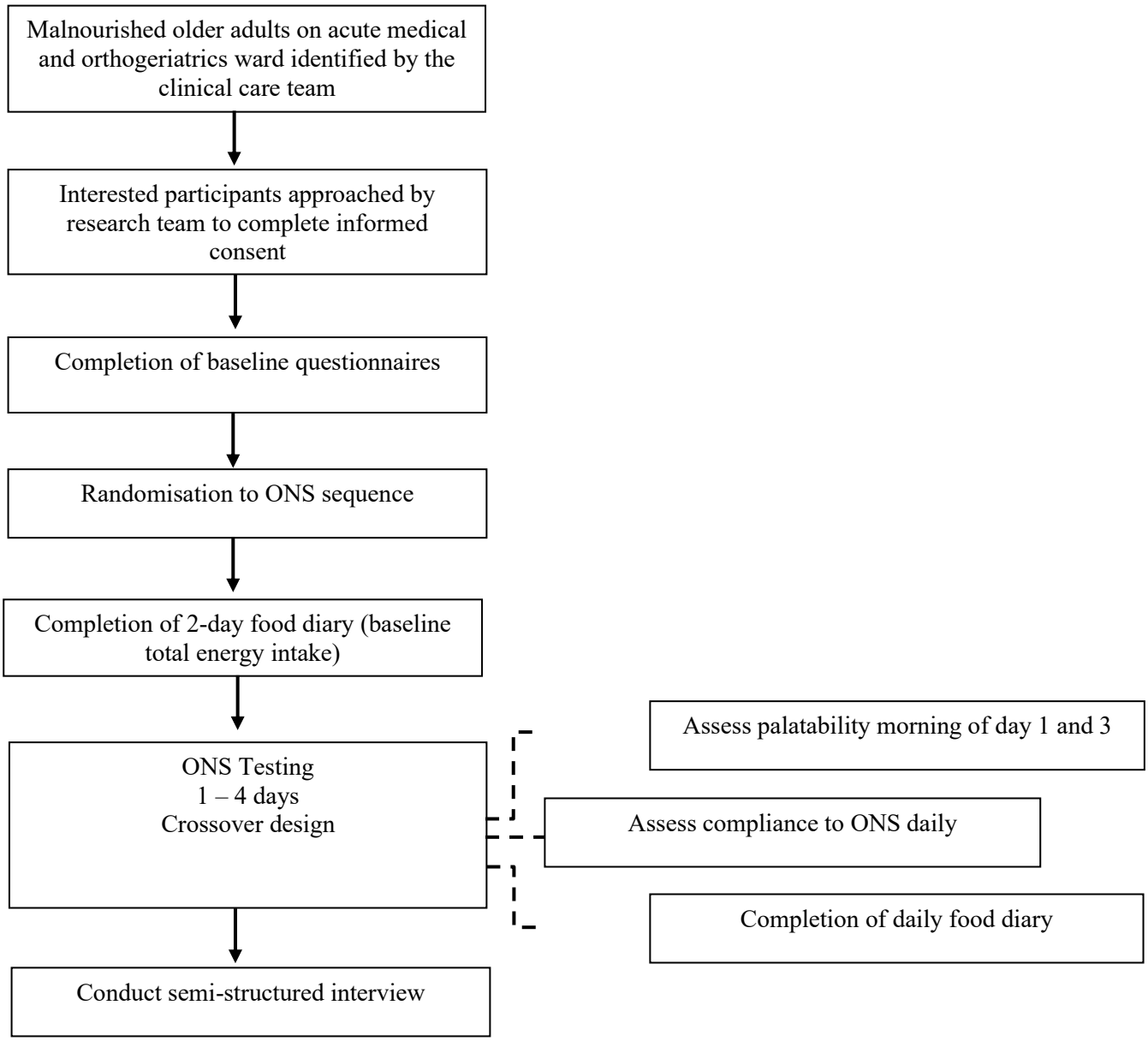
The current protocol has been developed and adapted from early pilot work, steering study procedures, and through consultation with geriatric consultants and lead dieticians at UHS. Public representatives have been involved in the design of the study and will critique any patient-facing resources, such as participant information sheets, consent forms and interview schedules.

The study sponsor (UHS) and funders were not directly involved in the design of this study. They will review research protocols and study documents to ensure they meet regulatory requirements. This provides the R&D Office with information on the considerations which have been made in the development of the protocol in a number of areas to help assess the level of risk to the Trust and how this can be mitigated. The sponsor will also review IRAS forms before submission for ethical review and will monitor the conduct of the study, including any amendments that need to be made. The sponsor will review annual progress reports and will be involved in the 'close out' of the study.

The study funder reviewed the protocol before funding was secured in order to ensure the proposed project aligned with research portfolios within UHS clinical divisions, and/or the UHS/UoS research infrastructure.

KEY WORDS: Malnutrition; older adults; oral nutritional supplement; compliance; palatability

STUDY FLOW CHART (Figure 1)



STUDY PROTOCOL

Compliance and palatability of fortified porridge compared to standard liquid-based ONS in hospitalised older adults with malnutrition.

1 BACKGROUND AND RATIONALE

Adequate nutritional intake is an important lifestyle factor and clinical consideration to maintain and maximise health and well-being in older people [1]. However, 1.3 million older people are malnourished in the UK, and 22% of hospitalised older adults are estimated to experience malnutrition [2, 3]. Malnutrition, also known as undernutrition, is defined as, “a state resulting from lack of uptake or intake of nutrition leading to altered body composition (decreased fat free mass) and body cell mass leading to diminished physical and mental function and impaired clinical outcome from disease” [4]. Malnutrition impairs patient recovery, increasing hospital length of stay and escalating healthcare costs. Indeed, the estimated health and social care expenditure associated with malnutrition in England was £19.6 billion in 2011-2012 and treating patients with malnutrition was over four times more costly than managing those without malnutrition [3, 5]. Moreover, malnutrition is a key contributing factor in the aetiology of sarcopenia and frailty and increases risk of morbidity and mortality [6-8]. Considering the adverse clinical outcomes associated with malnutrition, the identification and management of malnutrition is a vital patient-centred outcome to enhance older adult’s health and quality of life and to enable cost-effective treatment and care.

A range of factors could contribute to low dietary intakes and malnutrition of hospital in-patients, including acute, or chronic medical conditions, side effects of pharmacological treatment, cognitive impairment, lack of help at mealtimes, and inadequate energy and protein intake from poor hospital food menus [9-11]. Older adults may also have compromised appetite regulation - an anorexia of ageing [12]. Hence, clinicians need to consider optimising methods to support individualised nutritional care of hospital in-patients. One such method is the use of oral nutritional supplementation (ONS). ONS are energy and nutrient dense products designed to increase dietary intake when diet alone is insufficient to meet daily nutritional requirements [1]. There are a multitude of ONS options, including flavours, formats (e.g., liquid, powder), types (e.g., high protein, vegan) energy densities, and volumes [1]. According to expert consensus, ONS should contain both micro and macronutrients and provide at least 400 kcal and a minimum of 30 g of protein per day to improve nutritional status, lower the risk of complications and readmission, and to decrease the risk of functional decline after discharge [11].

Overall, research suggests favourable impacts of ONS on nutritional status and healthcare costs, while the impact on functional outcomes and mortality are more controversial [13-15]. In a Cochrane systematic review (62 trials; 10,187 participants), ONS typically in the form of commercial sip feeds improved weight change (2.2% increase) and reduced risk of complications for hospitalised older adults [14]. Few trials in the review indicated any functional benefit, no overall significant reductions in mortality, and limited evidence to suggest improvements in length of hospital stay when using ONS. Nevertheless, studies in which older adults were defined as undernourished showed statistically significant effects of ONS on reducing mortality [14]. Similarly, a systematic review and meta-analysis (36 trials; 3790 participants) investigating the effects of high protein ONS (>20% energy from protein) on clinical outcomes across settings and patient groups indicated significant reductions in complications, increased intake of protein and energy and improved weight [13]. Additionally, this review found reduced readmissions to hospital and improved grip strength in older adults using high protein ONS. Other research also corroborates the significant reductions in hospital readmissions in older patient groups using ONS [15, 16]. Therefore, it is not surprising that the clinical impacts of ONS have subsequent economic implications for healthcare, promoting cost savings in hospital settings and improved cost effectiveness, such as patients gaining quality adjusted life years [3, 17]. In a systematic review, 12 out of 14 trials comparing ONS with standard care demonstrated a significant

mean cost saving of 12.2%, and these savings were associated with significantly improved outcomes, such as 13% reduction in hospital stay [3]. Despite the myriad benefits of ONS alluded to above, a recent overview of systematic reviews and meta-analyses found discordance in the impact of ONS on patient outcomes potentially arising from heterogeneity of study designs, methodological rigour, differences in clinical background of patients and the etiological basis of malnutrition [18]. In addition, a burgeoning evidence base attests to the importance of considering acceptability and compliance of ONS on adequate intake and thus effectiveness of ONS in practice [19-23].

Patient compliance to ONS considers the relationship between the amount of ONS prescribed and the amount of ONS ingested and is important to maximise clinical and cost-effectiveness. There are numerous factors that may influence compliance including type, variety, volume, energy-density, duration and timing of supplementation and whether any instruction, or assistance has been given [11]. The European Society for Clinical Nutrition and Metabolism (ESPEN) recommend that compliance should be assessed regularly when ONS are offered to older people with malnutrition and the form of ONS should be adapted to suit patient's taste and eating capacities [1]. Higher energy density ONS appear to have better compliance rates than lower energy density ONS, possibly due to smaller volumes needing to be consumed [22, 24]. Typically, research has investigated the compliance of ready-made multi-nutrient liquids in older patient groups and has found a mean compliance with ONS of 67% in hospital, 81% in the community and an overall compliance of 78.8% across healthcare settings [22]. In other research, older hospitalised patient's compliance with ONS (sip feeds) was low (37%) on geriatric wards [20]. Wastage of ONS in older hospitalised patients (n = 22) over a 24-hour period incurred a wasted cost of £50.12, estimated as a net loss of £18, 294 per year [20]. The greatest wastage was seen in patients that disliked the taste of ONS (72%), indicating that poor palatability is an important barrier to compliance and should be considered when prescribing ONS.

Palatability refers to the hedonic (i.e., pleasantness) evaluation of sensory factors, such as taste and smell, leading to alterations in food or fluid consumption [25]. Supplemental preference may be affected by a multitude of factors such as taste, colour, smell, after taste and texture. Moreover, continual single use of a supplement can result in monotony and taste fatigue leading to reduced intake [26]. Typically, hospital patients are offered liquid based ONS (sip feeds). However, previous research has pinpointed that 56% of older adults on geriatric wards did not like sip feeds [20]. Hence, exploration of compliance to different ONS formats is an important research direction to maximise malnourished older adult's nutritional intake. Most research has investigated palatability, acceptability, and compliance of liquid type ONS indicating improved intake of lower thickness supplements [27], low volume, high energy and protein dense products [23, 24], and vanilla, coffee and strawberry milk-based supplements [19]. Factors reducing compliance include build-up of a mouthcoating from sip feeds [28, 29], abdominal bloating [19], alterations in mouthfeel when wearing dentures and changes in flavour perceptions depending upon medication status [30].

Malnourished hospitalised older adults should be offered an improved range and provision of ONS to suit patient preferences and maximise intake. For instance, an attractive alternative strategy is the use of energy and protein-dense meals (via fortification) or snacks (supplementation), including fortified bread, protein-enriched main meals and between meal snacks, such as biscuits, yoghurt and ice cream [31]. In a systematic review (546 patients, mean age 60-83 years), Mills and colleagues [31] concluded that compared with usual nutritional care, energy- and protein based fortification and supplementation could be employed as an effective, well-tolerated and cost-effective intervention to improve dietary intake amongst older inpatients, especially when standard ONS were not tolerated. Similarly, Taib and colleagues [32] investigated the acceptability and intake of an ice cream ONS (240 kcal/per portion) over 3 days in malnourished fracture patients (median 75 years). Compliance to the ice cream ONS was good (77%) and average daily energy intake (1006 kcal/day) was 41% higher

compared to baseline nutritional survey among patients. This research suggests that alternative ONS products are feasible in hospitalised malnourished older adults. Yet this is an understudied area, with limited data investigating compliance to alternative ONS products compared to ready-made drinks in hospital, such as powdered ONS and snacks, or their clinical effectiveness.

The ESPEN recommend, “When offered to an older person with malnutrition or at risk of malnutrition, compliance in ONS consumption shall be regularly assessed. Type, flavour, texture and time of consumption shall be adapted to the patient's taste and eating capacities.” [1]. In keeping with these recommendations, ONS variations according to flavours and categories need to be considered to improve patients’ compliance. Moreover, considering the detrimental consequences of malnutrition it is vital that hospitalised older people have access to optimum nutritional care packages, including palatable and acceptable ONS to enhance compliance, energy intake and maximise ONS effectiveness and clinical outcomes. Therefore, the aim of the current study is to investigate the compliance and palatability of fortified porridge compared to standard liquid based ONS, and to explore their acceptability on acute medical wards.

2 RESEARCH QUESTION/AIM(S)

This study aims to investigate the compliance and palatability of fortified porridge, containing high energy and protein content, to explore product acceptability in malnourished hospitalised older adults.

2.1 Objectives

The specific objectives include:

- To determine patient compliance to fortified porridge compared to standard liquid based ONS assessed through measurement of product intake (%).
- To examine the palatability of fortified porridge compared to standard liquid based ONS, including assessment of taste, flavour, and likeability.
- To assess the acceptability of product use on acute medical wards through qualitative semi-structured interviews with patients and healthcare professionals.

2.2 Outcome

Exploration of the compliance, palatability, and acceptability of the ONS product will help to determine whether the product is appropriate for further evaluation in future research, to determine sample sizes for a controlled trial to investigate clinical outcomes of ONS and to assess whether the ideas and findings can be shaped to be relevant and sustainable. The study will also help to determine suitability of the product for use in UHS and for a larger roll out of the product across Wessex.

Through collaborations between University of Southampton, University Hospital Southampton and Adams Vital Nutrition Ltd. the anticipated impacts include:

- Explore the usability of additional ONS products to facilitate management of malnutrition in patient’s at UHS.
- Lay a foundation for future randomised clinical trials.
- Dissemination of our research findings through scientific and lay platforms to encourage implementation in other settings.
- Improved nutrition support for older adults with malnutrition with potential benefit in health outcomes.

3 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

Study Design

A mixed methods randomised controlled crossover design will be conducted to determine compliance and palatability of fortified porridge in malnourished hospitalised older adults. A crossover design was chosen to account for heterogeneity in an older patient population (e.g., differences in disease states and oral sensory perceptions), in which participants will act as their own controls to better compare palatability of products. This study will be conducted at University Hospital Southampton (UHS) NHS Foundation Trust on geriatric acute medical wards comparing intake and palatability of 'build and restore' fortified porridge (treatment) and standard liquid based ONS (control) in a repeated measures crossover design. The acceptability of products will be assessed through qualitative interviews to explore patients and healthcare professionals' experiences and views of using the different nutritional supplements.

Intervention

Participants will be prescribed ONS twice per day for 4 days, in addition to normal meals, in a crossover design. Two ONS products (Table 1) will be tested for palatability and compliance including a new fortified porridge (treatment), and standard liquid-based ONS (control). Each ONS product will be tested over 2 days in a randomised crossover sequence (Figure 1). The products will be offered twice per day, in-between breakfast and lunch, and after dinner to reduce the detrimental long period of calorie absence experienced overnight [33]. The fortified porridge (treatment) is powdered and mixed with 100 ml boiling water in a carton with a choice of 4 flavours including golden syrup, apple and cinnamon, strawberries and cream, and bananas and custard. The liquid-based ONS (control) are ready-to-drink milkshakes. Participants will be offered the ONS in a screw-topped plastic bottle, and a choice from a variety of flavours (e.g., vanilla, strawberry, chocolate, banana, mocha, neutral, berries). ONS products will be prepared and distributed to participants by health care professionals working on the wards.

Table 1. ONS Product Information (see appendices for full product specification)

Group	Treatment	Control
Name	Vital Daily High Protein Oats (Adams Vital Nutrition Ltd.)	Anonymous readymade drink supplement
Description	Fortified 'build and restore' porridge ONS	Standard liquid-based ONS
Weight (g)	157	125
Energy (kcal)	230	306
Protein (g)	15	18.3

Data Collection

Participant Characteristics

Participant characteristics including age, domicile status, marital status, care provision, usual residence, frailty (PRISMA-7), sarcopenia (SARC-F), and appetite (SNAQ) will be assessed at baseline. Moreover, participants C-reactive protein [34] and National Early Warning Score [35] will be

recorded as markers of acute illness (recorded as part of standard care), a potential mediator of older adults' appetite [36].

Appetite will be measured using the Simplified Nutritional Appetite Questionnaire (SNAQ) [37], which has been validated to predict weight loss in community dwelling older adults and used to predict poor health outcomes in hospitalised older people [37-39]. SNAQ is a four-item tool comprising items 1, 2, 4 and 6 of the CNAQ, assessing appetite, satiety, taste of food and number of meals per day respectively. SNAQ has a maximum score of 20, with a score of ≤14 indicating poor appetite.

The Strength, Assistance with walking, Rising from a chair, Climbing stairs, and Falls (SARC-F) questionnaire will be used as a measure to assess for sarcopenia [40]. It comprises five components: strength, assistance in walking, rise from a chair, climbing stairs and falls. The scores range from 0 to 10, with a score of equal to or greater than four being predictive of sarcopenia and poor outcome.

Program of Research to Integrate Services for the Maintenance of Autonomy (PRISMA-7) screening tool will be used to characterise participants' frailty status [41]. The questionnaire contains seven items with a positive score of three or more indicating frailty. The PRISMA-7 tool has been shown to have high accuracy in identifying frail older adults in the community setting [42].

Primary Outcome Measures
Primary outcome measures will include compliance to ONS and palatability.

Compliance: Compliance to ONS will be assessed by the study team via careful documentation of ONS leftovers at 2 timepoints, including after lunch (for ONS given in the morning) and early morning the following day (for ONS given after dinner), to ensure enough time for consumption. Leftovers will be weighed (g) using weighing scales (Seca Model 875 digital weighing scale) and documented by the research team. Compliance will be calculated as the percentage of the mean ONS consumed per day. Moreover, the mean intake of ONS energy (kcal/day) and protein (g/day) consumed per day will be calculated and an estimation of the percentage ingested.

Palatability: Palatability ratings, including appearance, smell, taste, sweetness, texture, thickness, aftertaste, mouth feel, and overall likability will be assessed with a 7-point hedonic Likert scale (7 = definitely like, 6 = moderately like, 5 = mildly like, 4 = neither like nor dislike, 3 = mildly dislike, 2 = moderately dislike, 1 = definitely dislike). Hedonic scales have been used to assess palatability of ONS supplements across population groups [24, 32, 43] and have good reliability [44]. Palatability ratings will be completed by participants on initial introduction of each ONS at a standardised time of day (i.e., morning ONS on day 1 and 3) (Figure 2).

Outcome measures will be collected by the PI (SM) and recorded on paper data collection sheets (see appendix), which will be stored securely in a locked filing cabinet in a secure key card access research office at UHS. Data will be double entered into an excel spreadsheet and statistical software (SPSS v.28) on a secure password protected University computer. Only the CI, PI and University regulatory authorities will have access to the data.

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Secondary Outcomes Measures
Secondary outcome measures will include acceptability of the ONS products and total caloric intake.

Total caloric intake: Existing literature suggested that the effectiveness of ONS in improving energy intake can sometimes be compromised by the partial displacement of normal meals [45]. That is, despite compliance to ONS, total caloric intake might not be augmented by ONS through a potential decrease of habitual food intake. Therefore, total energy intake will be assessed through completion of

patient food charts, including estimated proportion of meals consumed. Food charts are a part of patients' standard care and will be completed by the nursing team. Patient completed food diaries have been reported as a valid method to measure energy intake in hospitalised older adults, in which the food diary predicted within ±17% weighted energy intakes in 70% of individuals [46]. Energy intake (kcal) will be calculated from these diaries via nutritional data supplied by hospital catering (Serco). The food diary will be completed 2 days before the start of testing to estimate normal total energy intake, and then will be completed daily during the 4-day testing period.

Acceptability: Acceptability of ONS products will be explored with semi-structured interviews. The semi-structured interviews will consist of several key open-ended questions that will help define the areas explored but allow the interviewer or interviewee to expand and diverge with the aim of pursuing or developing an idea with more depth. The interviews will seek to explore the views of hospitalised older adults and healthcare professionals working on geriatric medical wards, exploring the acceptability of the ONS products. The interviews will be audio-recorded for data collection purposes. Interviews with staff will take place one-to-one with the research assistant either in a private office space within UHS in-person, or remotely via telephone, or Microsoft Teams (depending on participant preference). Patients will be interviewed following completion of 4 days of ONS intervention at bedside, or in a private room at UHS, depending on personal preference.

Data Analysis

Quantitative data analysis

Data collected will be double entered into a secured database for analysis. Statistical analysis will be conducted using the statistical software SPSS. Descriptive statistics -median (IQR); mean (SD); number (%) – will be used to analyse ONS ingested (%), intake of energy (kcal/day), intake of protein (g/day), and palatability Likert scores. Palatability Likert scores will be categorised into positive, neutral and negative scores and presented in bar charts to illustrate comparisons of each ONS product [47]. Compliance rates will be split into comparable groups with low, medium and high compliance categorised as ≤ 30%, 31-79%, and ≥ 80%, respectively, and presented in bar charts. Normality tests, including skewness and kurtosis, will be conducted to determine suitable statistical analyses for measures (i.e., non-parametric vs. parametric tests). Primary outcome measures will be compared between groups (treatment vs. control) using a repeated measures t-test, or Wilcoxon test, depending upon normality. Total daily energy intake (kcal) will be compared between ONS groups and to control (i.e., before testing) with a repeated measures ANOVA with Bonferroni correction to assess the impact of ONS on normal meal intake.

Qualitative data analysis

Interviews will be transcribed verbatim and analysed using reflexive thematic analysis (TA) [48]. TA is a method for identifying, analysing and reporting patterns or themes within data and is widely used in qualitative research. There are six phases in the process of conducting TA: Phase 1 – familiarising with the data, Phase 2 – generating initial codes, Phase 3 – searching for themes, Phase 4 – reviewing themes, Phase 5 – defining and naming themes, and Phase 6 – producing the report. Analysis of qualitative data will be conducted using either Microsoft Word, or with the help of NVIVO, depending on the amount of data collected. Transcribed text will be read and coded separately and then together by two researchers. The codes will be analysed to generate concepts and ideas to determine the acceptability of the intervention, and to identify facilitators and barriers to the implementation process. The codes act as tags or labels to help catalogue key concepts embedded within the raw data. From the codes, themes will be developed to reflect the views and experiences of the patients and healthcare professionals regarding the intake and use of ONS products in hospital.

4 STUDY SETTING

This is a single-centre study taking place at University Hospital Southampton NHS Foundation Trust. Patients with malnutrition will be identified and recruited from acute medical wards at UHS.

5 SAMPLE AND RECRUITMENT

5.1 Eligibility Criteria

Older adults with malnutrition and staff on acute medical wards in UHS will be invited to participate in this study (see details below).

5.1.1 Inclusion criteria

Patients

- Older adults ≥65 years
- Patients on UHS acute medical wards
- Medium-high risk of malnutrition (MUST score 1-4)
- Able to provide written consent

Health Professionals (interviews)

- Working at UHS on the wards receiving the ONS intervention
- Able to provide written consent

5.1.2 Exclusion criteria

- ~~Patients that have used ONS in previous month~~
- Receiving enteral or parental nutrition
- Patients with a MUST score >4 (severely malnourished)
- Patients with a BMI ≤15
- Patients with chronic liver disease, renal failure, dysphagia
- Patients who have had major surgery within the preceding month
- Patients with a terminal illness
- Patients receiving end of life care
- Patients unable to eat by mouth (Nil By Mouth [NBM])
- Patients who require alternative ONS as advised by dietetic support

5.2 Sampling

Participants will be recruited from UHS using purposive sampling techniques (detailed below).

5.2.1 Size of sample

A sample size of 50 was chosen based upon guidance from previous literature investigating compliance and palatability of ONS [22, 29]. In a systematic review of 49 studies assessing ONS compliance, studies included 1-4 groups (median 2) with a median of 30 (interquartile range 23-41) participants in each group [22]. In the current study a repeated measures two tailed t-test will be applied to compare compliance and palatability between 2 conditions (treatment vs. control).

To explore acceptability, 10-15 interviews will be conducted among patients (N= 7-9) and health care professionals (N= 3-6) to share their thoughts on using the ONS products and to capture their views regarding implementation of ONS products on the wards.

5.2.2 Sampling technique

Older adults admitted to acute medical and orthogeriatric wards, who meet the eligibility criteria, will be recruited to the study. Purposive sampling will be used to recruit participants for interview, including a representative age range, ethnicity, and inclusion of a range of staff roles, including nurses (N= 2), health care assistants (N= 1), meal-time co-ordinators (N= 1), and doctors (N= 2).

5.3 Recruitment

Eligible patients will be identified and approached initially by their clinical care team before being approached by the research team (details below). Eligible healthcare professionals will be approached directly by the research team.

5.3.1 Sample identification

Malnourished older adults on UHS acute medical wards will be invited to participate in the study by a clinician (Dr Stephen Lim), assisted by a research assistant. Research staff will liaise closely with the patient's clinical care team to identify patients that are eligible to participate in the study, based upon screening and inclusion criteria. Invited patients will be given a participant information sheet and time to ask any questions and discuss what is involved in the study.

Screening checks to determine patient suitability to participate in the study will include the Malnutrition Universal Screening Tool (MUST). The MUST is a screening tool to identify adults who are malnourished, at risk of malnutrition, or obese through the assessment of weight status (BMI), change in weight, and the presence of an acute disease resulting in no dietary intake for more than 5 days [49]. A BMI (kg/m^2) of >20 scores 0, 18.5-20 scores 1, and <18.5 scores 2 on the tool. Unplanned weight loss in past 3-6 months (%) of <5 scores 0, 5-10 scores 1, and >10 scores 2 on the tool. If the patient is acutely ill and there has been or is likely to be no nutritional intake for >5 days an additional score of 2 is applied. These three independent scores are then added, and participants are categorised into low (score 0), medium (score 1), or high risk (score ≥2) of malnutrition. The MUST is valid, reliable and easy to use, and can be applied across patient groups [13, 49-51].

Eligible participants will then complete an informed consent form and baseline questionnaires.

Eligible staff will be approached directly by the research team. Interested staff will be given a participant information sheet to help them fully consider participation in the research.

5.3.2 Consent

The clinical care team will inform the research team of any interested patients. Interested participants will then be approached by the research team to explain the study in more depth and given a participant information sheet. Written consent will be obtained for older adults who are keen to participate in the study.

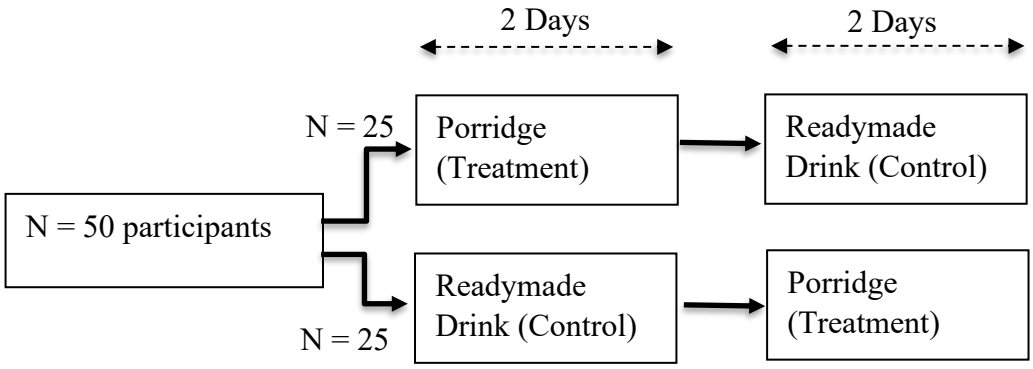
Participants will be given up to 2 days to decide if they would like to volunteer in the study. This will give participants time to consider their involvement in the study, to discuss the study with family and to ask any questions, while also enabling recruitment for the study before patients are discharged. All members of the study team are adequately trained in Good Clinical Practice (GCP) and have experience taking informed consent in previous research.

Following distribution of participant information sheets, staff will be given a week to decide if they would like to participate in the study. This time will allow them to fully consider participating in the study and to ask any questions they may have. If they are interested in volunteering to be interviewed, they will complete written informed consent.

5.4 Randomisation Procedure

Once participants have completed informed consent each participant will be randomised in a crossover procedure to groups using a computer-generated randomization tool, 'Research Randomizer' [52], to minimise sequence effects and bias (Figure 2). Patients will be allocated to one of two sequences at random in a 1:1 allocation to eliminate bias associated with group assignment while creating similar sized groups.

Figure 2. Randomisation procedure



6 ETHICAL AND REGULATORY CONSIDERATIONS

6.1 Assessment and management of risk

The risks involved in this study are minimal. On rare occasions ONS can cause bloating and some stomach discomfort. The benefits of using ONS far outweigh risks of consumption, including improving the intake of vital energy and protein to help manage malnutrition. Any nutritional products used in the study have passed food safety standards and manufacturers (e.g., Huegli) have insurance liability.

Products used in the study have been reviewed, verifying the suitability of the ONS content by a dietitian specialising in the care of older people (Miss Picton), and are consistent with ESPEN guidelines on ONS supplementation for hospitalised older adults. The research team will follow strict eligibility criteria, including use of screening tools (e.g., MUST) and will liaise closely with the participant's clinical care team before consent is sought from eligible participants. Participants will remain under the supervision of their clinical care team, following standardised nutritional care and monitoring of any adverse effects from ONS.

There is perceived to be a low burden to participants volunteering for the study, as the ONS supplementation period is low (4 days), and palatability questionnaires will take approximately 10 minutes to complete with assistance from the research team. The study has been designed to optimize benefit and minimize burden to participants. Initially more outcome measures were included, such as anthropometric assessment and an increased number of questionnaires, including assessment of activities of daily living. After careful consideration and review from co-applicants some secondary outcome measures were removed to reduce participant burden while keeping important measures in close alignment with the study aims.

Participants that volunteer for interview may find some of the content sensitive, such as exploration of their eating habits and the factors that influence dietary consumption. Participants will be made aware that the interview can be stopped at any time and that they can skip any of the questions. They will be made aware that refusing to answer questions or stopping the interview will in no way impact or change their patient care. If participants become upset during the interview they will be asked if they would like to continue, or the interview will be stopped. If a participant has a negative emotional reaction from an interview, they will be followed up by the research team and asked for permission to alert their clinical care team.

Any adverse events will be reported to the CI and PI and recorded in the study site file. The CI or PI will report adverse events to the research sponsor. The definition of an adverse event is: *"Any untoward medical occurrence in a patient which does not necessarily have a causal relationship with this study product (i.e., the nutritional supplement)". This includes "any unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the study intervention (i.e., the nutritional supplement)"*. This may include, for example, a cold, or an accident.

The definition of a serious adverse event is one that fulfils at least one of the following criteria:

- Is fatal – results in death (NOTE: death is an outcome, not an event)
- Is life-threatening
- Requires inpatient hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect

All serious adverse events should be reported to the study team (CI, or PI) and then onto the study sponsor within 24 hours of the investigator becoming aware of the event.

All study staff and clinicians in contact with patients are responsible for noting adverse events that are reported by the patient and making them known to appropriate medical staff. Patients entered into the

study must be encouraged from the outset of any study to contact their research nurse/team at the time of an event occurring.

At each visit, or study assessment, adverse events that might have occurred since the previous visit or assessment should be elicited from the patient. For source documentation verification these events need to be detailed in the patients' medical notes including the start dates (if known) of the onset of the event as well as the date the event stopped or changed, if applicable. Adverse events ongoing on completion of the study should be followed up as required by the protocol and as clinically indicated. The clock starts from the time the study team were made aware of the event. The ICH GCP Guidelines state that: *"All serious adverse events should be reported immediately to the sponsor"* (trial organisers), and that *"immediate reports should be followed promptly by detailed written reports"*.

Adverse events will be recorded on the Case Record Form (CRF), including a clear documentation of the event, the event start and stop time, the severity of the event, the action taken, and the event outcome. All copies of correspondence relating to any adverse event (e.g., emails and telephone conversations) will be retained in the main study site file.

6.2 Research Ethics Committee (REC) and other Regulatory review & reports

This study will require ethical approval from the Health Research Authority (HRA). We will submit this study for review to the HRA NHS Research Ethics Committee through the Integrated Research Application System.

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- All correspondence with the REC will be retained.
- It is the Chief Investigator's responsibility to produce the annual reports as required.
- The Chief Investigator will notify the REC of the end of the study.
- An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Discontinuation/Withdrawal of Participants from Study:

Each participant has the right to withdraw from the study at any time and request that any data collected be deleted. It will not be possible for the participant to withdraw their data once the analysis has started because the data collected will already be pseudonymised and have been used.

Participants can withdraw from the study without giving a reason by contacting the research team.

Withdrawal criteria:

- On the request of the research participant

- On the advice of the participant's clinical care team, such as in the event that the oral nutritional supplement becomes unsuitable for them

Regulatory Review & Compliance

Before any site can enrol participants into the study, the Chief Investigator/Principal Investigator will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance.

For any amendment to the study, the Chief Investigator/Principal Investigator, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator/Principle Investigator will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

Amendments

If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor must submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

Amendments also need to be notified to the national coordinating function of the UK country where the lead NHS R&D office is based and communicated to the participating organisations (R&D office and local research team) departments of participating sites to assess whether the amendment affects the NHS permission for that site. Note that some amendments that may be considered to be non-substantial for the purposes of REC still need to be notified to NHS R&D (e.g. a change to the funding arrangements).

The amendment history will be tracked through allocating version numbers and dates to the protocol and any study resources, which will be kept on electronic file by the CI and study sponsors.

6.3 Peer review

6.4 Patient & Public Involvement

9 patients (5 male) aged 71-99 years on geriatric wards at UHS completed a pilot palatability survey to explore Adams Vital Nutrition Build & Restore fortified oats. The majority of patients chose chocolate porridge over golden syrup (8/9). Palatability was measured on a 10-point Likert scale (e.g., 0, not tasty at all to 10, very tasty). Patients had a mean taste rating of 7.22, consistency of 7.14 and appearance of 7.33. Three patients ate the whole portion, 3 ate half, and 3 ate less than half of the portion. Patients were also asked at what time of day they would prefer to eat the product. Four patients preferred to eat the product for breakfast, 1 as a mid-afternoon snack, 2 preferred the product in the evening, and 2 patients would eat the product at any time of day. This pilot helped to inform patient facing materials, data collection templates, and gave early indication regarding the palatability of the trial product.

To help with further development of ONS flavours, a PPI survey was distributed to 25 older adults (age 86.23 ± 5.93 years; 56% female; 92% White British, 8% Indian) on UHS geriatric medical wards. We assessed patients' likability for porridge and porridge flavours using a 7-point Likert scale from 'definitely like' (7) to 'definitely dislike' (1). Analyses showed a median likability rating of 5 'mildly like' (IQR 3-6) for porridge with 60% circling a score in the 'like' section of the scale, 8% neither like nor dislike, and 32% circling scores in the 'dislike' section. Three participants explained they have difficulty swallowing, so even though porridge was not their favourite snack they would eat it as they can only manage soft foods. When asked 'what is your favourite type of snack to eat between meals?' most preferred fruit (n = 7, 28%), or biscuits (n = 6, 24%), and 16% preferred not to eat any snacks.

The top three flavours of porridge that participants were most likely to eat were golden syrup (44% like, 8% neither like nor dislike, 48% dislike), strawberries and cream (32% like, 8% neither like nor dislike, 60% dislike), and apple and cinnamon (32% like, 8% neither like nor dislike, 60% dislike). Participants were asked 'when you make porridge for yourself what flavour do you prefer to eat?' Participants preferred neutral porridge with sugar, strawberry jam, or golden syrup added (n = 18, 72%).

One public and patient representative (PPIR) provided input into this study proposal. They reviewed the plain English summary and study proposal and proposed minor changes. Their input will also be sought in the development of the study protocol. They will review all patient-facing materials to ensure that adequate information is provided to patients and that any written information is understandable and jargon-free. PPIR will also be invited to join the study management group. This group will aim to meet up quarterly to discuss the study progress and PPIR will be involved throughout the study process from development to dissemination of study findings.

In this study, the role of PPI includes:

- Reviewing patient-facing materials such as patient information sheet, consent form forms and questionnaires.
- Participating in the study steering group to support the delivery of the study.
- Providing input at every stage of the study to ensure that the focus of the study is primarily on delivering patient benefit.
- Ensuring that the processes of the study such as data collection, and interviews, are not too burdensome for patients.
- Recommending methods or avenues of disseminating research findings to provide a wider reach and ensure that patient and the public are informed of the research findings.

6.5 Protocol compliance

The Investigator agrees to comply with the requirements of the Protocol and Good Clinical Practice. Prospective, planned deviations or waivers to the protocol are not allowed under the UK regulations on Clinical Trials and must not be used e.g. it is not acceptable to enrol a subject if they do not meet the eligibility criteria or restrictions specified in the trial protocol.

Accidental protocol deviations can happen at any time. They must be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

Deviations from the protocol, which are found to frequently recur, are not acceptable and will require immediate action by the sponsor. Frequent non-compliances could potentially be classified as a serious breach.

6.6 Data protection and patient confidentiality

The study staff will ensure that the participants' anonymity is maintained. Data will be identified only by a participant ID number. All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with GDPR and the Data Protection Act 2018, which requires data to be anonymised as soon as it is practical to do so.

Participation and all the information collected about participants during the course of the research will be kept strictly confidential. Only members of the research team and responsible members of the University of Southampton may be given access to participant data for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to participant data. All of these people have a duty to keep participant information strictly confidential.

Data collected will be entered electronically on to a computer and stored on the university's networked storage. Access to this information will be password-protected. Hard copies of participant information will be stored in a locked filing cabinet in a secure office in our research unit and will be accessible only by the research team. Audio recordings for the interviews will be deleted once they have been transcribed. Codes are allocated to each participant to ensure that the data is anonymised. Only the researchers in this study will have access to the data.

In accordance with regulations we are required to keep participant data secure for 10 years. The data may be used in future studies by our research team. If this happens, participant data will be used anonymously (non-identifiable participant information) so participants cannot be identified. Any new research studies using participant data will be authorised by the local research ethics committee.

All participants will be made aware of the information collected during the research study during processes of informed consent through participant information sheets, discussions with the research team and completion of consent forms.

ARCHIVING

Archiving will be authorised by the Sponsor following submission of the end of study report.

Location and duration of record retention for:

- Essential documents: Patient case notes will be stored and maintained according to standard rules and procedures. Pathology results are stored and maintained according to standard procedures.
- Study data will be held for minimum of 5 years

Destruction of essential documents will require authorisation from the Sponsor.

Monitoring, Audits and Inspections

This study will be monitored and may be participant to monitoring and audit by University Hospital Southampton NHS Foundation Trust, under their remit as sponsor and other regulatory bodies to ensure adherence to ICH GCP, UK Policy Framework for Health and Social Care Research, applicable contracts/agreements and national regulations. All study related documents will be made available on request for monitoring and audit by UHS, the relevant REC or other licensing bodies.

6.7 Indemnity

The sponsor of the trial is University Hospital Southampton NHS Foundation Trust. For NHS sponsored research HSG (96) 48 reference no.2 refers. If there is negligent harm during the clinical trial when the NHS body owes a duty of care to the person harmed, NHS Indemnity covers NHS staff, medical academic staff with honorary contracts, and those conducting the trial. NHS Indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm. Ex-gratia payments may be considered in the case of a claim.

6.8 Access to the final study dataset

Access to data will be granted to relevant members of the research team and authorised representatives from the Sponsor for monitoring and/or audit purposes. The data may be used in future studies by our research team. If this happens, participant data will be used anonymously (non-identifiable participant information) so participants cannot be identified. Any new research studies using participant data will be authorised by the local research ethics committee.

7 DISSEMINIATION POLICY

7.1 Dissemination policy

The data arising from the study will be the intellectual property of the University of Southampton. On completion of the study, data will be analysed, and a final study report will be prepared. The study report can be accessed via clinicaltrials.gov. Research findings will be made available to research participants upon request.

The study findings will be presented at national and international scientific meetings. They will also be published in peer-reviewed journals to disseminate findings to the scientific community. Social media platforms such as Twitter, Facebook and blogs will also be used to disseminate research findings, which will achieve a wider reach of scientific and lay communities. Members of PPI in the steering group will also provide input on other dissemination methods and ideas.

This ONS acceptability study will provide a basis for future clinical trials working with Adams Vital Nutrition Ltd. and could help in the development of future ONS products.

7.2 Authorship eligibility guidelines and any intended use of professional writers

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authorship will be determined per the ICMJE guidelines and other contributors will be acknowledged.

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9. APPENDICIES

9.1 Appendix 1- Required documentation

Consultant Letter

Referee's Report

Data Collection Booklet

Interview Schedule

ONS Product Specification

9.2 Appendix 2 – Schedule of Procedures

Procedures	No. received per participant	Time	Who	Location
Written consent (patients & staff)	1	5-10 mins	SL & SM	Hospital wards
Baseline questionnaire data collection (patients)	1	15-20 mins	SM	Hospital wards
Completion of daily food diary/chart	6	15-20 mins	Nurses	Hospital wards
Measurement of ONS intake	8	variable	SM	Hospital wards
Assessment of ONS palatability (patients)	2	10-15 mins	SM	Hospital wards
Interview (patients & staff)	1	25-45 mins	SM	UHS office, hospital ward, telephone, or online depending on participant preference

9.3 Appendix 3 - Gantt Chart

	2022			2023				
	O/N	D	J/F	M/A	M/J	J/A	S/O	N/D
Ethical Approval								
Participant Recruitment								
ONS Testing (data collection)								
Qualitative Interview								
Data Analysis								
Report & Dissemination of Findings								

9.4 Appendix 4 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	1.1	31/05/2024	S J Meredith	Eligibility criteria have changed: 'Receiving ONS in previous month' has been taken out of the exclusion criteria.

Clinical Care Team Notification Letter

UHS ONS Compliance & Palatability Study: Compliance and palatability of fortified porridge compared to standard liquid-based ONS in hospitalised older adults with malnutrition

Dear UHS Clinical Care Team Date: **XXX**

Your patient, **XXX**, has agreed to take part in the above study. This is a mixed methods randomised controlled crossover design co-ordinated by the study management team at the University of Southampton and the research sponsor at University Hospital Southampton NHS Foundation Trust.

This study aims to investigate the compliance and palatability of fortified porridge (treatment) in malnourished hospitalised older adults compared to a liquid-based ONS (control). The acceptability of products will also be assessed through qualitative interviews.

This study will involve your patient consuming two different types of ONS twice per day for 4 days, in addition to normal meals, in a crossover design. The products will be offered in-between breakfast and lunch, and after dinner. We will assess your patient's compliance to ONS through measuring ONS leftovers, and we will assess palatability of ONS products using Likert scales. We will also assess your patient's frailty status (PRISMA-7), risk of sarcopenia (SARC-F) and appetite (SNAQ) at baseline. They may also be asked for an interview to explore their experiences of using the ONS products.

Your patient has been provided with verbal and written information for the study (copy enclosed) which explains why s/he has been approached to take part in the research, that the participation is entirely voluntary, and emphasises that they are free to withdraw from the study at any time without prejudicing their future medical care.

Should you have any questions or require further information about this research, please do not hesitate to contact the chief investigator in charge of the local study.

Dr Stephen Lim, Consultant Geriatrician, Academic Geriatric Medicine, University Hospital Southampton NHS FT, Tremona Road, Southampton, SO16 6YD Telephone: 02381206131.
Email: s.e.lim@soton.ac.uk

Yours sincerely,

Dr Samantha Jane Meredith

Research Fellow
University of Southampton
Academic Geriatric Medicine
s.j.meredith@soton.ac.uk

University Hospital Southampton NHS Foundation Trust

Scientific Peer Review Form

PROJECT TITLE	Compliance and palatability of fortified porridge compared to standard liquid-based oral nutritional supplementation in hospitalised older adults with malnutrition
CHIEF INVESTIGATOR	Dr Stephen Lim
STUDENT (if applicable)	

All studies which are requesting sponsorship from University Hospital Southampton NHS Foundation Trust will require **two** supporting peer reviews to assist in the verification of the scientific quality and robustness of the study.

Please note no internal peer review is required for projects where an external body is undertaking a review as part of a funding application but should include confirmation of the funding award with the Sponsorship request.

SCIENTIFIC QUALITY PEER REVIEW	ASSESSMENT CRITERIA			
	YES	NO	UNCLEAR	*N/A*
1. Study Design	☐	☐	☐	☐
Does the research have a clear protocol?	☒	☐	☐	☐
Is the research question or hypothesis clearly stated?	☒	☐	☐	☐
Are the project objectives described?	☒	☐	☐	☐
Are the objectives realistic?	☒	☐	☐	☐
Has other relevant research been reviewed?	☒	☐	☐	☐
Is the methodology appropriate to the research question?	☒	☐	☐	☐
Have the methods of measurement been described?	☒	☐	☐	☐

Has the reliability and validity of measurement been reviewed?	☒	☐	☐	☐
If available, are validated scales of measurement being used?	☒	☐	☐	☐
If No or Unclear has been marked for any of the above then please elaborate:				
2. Study sample and data analysis	☐	☐	☐	☐
Is the proposed population group appropriately representative?	☒	☐	☐	☐
Is the sample size justified and realistic?	☒	☐	☐	☐
Are the methods of data analysis (statistical or otherwise) described and appropriate?	☒	☐	☐	☐
If No or Unclear has been marked for any of the above then please elaborate:				
3. Impact and importance	☐	☐	☐	☐
Are the expected values and benefits of the research clear?	☒	☐	☐	☐
Will the research add to current knowledge or have training value?	☒	☐	☐	☐
Is the research generalisable i.e. have potential application beyond the Trust?	☒	☐	☐	☐
Will the findings lead to significant health gains and/or benefit the Trust/ NHS/ population?	☒	☐	☐	☐
If No or Unclear has been marked for any of the above then please elaborate:				

4. Dissemination	☐	☐	☐	☐
Do the researchers intend to disseminate research findings in an appropriate journal ?	☒	☐	☐	☐
Will the results of the research be made available to research participants?	☒	☐	☐	☐
If No or Unclear has been marked for any of the above then please elaborate:				
5. Feasibility	☐	☐	☐	☐
Is the research feasible within the local context?	☒	☐	☐	☐
Is the project feasible within the timeframe and resources proposed?	☒	☐	☐	☐
Is the proposed research likely to put the Trust, Trust staff, participants in the research or the applicants at risk, which are such that these should specifically be taken into account when deciding whether or not to support the research?	☐	☒	☐	☐
Where relevant, has a multidisciplinary and multi-professional approach to addressing the research question been adopted?	☒	☐	☐	☐
If No or Unclear has been marked for any of the above then please elaborate: Research is unlikely to put trust/staff/patients at specific risk to be taken into account.				

6. Consumer Involvement	☐	☐	☐	☐
Where relevant, have patients or their representatives been involved in this project?	☒	☐	☐	☐
If No or Unclear has been marked for any of the above then please elaborate:				

OVERALL RATING (Scale of 1-5 were 1 indicates poor, 3 acceptable and 5 excellent)	5

Overall Comments

Please provide comments you may wish to make on the proposal, particularly any suggestions as to how the project could be amended. Your comments will be used to provide feedback to the Principal Investigator.

This study proposal demonstrates potential for direct patient benefit for older hospital inpatients with malnutrition, who's management poses a significant clinical challenge. The project appears feasible and deliverable in the proposed timeframe with no concerns within the protocol or intervention identified.

Additional data which might be considered for collection would be markers of acute illness such as early warning score and c-reactive protein routinely collected in clinical care, which will not add to participant burden but may be useful to determine factors affecting palatability and compliance and for future trials.

REVIEWER RECOMMENDATION	*Approve:* ☒ *Approve with amendments described above:* ☐ *Resubmit after amendments described above:* ☐ Reject: ☐
Signature: **(please provide a physical signature and not a copy of a scanned example)**	
Printed Name:	*Dr Natalie Cox*
Job Title & Organisation:	*Visiting research fellow academic geriatric medicine and specialist registrar geriatric medicine.*
Date:	*05/10/2022*

University Hospital Southampton NHS Foundation Trust

Scientific Peer Review Form

PROJECT TITLE	Compliance and palatability of fortified porridge compared to standard liquid-based oral nutritional

	supplementation in hospitalised older adults with malnutrition
CHIEF INVESTIGATOR	Dr Stephen Lim
STUDENT (if applicable)	

All studies which are requesting sponsorship from University Hospital Southampton NHS Foundation Trust will require **two** supporting peer reviews to assist in the verification of the scientific quality and robustness of the study.

Please note no internal peer review is required for projects where an external body is undertaking a review as part of a funding application but should include confirmation of the funding award with the Sponsorship request.

SCIENTIFIC QUALITY PEER REVIEW	**ASSESSMENT CRITERIA**			
	YES	**NO**	**UNCLEAR**	***N/A***
1. Study Design	☒	☐	☐	☐
Does the research have a clear protocol?	☒	☐	☐	☐
Is the research question or hypothesis clearly stated?	☒	☐	☐	☐
Are the project objectives described?	☒	☐	☐	☐
Are the objectives realistic?	☒	☐	☐	☐
Has other relevant research been reviewed?	☒	☐	☐	☐
Is the methodology appropriate to the research question?	☒	☐	☐	☐
Have the methods of measurement been described?	☐	☐	☒	☐
Has the reliability and validity of measurement been reviewed?	☒	☐	☐	☐
If available, are validated scales of measurement being used?	☒	☐	☐	☐
If No or Unclear has been marked for any of the above then please elaborate: - It would be helpful to clarify how and who will prepare the ONS products on wards (are these the HCPs that will be interviewed too?). How would the leftovers of ONS				

will be measured (?visually) to ensure that it is standardised ? Are the food diaries part of usual care already on the wards? -				
2. Study sample and data analysis	☒	☐	☐	☐
Is the proposed population group appropriately representative?	☒	☐	☐	☐
Is the sample size justified and realistic?	☒	☐	☐	☐
Are the methods of data analysis (statistical or otherwise) described and appropriate?	☒	☐	☐	☐
If No or Unclear has been marked for any of the above then please elaborate:				
3. Impact and importance	☒	☐	☐	☐
Are the expected values and benefits of the research clear?	☒	☐	☐	☐
Will the research add to current knowledge or have training value?	☒	☐	☐	☐
Is the research generalisable i.e. have potential application beyond the Trust?	☒	☐	☐	☐
Will the findings lead to significant health gains and/or benefit the Trust/ NHS/ population?	☒	☐	☐	☐
If No or Unclear has been marked for any of the above then please elaborate:				
4. Dissemination	☒	☐	☐	☐
Do the researchers intend to disseminate research findings in an appropriate journal ?	☒	☐	☐	☐
Will the results of the research be made available to research participants?	☒	☐	☐	☐

If No or Unclear has been marked for any of the above then please elaborate:				
5. Feasibility	☒	☐	☐	☐
Is the research feasible within the local context?	☐	☐	☒	☐
Is the project feasible within the timeframe and resources proposed?	☒	☐	☐	☐
Is the proposed research likely to put the Trust, Trust staff, participants in the research or the applicants at risk, which are such that these should specifically be taken into account when deciding whether or not to support the research?	☐	☒	☐	☐
Where relevant, has a multidisciplinary and multi-professional approach to addressing the research question been adopted?	☒	☐	☐	☐
If No or Unclear has been marked for any of the above then please elaborate: As above, some clarity on preparation of the ONS whether if this will be by study team or HCP to ensure it's feasible within a busy ward setting				
6. Consumer Involvement	☒	☐	☐	☐
Where relevant, have patients or their representatives been involved in this project?	☒	☐	☐	☐
If No or Unclear has been marked for any of the above then please elaborate:				

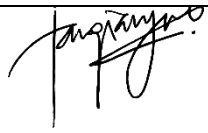
OVERALL RATING (Scale of 1-5 were 1 indicates poor, 3 acceptable and 5 excellent)	4

Overall Comments

Please provide comments you may wish to make on the proposal, particularly any suggestions as to how the project could be amended. Your comments will be used to provide feedback to the Principal Investigator.

Clear background and aims of the study with key and relevant outcomes measures. Minor clarification on the methods for data collection would be helpful as described above.

REVIEWER RECOMMENDATION	*Approve:* ☐ *Approve with amendments described above:* ☒ *Resubmit after amendments described above:* ☐ Reject: ☐
Signature:	

(please provide a physical signature and not a copy of a scanned example)	
Printed Name:	*Qian Yue Tan*
Job Title & Organisation:	*Specialist Registrar Geriatric Medicine and Clinical Research Fellow Academic Geriatric Medicine, University Hospital Southampton NHS FT*
Date:	*01.09.2022*

Date Information Collected: | | | | | | | (d d m m y y)

Gender: Male = 0 Female = 1 | |

Date of Birth: | | | | | | | (d d m m y y)

SOCIAL CIRCUMSTANCES

Marital status:
Single = 1
Married = 2
Divorced or separated = 3
Widowed = 4
Cohabiting = 5
| |

Usual Residence:
Private home living alone = 1
Private home living with friends or relatives = 2
Sheltered accommodation = 3
Residential/Rest Home = 4
Nursing Home = 5
| |

Care provision:
- **No care required = 0**
- **Informal provision = 1**
- **Formal provision = 2**

| |

Tobacco and alcohol consumption:

Smoking Never = 1 Ex = 2 Current = 3 | |

Cigarette pack years | | | |

Alcohol units per week | | |

Short Nutritional Assessment Questionnaire (SNAQ)

1. My appetite is:
   a. Very Poor
   b. Poor
   c. Average
   d. Good
   e. Very Good

2. When I eat:
   a. I feel full after eating only a few mouthfuls
   b. I feel full after eating about a third of a meal
   c. I feel full after eating over half a meal
   d. I feel full after eating most of the meal
   e. I hardly ever feel full

3. Food tastes:
   a. Very bad
   b. Bad
   c. Average
   d. Good
   e. Very good

4. Normally I eat:
   a. Less than one meal a day
   b. One meal a day
   c. Two meals a day
   d. Three meals a day
   e. More than three meals a day

Total Score: _____/20

PRISMA-7 Questionnaire

	Patient Questions	Yes	No
1.	Are you older than 85 years?		
2.	Are you male?		
3.	In general, do you have any health problems that require you to limit your activities?		
4.	Do you need someone to help you on a regular basis?		
5.	In general, do you have any health problems that require you to stay at home?		
6.	If you need help, can you count on someone close to you?		
7.	Do you regularly use a stick, walker, or wheelchair to move about?		
	Total checked:		

SARC–F screening tool

Component	Question	Scoring
Strength	How much difficulty do you have in lifting and carrying 10lb (5 bags of sugar)?	None = 0 Some = 1 A lot or unable = 2
Assistance in walking	How much difficulty do you have walking across a room?	None = 0 Some = 1 A lot, use aids, or unable = 2
Rise from a chair	How much difficulty do you have transferring from a chair or bed?	None = 0 Some = 1 A lot or unable without help = 2
Climb stairs	How much difficulty do you have climbing a flight of 10 stairs?	None = 0 Some = 1 A lot or unable = 2
Falls	How many times have you fallen in the past year?	None = 0 1 – 3 falls = 1 ≥ 4 falls = 2
	Total score	

ONS INTAKE

Date: _____ Ward: _____

ONS Product (please circle & write flavour):

Build & Restore Porridge (_____) / Fortisip (_____)

MORNING ONS

Amount given (g): _____ Amount left (g): _____

Total Intake (g): _____

Total Energy Intake (kcal): _____ Total Protein Intake (g): _____

EVENING ONS

Amount given (g): _____ Amount left (g): _____

Total Intake (g): _____

Total Energy Intake (kcal): _____ Total Protein Intake (g): _____

TOTAL ONS INTAKE

Amount given (g): _____ Amount left (g): _____

Total Intake (g): _____

Total Energy Intake (kcal): _____ Total Protein Intake (g): _____

PALATABILITY

Date: _____ Ward: _____

ONS Product (please circle & write flavour):

Build & Restore Porridge (_____) / Fortisip Compact (_____)

Look at the product. Note: Do not taste yet! Please, answer the following question (circle):
Based on the sample appearance how much do you expect to like the taste of this product?


Definitely Like	Moderately Like	Mildly Like	Neither Like nor Dislike	Mildly Dislike	Moderately Dislike	Definitely Dislike

Smell the product. Note: Do not taste yet! Please, answer the following question (circle):
Based on the sample smell, how much do you expect to like the taste of this product?


Definitely Like	Moderately Like	Mildly Like	Neither Like nor Dislike	Mildly Dislike	Moderately Dislike	Definitely Dislike

Please, take a bite/mouthful and answer the following question:
How much do you like the **taste** of this product?


Definitely Like	Moderately Like	Mildly Like	Neither Like nor Dislike	Mildly Dislike	Moderately Dislike	Definitely Dislike

Please take another bite/mouthful and answer the following questions:
How much do you like the **sweetness** of this product?


Definitely Like	Moderately Like	Mildly Like	Neither Like nor Dislike	Mildly Dislike	Moderately Dislike	Definitely Dislike

How much do you like the **texture/mouth feel** of this product?


Definitely Like	Moderately Like	Mildly Like	Neither Like nor Dislike	Mildly Dislike	Moderately Dislike	Definitely Dislike

How much do you like the **thickness** of this product?


Definitely Like	Moderately Like	Mildly Like	Neither Like nor Dislike	Mildly Dislike	Moderately Dislike	Definitely Dislike

Please answer the following questions after swallowing the product.
After swallowing, how much do you like the **aftertaste** of this product?


Definitely Like	Moderately Like	Mildly Like	Neither Like nor Dislike	Mildly Dislike	Moderately Dislike	Definitely Dislike

After swallowing, how much do you like the **feeling in your mouth** associated with the product?


Definitely Like	Moderately Like	Mildly Like	Neither Like nor Dislike	Mildly Dislike	Moderately Dislike	Definitely Dislike

Indicate to what extent you agree with this statement:

"I like this product and would be happy to choose this product in future"


I strongly agree	I largely agree	I agree somewhat	I neither agree nor disagree	I disagree somewhat	I largely disagree	I strongly disagree

Comments:

_____

_____

_____

_____

_____

_____

Interview Schedule – Patients

A) Explore general eating behaviours and food intake

1. In general, what do you normally eat during the day?
2. Is there anything that puts you off from eating, or that you struggle with when eating, or getting food?
    - Explore appetite
    - Explore food preparation and cost
    - Explore physical abilities (e.g., teeth, pain)
3. What kind of things encourage you to eat regularly, or makes eating easier?
    - Explore support from others
    - Taste preferences
    - Food preparation

B) Explore experiences of eating in hospital

4. What are your views and experiences of the food you have eaten in the hospital?
5. Did you need any help/support when eating your food?

C) Explore experiences using ONS in hospital

6. What did you think about the drinks (liquid-based ONS) you were given in-between your meals?
    - What were the good things about the drink?
    - Were there any bad things about the drink, or anything to improve?
    - What did they taste like?
    - Did you manage to drink both drinks over the day? Explore supplement fatigue/boredom
7. What did you think about the porridge (fortified ONS) you were given between your meals?
    - What were the good things about the porridge?
    - Were there any bad things about the porridge, or anything to improve?
    - What did the porridge taste like? (explore palatability when hot and cold)
    - Did you manage to eat both porridge supplements over the day? Explore supplement fatigue/boredom

8. What are your favourite snacks? Is there anything that you would prefer to eat in-between your meals in the hospital?

D) Explore perceived eating/food improvements required in hospital

9. What could improve your experience of eating food in the hospital?
10. What kind of food would you like to eat in hospital?

E) Explore nutrition/diet transition from hospital to community

11. When you leave hospital how confident are you that you can eat a healthy diet? Explore answer e.g., what makes you this confident?
12. Would you consider eating anything like the porridge or drinks in-between meals when you are at home? Why is this?

F) Explore any other comments

13. Do you have anything else to say about your diet/eating?
14. Do you have anything else to say about the porridge or drinks that you were given in-between your meals in hospital?

Interview Schedule – Staff

A) Explore staff role in malnutrition management

1. Could you explain what your job role is at the hospital?
2. Within your job role could you explain/describe the input you have regarding an older patient's nutrition and eating?
3. If you come across a patient with malnutrition what is the process for treatment? In what ways does the hospital optimise nutrition for older patients with malnutrition?

B) Explore general use of ONS in hospital

4. In general, what is the prescription and management of ONS like in hospital for older malnourished patients?
5. What are your views about the use of ONS for older patients with malnutrition?
6. What are the benefits of using ONS?
7. What are your concerns with using ONS?
8. What are the barriers to using ONS in hospital with patients? In your view, what are the things that patients struggle with when using ONS?
9. How can these things be addressed? What factors facilitate the use of ONS in hospital with older patients?

C) Explore specific ONS products used in the trial

10. What do you think about the use of liquid-based ONS for malnourished patients in hospital?
    - Benefits of the ONS?
    - Disadvantages of the ONS, or anything to improve?
11. What do you think about the fortified porridge for malnourished older patients?
    - Benefits of the porridge? Good things about the porridge?
    - Disadvantages, or barriers when using the porridge?
    - Would you use the porridge regularly with your patients? Why?
12. In your view, what are the best types of ONS to use in hospital? Why?
13. What needs to be changed to optimise patients' nutrition in hospital?

D) Explore perceptions of future improvements required for malnourished older adults nutritional care/support

14. Do you feel you have sufficient support and resources to deliver optimal malnutrition management for older patients?
15. Does anything need to be changed to improve nutrition support for malnourished older adults in hospital?
16. Do you have anything else you would like to say about using ONS to manage malnutrition in hospital?
17. Do you have anything else you would like to add about the porridge or liquid-based ONS used in this study?

Anonymous liquid-based ONS product specification

Ingredients : Vanilla flavour: Cow's **milk** proteins, water, maltodextrin, sucrose, vegetable oils (rapeseed oil, sunflower oil), magnesium hydrogen phosphate, emulsifier (**soy** lecithin), flavouring, choline chloride, potassium citrate, sodium L-ascorbate, dipotassium hydrogen phosphate, ferrous lactate, retinyl acetate, colour (curcumin), DL-α-tocopheryl acetate, copper gluconate, zinc sulphate, manganese sulphate, calcium D-pantothenate, thiamin hydrochloride, pyridoxine hydrochloride, nicotinamide, riboflavin, sodium fluoride, pteroylmonoglutamic acid, chromium chloride, potassium iodide, sodium molybdate, sodium selenite, D-biotin, phytomenadione, cholecalciferol, cyanocobalamin. Allergy Advice: For allergens, see ingredient in **bold**.

Shelf life : 12 months. Best before date: see side of bottle.

Storage : Store in a cool, dry place (5-25°C). Shake well before use. Once opened, close the bottle and store in a refrigerator for a maximum of 24 hours.

Suitability :
Halal, Kosher and Vegetarian

This is intended to show suitability of products for religious or dietary reasons. Some products may be suitable for kosher or halal diets but only products with Kosher approval or Halal certification have been identified here. Some individual flavours/variants may not be suitable and for more information please call our Resource Centre.

Macro-Nutrients :

Nutrients	Unit	per 100ml	per 125ml
Energy	kcal	245	306
Energy	kJ	1029	1286
Protein	g	14.6	18.3
nitrogen	g	2.3	2.9
Protein	% of total energy	24	24
Carbohydrate	g	25.1	31.4
polysaccharides	g	11.4	14.3
sugars	g	13.7	17.1
- lactose	g	<0.35	<0.44
Carbohydrate	% of total energy	41	41
Fat	g	9.6	12
saturates	g	0.86	1.08
- monounsaturates	g	5.7	8.1
- polyunsaturates	g	3.0	3.8
Fat	% of total energy	35	35
Fibre	g	0	0
Fibre	% of total energy	0	0

Vitamins :

Nutrients	Unit	per 100ml	per 125ml
Vitamin A	µg	260	325
Vitamin D	µg	2.08	2.60
Vitamin E	mg (α-TE)	4.90	6.13
Vitamin K	µg	18.9	23.6
Thiamin	mg	0.52	0.65
Riboflavin	mg	0.56	0.70
Niacin	mg (mg NE)	0.70 (4.12)	0.88 (5.15)
Pantothenic acid	mg	1.53	1.91
Vitamin B6	mg	0.61	0.76
Folic acid	µg	80.9	101.1
Vitamin B12	µg	0.90	1.13
Biotin	µg	10.1	12.6
Vitamin C	mg	30.7	38.4

Minerals :

Nutrients	Unit	per 100ml	per 125ml
Sodium	mg (mmol)	35.0 (1.52)	43.8 (1.90)
Potassium	mg (mmol)	97.6 (2.50)	122 (3.13)
Chloride	mg (mmol)	60.0 (1.69)	75 (2.11)
Calcium	mg (mmol)	350 (8.73)	438 (10.9)
Phosphorus	mg (mmol)	282 (9.11)	353 (11.4)
Magnesium	mg (mmol)	54.0 (2.22)	68 (2.78)
Iron	mg	2.19	2.74
Zinc	mg	2.58	3.23
Copper	mg	0.35	0.44
Manganese	mg	0.64	0.80
Fluoride	mg	0.18	0.23
Molybdenum	µg	21.5	26.9
Selenium	µg	15.4	19.3
Chromium	µg	13.0	16.3
Iodine	µg	49.0	61.3

Other nutrient information :

Nutrients	Unit	per 100ml	per 125ml
Choline	mg	99.4	124.3
Water	g	62	78
Osmolarity	mOsmol/l	570	570
Potential renal solute load	mOsmol/l	971	971
pH		6.6	6.6

Adams Vital Nutrition Ltd. Vital Daily High Protein Oats - product specification

Product Specification

VITAL DAILY PORRIDGE GF **GOLDEN SYRUP**

Valid in:	United Kingdom
Manufactured in:	UK
General description:	Golden Syrup flavour porridge fortified with vitamins and minerals

Product information

suitable for
vegans contains
no yeast extract
high protein
gluten free

According to regulation 828/2014/EU

Characteristics

Texture:	powder
Texture (after preparation):	homogeneous
Convenience:	instant

Preparation		Cooking time: 0 minutes	
Quantity	Ingredient	Temperature	Instruction
57.00 g 100.00 g	product water	- -	57g powder to 100ml boiling water. Mix well
Yield ca.: 157.000 g			

Shelf life (provisional)

12 Months

Storage instructions

Keep in a cool and dry place (8-25°C) and protect from light and frost. Always close the container properly.

Nutrition Information	Unit	Typical value per 100g	GDA [%]* typical value per 100g	Per serving per 100g	GDA [%]* per serving per 100g	Per serving per 157g	GDA [%]* per serving per 157g
Energy	kJ	1652		600		**941**	
	kcal	391	20	142	7	**223**	11
fat	g	7.8	11.1	2.8	4.0	**4.4**	6.3
of which:							
- saturates	g	1.6	8.0	0.6	2.9	**0.9**	4.6
carbohydrate	g	55.8	21.5	20.3	7.8	**31.8**	12.2
of which:							
- sugars	g	32.7	36.3	11.9	13.2	**18.6**	20.7
fibre	g	4.5		1.6		**2.6**	

protein	g	21.2	42.4	7.7	15.4	**12.1**	24.2
salt**	g	0.75	12.51	0.27	4.54	**0.43**	7.13

**Salt calculated from the sodium content * 2.5

* = % of the daily "reference intake of an average adult (8400 kJ / 2000 kcal)". The nutritional needs of individuals may be higher or lower, based on gender, age, level of physical activity and other factors.

Additional Nutrition Information	Unit	Typical value per 100g	GDA [%]* typical value per 100g	Per serving per 100g	GDA [%]* per serving per 100g	Per serving per 157g	GDA [%]* per serving per 157g
moisture	g	8.0					
salt (NaCl)	g	0.3		0.1		0.2	
calories out of protein	kcal	85		31		48	
sodium	g	0.30		0.11		0.17	

Health&Nutrition information value	Unit	100% RDA	Typical value per 100g	%*	Per serving per 100g	%*	Per serving per 157g	%*
calcium	mg	800.00	368.98	46.12	133.96	16.74	**210.32**	26.29
copper	mg	1.00	0.95	94.87	0.34	34.44	**0.54**	54.07
iodine	µg	150.00	63.00	42.00	22.87	15.25	**35.91**	23.94
iron	mg	14.00	11.52	82.30	4.18	29.88	**6.57**	46.91
magnesium	mg	375.00	133.33	35.55	48.41	12.91	**76.00**	20.27
phosphorus	mg	700.00	363.71	51.96	132.05	18.86	**207.31**	29.62
potassium	mg	2000.00	194.21	9.71	70.51	3.53	**110.70**	5.53
selenium	µg	55.00	37.60	68.36	13.65	24.82	**21.43**	38.97
zinc	mg	10.00	8.99	89.91	3.26	32.64	**5.13**	51.25
biotin	µg	50.00	33.91	67.82	12.31	24.62	**19.33**	38.66
folic acid	µg	200.00	235.10	117.55	85.35	42.68	**134.01**	67.00
niacin	mg	16.00	7.46	46.64	2.71	16.93	**4.25**	26.59
pantothenic acid	mg	6.00	3.09	51.57	1.12	18.72	**1.76**	29.39
riboflavin	mg	1.40	0.93	66.40	0.34	24.11	**0.53**	37.85
thiamin	mg	1.10	1.20	108.68	0.43	39.46	**0.68**	61.95
vitamin A	µg	800.00	360.00	45.00	130.70	16.34	**205.20**	25.65
vitamin B12	µg	2.50	1.44	57.60	0.52	20.91	**0.82**	32.83
vitamin B6	mg	1.40	1.01	72.02	0.37	26.15	**0.57**	41.05
vitamin C	mg	80.00	108.16	135.20	39.27	49.09	**61.65**	77.07
vitamin D	µg	5.00	18.00	360.00	6.54	130.70	**10.26**	205.20
vitamin E	mg	12.00	7.69	64.10	2.79	23.27	**4.38**	36.54
vitamin K	µg	75.00	46.80	62.40	16.99	22.65	**26.68**	35.57

* = % recommended daily allowances