nutRition intervEntions For malnouRished oldEr adultS in care Homes (REFRESH) – a parallel, superiority, three-arm cluster randomised controlled trial

REFRESH trial

nutRition intervEntions For malnouRished oldEr adultS in care Homes

PROTOCOL

Version 4.0 12MAR2026

RESEARCH REFERENCE NUMBERS

IRAS number:	334241
ISRCTN:	ISRCTN15687909
SPONSOR'S number:	6324
FUNDER'S reference:	NIHR160348

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

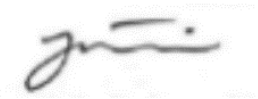
SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigators agree to conduct the trial in compliance with the approved protocol and in accordance with the UK Policy Framework for Health and Social Care Research, the Data Protection Act 2018), the principles of Good Clinical Practice (GCP) and the Sponsor's (and any other relevant) standard operating procedures (SOPs).

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 clinical investigation without the prior written consent of the Sponsor.

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

For and on behalf of the Trial Sponsor:

Signature:	Date (dd/mm/yyyy):
	

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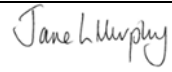	

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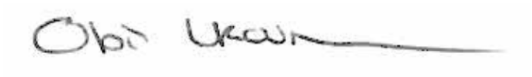
Signature: 	Date (dd/mm/yyyy):

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PROTOCOL AMENDMENT HISTORY

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
N/A	V1.1	11JUN2025	Emily Stanyard	Funder approval to update 3-month pilot phase to 6-months.
N/A	V1.2	26JUN2026	Katherine Beaney and Emily Stanyard	Minor updates following Sponsor review (change of Sponsor rep email address and data custodian). Minor updates following Funder review (clarification added to the pilot phase section (5.3) as to the action for each outcome scenario). DMEC chair added.
N/A	V2.0	02SEP2025	Emily Stanyard, Mary Hickson, Jane Murphy, Jade Chynoweth, Naomi Shaw	Updates following REC review: - Background updated to better reflect the challenges faced by care homes. - Secondary outcome table amended to show care home staff support with questionnaire completion. - Sections 4.1 (ONS) and 4.2 (FF) updated to clarify process if a resident declined consumption.

				- Nominated consultee process clarified. - Easy read information sheet process added. - Observation procedures updated. - Withdrawal process clarified. Other changes: - Addition of TSC member. - Inclusion of end-of-life exclusion criteria. - Bath and Bristol added to Dorset/Hampshire study region. - CONSORT diagram updated to reflect updated region and that ONS will not be prescribed. - FAST reference corrected. - Stratification process clarified. - Update to co-Chief Investigator Jane Murphy's organisation. - Minor typographical and grammatical edits.
N/A	V2.1	01OCT2025	Emily Stanyard	Updates following REC review: - Clarification and more detail added to the nominated/personal consultee declaration process. - Update to easy read information sheet section: removal of 'optional consent points' explanation which have been removed from the easy read document.
SA0126	V3.0	12JAN2026	Emily Stanyard	- ISRCTN number added. - Study number format corrected. - Clarified that the Dorset/Hampshire/Bath/Bristol area may also include other areas covered by South West Central and South Central RRDNs depending on fieldworker and RRDN availability. - Table 6: Extended the arrow indicating when safety events are reportable to ensure consistency with the safety reporting section

				(from the point of consent/declaration). - Clarified and simplified the research training section. - Outlined that a secure password-protected spreadsheet may be used to facilitate the consent/declaration process by documenting contact with consultees/residents and their contact details. - Broadened the consent process to allow occasions where RPs may obtain consent or the declaration from residents/consultees.
SA0226	V4.0	20MAR2026	Emily Stanyard	- Care home baseline data fields updated. - Clarifications to the personal consultee process. - Updates to timelines within existing grant period. - Update to the eligibility criteria to include residents already receiving supplements who may benefit from participation, with clarification on how the intervention will be managed for these residents.

KEY TRIAL CONTACTS

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i. LIST OF CONTENTS

SIGNATURE PAGE....2
PROTOCOL AMENDMENT HISTORY....3
KEY TRIAL CONTACTS....5
ii. LIST OF ABBREVIATIONS....10
iii. TRIAL SUMMARY....13
iv. FUNDING AND SUPPORT IN KIND....17
v. ROLE OF TRIAL SPONSOR AND FUNDER....17
vi. ROLE OF THE COORDINATING CLINICAL TRIALS UNIT (CTU)....17
vii. ROLES OF TRIAL OVERSIGHT COMMITEES AND GROUPS....17
viii. PROTOCOL CONTRIBUTORS....18
ix. KEY WORDS....18
x TRIAL FLOW CHARTS....19
1 BACKGROUND....21
2 RATIONALE....23
3 OBJECTIVES AND OUTCOME MEASURES....24
4 TRIAL INTERVENTIONS....28
5. TRIAL DESIGN....34
6. TRIAL SETTING....37
7. ELIGIBILITY CRITERIA....38
8 TRIAL CONDUCT....39
9 STAFF TRAINING....51
10 PROCESS EVALUATION....51
11 STUDY WITHIN A PROJECT (SWAP) - Nutritional Care of culturally diverse older adults living in care homes....55
12 PAYMENTS....59
13 WITHDRAWAL....59
14 END OF TRIAL....60
15 SAFETY MONITORING....60
16 STATISTICS AND DATA ANALYSIS....64
17 DATA MANAGEMENT....67
18 MONITORING, AUDIT & INSPECTION....69
19 PUBLIC AND PATIENT INVOLVEMENT....69
20 ETHICAL AND REGULATORY CONSIDERATIONS....70
21 DISSEMINATION POLICY....73
22 REFERENCES....76

ii. LIST OF ABBREVIATIONS

A&E	Accident & Emergency
ADL	Activities of Daily Living
AE	Adverse Event
ALCOA+	attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring, available
BDA	British Diabetic Association
BU PIER	Bournemouth University Public Involvement in Education and Research
CEA	Cost-Effectiveness Analysis
CFS	Clinical Frailty Scale
CHEERS	Consolidated Health Economic Evaluation Reporting Standards
CI	Chief Investigator
CMO	Context-Mechanism-Outcome
CONSORT	Consolidated standards of reporting trials
CQC	Care Quality Commission
CRF	Case Report Form
CTCAE	Common Terminology Criteria for Adverse Events
CTIMP	Clinical Trials of Investigational Medicinal Products
CTU	Clinical Trials Unit
CVD	Cardiovascular Disease
DEMQoL-CH	Dementia-specific Quality of Life (care homes)
DMEC	Data Monitoring and Ethics Committee
DMP	Data Management Plan
ECG	Electrocardiogram
eCRF	Electronic Case Report Form
EDI	Equity, diversity and inclusion
EMI	Elderly Mentally Infirm
ENRICH	NIHR Enabling Research in Care Homes
EOI	Expression of Interest
EQ-5D-5L	EuroQol-5 Dimensions-5 Levels
FREIC	Faculty Research Ethics and Integrity Committee
FAST	Functional Assessment Staging Tool
FF	Fortified Food
GCP	Good Clinical Practice
GDPR	General Data Protection Act
GI	Gastrointestinal
HCSUQ	Health and Care Service Use Questionnaire

HEI	Higher Education Institutions
HRA	Health Research Authority
HRQoL	Health-Related Quality of Life
IBD	Inflammatory Bowel Disease
IBS	Irritable Bowel Syndrome
ICC	Intra-cluster correlation coefficient
ICER	Incremental Cost-Effectiveness Ratio
IMCA	Independent Mental Capacity Advocate
ISF	Investigator Site File (This forms part of the TMF)
ISRCTN	International Standard Randomised Controlled Trials Number
ITT	Intention-To-Treat
Kcals	Kilocalories
MBI	Modified Barthel Index
MCA	Mental Capacity Act (2005)
MedDRA	Medical Dictionary for Regulatory Activities
MHRA	Medicines and Healthcare products Regulatory Agency
MNA	Mini Nutritional Assessment
MUST	Malnutrition Universal Screening Tool
NCI	National Cancer Institute
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NPT	Normalisation Process Theory
ONS	Oral Nutritional Supplement
PAG	Public Advisory Group
PenCTU	Peninsula Clinical Trials Unit
PPI	Patient and Public Involvement
PPIE	Patient and Public Involvement and Engagement
PRN	*pro re nata* (as needed)
PT	Preferred Term
QA	Quality Assurance
QALY	Quality Adjusted Life Year
QoL	Quality of Life
RCT	Randomised Controlled Trial
RDN	Research Delivery Network
REC	Research Ethics Committee
RIS	Resident Information Sheet
RP	Research Partner

SAE	Serious Adverse Event
SAG	Stakeholder Advisory Group
SD	Standard Deviation
SHEAP	Statistical and Health Economics Analysis Plan
SMS	Short Message Service
SOC	System Organ Class
SOC*	Service Organisation Control
SOP	Standard Operating Procedure
SWAP	Study within a Project
TIDieR	Template for Intervention Description and Replication
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee
UK	United Kingdom
UKCRC	UK Clinical Research Collaboration
USM	Urgent Safety Measures
WHO	World Health Organisation

iii. TRIAL SUMMARY

Trial Title	nutRition intervEntions For malnouRished oldEr adultS in care Homes – a parallel, superiority, three-arm cluster randomised controlled trial.	
Trial Acronym	REFRESH	
Trial Design	A parallel, superiority, three-arm cluster randomised controlled trial comparing oral nutritional supplements and fortified food with usual nutritional care in care homes.	
Planned Sample Size	1530 participants.	
Planned Number of Sites	90 care homes.	
Research Question	In older adults with or at risk of malnutrition living in care homes, what is the clinical and cost-effectiveness of oral nutritional supplements (ONS arm) and fortified food (FF arm) compared to routine practice (usual care arm)?	
	Objectives	**Outcome Measures**
Primary	To compare the health-related quality of life of care home residents (with or at risk of malnutrition) receiving the ONS and FF with those receiving usual care, at 6 months' follow-up.	EuroQol-5 Dimensions-5 Levels (EQ-5D-5L) Proxy Version 2
Secondary	1. Evaluate the effects of ONS and FF compared to usual care at 6 months' follow-up on: i. Dementia-specific Quality of Life ii. Nutritional status iii. Weight iv. Dietary intake v. Functional limitations vi. Acceptability and adherence vii. Morbidity viii. Mortality *(and at 12 months)* ix. Health-related quality of life *(12 months for secondary outcome)* x. Health and social care resource use *(and at 12 months)*	i. Dementia-specific Quality of Life (care homes) (DEMQoL-CH) ii. Mini Nutritional Assessment (MNA score) iii. Weight (kg) iv. 3-day photographed food records and food record charts v. Modified Barthel Index (MBI) vi. 3-day photographed food records and food record charts interviews/focus groups vii. Antibiotic use (count) viii. Registered death records ix. EuroQol-5 Dimensions-5 Levels (EQ-5D-5L) Proxy Version 2 x. Bespoke Health and Care Service Use Questionnaire (HCSUQ)
Trial Population		
Trial Participants	1530 adults over the age of 65 years who are with or at risk of malnutrition.	

Inclusion Criteria	1. Permanent resident in a care home (not respite or intermediate care). 2. Aged ≥ 65 years at the time of consent. 3. Able to eat and drink. 4. With or at risk of malnutrition as measured by scoring 1 or more out of 6 on the Malnutrition Universal Screening Tool (MUST). 5. Able to obtain informed consent from the individual or a consultee based on the presumed will of an incapacitated adult
Exclusion Criteria	1. Fed *via* feeding tube. 2. Active cancer treatment or recent major surgery. 3. Considered by the care home staff to be approaching the end of life, where participation in the study would not be appropriate. 4. Already receiving nutrition support (ONS or fortified meals) with individualised dietetic advice from a dietitian (see Section 7.3).
Care Homes	
Eligibility Criteria	1. Long-term residential care setting where older adults receive 24-hour care and support. 2. Care home-owner permission to take part. 3. Not taking part in other research studies which could affect the conduct of this trial e.g. a nutrition intervention trial or other complex intervention.
Intervention	
Description of Interventions	Interventions are assigned by care home (cluster) randomisation, not individual randomisation. Residents in each care home are consented individually. All residents will continue to receive the routine nutritional care provided in the care home. **ONS arm:** Residents receive two standard ready-to-drink supplements daily providing approximately 600 kcals and 24 g protein per day in addition to meals. **FF arm:** Care homes randomised to the fortified food arm will instigate a menu providing fortified food (usual foods and drinks with added ingredients to increase nutrient density) for participating residents. As well as fortifying the menu meals, each resident included in the trial will also receive fortified snacks and drinks made from normal ingredients. **Usual care arm:** Residents in the usual care (control) arm will receive the routine care provided in the care home.
Intervention Duration	12 months
Process Evaluation	
Aim	The process evaluation will provide insight into the fidelity and quality of implementation, providing information about causal mechanisms and contextual factors and understanding of why the intervention might fail or have unexpected consequences.

Summary	Observations, interviews/focus groups and questionnaires will be undertaken as part of the process evaluation.
Participants	Care home residents, relatives/friends, care home staff and other healthcare professionals.
Inclusion Criteria	**Residents and relatives/friends:** 1. Already participating in the main trial and resident in a home selected for the process evaluation. 2. Has mental capacity to take part (this is assessed during the consent process for the main trial. Only those with mental capacity will be asked if they wish to take part in the process evaluation). 3. Willing to give consent. 4. A relative or friend involved in the care of a resident meeting Criterion 1, who is willing to be interviewed on their behalf and willing to give consent. **Care home staff:** 1. Employed by a Care Home participating in REFRESH and selected for participation in the Process Evaluation. 2. Employed in a caring role and involved in the care of REFRESH participants. **Other healthcare professionals:** 1. Involved in the nutritional care of a participating resident in a home selected for the process evaluation.
Exclusion Criteria	**Care home staff:** 1. Have a significant proportion of time caring for residents who are not enrolled in the trial.
Study Within a Project (SWAP)	
Aim	To understand how recruitment and retention of older residents from different ethnic backgrounds can be improved.
Summary	Observations, interviews/focus groups and dietary record collection will be undertaken as part of the SWAP.
Participants	Care home residents, relatives/friends and care home staff.
Inclusion Criteria	**Residents:** • Are a resident in a care home participating in the main REFRESH trial. • Identify they are from an ethnic minority group including UK South Asian and Black African & Caribbean communities. For residents unable to consent a family member or friend may be recruited. If the resident does not have the communication or language skills necessary to participate, they may choose a family member or friend to speak on their behalf. **Care home staff:** • Care for residents enrolled in the SWAP.
Timescales	

Planned trial period	January 2025: Grant start. January 2026: Start of Cohort 1 resident recruitment. September 2026: Start of Cohort 2 resident recruitment. December 2026: Start of Cohort 3 resident recruitment. June 2028: Completion of follow-ups. November 2028: End of data analysis. December 2028: Grant end.
Trial duration	48 months
Planned open to recruitment	January 2026
Planned end of recruitment	May 2027
Follow-up duration	6 and 12 months.

iv. FUNDING AND SUPPORT IN KIND

FUNDER(S)	FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN
National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) Programme	£2,759,478.35

This trial is funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) Programme. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

v. ROLE OF TRIAL SPONSOR AND FUNDER

The Sponsor for this trial, University of Plymouth, assumes overall responsibility for the initiation and management of the trial. The Sponsor may delegate specific tasks to any other individual or organisation that is willing and able to accept them. Any delegated tasks will be clearly recorded in a matrix of task allocations. Although tasks may be delegated, the overall responsibility remains with the Sponsor.

The Sponsor and funder will not have direct involvement in trial design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results. The trial was designed by the Chief Investigators (CI) and co-applicants with support from Peninsula Clinical Trials Unit (PenCTU).

vi. ROLE OF THE COORDINATING CLINICAL TRIALS UNIT (CTU)

The Sponsor of the trial has allocated tasks associated with overall trial management and data management to the Peninsula Clinical Trials Unit – UK Clinical Research Collaboration (UKCRC) registration no. 31. A detailed breakdown of tasks undertaken by CTU on behalf of the CI and trial Sponsor is described in the task allocation matrix. PenCTU's management of the trial includes the delivery of site initiation training and monitoring.

vii. ROLES OF TRIAL OVERSIGHT COMMITEES AND GROUPS

- **The Trial Management Group** (TMG) is chaired by the CIs and includes representation from the Sponsor, statistics team, PenCTU and patient representatives. It also includes representation from co-investigators and lead for the process evaluation (JM/LF). The TMG will meet monthly to review trial progress and to ensure appropriate management of the trial.
- Trial oversight will be provided by an independent **Trial Steering Committee** (TSC). The Trial Steering Committee (TSC) is an executive oversight body operating on behalf of the Sponsor and will make decisions as to the future continuation (or otherwise) of the trial. The TSC has an independent chair (Professor Pip Logan), independent trial experts (Professor Alicia O'Cathain, Dr Rachel Brierley, Dr Lee Hooper, Dr Joanna Thorn), three Patient and Public Involvement (PPI) representatives (June Clark, Kate Hawley, William Wilson), an independent statistician (Professor Andrew Copas) and a care home representative (Debbie McGinnes). The TSC will meet every 6-7 months or at least yearly in accordance with an agreed set of terms of reference, detailed in the TSC Charter, to review the progress of the trial and will report to the Sponsor and Funder. The roles, constitution and composition of the committee will be in

accordance with NIHR Research Governance Guidelines[1] and will be described in a committee-specific charter produced by the CTU. Independence of committee members will be as defined in the NIHR Research Governance Guidelines.

- **Stakeholder Advisory Group** (SAG). A Stakeholder Advisory Group (SAG) has been convened from a range of collaborating organisations, some of which have already been consulted in the development of the proposal. The SAG will meet at least 6 times over the trial and provide their insights, expert advice and guidance on trial delivery, development of resources and materials, links to care home providers for recruitment and dissemination.
- **Public Advisory Group** (PAG). A public advisory group of 6-8 people (relatives, friends & residents) will be actively involved during the whole trial (co-production of trial documentation, lay summaries, interpret findings & guide dissemination). The group have been recruited from BU PIER (Bournemouth University Public Involvement in Education and Research) partnership's extensive local and national networks (www.bournemouth.ac.uk/pier). BU is a collaborator on VOICE Global, the national digital PPI platform (https://voice-global.org/). PAG members will be recruited from both local networks and VOICE Global ensuring the PAG includes a diverse range of voices, including cultural, social, and economic differences, and people currently underserved by research and those most marginalised. All public involvement activities, including Mr Foy's role as PPI co-applicant will be active and partnership based and fully supported by Dr Kate Jupp throughout the project.
- **Data Monitoring and Ethics Committee** (DMEC). A DMEC will be convened in order to monitor the safety and ethics of the study by overseeing recruitment, primary outcome data completeness and serious adverse events (SAEs). The committee will include an independent chair, an independent statistician and another independent member. Operating procedures for the DMEC will be agreed before the start of the study and incorporated into a DMEC Charter, updated from time to time as required. The committee may meet approximately every 6 months, before the TSC meetings.

viii. PROTOCOL CONTRIBUTORS

The whole research team (see Key Trial Contacts) have contributed to the development of this protocol, as well as the Senior Trial Manager (Helen Neilens) and Trial Managers (Emily Stanyard and Katherine Beaney). Protocol contributors are responsible for inputting into the design of the trial, ensuring that it is designed transparently and efficiently.

ix. KEY WORDS

Malnutrition, care homes, fortified foods, oral nutritional supplements, nutritional interventions

x TRIAL FLOW CHARTS

Figure 1: Participant and Protocol Flow Chart

Refer to Section ii. List of Abbreviations

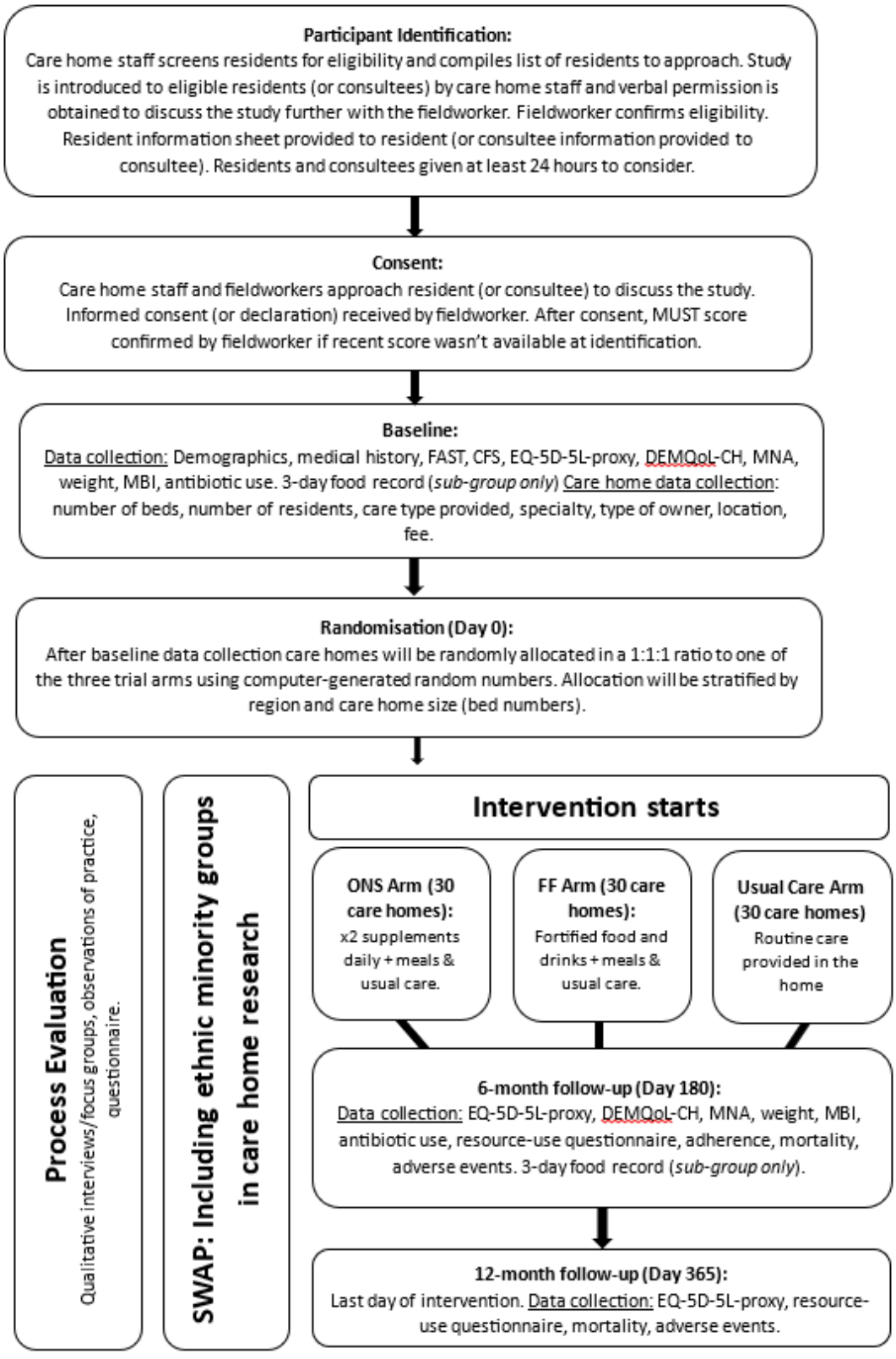
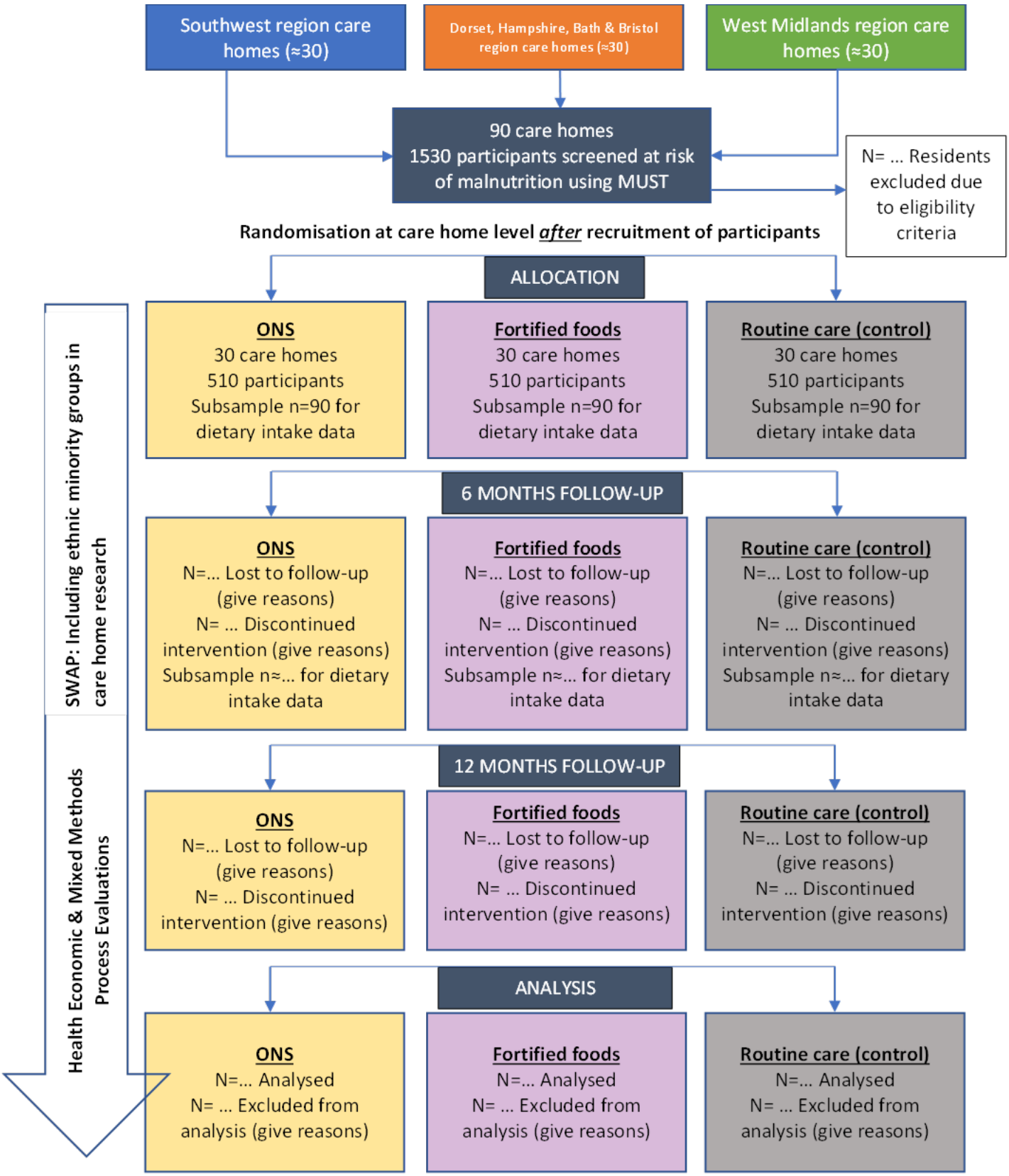


Figure 2: Expected flow of participants (draft CONSORT diagram)


Southwest region care homes (≈30)
Dorset, Hampshire, Bath & Bristol region care homes (≈30)
West Midlands region care homes (≈30)
90 care homes
1530 participants screened at risk of malnutrition using MUST
N= … Residents excluded due to eligibility criteria
Randomisation at care home level after recruitment of participants
ALLOCATION
ONS
30 care homes
510 participants
Subsample n=90 for dietary intake data
Fortified foods
30 care homes
510 participants
Subsample n=90 for dietary intake data
Routine care (control)
30 care homes
510 participants
Subsample n=90 for dietary intake data
6 MONTHS FOLLOW-UP
ONS
N=… Lost to follow-up (give reasons)
N= … Discontinued intervention (give reasons)
Subsample n≈… for dietary intake data
Fortified foods
N=… Lost to follow-up (give reasons)
N= … Discontinued intervention (give reasons)
Subsample n≈… for dietary intake data
Routine care (control)
N=… Lost to follow-up (give reasons)
N= … Discontinued intervention (give reasons)
Subsample n≈… for dietary intake data
12 MONTHS FOLLOW-UP
ONS
N=… Lost to follow-up (give reasons)
N= … Discontinued intervention (give reasons)
Fortified foods
N=… Lost to follow-up (give reasons)
N= … Discontinued intervention (give reasons)
Routine care (control)
N=… Lost to follow-up (give reasons)
N= … Discontinued intervention (give reasons)
ANALYSIS
ONS
N=… Analysed
N= … Excluded from analysis (give reasons)
Fortified foods
N=… Analysed
N= … Excluded from analysis (give reasons)
Routine care (control)
N=… Analysed
N= … Excluded from analysis (give reasons)
SWAP: Including ethnic minority groups in care home research
Health Economic & Mixed Methods Process Evaluations

1 BACKGROUND

More older people are moving into care homes, many are malnourished or at risk of malnutrition. Malnutrition harms their health, reduces their quality of life, and increases the risk of falls and infections. Malnourished older care home residents need more General Practitioner (GP) and hospital appointments, and experience slow recovery from illness. We know that treating malnutrition is costly; £23.5 billion/year in health and social care costs in the United Kingdom (UK). Over half of these costs are related to malnutrition in older adults. Currently, the recommended first approach for treating malnutrition in care homes is to provide food with extra protein, calories, vitamins, and minerals (fortified foods). If that is not enough, the second approach is to use powdered or liquid supplements (prescribed oral nutritional supplements; ONS).

Approximately 361,000 older people live in care homes in England, and around 80% have multiple long-term conditions and complex care needs[2,3], including frailty and dementia[4]. Between 26% and 42% of care home residents are malnourished or at risk of malnutrition[5], exposing them to detrimental health consequences. Care homes can face considerable challenges to treat and manage underweight and malnutrition for their residents. Delivering a highly flexible, individually centred food service can be costly and available funding does not always allow for this. Consequently, preprepared meals are often used with less flexibility in portion size and choices, catering services are delivered by external suppliers with less ability to respond to individual choices and requirements, and cheaper options may be favoured (less nutritious, more processed). Therefore, the recommendations for using fortified food first are not always followed, and associated health and care costs can continue to rise. There are a number of reasons why prescribed ONS are often used as the first approach. Care home staff may lack the knowledge and skills to provide fortified menus, snacks and drinks and often believe ONS are the best treatment given variable access to training and support for managing malnutrition. Prescribed ONS might also be perceived as more convenient to use than fortified food and it is cheaper for the care home (they do not fund ONS in England). Moreover, prescribed ONS further to a hospital stay might not be monitored effectively to best treat malnutrition. Consequently, many ONS are wasted because residents do not like them without follow-up on their use, or the care homes lack appropriate guidance and training and use ONS inappropriately.

Despite the ubiquitous use and huge cost (approx. £14 million/month in England) of ONS, there is little evidence to support their effectiveness or cost-effectiveness in older adults with or at risk of malnutrition[6]. Since a trial is in progress (STREAM)[7] examining the use of ONS in older adults living at home, the gap in the evidence is in care homes. The need for well-designed research in care homes is well recognised[8] to inform high-quality person-centred care[9] and for research to include older care home residents[10]. We have conducted feasibility work in this population comparing ONS and fortified foods with routine care, indicating a full trial is feasible and acceptable to residents and staff[11,12].

In this protocol, we use the expression ‘care home’ as an umbrella term to describe all long-term care facilities where older people live in full time, including those with and without on-site registered nurses (named nursing and residential homes respectively). We define malnutrition as under-nutrition as opposed to over-nutrition.

2,345

The Health and Social Care Act[13] requires care homes to ensure appropriate nutrition and hydration for residents as outlined by the Care Quality Commission (CQC). In care homes, food should meet the nutritional needs of the residents, their taste preferences, cultural norms, and contribute to pleasure in

their lives. The National Institute of Health & Care Excellence (NICE) Guidelines CG32 on nutritional support for adults[14] and other clinical pathway[15] recommend nutritional support for those at risk of malnutrition. Nutritional support includes dietary counselling (meal adaptation, advice on food intake), food fortification (increased nutrient & energy content of recipes without increasing the portion size), and prescribed ONS. Guidance indicates a food-based approach should be used first (dietary counselling, fortification) and ONS should be a second line option[16].

Dietitians have a key role to provide appropriate interventions through dietary advice and nutritional support. However, care staff, with appropriate training provided by dietitians, are well-placed to identify those residents at risk of malnutrition and provide appropriate first-line dietary support to promote weight gain and improve the nutritional status. Malnutrition care pathways guide when to refer for specialist nutritional support from a registered dietitian, who may advise the use of ONS.

2 RATIONALE

To understand how malnutrition is currently managed in care homes, we worked with the Older People Specialist Group (British Dietetic Association; BDA) and commissioned a national survey of dietitians who provide nutritional support for older people in UK care homes. We received over 45 responses from across the country with dietitians reporting a huge variation in how malnutrition is managed. Care pathways are implemented in some but not all, with some care homes relying solely on ONS, whilst others aim to use food first. One dietitian reported that the team was:

"*really trying to implement a food-based approach. This varies according to management, food budget, skills of catering staff. Some GPs feel compelled to prescribe ONS as a 'fix'. Sometimes it isn't managed at all until it is flagged with other comorbidities, such as pressure ulcers. Dietetic support is inadequate*."

We have shown from our own study that prescribed ONS are often used first as they are viewed as effective in managing malnutrition[17]. They are also prescribed in hospitals (at very little cost) and continued in care homes (at full cost), often with little monitoring or review due to a lack of access to dietetic services.

Evidence in older adults for ONS to reduce malnutrition or its associated adverse outcomes is limited[6] and there is a need for well-designed research to improve outcomes for diverse populations of older people across health and social care settings[18]. The evidence for food-based approaches for the management of malnutrition is similarly limited, particularly for older people in care homes[19]. Interventions of longer duration are needed[20]. A recently published systematic review and meta-analysis showed that fortified menus in care homes may increase energy and protein intake, compared with standard menus, though cost-effectiveness was inconclusive[21]. The analysis included only 2 of 16 studies from UK care homes, one of which was our feasibility study[12,20], highlighting the need for further research of food-based interventions and use of fortified diets in UK based care homes.

Malnutrition contributes to increased health care utilisation and health and social care expenditure (c. £23.5 billion per annum)[22] and part of this cost is the use of ONS. The Commercial Medicines Directorate, National Health Service (NHS) England, reports the escalating costs of ONS: £160 million in 2021-22 (approx. £14 million/month). ONS formulation does not suit all tastes and needs, consequently many are wasted[23]. Only one UK study[24] examines cost-effectiveness in care homes

which does not support firm conclusions regarding the use of ONS, thus, a health economic evaluation is crucial to include as part of this proposed trial.

A review of the World Health Organisation (WHO) and International Standard Randomised Controlled Trial Number (ISRCTN) trial registries identified very few nutrition trials in care homes, emphasising the need for this research in this setting. None of the identified trials were UK-based. Those registered included trials of interventions for improving nutrition knowledge of staff, volunteers, or family to reduce malnutrition risk[25], improving mealtime intake and nutritional status following a communication protocol or family style dining[26], and a cluster randomised controlled trial (RCT) of a combined activity and nutrition intervention for older people with frailty over a 6-month period[27]. Thus, given this identified gap in the evidence base, the REFRESH trial will investigate ONS and fortified food, each compared to routine practice, in older adults living in care homes, with or at risk of malnutrition.

The main impact will be evidence to support the most effective method to treat and manage malnutrition in care homes. Improving the management of malnutrition will help reduce deterioration in mental and physical health and wellbeing for older people, leading to the potential for improved quality of life, pleasure in eating, maintaining independence for as long as possible, reducing carer burden and associated costs. The health and care system will also benefit since this population group are high users of these services.

Effective provision of nutritional care and improved management of malnutrition will reduce resource use (e.g., reduced hospitalisations, infections that require NHS resources). Thus, as a successful definitive trial, we would expect the new knowledge to be adopted across integrated NHS & Social Care systems and impact evidence-based practice guidelines (NICE) and national (Malnutrition Care Pathway) and regional care pathways for managing malnutrition. This would be guided through the involvement of public advisors, policy makers and commissioners on our SAG.

3 OBJECTIVES AND OUTCOME MEASURES

3.1 Research question and PICO

In older adults with or at risk of malnutrition living in care homes, what is the clinical and cost-effectiveness of oral nutritional supplements (ONS arm) and fortified food (FF arm) compared to routine practice (usual care arm)?

Population (P): in older adults with or at risk of malnutrition living in care homes

Intervention (I): oral nutritional supplements; fortified food

Comparison (C): compared to routine practice

Outcome (O): health-related quality of life at 6-months' follow-up, measured using the EQ-5D-5L-proxy, to assess clinical and cost effectiveness

To inform the study findings a parallel process evaluation providing data from the perspectives of residents, staff and relatives to meet the objectives below will be included.

3.2 Objectives

3.2.1 Primary objective

The primary objective is to compare the health-related quality of life of care home residents (with or at risk of malnutrition) receiving the ONS and FF with those receiving usual care, measured using EQ-5D-5L-proxy, at 6 months' follow-up.

3.2.2 Secondary objectives

1. Evaluate the effects of ONS and FF compared to usual care on:
   - Dementia-specific Quality of Life (DEMQoL-CH) at 6 months post-randomisation,
   - Nutritional status (Mini Nutritional Assessment (MNA)) at 6 months post-randomisation,
   - Weight (kg) at 6 months post-randomisation,
   - Dietary intake (3-day photographed food records and food record charts used to estimate nutrient content) at 6 months post-randomisation,
   - Functional limitations (Modified Barthel Index (MBI)) at 6 months post-randomisation,
   - Acceptability and adherence (3-day photographed food records and food record charts at 6 months post-randomisation),
   - Morbidity (antibiotic usage) at 6 months post-randomisation,
   - Mortality (registered death records) at 6 months and 12 months post-randomisation,
   - EQ-5D-5L-proxy at 12 months post randomisation.

2. Evaluate the cost-effectiveness of ONS and FF compared to usual care at 6- and 12-months post randomisation by measuring the cost of delivering the ONS and FF interventions, participant health and social care resource use (bespoke health and care service use questionnaire) and health-related quality of life (EQ-5D-5L utility values).

3.3 Outcome measures

3.3.1 Primary outcome

Table 1: Primary outcome overview

Outcome	Measurement tool	Measured by	Month		
			Baseline	6*	12*
Health-related quality of life (HRQoL)	EQ-5D-5L Proxy Version 2	Fieldworker (Care home staff acting as proxy)	X	X (primary)	X (secondary)
The EQ-5D-5L has five dimensions (mobility, self-care, usual activities, anxiety/depression, pain/discomfort), each with five response levels (no problems, slight problems, moderate problems, severe problems, extreme problems). Each combination of responses across the five dimensions represents a unique 'health state', and each health state has a corresponding utility value. Utility values are on a scale where zero is equivalent to being dead and one is equivalent to full health, with negative values representing states of health considered worse than being dead. Utility values will be derived from responses to the EQ-5D-5L questionnaire using the approach recommended by NICE at the time of analysis. See Section 8: Trial Conduct for details of the processes that will be used to collect this measure.					

* Months 6 and 12 post-randomisation

3.3.1.1 Rationale for primary trial outcome

The primary trial outcome is the EQ-5D-5L utility score, a generic measure of health-related quality of life (HRQoL)[28]. The selection of the EQ-5D-5L was informed by the importance of quality of life (QoL) for older people living in care homes[29] and the potential for nutrition-based interventions to improve HRQoL in this population[29,30]. A proxy version of the EQ-5D-5L is available with evidence of validity, and it is the most commonly used QoL measure in care home research[31].

Our consultation with Patient and Public Involvement and Engagement (PPIE) members regarding choice of primary outcome measure and appropriate questionnaire tools resulted in support for this tool. They felt it was a useful outcome as it was short and easy to complete, it would pick up changes over 6-months, and even a change of one level in one domain would represent a positive worthwhile improvement. Of the five EQ-5D-5L dimensions (self-care, usual activities, mobility, anxiety/depression, and pain/discomfort), the latter three were considered the most relevant to care home residents, and nutrition has been shown to influence all three[32-34].

Feasibility data and other studies show high levels of missing data (26%) for EQ-5D instruments in older care home residents[35]. This may be due to the high prevalence of dementia in this group, with up to 80% of residents having some level of cognitive impairment. Therefore, a proxy version of the EQ-5D-5L completed by care home staff will be used in this study to reduce the amount of missing data. Furthermore, life expectancy in care homes is 2.2 to 7.0 years[36] and the EQ-5D-5L provides a value to assign to those who are dead. Thus, using this measure offers a high possibility of complete data on the primary outcome.

3.3.2 Secondary outcomes

Table 2: Secondary outcome overview

The secondary outcomes marked with an asterisk (*) indicate the outcomes that are included in the core set for malnutrition intervention studies[37].

Outcome	Measurement tool	Measured by	Month		
			Baseline	6*	12*
Dementia-specific Quality of Life (QoL)	DEMQoL-CH	Fieldworker (Care home staff completing questionnaire)	X	X	
This is designed for use in care homes[38], providing QoL data specific to those with dementia or cognitive decline (≈80% of care home residents), therefore important to include in addition to the generic EQ-5D-5L. The tool includes 32 questions, each on an ordinal scale from 1 to 4, covering feelings, memory, everyday life and an overall assessment, providing a summed score between 32-128, where a higher score indicates better Quality of Life (QoL). It is a relatively new tool with limited psychometric and feasibility testing[38,39] and there are no previous studies examining its relationship to nutritional status; two reasons for use as secondary outcome rather than the primary outcome.					
Nutritional status*	MNA[40]	Care home staff & Fieldworker	X	X	
When testing a nutritional intervention, it is important to measure nutritional status. Improved nutritional intake will maintain or improve status. This is a validated nutrition screening and assessment tool suitable for older adults. It includes six items, two which are scored 0-3 and four					

which are scored 0-2. The total score ranges from a possible 0 to 14, and ≤11 indicates risk of malnutrition.					
Weight*	Sitting or hoist weight (kg)	Routine data	X	X	
The first effect of the interventions tested in this trial is to maintain or increase body weight. Improved nutritional intake will result in maintained or increased weight and lowering of malnutrition risk. This is a routine measure for all care home residents.					
Dietary intake*	3-day food record, using a photographic food record and food record charts	Care home staff & Fieldworker	X	X	
A sub-group will be selected (n=270), on which food record data will be collected for 3 days. The sub-group will be randomly selected once consenting at site is complete, using a validated R script developed by the trial statistician in conjunction with the data manager. The 3 participants who are selected at each care home will be assigned to the food record group in Research Electronic Data Capture (REDCap)[41,42]. Staff, field worker or member of the research team will collect either a food record chart detailing the food eaten and/or a photograph of each meal before and after consumption. The field worker or trained member of the research team will convert this information to weights of foods eaten, enter the data into dietary software (Nutritics) and calculate nutrient intake for energy, protein, carbohydrate, fat, fibre and fluid. Dietary data are inherently prone to error, but quantifying intake is crucial to understand the mechanism of action of the interventions. The 3 days do not need to be consecutive and can be organised to suit the routine of the resident and care home but must be +/- 7 days of the baseline and 6-month data collection dates.					
Functional limitations*	MBI[43-45]	Care home staff & Fieldworker	X	X	
Functional ability is another outcome important to care home residents; whilst their function may be impaired maintaining current function is vital, and good nutrition will influence this. The MBI is a well validated and reliable tool to measure ability to complete activities of daily living (ADL). Ten functional skills are assessed, and it typically takes 1-2 minutes to complete if the person is known to the assessor. A score (ranging from a possible 0 to 20) is calculated with a low number indicating greater dependency. There are known ceiling effects, but these are of less concern in the care home population. It is the most frequently used tool for measuring functional limitations and activities of daily living in care home research[31].					
Acceptability* and adherence	3-day food record, using a photographic food record and food record charts	Care home staff & Fieldworker		X	
Adherence to the amount of ONS and fortified food consumed will be assessed through the dietary data collection (see dietary intake above). Fidelity of intervention delivery will be assessed through the process evaluation (see Section 10).					
Infection rate (as a marker of morbidity)	Use of antibiotics as a marker of infection rate	Fieldworker	X	X	
Infections are common in older adults and have several consequences including cognitive decline, hospitalisation and death. An improved food intake may reduce the likelihood and duration of					

infections. As a simple marker of the occurrence of significant infections, we will monitor the use of antibiotics from care homes records.					
Resource use	HCSUQ	Care home staff & Fieldworker		X	X
Data on the use of health and social care will be extracted from care home records to inform the health economic analysis. The questionnaire has been designed with input from the study SAG and PAG and is informed by previous instruments used in this population and by current best practice guidance. It includes primary and community health care (e.g. GP appointments, district nurse visits), secondary health care (e.g. hospital appointments and admissions, accident and emergency [A&E] visits) and contacts with social care professionals.					
Mortality	Registered death records	Fieldworker		X	X
A relatively high mortality rate is expected in this population. Improved nutritional care can reduce the risk of mortality by ensuring optimal weight is maintained and micro-nutrient requirements are met. These data will be collected from care home records.					

* Months 6 and 12 post-randomisation

Where possible, the same proxy will complete the measures for the same participant at later timepoints.

4 TRIAL INTERVENTIONS

Logic models (Figures 3 and 4) outline the contextual factors for the care homes randomised into the ONS and FF arms[46], and shows the inputs, activities, outputs and impacts to conceptualise the factors underpinning the interventions. Implementation and evaluation will be informed by Normalisation Process Theory (NPT)[47] concerned with the activities individuals and organisations are required to carry out to embed and normalise new, complex ways of working into daily routine practice. NPT is underpinned by four constructs: i) **coherence or sense making** (focuses upon participants' understanding of the intervention prior to working with it); ii) **cognitive participation** (focuses upon the extent to which participants are committed to working with the intervention; iii) **collective action** (focuses upon the efforts involved in using the intervention in practice; iv) **reflexive monitoring** (focuses upon participants' evaluations and appraisals of the intervention). The Template for Intervention Description and Replication (TIDieR) checklist[48] will be used to describe the interventions.

4.1 Oral Nutritional Supplement (ONS) Arm

Residents in care homes randomised to the ONS arm will receive two ONS to be given at suitable points within the day between mealtimes, daily for 12 months. The nutritional content of the ONS options are shown in Table 3. These will provide approximately 600 kcals and 24 g protein daily (to meet 1.2-1.5 g protein/kg body weight/day). The delivery times will be decided by care staff to suit the individual and the care home routines. ONS are already commonly used in care homes and so there will already be a process in place to ensure residents receive these supplements. We will work with care homes to follow their usual processes and use a supplement they usually use or are familiar with. We are specifically avoiding using one branded product to ensure the findings are generalisable across a range of manufactured ONS brands. We anticipate ordering direct from the manufacturer and delivering direct to the care home on a monthly basis.

Residents will continue to receive meals and nutritional care according to the care home's usual routines. If the resident is already receiving ONS and the care home is randomised to the ONS group: The fieldworker will liaise with the research partner and the care home staff to determine the

appropriateness of giving the additional study supplements. If not suitable, the resident will continue with the prescribed supplements but will not be given the additional study supplements (see Table 4). The GP will be informed of the additional supplements.

The care home should continue to follow its usual procedures when a resident chooses not to consume their oral nutritional supplement on a given day. Residents should never feel pressured to consume the supplement; for example, they may simply not wish to have it that day, or if they dislike the flavour, an alternative may be offered. Adherence to the intervention will be measured during the dietary data collection (see Section 3.3.2) and process evaluation (see Section 10). If a resident refuses the ONS consistently, it may be appropriate to consider initiating discussions around withdrawal (See Section 13).

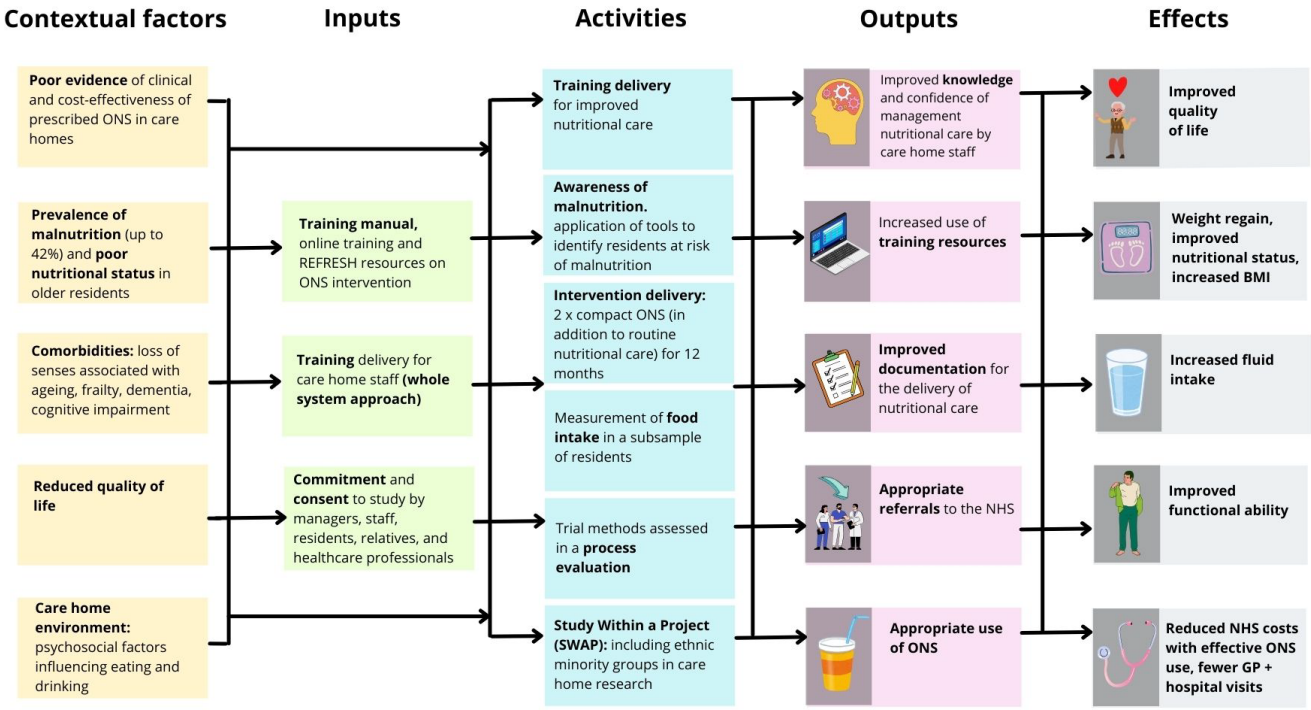
Table 3: Examples of ONS types and composition (per 125 mL bottle)

ONS	Volume	kcal/ml	Energy content (kcal)	Protein content (g)	Fat content (g)	Carbohydrate content (g)
Altraplen Compact	125ml	2.4	300	12	12	36
Ensure Compact	125ml	2.4	300	12.8	11.7	36
Fortisip Compact	125ml	2.4	300	12	11.6	37.7

Information taken from: https://nualtra.com/products/altraplen-compact, https://www.proconnect.abbott/uk/en/home/adult/products/Ensure-Compact.html, https://www.nutricia.co.uk/hcp/pim-products/fortisip-compact.html#accordion-f265d6fcdc-item-b8eafc604c

A logic model (Figure 3) outlines the contextual factors for the intervention, inputs, activities and outputs and to conceptualise the factors underpinning the ONS intervention.

Figure 3. Proposed logic model for the REFRESH ONS intervention



4.1.1 Safety issues

At baseline we will identify residents who need a modified consistency, have lactose intolerance, and have specific dietary needs and preferences (vegetarian, vegan, coeliac, allergy, other) (see Section 8.2). The intervention will be adapted to meet the needs of these residents.

The ONS listed in Table 3 are naturally thick fluids (Level 1-2). If the participant is recommended to consume fluids thicker than this (Level 3-4) the option of a thickened supplement will be offered (e.g. pudding type supplement with a similar nutrient profile). The recommendations of the health professional (e.g. speech and language therapist) involved will be followed to meet the needs of the individual resident.

Manufactured ONS are all suitable for people with a lactose intolerance, vegetarian, and gluten free, and other requirements such as vegan and dairy allergy can be accommodated.

Since all participants will continue to receive nutritional care according to the care home's usual routines, any deterioration in the resident's condition will mean the usual pathway of care is followed. This may mean a dietitian referral is made, and food fortification may be introduced to supplement the ONS[14,15]. Other referrals may also be made as judged appropriate.

4.1.2 Non-trial residents

The storeroom/cupboard where the ONS is stored for the purposes of the study will be marked 'for research only' to make it clear that the ONS should not be given to residents who are not in the study. The specifics of how this labelling will be achieved will be discussed with the care home manager and align with their usual practices (e.g. storage location etc).

4.2 Fortified Food (FF) Arm

Care homes randomised to the fortified food arm will instigate a menu providing fortified food (usual foods and drinks with added ingredients to increase nutrient density for participating residents) for 12 months. As well as fortifying the menu meals, each resident included in the trial will also receive

fortified snacks and drinks made from normal ingredients. The fortified menu will be very similar in content to the usual menu, but some items will be fortified (e.g. porridge, mashed potato, soups etc.). We will provide a list of nutrient dense ingredients that can be used to fortify different items on the menu (e.g. milk powder, peanut butter, cheese, eggs etc.). We aim to offer a fortified diet covering multiple meals, snacks and drinks using easily accessible nutrient dense ingredients.

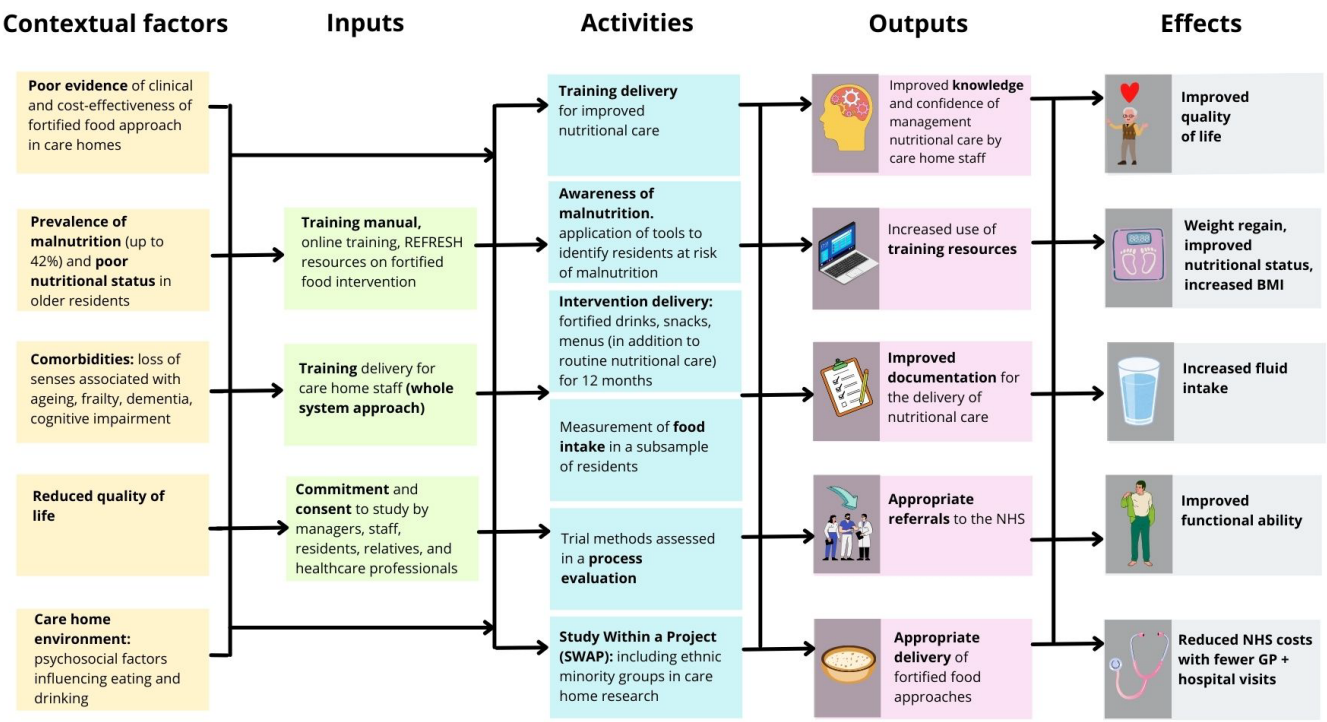
The care home will receive advice and support, example recipes and options for purchased fortified meals from known suppliers. Foods will be selected to suit the resident's taste preferences and cultural norms which meets the BDA Care Home Digest guidelines[49]. We will work with individual care homes to establish the best strategy for each home and keep records of this process so that we can recommend suitable strategies for implementing fortified menus when reporting results. Some care homes may already be fortifying some foods; we will work with care homes to increase the level of fortification and improve the range of foods and drinks which are fortified, with a focus on improving protein and micro-nutrient (vitamins and minerals) content rather than just energy content. The care home will receive an additional cost per resident in the trial to cover the increased costs of food.

Residents will continue to receive nutritional care according to the care home's usual routines. If the resident is already receiving ONS and the care home is randomised to the FF group, the resident will continue the original ONS so as to not change their usual care (see Table 4).

The care home should continue to follow its usual procedures when a resident chooses not to consume the fortified food on a given day. Residents should never feel pressured to consume the food or drink; for example, they may simply not have an appetite that day, or they may dislike the meal. Adherence to the intervention will be measured during the dietary data collection (see Section 3.3.2) and process evaluation (see Section 10). If a resident refuses the FF consistently, it may be appropriate to consider initiating discussions around withdrawal (See Section 13).

A logic model for the fortified food intervention is provided in Figure 4.

Figure 4: Proposed logic model for the REFRESH fortified food intervention



4.2.1 Safety Issues

At baseline we will identify residents who need a modified consistency, have lactose intolerance, and have specific dietary needs and preferences (vegetarian, vegan, coeliac, allergy, other) (see Section 8.2). The intervention will be adapted to meet the needs of these residents.

If the participant is recommended to consume modified texture diet and/or thickened fluids the care home staff will adapt the fortified foods in accordance with the recommendations of the professional (e.g. speech and language therapist) and the resident's own preferences and requirements (e.g. lactose intolerance, gluten free, vegan, vegetarian etc).

Since all participants will continue to receive nutritional care according to the care home's usual routines, any deterioration in the resident's condition will mean the usual pathway of care is followed. This may mean a dietitian referral is made and ONS may be introduced to supplement the fortified foods[14,15]. Other referrals may also be made as judged appropriate.

4.2.2 Non-trial residents

Residents not recruited to the trial will be offered the usual menu and will not be offered items that have been fortified for the purposes of the trial. The specifics of how this will be ensured will be discussed with the care home manager and align with their usual practices (for example, lists in the kitchen and on drinks trolley, use of different coloured trays).

4.3 Usual Care Arm

Care homes randomised to the usual care arm should manage malnutrition as they usually would. Usual care will vary across care homes. We will observe and evaluate what constitutes usual care as part of the process evaluation (see Section 10).

If the resident is already receiving ONS and the care home is randomised to the usual care group, the resident will continue the original ONS so as to not change their usual care (see Table 4).

Table 4: Management of residents already receiving ONS

Care Home Randomisation Group	Management Plan
ONS	The fieldworker will liaise with the research partner and the care home staff to determine the appropriateness of giving the additional study supplements. If not suitable, the resident will continue with the prescribed supplements but will not be given the additional study supplements. The GP will be informed of the additional supplements.
FF	Resident will continue the original ONS so as to not change their usual care.
Usual Care	Resident will continue the original ONS so as to not change their usual care.

4.4 Intervention Training

Following randomisation to the FF or ONS arm, in-person or online manualised training will be delivered by fieldworkers. The training will take place as soon as possible following randomisation.

The training has been co-designed with the SAG, with input from the PAG, and follows best practice guidance[50] for care staff.

We aim to have two levels of training:

- malnutrition awareness training
- management of malnutrition training tailored to the allocated intervention.

The aim of the **malnutrition awareness training** will be to provide staff with necessary skills and knowledge to enable them to able to identify residents at risk of malnutrition. Malnutrition awareness training components will include: causes, risk factors and consequences of malnutrition, and identification of residents at risk including signs of malnutrition and a brief overview of the use of the MUST screening tool. This training is targeted at the catering team, care workers and nursing staff. It will be designed to last approximately 45 mins and be delivered face to face and online.

The **management of malnutrition training** will enable the care home staff to be able to design person centred nutrition care plans for residents at risk of malnutrition. There will be different training provided dependent on the intervention the care home has been randomised too, one for the FF arm and one for the ONS arm.

For the FF arm, the training will include person-centred care particularly for those with dementia, identification of nutrient dense ingredient options, tailoring and personalisation of fortified food to dietary cultural and religious preferences. A list of recipes and possible ingredients for fortification will also be provided alongside the training.

The ONS training will include aspects such as timing of delivery and storage of ONS, and administration of ONS for residents with varied dietary requirements.

The training will include two sections:

1) Aimed at all staff in the care home including care staff, senior management, administrators and activity co-ordinators to allow everyone to understand the principle of the intervention and why it is important. This will be no more than 10 minutes and available online.
2) Aimed at staff involved in delivering the intervention to residents including, care assistants, nursing staff, catering staff, day to day management staff. This will be delivered initially face to face but also available online. It will take approximately 1 hour. The key personnel who need to complete this training:
    - Care home manager
    - Lead catering member of staff
    - Nutrition champion - see Section 4.5
    - Other relevant care workers

Care homes in the usual care arm will not receive specific training on treating malnutrition and will be advised that they need to continue managing malnutrition as they usually would. Training provided to the care homes in the intervention arms will be made available to care homes in the usual care arm after the trial has ended.

The success of the training programme will be assessed quantitatively from the following measures

- Numbers of care home staff who attended in-person intervention training (recorded as % total number of available care home staff)
- Numbers of staff who successfully completed short online multiple-choice test (can be taken multiple times) and gain a certificate to evidence learning to assess staff competence and learning (recorded as % care home staff who attended in-person training and passed the test)
- Engagement with online intervention training from website metric analysis e.g. number of visits, type of resources accessed.

To further determine the success of the training programme, research staff involved in the delivery of the intervention training to staff in the care homes will be asked for feedback about delivering the training.

4.5 Nutrition Champions

We plan to recruit nutrition champions in each care home from the staff to support the roll out of the interventions in the care home. Champions have been successfully used in other trials[51] and thought to be key for sustainable system change in nutritional interventions in care homes[52]. In addition, a recent systematic review has suggested that champions can be effective in improving the use of innovations within a facility (i.e. care home level)[53]. In the homes assigned to one of the intervention groups, a member of the care home staff will be appointed as an 'in-house' nutrition champion, who will be somebody who volunteers to help disseminate information, promote, and embed the training during the trial, and support data collection. Nutrition champions will also alert the fieldworkers to any new staff and ensure they have access to the training.

They will be selected by the care home management team as someone who will be provided the time to engage in all the training and be a point of contact for other care staff in the home.

We will offer a £25 voucher to show our appreciation to staff who take on this important role.

4.6 Assessment of adherence with intervention

Adherence to amount of ONS and fortified food consumed will be assessed through the dietary data collection (see Section 3.3.2).

Fidelity of intervention delivery will be assessed through the process evaluation (see Section 10).

5. TRIAL DESIGN

REFRESH is a parallel, superiority, three-arm cluster randomised controlled trial, which aims to assess the clinical and cost-effectiveness of ONS versus usual care and FF versus usual care.

The trial design is summarised in the participant and protocol flow chart (Figure 1).

5.1 Design considerations for minimising bias

Cluster randomisation is used as it is impractical to deliver the interventions to different individuals in the same care home, which could lead to 'contamination' between treatment groups.

Initial training for care home staff and clearly defined treatment processes will limit performance bias (how the treatment is delivered to residents). The process evaluation will help identify where different processes have been used between care homes.

Attrition bias has been minimised by the selection of a primary outcome which has a value for death and collected by the care home staff as a proxy. We have estimated the mortality rate at 30% at 6 months and because the EQ-5D-5L has a value for death, all participants who have died can be included in the analysis of this outcome. Residents who move from the home for other reasons or wish to withdraw from the trial will be the only participants lost to follow-up and we have estimated this at 5% and adjusted our sample size accordingly. Attrition bias may affect secondary outcome measurements to a greater degree due to the high expected mortality rate.

Attrition may also occur due to a cluster withdrawing. We have allowed for one care home (cluster) in each trial arm to drop out over the 12 months of the study.

The protocol will be made publicly available, and a fully pre-specified analysis plan will be written to minimise reporting bias.

5.2 Blinding

The nature of the interventions means that blinding is not possible within care homes. Care home staff, residents, and fieldworkers will be able to see that high numbers of ONS are in use or fortified foods are used in menus and snacks. At least one of the statisticians will also be unblinded to help with DMEC report preparation; those statisticians will not be involved in the writing of the statistical and health economic analysis plan.

We will recruit and consent residents and collect baseline data before their care home (cluster) is randomised to ensure allocation concealment and prevent selection bias that can otherwise occur if clusters are randomised before participants are recruited.

The statistical and health economic analysis plan will be written by the blinded statisticians and health economist whilst blind to trial arm status. The analysis plan will be signed-off before the database is locked (which occurs after the 12-month follow-up data collection). The health economist and blinded statisticians will be blind until the completion of the primary outcome analysis and unblinded for all other (secondary) analyses. All analyses will be completed after 12-month follow-up data collection despite the primary outcome being at 6 months.

5.3 Internal pilot for study progression

The internal pilot will aim to recruit 30 care homes over a six-month period to determine whether the trial will progress, where green indicates progression, amber indicates progression with remedial action following discussion with the TSC, DMEC and funder, and red (in any of the two criteria) indicates discussion with the TSC, DMEC and funder and likely termination of the trial. A report will be submitted and reviewed by the TSC and DMEC and submitted to the funder post end of pilot phase.

Table 5 shows that if 14 or fewer sites are recruited in the first 6 months or if 254 or fewer individuals within the sites are recruited, the trial is unlikely to be viable and termination may be considered.

Table 5: Progression Criteria

Progression criteria	Red	Amber	Green
Number of sites opened	<50% (n≤14)	50-99% (n=15-29)	100% (n=30)
Total number of residents recruited	<50% (n≤254)	50-99% (255-509)	100% (n=510+)

5.3.1 Rationale for the internal pilot

There is a lack of care home research therefore an internal pilot will be conducted to support the decision to progress to the main trial based on recruitment rates of care homes and residents over 6 months.

5.4 Assessment and Management of Risk

Internal risk assessments for the trial will be developed by the trial management team at PenCTU and will be regularly updated throughout the trial. The risk assessment will consider all potential risks associated with the trial which may include trial participants, reliability of the trial results, data confidentiality and trial organisation. The risk assessments will report on the total risk score and category of each risk and any management or mitigation strategies. The main identified risks are described below.

Potential for risk of harm to the individual from intervention: The potential for the intervention to cause harm is low, but may include related gastrointestinal (GI) symptoms, and poorly controlled blood glucose exacerbated by ONS intake in residents with diabetes (note these won't be recorded in the electronic case report form (eCRF) as they are expected events – see Section 15.2 Operational

Definitions). Our feasibility study[12] recorded only 3 (2.7%) residents with adverse events out of 110 recruited who were malnourished or at risk of malnutrition.

GI symptoms may be caused by lactose intolerance which is rare in north Europeans but more common in other ethnic groups. The presence of lactose intolerance will be checked during baseline data collection, so that the intervention can be adjusted to suit their needs (see Section 8.2).

The most significant risks to the research project are:

Poorly developed intervention: We have made considerable efforts to engage with a wide range of stakeholders to inform the design of the intervention including older people living in care homes and family/friends, care home managers, care staff and health care professionals responsible for the care of older people in care homes and involved in the treatment and management of malnutrition e.g. Dietitians, Speech and Language Therapists, Nurses, Pharmacists. The fidelity of the intervention will also be monitored during the trial, particularly at the transition from pilot to main trial and refinements required will be made as required.

Achieving recruitment numbers required: A potential concern is the identification of eligible residents who are willing to participate. We have been conservative in our estimates of malnutrition risk using a mid-point of 34% (26-42% of care home residents are at risk of malnutrition[5]) and targeting larger care homes (>50 beds), having checked the number of large homes in each region. The research team has developed strong networks across the three regions with care home member organisations and has involvement of the National Care Forum at a national level to support recruitment. We will use inclusive approaches for recruitment[54], informed by the SWAP to reach under-researched older residents from ethnic minority groups.

Poor retention of participants: The feasibility study had a loss to follow-up rate of 32%[12]. Mortality was the primary reason (25%) and moving homes (4%) or entering end of life care or hospitalisation (3%) were the other reasons. We have mitigated against mortality by selecting a primary outcome which enables us to assign a score for those who die. Using a proxy measure means even those with severe ill health will be scored. It is only those who move homes who will be lost for the purposes of the primary outcome (see Section 13.1).

There is a risk of care homes (clusters) dropping out but to keep this to a minimum and to ensure optimal collection of secondary outcomes, we will utilise evidence-based person-centred strategies to overcome challenges of conducting research in care homes[55] to promote retention of older residents[10] and the home itself. The research team has extensive experience of working in this setting and will pay particular attention to relationship building with the whole care home, and regular contact with residents and their family/friends to value their contribution to the research and the potential benefits for their health and wellbeing. Our SWAP will also enable us to explore issues relating to retention of ethnic minority groups. To support retention the TMG will monitor follow-up and retention rates monthly and particularly at the transition from pilot to main trial. As such, we will have opportunity to revise and refine trial processes as required to ensure retention rates are optimised during the main trial and mitigate loss to follow-up.

Lack of inclusivity: We will use inclusive approaches to optimise recruitment and engagement of residents throughout the trial in accordance with published guidance[54]. All trial staff and research team will have received training in conducting research in care homes as well as cultural competency training that raises awareness of the issues and need to involve residents from ethnic minority groups[56].

Lack of blinding: The nature of the interventions mean that blinding is not possible. It will be readily apparent to all working and living in the home that high number of ONS are in use or FF are used in menus and snacks. We have mitigated this limitation by blinding at baseline. In addition, the statisticians will be blinded, at least, up until the time the statistical and health economics analysis plan (SHEAP) is finalised. The SHEAP will be signed off prior to completion of follow-up data collection and data analysis.

Contamination of the usual care arm: In the usual care arm, we will ask staff to follow their usual practices regarding nutritional care. However, since they are taking part in a nutrition-related study it is possible that they will become more alert to malnutrition risk and act more assiduously than previously. This may reduce the difference in outcomes between the control and intervention arms. These care homes will receive no training in how the tested interventions should be delivered and their purpose as a control will be explained carefully. We will still need to maintain good working relationships to ensure the homes do not drop out and the process evaluation will document the extent to which ONS and FF are administered in the control arm, as well as describing what 'routine care' is. To retain their engagement in the study any training packages will be provided to them at the end of the study.

Overburdening of care home staff: We recognise that care staff are already very busy caring for their residents. Having their support is crucial but we have developed research processes that will be in accordance with their usual care and full support will be provided by the fieldworkers and research team. Training is designed to be in easily accessible bitesize chunks which has been developed with other professionals who work in the residential care home environment.

6. TRIAL SETTING

The trial will be conducted in long-term residential care settings where older adults receive 24-hour care and support, with or without on-site registered nursing staff.

Ninety care homes (anticipating that an average of 17 residents per care home will meet the inclusion criteria and be consented) will be recruited to capture rural, urban and city locations, type of owner (private or other e.g. local authority, charity), geographical spread and homes serving economically and ethnically diverse areas: We are proposing to start our recruitment in the following areas but will seek sites outside these regions if necessary:

- **Southwest England (mainly Devon & East Cornwall)** – 96% white[57], mixed picture of deprivation including areas of the most and least deprived in England[58], largely rural[59], 131 potential care homes.
- **Dorset, Hampshire, Bath and Bristol (as well as other areas covered by South West Central and South Central RRDNs depending on fieldworker and RRDN availability)** – 92% white[57], pockets of highly deprived areas, but mainly areas sitting in the middle of the deprivation spectrum[58], largely rural with urban city and town[59], 211 potential care homes.
- **West Midlands (including Birmingham)** – 72% white[57], relatively high levels of deprivation, with four local authorities in the 10% most deprived in the country[60], urban with major conurbation[59], 129 potential care homes.

The internal pilot phase of the trial will attempt to use care homes from the above geographical areas, although there may be a need to expand to other geographical areas depending on the ability to recruit the required number of care homes for the trial.

Participating care home staff are supported by a Principal Investigator (likely to be the care home manager) and field workers. For the purposes of this study, the term Principal Investigator will be replaced with Research Partner (RP) to create a more approachable and collaborative tone.

Fieldworkers may be registered dietitians, nurses or research assistants who will be the main point of contact for the care homes with the research team, who will support recruitment of care homes, recruitment of the residents, data collection, training, and will maintain excellent communication and working relationships with the care homes to sustain their participation. Support may be requested from the Research Delivery Network (RDN) agile team, who will support care homes by undertaking tasks associated with the fieldworker role.

All trial activities will be conducted in the care homes (i.e., recruitment, intervention, follow-up), therefore participants will not be required to travel for any trial activities.

Care homes within the same care home group, located in the same geographical area in close proximity, and managed by the same senior team, will be treated as a single cluster. They will be randomised to the same trial arm, with a shared RP across the homes and a deputy RP appointed in each home.

7. ELIGIBILITY CRITERIA

7.1 Care Home Eligibility Criteria

Care homes must satisfy all the following criteria to be considered as a participating site:

- Long-term residential care setting where older adults receive 24-hour care and support.
- Care home owner permission to take part.
- Not taking part in other research studies which could affect the conduct of this trial e.g. a nutrition intervention trial or other complex intervention.

The selection of care homes will be guided by fieldworker travel time, with a maximum one-way travel limit of two hours to any given care home.

7.2 Care Home Baseline Data

Table 6 lists the data collected about each care home at baseline.

Table 6: Care Home Baseline Data

Care home data	Number of beds Number of residents at the time of screening Care type provided (residential, nursing, dual) Type of owner (private, local authority, charitable, other) Location (care home postcode) - *Where more than one care home is included as a single 'site' the main address will be used for the location.* Average weekly fee/bed

7.3 Participant Eligibility Criteria

1530 adults over the age of 65 years who are with or at risk of malnutrition will be recruited. Minimal exclusions are indicated to ensure the generalisability of the results.

7.3.1 Inclusion criteria

Residents must satisfy all the following criteria to be enrolled on the trial:

1. Permanent resident in a care home (not respite or intermediate care).
2. Aged ≥ 65 years at the time of consent.
3. Able to eat and drink.
4. With or at risk of malnutrition as measured by scoring 1 or more out of 6 on the MUST*.
5. Able to obtain informed consent from the individual or a consultee based on the presumed will of an incapacitated adult.

*If the MUST screen is not routinely completed or the score is greater than 1 month old at the time of consent, the fieldworker should confirm the participant's eligibility by completing the MUST[61] or re-scoring it. This will be done once the resident, or consultee has provided consent to take part.

A MUST score of 0 indicates a low risk of malnutrition, a score of 1 indicates a medium risk of malnutrition and scores 2-6 indicate high risk of malnutrition. Therefore, a score of 1 or more would confirm the participant's eligibility.

A cut point of 1 is used because MUST uses three criteria to assess overall risk of malnutrition, and each can independently predict clinical outcome. People with a MUST score of 2 are frequently underweight but those with a score of 1 may be at risk of malnutrition but not underweight. If a MUST score of 2 or more is used this could lead to underestimation of malnutrition risk in obese older adults. A MUST score of 1 or more will reduce this risk[62].

7.3.2 Exclusion criteria

Residents who meet any of the following criteria will be excluded from trial participation:

1. Fed *via* feeding tube.

2. Active cancer treatment or recent major surgery*.

3. Considered by the care home staff to be approaching the end of life, where participation in the study would not be appropriate†.

4. Already receiving nutrition support (ONS or fortified meals) with individualised dietetic advice from a dietitian‡.

*Both of which would be major moderator factors by significantly impacting on the person's food intake irrespective of the intervention given.

†In cases where there is uncertainty, this decision will be made collaboratively by care home staff, in consultation with the resident (where possible), and a consultee (if applicable). Care home staff, who are leading initial discussions about the study, will use their professional judgment on a case-by-case basis to ensure that the decision reflects the resident's condition, preferences, and advice of the consultee (if applicable).

‡Residents will be eligible if they have been:

a. prescribed ONS short term (e.g. after a hospital stay) and have not yet been reviewed by a dietitian.
b. prescribed ONS not specifically for malnutrition (e.g. for wound healing, haemo-dialysis).
c. prescribed ONS by or on the recommendation of a health professional other than a dietitian (e.g. nurse or GP).
d. discharged from dietetic care but are still on ONS.

See Section 4 for details on how the intervention will be managed for residents already receiving prescribed supplements.

8 TRIAL CONDUCT

Please refer to the schedule of events in Table 7 below for a summary of the study visits and the procedures and data collected at each visit.

Table 7: Schedule of Events

Procedures and Data Collection	Consent	Baseline	Randomisation	Intervention phase	
				6-month follow-up	12-month follow-up
Day			**0**	**180 (+/- 14 days)**	**365 (+/- 14 days**
Informed consent	✓				
Eligibility confirmation	✓				
Group allocation			✓		
Intervention delivery			→	→	→
Care home data		✓			
Demographics		✓			
Medical history		✓			
Stage of dementia*		✓			
Frailty status*		✓			
Health related quality of life*		✓		✓	✓
Dementia-specific quality of life*		✓		✓	
Nutritional status*		✓		✓	
Weight*		✓		✓	
Dietary intake and adherence and acceptability*		✓		✓	
Functional limitations*		✓		✓	
Morbidity*		✓		✓	
Resource use*				✓	✓
Mortality*				✓	✓
SAE reporting	→	→	→	→	→

**Measured by: FAST, CFS, EQ-5D-5L Proxy Version 2, DEMQoL-CH, MNA, sitting or hoist weight – kg, 3-day food record, using a photographic food record and food record charts, MBI, antibiotic use, HCSUQ, registered death records.*

8.1 Recruitment

8.1.1 Care home identification

Thirty (30) care homes in each region will be identified by drawing on our established networks and NIHR Enabling Research in Care Homes (ENRICH), with inclusive strategies to reach those from diverse and under-represented groups, also informed by the SWAP.

The research team has strong links nationally with member organisations including the National Care Forum, and within each area to regional networks of care home providers, e.g. in Devon; Health

Innovation South West, Devon Care Homes Collaborative and Devon County Council Provider Engagement Network, in Dorset and Hampshire; Partners in Care, Hampshire Care Association, Hampshire and Isle of Wight Healthcare NHS Foundation Trust Care Home Research Partnership, Health Innovation Wessex, in Birmingham; West Midlands Care Association and Health Innovation West Midlands. We will engage with these groups through social media, direct contact, and speaking directly at networking meetings.

We will implement a number of strategies to ensure engagement and retention of the care homes, and to greatly value and respect the work of care home staff. Our experience aligns with a finding of the review by Peryer et al.[46] that 'maintaining care home staff engagement was a key driver to successful implementation'.

We will identify key gatekeepers who support access and establish good relationships with the care homes to enable planning of productive research visits e.g. best times of the day to visit and understand staff shift patterns to help foster strong relationships. Care homes employ administrative staff to support the running of the home and to support visitors and involvement in research. We will work closely with them to build rapport between the research team, residents, care home staff and relatives and identify the most appropriate times to visit and locations to undertake research measures and data collection. Lead nurses, as well as care home managers, are also key facilitators to help encourage staff to be involved from the outset and understand the importance of the research to improve delivery of nutritional care. We recognise the need for careful planning and continuous engagement with staff. Each care home setting is complex and different, so the research team will be flexible and allow extra time to carry out research activities as required.

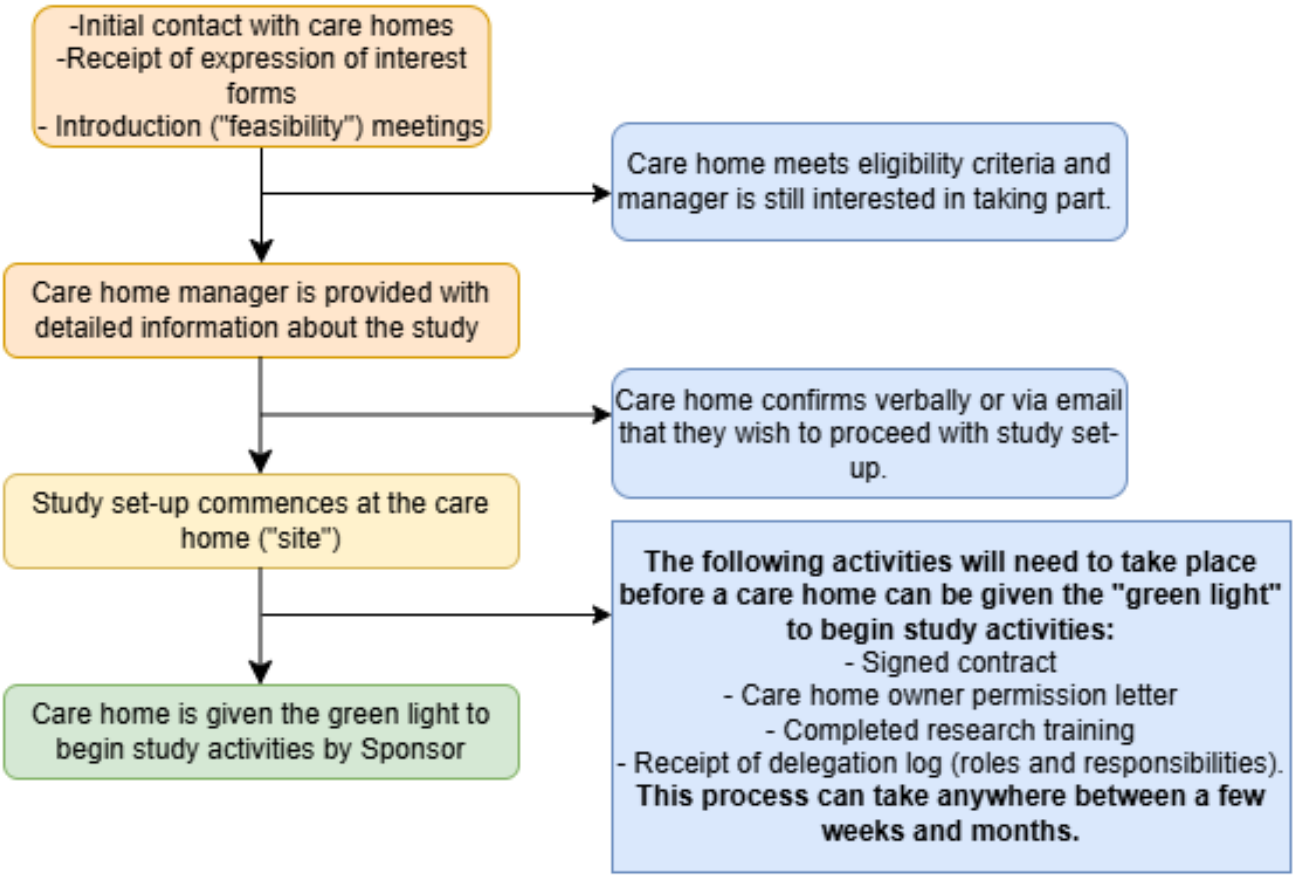
We will foster a whole care home systems approach with staff, residents, and their visitors to encourage engagement and raise awareness. Communication and relationship building are needed throughout the research to remind existing staff of required procedures and to foster relationships with new staff who join the care home during the research period. All staff in the care home will be informed about and kept up to date with trial processes through verbal presentations and posters displayed throughout the care homes. Staff and residents will be provided with regular newsletters about trial progress and milestones achieved and 'thank yous', such as festive cards, boxes of biscuits; these are an important part of thanking staff and residents for their time. In our experience such engagement strategies are well received and signs of appreciation to increase engagement and awareness. We will communicate regularly with the care home, including study visit reminders, via their preferred methods (Short Message Service [SMS], email, phone call).

As members of the research team will require spending periods of time in each care home, we will forge strong relationships with staff and residents, primarily through their communication approach and style. They will come to know the residents and staff through conversation, rather than solely collecting data at their visits, and build a rapport over the duration of their involvement in the trial. As such, we will take a friendly approach to make a real difference to the atmosphere encountered when conducting research visits to facilitate engagement and research activities.

Recruitment will be in three cohorts to include an internal pilot (in Cohort 1) and to distribute the workload evenly over the time of the trial. At each cohort we will aim to recruit approximately 10 care homes, resulting in 30 care homes in each region by the end of the trial.

Identified care homes will be provided with a trial synopsis and if interested, will be asked to complete an expression of interest (EOI) form, which will ask for various details to confirm the care home's eligibility (as in Section 7.1). Care homes that are deemed ineligible will be informed. The care home managers of interested eligible care homes will be contacted to arrange a feasibility meeting with the study team to discuss the trial and their participation in further detail.

Figure 5: Care Home Recruitment Flow Chart



8.1.2 Participant Identification

Care home staff will screen residents for eligibility from the care records and compile a list of residents to approach. If the care home does not have a MUST score for any resident on this list, they must justify why they are at risk of malnutrition e.g. recent weight loss, low appetite and/or reduced intake.

Recruitment performance at each site will be closely monitored by the TMG. The stages of the recruitment process are summarised in Figure 2: Expected flow of participants.

8.1.3 Screening and Eligibility

The study will be introduced to all eligible residents (or consultees, see Section 8.1.4) by delegated care home staff, either verbally or using the Study Summary Flyer. If they are interested in finding out more, verbal permission will be sought for the fieldworkers to discuss the study further with them. A recruitment pack containing a Study Summary Flyer (if not already provided), and a resident information sheet (RIS) will also be provided by delegated care home staff or the fieldworker. This can be given face-to-face, by post or via email. The fieldworker will confirm eligibility prior to consent by speaking to the care home staff. The consent processes detailed in Section 8.1.5.2 will be followed. If the MUST screen is not routinely completed or the score is more than 1 month old, the fieldworker should confirm the participant's eligibility by completing the MUST[61] or re-scoring it. This will be done once the resident, or consultee has provided consent to take part. If the participant is deemed no longer eligible once the MUST screen has been completed, the participant (or consultee) will be informed that they are no longer eligible to take part. This will be explained in the RIS before consent is obtained.

This data will be recorded by fieldworkers via REDCap, to ensure reporting is in line with the consolidated standards of reporting trials (CONSORT) guidelines. Data will be pseudo-anonymised

and include the following non-identifiable information: year of birth, sex at birth, ethnic group, registered to the trial or not, reason if not eligible, reason if eligible but declined (if known). If the participant or consultee chooses to provide the consent or declaration remotely rather than in-person or over the phone, the completed form will be stored on REDCap. This means that their name and email address (and in the case of a declaration, the consultee's name and email address) will be collected. Participants and consultees will be informed of this in the information sheet.

8.1.4 Assessing Capacity

We will involve residents lacking capacity and seek personal consultee or nominated consultee agreement for such residents to participate. All residents will be assumed to have capacity unless assessed to lack capacity in accordance with the Mental Capacity Act (MCA) 2005 guidance[63] and the information that is recorded in the care notes.

The care home staff will have a preconception about the resident's capacity, and this should be discussed with the field worker, alongside reviewing the care records.

To fully assess capacity, the fieldworkers and/or care home staff will assess whether the resident can:

- Understand the purpose and nature of the research.
- Understand what the research involves, its benefits (or lack of benefits), risks and burdens.
- Understand the alternatives to taking part.
- Be able to retain the information long enough to make an effective decision.
- Be able to make a free choice.
- Be capable of making this particular decision at the time it needs to be made.

The fieldworkers and/or care home staff will do this by going through the trial with the potential participant and asking them to relay specific information about the trial back to confirm their understanding. If there is any doubt regarding the participant's understanding of the trial and what is being asked of them, the care home staff and/or field workers will follow the process for receiving consent from a consultee (see Section 8.1.5.2).

Ongoing informal capacity assessments will be conducted by the field workers at each follow-up visit. Where a participant is able to consent at the time, but later becomes incapacitated, a consultee will be approached to provide a declaration. If a participant lost capacity during the study and an appropriate consultee could not be identified to provide advice, the participant would be withdrawn from the study. Where a participant lacked capacity at the time of the consent but later regains capacity, the resident will be required to provide informed consent, which will replace the consultee declaration, using the Resident Informed Consent Form. If a participant gained capacity during the study and did not wish to continue their participation, they would be withdrawn from the study.

8.1.5 Informed Consent

8.1.5.1 Participant has the capacity to consent for themselves.

Informed consent must be obtained prior to the participant undergoing procedures that are specifically for the purposes of the trial and not part of routine care at the participating care home (including the collection of indirectly identifiable participant data).

Once the recruitment pack has been provided to residents/consultees they will have at least 24 hours to read the information and talk it through with others before discussing the study with the fieldworker. Time will be given to introduce the study and discuss what it involves, including the nature and objectives of the study and possible risks associated with participation. Potential participants will be advised that they have the right to refuse participation, and that they are free to withdraw at any time, without giving reasons and without prejudicing their further treatment. They will also be advised on how their data will be used and signposted to further information about data used for research purposes. If the resident agrees to take part, formal consent will be obtained by the fieldworker* using a trial-specific informed consent form. Individual clauses from the consent form will be read out to the

resident. The resident will respond to each clause in turn, to confirm their understanding and agreement. The individual receiving consent should ensure that the participant initials each statement box that they wish to consent to. The participant should print their full name, provide a wet-ink signature and date of consent, if they are able to. If the participant has the capacity to consent but they are unable to write, they should make any mark that they are able to on the consent form. This should be witnessed by somebody independent of the trial, who should print their full name, wet-ink signature, and date on the form. The individual obtaining consent should also print their full name, wet-ink signature, and date of consent on the consent form.

*In certain situations, it may be appropriate for the RP to obtain consent from the resident, or declaration from the consultee. For instance, this could occur when a resident or their consultee wishes to provide face-to-face consent or a declaration at a time when the fieldworker is not present at the care home. If the RP has the necessary experience and is authorised on the delegation log to obtain consent, they may do so, provided they have received appropriate support in the process. While fieldworkers will typically lead the discussion, there may be occasions where the consent/declaration form is completed by the RP.

Original versions of completed consent forms should be stored in the Investigator Site File, and copies should be provided to the participant and filed in the care home records.

We will use accessible language, and trial materials will be designed using good practice for accessibility guided by the PAG. The information sheets can be printed in alternative formats depending on the request of the resident/consultee (i.e., different font, different font sizes). The research should be introduced in an informal and welcoming manner and, in so doing, reassure residents that all questions are welcome and that the research is inclusive.

An overview of the consent process will be documented on the study consent form, a copy of which will be filed in the participant's care records.

The process can take place face-to-face (when the fieldworker attends the care home). Alternatively, the process can be undertaken remotely (either electronically or via the telephone) – see Section 8.1.5.3.

8.1.5.2 Participant does not have the capacity to consent for themselves.

All residents will be assumed to have capacity unless assessed to lack capacity in accordance with the MCA 2005 guidance[63] and recorded in the care notes. Under the MCA, no one gives consent on behalf of a person lacking capacity, therefore the role of the consultee is to consider the wishes and feelings of the person and give advice to the researcher regarding whether they believe the participant would have wanted to take part, if they were able to decide for themselves. If at any point, the participant conveys in any way what could be deemed as not wishing to participate in the trial, this should precede any declaration provided by the consultee and the participant's involvement in the trial should end.

Personal Consultee

If the participant does not have the capacity to consent for themselves, the researcher is required to seek advice from a personal consultee. A personal consultee is someone who is unconnected with the conduct of the research project, and someone whom the person who lacks capacity would trust with important decisions about their welfare but is not acting in a professional or paid capacity. These could include a close relative or friend, carer (unpaid), an individual with Lasting Power of Attorney, or a court-appointed deputy. A personal consultee must themselves have capacity and be willing to engage with the researcher regarding the potential participation of the individual who lacks capacity. It should be made clear to the personal consultee that they are not obliged to undertake the role of the consultee if they do not want to.

Nominated Consultee

If the resident does not have anybody willing to act as a personal consultee, a nominated consultee can be sought once all avenues to seek a personal consultee have been exhausted. A nominated

consultee is somebody who has a professional relationship with the participant. They must have no connection with the trial and must be willing to be consulted about the participation of the resident who lacks capacity. For example, care home staff (not on the trial delegation log), a paid carer, doctor, solicitor, or an appointed Independent Mental Capacity Advocate (IMCA). The fieldworker will work closely with the care home staff (who will be familiar with the residents and their circumstances) to identify the most appropriate nominated consultee. This process will be tailored to each individual resident, recognising that the most suitable consultee may vary depending on the resident. Nominated consultees should not feel pressured into providing a declaration for a resident. Care homes receive a small reimbursement for their time for taking part in the study, but individual staff members will not financially benefit for acting as a nominated consultee for a resident in the study.

It is recognised that nominated consultees may not have known the resident before they lost capacity. In these cases, the MCA guidance will be followed whereby the nominated consultee may consider views from family, friends or carers who may not be willing or able to act as a consultee (if such individuals are involved in the resident's life). Where appropriate, other professional colleagues involved in the person who lacks capacity's welfare may also be approached for a view. The nominated consultee should consider this when determining whether to provide a declaration

The care home staff will have knowledge of the family relationships and usual point of contact of the residents in their care. This will be based on care records, day-to-day interactions and engagement with residents and their families. As such, care home staff are well placed to advise the fieldworker on whether a resident has a personal consultee who can be approached, and also whether that individual is likely to be responsive and engaged. If it is known that the resident does not have anybody who can act as a personal consultee (e.g., no known family or friends involved in their care), a nominated consultee can be approached immediately.

If the resident does have somebody who may be able to act as a personal consultee, all reasonable efforts will be made to contact that individual. However, if no response is received within 1 week, the process for approaching a nominated consultee will be initiated. This timeframe is intended as a guide rather than a strict cut-off. If the identified personal consultee is known to be well-engaged but simply requires more time, or where the care home staff are aware of an alternative personal consultee who could be contacted, the fieldworker and care home staff will use their judgement to allow a longer period before moving to the nominated consultee route whilst considering the time constraints of the study timelines. Fieldworkers will use a template to introduce the study to the personal consultee. The template will explain that if no response is received within 1 week, the nominated consultee process will be initiated.

The process can take place face-to-face (the same process as described in Section 8.1.5.1), with the fieldworker and/or care home staff arranging a time to meet with the consultee at the care home. Alternatively, the process can be undertaken remotely (either electronically or via telephone) – see Section 8.1.5.3.

A password-protected spreadsheet, accessible only to authorised study team members, will be used to record contact details and contact with residents or consultees to facilitate the consent/declaration process. Residents/consultees will only be contacted by the fieldworkers once they have confirmed to care home staff that they are happy to discuss the study further with them. Data will be stored securely and retained only as long as necessary.

<u>Easy Read Information Sheet</u>

The Easy Read Information Sheet is intended as an optional supplementary document to support communication with residents who may not have full capacity to provide independent consent, but who do have some level of understanding. Its purpose is to facilitate inclusive conversations about the study, enabling residents to engage with the information to the extent that they are able.

In cases where a resident lacks capacity, a consultee will be approached to provide a declaration (as described above). The consultee will receive the full standard information sheet. However, the Easy

Read version may be used alongside this process to involve the resident in the decision-making discussion, where appropriate.

8.1.5.3 Remote and Telephone Consent

Since this is a low-risk, non-Clinical Trials of Investigational Medicinal Products (CTIMP) study with risks no higher than that of standard medical care, and in accordance with the Health Research Authority (HRA) and MHRA joint statement on electronic consent methods published on 24th September 2018, remote declarations may be documented utilising an e-consent mechanism *via* REDCap.

The trial should initially be introduced to the consultee over the phone by a member of staff at the care home, and if they are happy to receive further information, the recruitment pack sent via email or in the post, depending on their preference. After the consultee has been given sufficient time after receiving the recruitment pack (at least 24 hours), the fieldworker should contact the consultee at which point they will be given the opportunity to understand the nature, objectives, significance and risks of the trial, and will be encouraged to ask any questions they have, so that they can make an informed decision about whether to provide advice that the resident would want to take part. The declaration form will be presented in an electronic format and declaration will be recorded using a tick box for each clause, a typed name, and confirmation of the declaration. There will be no follow-up with a paper (wet ink) declaration form, as the electronic signature constitutes documented informed advice. A copy of the eDeclaration form will be made available to the consultee.

Remote consent can also take place with residents who wish to have more time to consider the study after being provided with the recruitment pack.

For residents/consultees who do not wish to provide the consent or declaration electronically (i.e., due to technological difficulties), consent or declarations can also be provided over the telephone. If the consent/declaration is received *via* telephone, the fieldworker will complete the telephone consent/declaration form, with permission, on the participant's or consultee's behalf. A copy of the form will be given to residents on the fieldworker's next scheduled visit, given to care home staff to pass to consultees on their next visit, or alternatively sent *via* the post.

If consent/declaration is received via the telephone, the person receiving the consent/declaration will use the telephone consent/declaration forms and will initial next to each clause indicating that the consultee/participant has verbally understood and agreed to each point. The person receiving the telephone consent/declaration must sign the form to confirm that the consultee/participant has understood the information sheet and verbally agreed to the consent clauses.

Fieldworkers will follow a study-specific work instruction with details on how to receive consent in-person, via telephone or remotely.

8.1.5.4 Consent of non-English speaking residents.

Where residents are identified as being non-English speakers, translated versions of the main RIS and consent form will be available in a number of languages. Translation and interpreter costs have been included for participants who are unable to read or speak English.

To identify translation requirements potential participating care homes will be asked to identify the top languages spoken in their care homes, and information sheets and consent forms will be translated into these languages. Care home staff and/or family who speak the relevant language may also act as an interpreter during the consent process. Subsequent data collection is performed with a proxy rather than the resident themselves, and therefore this process relates only to the consent process.

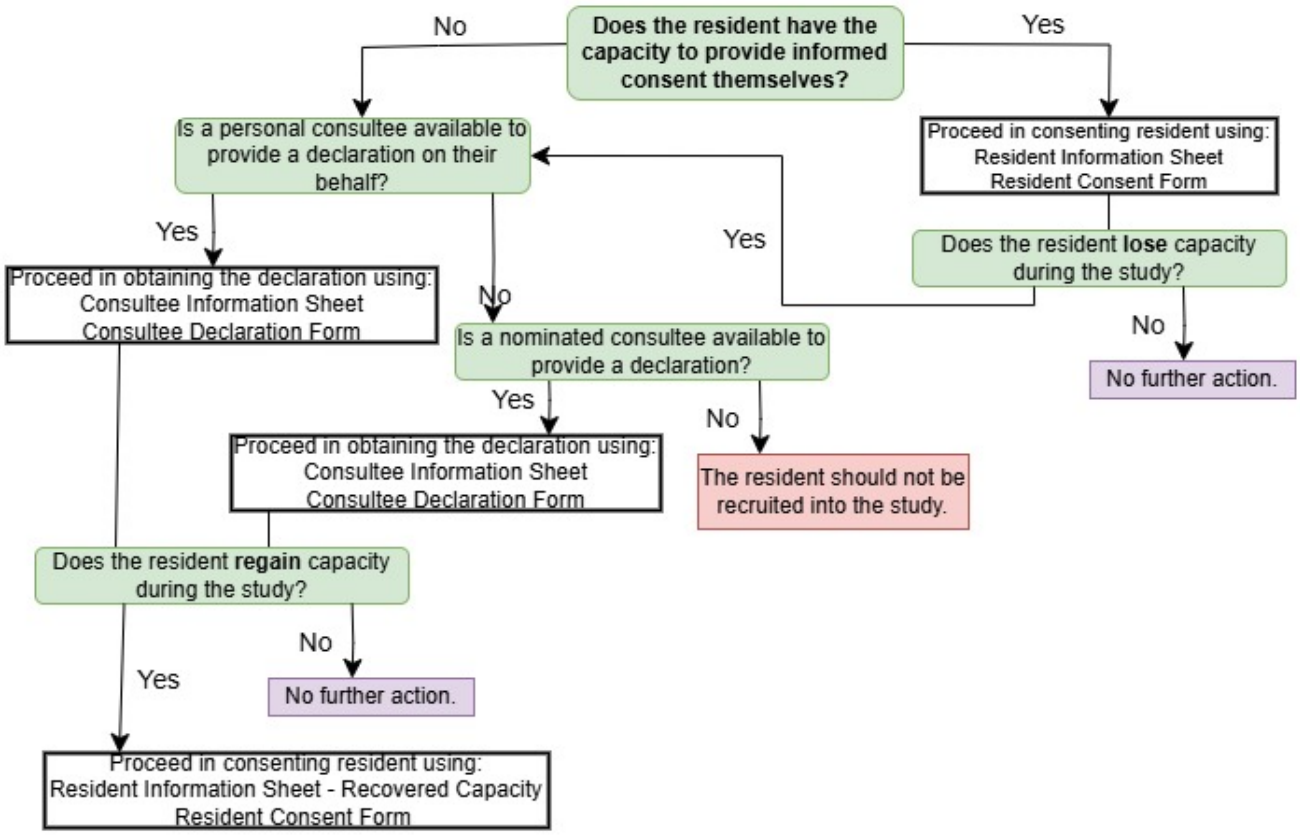
8.1.5.5 Responsibilities

Whilst the fieldworker will be responsible for obtaining consent from the residents or their consultees, support from the RP will be required as they retain overall responsibility for the conduct of research at their site. They must ensure that any person delegated responsibility to participate in the informed

consent process is duly authorised, trained and competent to participate. The RP takes responsibility for ensuring that all vulnerable participants are protected and participate voluntarily in an environment free from coercion or undue influence. Where a participant is required to re-consent (e.g., in the case of a resident regaining capacity after a consultee has provided a declaration on their behalf), or new information is required to be provided to a participant, it is the responsibility of the RP to ensure this is done in a timely manner.

The fieldworker will update the study database to confirm that the resident is eligible and has provided informed consent (or the consultee).

Figure 6: REFRESH Consent Flowchart



8.2 Baseline Data

Fieldworkers will be responsible for collecting and recording data in REDCap but they will seek the input of care home staff as the proxy (see Table 1 and 2). Where possible, the same proxy will complete the assessments for the same participant at each visit.

The fieldworker will arrange to attend the care home to capture the baseline data for the participants who have consented to be part of the trial, this should occur over the course of around a week.

To characterise the resident and care home population and summarise balance at baseline across the trial arms the following data will be collected and entered onto the trial's REDCap database:

Table 8: Baseline data collection

Characteristics	Descriptive data

Demographics	• Month/year of birth • Sex at birth • Ethnic group • Socioeconomic status measured by funding source (self-, NHS-, council-, or combination funded place) and previous employment • For residents in dual status homes, the status of their residence – nursing, residential, EMI • The level of care category: low, medium, high and very high • Marital/civil partnership status • Religion/belief
Medical History	• Are any of the following co-morbidities present: Dementia/cognitive impairment/memory loss Diabetes GI disease (e.g. coeliac, IBS – irritable bowel syndrome, IBD - inflammatory bowel disease, diverticulitis, etc) Cardiovascular disease (CVD) (stroke, heart disease, peripheral vascular disease etc) • Ability to eat independently – Y/N Independent: able to eat and drink without any additional support from carers. The resident may require visual monitoring and prompting from carers, the use of adapted cutlery, plates or cups, and the need for modified texture such as the carer cutting up the food; all these would still count as being able to self-feed. Not independent: the resident requires close monitoring and regular frequent prompting, and may require physical help to place some or all the food or drink into their mouth. • Presence of pressure injury – Y/N • Presence of lactose intolerance – Y/N • Recommended to have modified consistency food or drink – Y/N • Specific dietary needs and preferences (vegetarian, vegan, coeliac, allergy, other) If Yes to any of the above three questions, during the intervention training the fieldworker should discuss with the care home any modifications needed for FF or ONS interventions • Number of current medications: 0-5, 6-10, >10 (not including pro re nata (PRN) medication)
Stage of dementia	Functional Assessment Staging Tool (FAST)[64,65] - The scale consists of seven stages, each representing a distinct level of cognitive and functional decline. The fieldworker will obtain this score from a member of the care home staff who knows the resident well.

Frailty status	Clinical Frailty Scale (CFS)[66] – The scale consists of nine stages, each representing a degree of frailty. The fieldworker will obtain this score from a member of the care home staff who knows the resident well.

In addition to the above descriptive data, outcome data listed in Table 1 and 2 will be collected by the care home staff and fieldworker at baseline.

- HRQoL - EQ-5D-5L Proxy Version 2
- QoL - DEMQoL-CH
- Nutritional status - MNA
- Weight – sitting or hoist weight (kg)
- Dietary intake data collection - 3-day food record, using a photographic food record and food record charts
- Functional limitations - MBI
- Infection rate (as a marker of morbidity) - Antibiotic use

8.2.1 EQ-5D-5L-Proxy Version 2 data collection procedure

To complete the EQ-5D-5L Proxy Version 2 questionnaire, the proxy is asked to indicate how the resident would rate their own health if they were able to communicate it, by ticking the box next to the most appropriate statement in each of the five dimensions[67].

Previous research has shown that proxy respondents tend to report the subject's HRQoL as worse than the subject's own self-assessment; different proxy respondents may adopt a different reference point depending upon their relationship with the subject; and the perspective adopted by a proxy respondent (i.e. the proxy's own assessment of the subject's HRQoL versus how the subject would assess this themselves) may also influence their responses[68]. To mitigate against these factors, we have devised the following protocol for collecting these data. The EQ-5D-5L-proxy will be completed for each resident by a permanent member of the care home staff who knows the resident well. To ensure consistency we will strive to make sure that the same member of staff acts as the proxy for any given resident at all three time points. Care home staff acting as proxies will be assigned an ID, which will be entered on the EQ-5D-5L form, so that any changes in the proxy for a given resident can be identified. At each time point brief training will be provided to the proxy by the field worker, and the proxy will be instructed to adopt the perspective of the resident. A proxy will be used even when the resident has capacity since research suggests a professional proxy-assessment is systematically lower than self-assessment, so for inter-respondent consistency either self-report OR proxy-report should be used throughout[69]. Given the possible fluctuating mental capacity of residents and early-stage undiagnosed dementia, a proxy provides greater intra-respondent consistency than self-report. It will not be possible for the member of staff providing the proxy responses to be blind to the intervention. This is a limitation of the trial design, but one that is not possible to avoid.

8.3 Randomisation (Day 0)

Following recruitment of the trial participants and completion of the baseline assessments, care homes (clusters) will be randomly allocated in a 1:1:1 ratio to one of the three trial arms (30 care homes per trial arm) using block randomisation via computer generated random numbers. Care homes will be sequentially randomised (i.e., individually as soon as they are ready for allocation) following collection of the baseline data, rather than being randomised in batches (i.e., at the same time as other care homes). The care home staff will be informed of their allocation, and arrangements will be made to

supply the care home with the intervention if randomised to one of the intervention arms and for training to be delivered. The fieldworker will schedule the 6-month follow-up with the care home staff.

The randomisation sequence will be generated by a statistician independent to the trial team. Randomisation of care homes (clusters) will be stratified by each of the three regions and the number of residents in the care home recruited to the study (two categories: <22 and ≥22 residents recruited) and implemented through a secure web-based system on REDCap, ensuring allocation concealment. Cohort will not be a stratification factor for randomisation, but it will be adjusted for in the analysis.

The fieldworker will be responsible for randomising care homes *via* REDCap. An unblinded, automated confirmation email will be generated when a care home is randomised, and sent to the RP, fieldworker and other delegated members of the study team.

8.4 6-Month Follow-up (Day 180 +/- 14 days)

Fieldworkers will be responsible for collecting and recording data in REDCap but they will seek the input of care home staff as the proxy (see Table 1 and 2). Where possible, the same proxy will complete the assessments for the same participant at each visit.

The fieldworker will attend the care home to capture the 6-month follow-up data for the participants who have consented to be part of the trial, this should occur over the course of around 3 days.

The outcome measures listed in Table 1 and 2) will be collected by the care home staff and fieldworker at the 6-month follow-up and entered onto the trial's REDCap database:

- HRQoL - EQ-5D-5L Proxy Version 2
- QoL- DEMQoL-CH
- Nutritional Status - MNA
- Weight - sitting or hoist weight (kg)
- Dietary intake data collection, adherence and acceptability - 3-day food record, using a photographic food record and food record chart
- Functional limitations - MBI
- Infection rate (as a marker of morbidity) - Antibiotic use
- Resource use - HCSUQ
- Mortality – registered death records

The fieldworker will schedule the 12-month follow-up with the care home staff.

8.5 12-Month Follow-up (Day 365 +/- 14 days)

Fieldworkers will be responsible for collecting and recording data in REDCap but they will seek the input of care home staff as the proxy (see Table 2). Where possible, the same proxy will complete the assessments for the same participant at each visit.

The fieldworker will attend the care home to capture the 12-month follow-up data for the participants who have consented to be part of the trial, this should occur over the course of around 1 day.

The outcome measures listed in Table 2 will be collected by the care home staff and fieldworker at the 12-month follow-up and entered onto the trial's REDCap database.

- HRQoL - EQ-5D-5L Proxy Version 2
- Resource use - HCSUQ
- Mortality – registered death records

8.6 Potential for Long-Term Follow-up

A long-term follow-up is not within the scope of this trial, but residents/consultees who consent to take part in the main study will be asked whether would be happy for their data to be accessed or collected from their care home records beyond the 12-month follow-up for the trial, in order to help researchers look at any long-term effects and improvement. They are informed that researchers will seek ethical approval before doing this. This is an optional clause on the consent/declaration form and will not affect the resident's participation in the main trial.

9 STAFF TRAINING

9.1 Research Training and support

As well as intervention training as described in Section 4: Trial Intervention, care home staff will receive training videos relating to relevant research elements, that incorporate GCP training. Care home staff will therefore not complete separate GCP training. All care home staff on the delegation log will be required to complete the research-training that is relevant to their role on the study. It is the responsibility of the RP to ensure that care home staff members have accessed the training modules relevant to their role on the study. The RP should be complete the training modules prior to the care home receiving the green light to begin recruitment. This is except for the data collection training module, which would be more beneficial for staff to access before the data collection begins, rather than before greenlight. The training will be short videos covering the following elements: study overview, data collection, resident identification, consent process overview, safety reporting. Any questions that staff have will be directed to the research team who will be available to discuss anything with them to ensure full understanding throughout the study.

Once the training is complete, the care home staff will receive a certificate of completion.

10 PROCESS EVALUATION

A mixed method process evaluation will be undertaken concurrently with (but independently of), the main trial, informed by the principles of realist evaluation[70-72], guided by the MRC framework for process evaluation of complex interventions[73] (see Figure 1 Participant and Protocol Flow Chart) and using normalisation process theory[47,74] to guide data collection and analysis.

A process evaluation provides insight into fidelity and quality of implementation, provides information about causal mechanisms and contextual factors and understanding of why the intervention might fail or has unexpected consequences[73]. The fidelity of the intervention delivery will be guided by Hasson et al.'s[75] conceptual framework. Bespoke documentation will be created to collect data on intervention fidelity. Observations and interviews/focus groups will be conducted by qualitative researchers trained in process evaluation methods.

A realist evaluation will provide a theoretical framework to explore the general factors and characteristics that enable or hinder the delivery of interventions in care homes. This approach in the internal pilot phase will generate insights to refine the implementation of the interventions in the main trial phase. Any refinements to the intervention arms will be documented, and corresponding updates will be made to the logic models (Figures 3 and 4). Realist evaluation focuses on how and why interventions work (or fail) in specific contexts, acknowledging that outcomes are shaped by the interaction between context and mechanisms. The review and revision of the initial programme theory will be guided by the development of context–mechanism–outcome (CMO) configurations, which are central to the realist methodology.

10.1 Observations, Interviews and Focus Groups

Two care homes from each region (six care homes in total) will be purposively selected to take part in the process evaluation.

Selection will be purposive to include:

- Care homes with nursing provision; care homes without nursing provision
- Independently owned care homes; corporate owned care homes
- Two care homes from each geographic location, one from each of the ONS and FF arms

10.1.1 Observations

Observations will be undertaken in the two intervention arms. A checklist (See Observations checklist for process evaluation) will be provided to researchers to ensure that the same aspects are assessed across sites. This will include:

- Up to 12 observations of key nutrition activities in each of the process evaluation care homes. Including:
    - mealtimes, snack provision, drinks trolley rounds, and food preparation, all in communal areas only.
    - staff meetings where nutrition is being discussed. Researchers will observe only conversations about the participants who have consented to take part in the study. This will avoid inadvertent exposure to confidential information about any residents who have not consented to participate. Observations in staff meetings may include discussions about the concerns or challenges around ONS/fortified food, staff understanding of the purpose of ONS/fortified foods and the consideration of nutrition in the context of holistic care. See the Observation checklist for process evaluation for a full list of what may be observed.

10.1.1.1 Consent for observations

Most residents will be familiar with observations taking place in the care home for the purposes of audits and inspections. A flyer will be provided to care home residents and/or their family/carers to inform them when the observations will be taking place and to give them the opportunity to opt out. A poster will also be displayed in communal areas of the care home (see Observation poster and flyer – SWAP and process evaluation). This will happen at least 2 weeks before the observations are due to take place. If residents or consultees wish to discuss the observations further before deciding whether to opt out, care home staff who know the resident's/consultee's communication preferences best will help the researcher guide those conversations. Care home staff may also choose to remind residents/consultees about the observations in other ways, such as through newsletters or residents/family meetings.

When observing in communal areas it will be made clear that the observations are of processes and procedures in general, and not of individuals. For confidentiality, researchers will only be present in meetings when consented residents are being discussed.

10.1.1.2 Process for observations

At the start of every observation, researchers will introduce themselves to anyone in the area and will wear a name badge identifying them as the researcher. Another opportunity for residents to opt out of being present during the observation will be provided. If any residents who have opted out are present in a communal area at the time the researcher intends to conduct observations, the observation will be postponed. During this period, the researcher may choose to observe a different communal area where only residents who have not opted out are present. If repeated attempts to conduct observations are unsuccessful due to the presence of opted-out residents, the care home may be replaced with another. The researcher/fieldworker will use the Observation checklist to focus attention on the specific processes and procedures being observed in that session. This checklist will be developed iteratively as the observations progress to ensure it remains relevant and supportive for the researcher.

10.1.2 Interviews and Focus Groups

Interviews and focus groups will be undertaken with stakeholders in each care home conducted either online, by phone or in person. This will include residents, relatives/friends, care home staff (including senior management, registered nurses, and care workers), and other healthcare professionals (dietitians, speech and language therapists, occupational therapists, pharmacists, GPs).

Semi-structured interviews or focus groups will be based on topic guides developed in consultation with the study PAG and SAG. Interviews or focus groups will be based on constructs from NPT[47,74], guided by previous studies using NPT in care homes[76,77] to identify facilitators and barriers to intervention implementation (in the intervention care homes).

A flexible approach will be used to organise interviews and focus groups, using the method most appropriate for the care home, their staff and residents and family who consent to take part. We anticipate residents and/or their family/friends are most likely to prefer an interview at a time and place which suits them, including online. Care workers may prefer either an interview or focus group and we will organise this at a time and format which suits the care home. Where other healthcare professionals who are involved in the nutritional care of residents at the home (e.g. dietitian, occupational therapist, speech and language therapist) and are willing to consent to take part, it is likely it will be easier to plan an interview rather than invite them to join a focus group. This may be preferable online.

Purposive sampling will be used to select the sample of participants to ensure representation from a range of roles of staff, residents and relatives/friends in the interviews and focus groups. Up to 20 interviews and/or focus groups (or until data saturation is reached[78]) will take place across the six care homes selected for the process evaluation. Interviews with staff who have been involved with the delivery of intervention training will also be conducted. This includes the trial co-ordinator, field workers, and other study staff (lasting 30-60 mins, conducted either online, over the phone or in-person).

Demographics of participants will be collected including their age, gender, identified ethnic background and time as a resident (for residents), age group, gender, relationship to the resident and identified ethnic background (for relative/friends), or their age group, gender, identified ethnic background, role within the care home and time in that role (for staff). This will contextualise the responses within the interviews.

Discussions will include the experience of the supplement drinks and fortified foods (See the process evaluation topic guides).

10.1.2.1 Eligibility and Informed consent for interviews and focus groups

<u>Residents and relatives/friends</u>

Inclusion criteria:

1. Already participating in the main trial and resident in a home selected for the process evaluation.
2. Has mental capacity to take part (this is assessed during the consent process for the main trial. Only those with mental capacity will be asked if they wish to take part in the process evaluation).
3. Willing to give consent.
4. A relative or friend involved in the care of a resident meeting Criterion 1, who is willing to be interviewed on their behalf and willing to give consent.

There is an optional clause on the main study consent form where the resident (or consultee) can indicate whether they would be happy to be contacted about taking part in interviews or focus groups. Those who consented to being contacted will be approached by the researchers who will provide specific information and give at least 24 hours to consider participation. The researcher will answer any questions that they might have concerning the interviews or focus group. Informed consent will be

taken either face-to-face, electronically or over the phone. After consent has been received, a date and time for the interview or focus group will be scheduled.

Care home staff

Inclusion criteria:

1. Employed by a Care Home participating in REFRESH and selected for participation in the Process Evaluation.
2. Employed in a caring role and involved in the care of REFRESH participants.

Exclusion criteria

1. Have a significant proportion of time caring for residents who are not enrolled in the trial

Other healthcare professionals

Inclusion criteria:

1. Involved in the nutritional care of a participating resident in a home selected for the process evaluation.

Researchers undertaking the process evaluation will provide information about the interviews and focus groups to care home staff and other healthcare professionals and give them at least 24 hours to consider participation. The researcher will answer any questions that they might have concerning the process evaluation. Care home staff and other healthcare professionals invited to take part in the process evaluation will provide informed consent either face-to-face or over the phone. After consent has been received, a date and time for the interview (and observations) will be scheduled.See the process evaluation topic guides for the proposed content for each of the above groups.

10.2 Evaluation of usual care

The aim is to understand the characteristics of the approaches used to treat and manage malnutrition in all care homes in the 'usual' care arm across the three cohorts, because this will vary between care homes recruited into the trial. Evaluation of usual care is also recommended in complex intervention trials to support understanding of the fidelity of implementation and delivery of interventions[79].

A study specific proforma questionnaire (see Usual care questionnaire) has been developed to document usual care, using closed- and open-ended questions, completed by care home manager and/or senior care home staff supplemented by relevant information including local policy guidelines to manage malnutrition, mealtime menus and snacks. The usual care questionnaire data will be analysed using content analysis and deductive approach[80] in terms of pre-determined categories of structures, processes, outcomes, variations between care homes.

10.3 Acceptability Questionnaire

The acceptability of the intervention will be assessed drawing on Sekhon's theoretical framework of Acceptability[81], that consists of seven component constructs (affective attitude, burden, perceived effectiveness, intervention coherence, ethicality, opportunity costs, self-efficacy). All staff (e.g. catering staff, care workers, care home managers) trained in delivering the intervention in the 60 care homes allocated to one of the two intervention arms will be invited to complete the theory informed questionnaire[82] (online), between 6 and 12 months after completing the intervention training. Staff will be informed that the completion of the questionnaire is optional and can be paper-based if preferred.

10.4 Analysis of qualitative and quantitative data

Digitally recorded interview and focus group data will be pseudonymised and transcribed verbatim, using a professional transcription service. Transcripts will be analysed using an inductive and deductive thematic approach[83], and develop a thematic framework based on emerging themes,

facilitated by NVivo 12 software. A proportion of the transcripts (20%) will be double-coded, and any discrepancies discussed until consensus reached[84,85].

Descriptive statistics will be applied for fidelity checklist used for observations and analysis of acceptability data.

RAMESES II reporting guidelines will be used[86]. In accordance with the realist method, data will be synthesised in the form of CMO configurations: Context – description of the setting where the intervention is introduced; Mechanism – local response to the intervention which informs changes to practice; Outcome – impact of intervention on outcome measures and process.

11 STUDY WITHIN A PROJECT (SWAP) - Nutritional Care of culturally diverse older adults living in care homes.

11.1 Background

We will follow the NIHR INCLUDE Ethnicity Framework[56] working together with our PAG in this trial. Guided by a toolkit[87] to increase participation of ethnic minorities, a SWAP has been included to understand how we can improve recruitment and retention of older residents from different ethnic backgrounds. This study will contribute to our understanding of inclusive approaches to recruit older residents from ethnic minority groups, who are under-researched and often less engaged or included in research[56]. This will add to the body of knowledge to support future research, as well as enabling the trial to reflect the increasing diversity of the UK's older population living in care homes.

11.2 Rationale

The UK has a culturally and ethnically diverse ageing population with the largest increase being Asian and Black African & Caribbean ethnic minority groups[57]. As such they represent a growing minority of care home residents (around 4.5% to 5.1%)[88] and highlight the need for care provision to respond to ethnic and multicultural diversity.

Limited studies of older residents in care homes, especially those exploring the experiences of people with dementia from ethnic minorities, show that the provision of culturally familiar foods helped to foster a sense of cultural identity and dignity, improved appetite, and nutritional intake, promoted reminiscence and generally improved quality of care[89]. Thus, it highlights the importance of cultural foods and mealtimes to support wellbeing and social connectedness, ensure dietary needs are met with sensitivity to religious beliefs and practices, and how understanding cultural backgrounds can influence attitudes and experiences to guide the provision of good nutritional care in care homes. The need to explore and understand the barriers to including older residents from different cultural backgrounds in trials, and to help optimise retention and contextualise interventions in this trial, suggest that a focussed SWAP is warranted. Not only will the study findings inform the following cohorts, but the data will also contribute to a body of evidence around recruitment and retention of older people from these under researched groups living in care homes.

This SWAP will build on existing knowledge and approaches to both recruit and retain residents from ethnic minority groups[56] and to explore how their background can influence experiences related to improving the provision of nutritional care in care homes. Findings from recruitment in the internal pilot will then be used to improve recruitment of different ethnicities for the remainder of the project.

Culture and ethnicity both heavily influence food choices and practices, but they do so in distinct ways. Culture refers to the shared beliefs, values, behaviours, and traditions of a group of people, while ethnicity is often linked to shared ancestry, language, and cultural heritage. Food preferences, preparation methods, and the significance of food in rituals and celebrations are all deeply influenced by both culture and ethnicity. Here, for conciseness, we have used the terms 'culture' and 'cultural' but it should be understood to include ethnicity.

11.3 SWAP objectives

- Examine the barriers to recruitment and strategies to support retention of older residents from different cultural backgrounds.
- Examine dietary intake in the care home setting (how much do residents eat, when, what and is it adequate, to establish the potential issues, barriers and facilitators to good nutrition).
- Examine cultural issues which may impact on intake (explore and understand the barriers specifically relating to residents from different cultural backgrounds to contextualise nutritional interventions).
- Examine how to ensure people from diverse cultural backgrounds can be catered for and included in future nutritional studies in this population.
- Investigate whether the effect of ONS and FF compared with usual care on quality of life at 6 month follow up differs across categories defined by ethnic group if the sample size is sufficiently large for this sub-group analysis.

11.4 SWAP outcomes

The outcomes or activities associated with each of the objectives are listed in table 9.

Table 9: SWAP objectives and data collection

Objectives	Outcome Measures or activity	Timepoint(s) of evaluation of this outcome measure/activity
Examine the barriers to recruitment and strategies to support retention of older residents from different cultural backgrounds.	Semi-structured interviews or focus groups **with residents or resident's family and care home staff** about the study processes relating to recruitment and retention to be analysed using thematic analysis.	Between randomisation and month 6.
Examine dietary intake in the care home setting (how much do residents eat, when, what and is it adequate, to establish the potential issues, barriers and facilitators to good nutrition).	3-day dietary records using photographic methods and food record charts, with subsequent estimated energy, protein, fat, carbohydrate, fibre and fluid intake. Observation of key nutrition activities in care homes.	6 months post-randomisation. Between baseline and month 6.
Examine cultural issues which may impact on intake (explore and understand the barriers specifically relating to residents from different cultural backgrounds to contextualise nutritional interventions).	Semi-structured interviews or focus groups **with residents or resident's family** about eating preferences, cultural food norms and food and drink habits and customs in the care home, to be analysed using thematic analysis.	On-going process of qualitative data accumulation and analysis.
Examine how to ensure people from diverse cultural backgrounds can be catered for and included in future nutritional studies in this population.	Semi-structured interviews or focus groups with **care home staff** about eating preferences, cultural food norms and food and drink habits and customs in the care home, to be analysed using thematic analysis.	On-going process of qualitative data accumulation and analysis.

Investigate whether the effect of ONS and FF compared with usual care on quality of life at 6 month follow up differs across categories defined by ethnic group.	EQ-5D-5L-Proxy assuming there are enough participants from ethnic minority backgrounds to enable this sub-analysis.	6 months post-randomisation.

11.5 SWAP design

The SWAP will occur during the internal pilot phase of the study. The SWAP will build on existing knowledge and approaches to both recruit and retain residents from ethnic minority groups[56] and to explore how their background can influence experiences related to improving the provision of nutritional care in care homes. Qualitative methods will be used to explore the barriers and preferred approaches with older residents and their relatives/friends. We will work with our identified locations to recruit residents and their relatives/friends, purposively sampled from South Asian and Black African & Caribbean ethnic minority groups, meeting the main trial eligibility criteria.

One-to-one semi-structured interviews or focus groups will be conducted with between 15-20 residents and/or their relatives/friends (as appropriate) and care home staff using a pre-designed topic guide, informed by existing literature and advice from the study SAG and PAG. Interviews will last approximately 30 minutes but no more than 60 minutes and will be audio-recorded and transcribed verbatim. Interviewees will be asked about their experiences of the study processes, the provision of food and drink, eating preferences, cultural food norms and food and drink habits and customs, priority areas to guide the intervention, and barriers to inclusion at an individual or care home level.

The same approach in organising interviews and focus groups will be used as discussed in Section 10.1.2.

In addition to interviews and observations, the dietary intake of the participants will be examined to understand how much residents eat, when, what and whether it is adequate, to establish the potential issues, barriers and facilitators to good nutrition.

11.6 SWAP Eligibility criteria

Residents and relatives/friends

Inclusion criteria:

Residents who:

- Are a resident in a care home participating in the main REFRESH trial
- Identify they are from an ethnic minority group including UK South Asian and Black African & Caribbean communities

For residents unable to consent a family member or friend may be recruited. If the resident does not have the communication or language skills necessary to participate, they may choose a family member or friend to speak on their behalf

Care home staff (care assistants, nurses or catering staff):

Inclusion criteria:

- Care for residents enrolled in the SWAP

11.7 SWAP Sampling

We will seek up to 10 residents (or a relative/friend) and 10 members of staff, aiming for one member of staff for each resident who participates.

Purposive sampling will be employed to ensure a varied sample with participants from both South Asian and Black African & Caribbean backgrounds, and those who have lived in the care home for varying time spans (e.g. > or < 3 months).

Staff participants may work in any caring role in the care home where the resident participant lives, and we will seek to include a mixture of roles among care assistants, nurses and catering staff.

All participants who meet the criteria will be provided with information about the SWAP until the recruitment target is reached.

11.8 Consent

Specific consent will be sought from the participants for the SWAP.

There is an optional clause on the main study consent form where the resident (or consultee) can indicate whether they would be happy to be contacted about taking part in interviews or focus groups. Residents and relative/friends who consented to being contacted can be approached by the researchers undertaking the SWAP, who will provide them with information about it. At least 24 hours will be given for them to consider participation. The researcher will answer any questions that they might have concerning the SWAP. Residents, relatives/friends and care home staff invited to take part in the SWAP provide informed consent either face-to-face, or via phone.

Residents in participating care homes who have declined to take part in the main study may also be approached to take part in this study. This will enable data to be collected about why individuals do not take part in research studies, as well as to ensure that people from a variety of ethnic groups may be included. The care home staff will ask residents or their families if they are interested and obtain their permission to put them in contact with the researchers, who will follow previously described processes to seek consent.

11.9 SWAP conduct

Once a resident (or relative/friend) or member of staff has consented to take part in the SWAP the field worker (or other researcher) will organise a date and time to conduct the interview. This will be at a time convenient to that individual. Due to the large geographical area and the limited researcher capacity, interviews will be conducted either online, over the telephone, or face-to-face, depending on the participants wish and the researcher's availability.

Demographics of participants will be collected including their age, gender, identified ethnic background and time as a resident (for residents), age group, gender, relationship to the resident and identified ethnic background (for relatives/friends), or their age group, gender, identified ethnic background, role within the care home and time in that role (for staff). This will contextualise the responses within the interviews.

The interview will take place in a private setting, be recorded verbatim, and the recording will be stored until transcription on a secure University of Plymouth OneDrive folder. Once transcribed and anonymised the recording will be deleted.

Following transcription, data will be analysed using inductive and deductive thematic analysis[83] to develop and refine themes (facilitated by NVivo software). Findings will be discussed with the public advisory group to guide interpretation.

Alongside the process evaluation, the findings will help guide the transition from internal pilot to main trial phase, refine recruitment processes and provide recruitment strategies to support inclusivity and inform similar interventions in the future. It is also anticipated that with the support of the PAG, the findings from the SWAP will help us to refine trial materials, including participant information flyer, consent forms and preferred approaches to present materials e.g. written, spoken or multimodal to support inclusive recruitment and retention. It will also inform the delivery of nutritional care to people from diverse cultural backgrounds in the care home setting.

11.9.1 Dietary intake data and observations

Dietary records will be extracted from the main trial if they were collected for the main trial to measure adherence (photo records as described in Section 3.3.2). If not already collected, then it will be for the SWAP participants also.

In addition, the researcher will observe key nutrition activities (e.g. mealtimes, drink and snack rounds, kitchen preparation and care worker nutrition discussions), making field notes and using an observation checklist (See Observation checklist for SWAP) to understand the processes and context for the interview data. At least one mealtime in each care home where a participant lives will be observed.

The same approach to observations will be taken as in the process evaluation (described in Section 10.1.1).

12 PAYMENTS

Payments to the participants will not be made to compensate for their time during the trial. All trial assessments and visits will take place in the participant's place of residence and therefore travel for visits additional to normal care will not be required.

A small value voucher will be provided to staff who take on the role of the nutrition champion and for all those who are interviewed as part of the process evaluation or the SWAP (residents, family, friends and staff included).

13 WITHDRAWAL

Each participant has the right to withdraw[90] from the trial at any time. Participants (or consultees) will be made aware (*via* the RIS or fieldworkers) that if they withdraw from the trial, all trial data collected until that point will be kept for the analysis. Data collected up to the point of withdrawal will be retained and used in analysis, any intention to utilise such data is be outlined in the information sheet.

The RP may withdraw a participant from the trial or withdraw from aspects of the trial (i.e., intervention) if it is determined that the participant's health is compromised by remaining in the trial. All data collected from withdrawn participants will be included in the trial report.

An RP may decide to withdraw a participant from the trial or reduce their participation at any time for any reason including but not limited to:

- Ineligibility (arising during trial or retrospective having been overlooked at screening)
- An SAE which results in an inability to continue to complete trial procedures.
- Consent is withdrawn.

Any participant who withdraws will be asked to provide a reason but will be made aware that they are under no obligation to provide one, and that their withdrawal from the study shall in no way affect their access to ongoing treatment. The reason for withdrawal will be clearly stated (wherever possible) and recorded in the Case Report Form (CRF) and participant's care home records. If the participant is withdrawn due to an SAE related to the intervention or trial assessments, the RP (or delegated member of staff) will ensure the resident is monitored until the SAE has resolved or stabilised.

If the participant is withdrawn from the intervention only, if willing, all scheduled assessments (i.e., follow-ups) will be carried out as planned, but no further trial intervention will be consumed.

If a resident in one of the intervention groups consistently refuses the ONS or FF or shows signs of distress or agitation around mealtimes, it may be appropriate to initiate discussions regarding potential withdrawal from the intervention. It is important to distinguish between occasional non-adherence and a decision to withdraw - for instance, a resident may simply not wish to consume the ONS on a particular day.

In cases of consistent refusal or where the resident is showing signs of distress or agitation, care home staff should follow their usual procedures, considering all possible reasons for the resident's reluctance - such as illness, mouth pain, or dislike of the food or supplement offered that day, with the process being documented in the resident's care home records and discussed at staff meetings as per their usual processes. If the resident has capacity, the fieldworker or RP should explore the reasons for refusal directly with the resident and discuss whether they wish to withdraw from the study, either entirely or just from the intervention. If the resident lacks capacity, this discussion should be held with their consultee and/or care home staff.

13.1 Loss to follow-up

The protocol has been designed to ensure low numbers of participant attrition. All trial visits will take place in the resident's care home, meaning that they do not need to leave to attend any additional trial visits.

Follow-up assessments will be performed with a member of staff acting as proxy, meaning that participants are not required to complete any assessments themselves.

The feasibility study had a loss to follow-up rate of 32%[12]. Mortality was the primary reason (25%) and moving homes (4%) or entering end of life care or hospitalisation (3%) were the other reasons. We have mitigated against mortality by selecting a primary outcome which enables us to assign a score for those who die. Using a proxy measure means even those with severe ill health will be scored. It is only those who move homes who will be lost for the purposes of the primary outcome.

Participants who move to a non-participating care home during the study will not be followed for any outcomes and will therefore be considered lost to follow-up. This is since the care home staff from the care home that has agreed to participate in the study need to report outcomes on behalf of the participants; and there are insufficient resources for following up participants that leave their care home.

14 END OF TRIAL

Residents will complete their involvement in the trial after their 12-month follow-up visit has concluded. The end of the trial is defined as completion of any data collection following the final participant's 12-month follow-up visit. Participating care homes will be notified of the end of their involvement in the trial and the Research Ethics Committee (REC) will be notified within 90 days of the end the of trial. The clinical trial report will be written within 12 months of the end of the trial.

For instances where the trial may be terminated prematurely, see Section 5.3 Internal pilot for study progression.

Residents in the FF or ONS arm will continue to receive nutrition support according to the care home's usual practice. Trial ONS supplement delivery will cease, and the care home may decide to change the fortification regimen they have followed during the trial. However, care home staff may use their usual referral processes to obtain further ONS supplies, or dietetic assessment should their care pathway indicate this is needed.

15 SAFETY MONITORING

15.1 Definitions

Table 10: Safety monitoring definitions

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a patient or participant taking part in health care research, which may or may not have a causal relationship with

	the research. An adverse event can be any unfavourable and unintended sign, symptom, or disease that occurs during the time a participant is involved in the study, whether or not it is considered to be related to the intervention.
Serious Adverse Event (SAE)	An AE is considered serious* if it fulfils one or more of the following criteria: • results in death • is life-threatening** • requires inpatient hospitalisation or prolongation of existing hospitalisation*** • results in persistent or significant disability/incapacity • requires medical intervention to prevent one of the above or is otherwise considered medically significant by the investigator (e.g., participant safety is jeopardised). * Serious" and "severe" are not synonymous. “Serious” refers to a specific definition for the outcome of an event (see above), whilst “severe” refers to the intensity of an event (e.g., mild, moderate, severe). For example, it is possible to have a “severe” headache, but the headache itself is not a “serious” event **The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe. ***Hospital admissions for elective procedures **will not be reported as SAEs.** Only unplanned hospital admissions will be reported as SAEs if viewed as related to the intervention or trial procedures and unexpected. This includes visits to emergency departments.

15.2 Operational Definitions

Whilst participants are unlikely to experience any harm as direct result of taking part in this trial, processes will be implemented to ensure that such harms are detected and monitored appropriately. The safety of all participants will be monitored throughout the trial, from the point of consent/declaration until the end of the 12-month follow-up, or the end of the intervention, whichever occurs last. Safety events will be reported in line with the pathway detailed in the following sections.

In the context of clinical care and in accordance with local practice, all AEs occurring on the trial should be recorded in the resident’s care home records by care home staff. Given the population and setting we expect significant numbers of adverse and serious adverse events but expect most to be unrelated to the trial interventions, because the likelihood of participants being harmed by the intervention or any of the trial procedures is very low. **Therefore, a pragmatic approach will be taken whereby only events deemed to be serious in nature (SAEs), unexpected, and related to the trial intervention and/or procedures will be subsequently reported via the eCRF.**

Pre-existing conditions (documented in the care records) do not qualify as an AE unless they worsen during trial participation.

Any reported SAEs which are ongoing at the point of the final visit, must be followed up until the event has resolved, stabilised or has been fully investigated to the satisfaction of the RP and Sponsor.

Events should be recorded using V5.0 of the Common Terminology Criteria for Adverse Events (CTCAE) provided in the National Cancer Institute (NCI).

Detailed instructions for the recording and reporting of serious adverse events will be provided to participating care homes by the PenCTU in the form of a Work Instruction.

15.3 Recording and reporting of SAEs

The primary means of detecting serious adverse events will be *via* the care home staff through their interactions with the participants.

The 6- and 12-month follow-up involves the collection of resource-use data, so fieldworkers should ensure that any (non-elective) hospitalisations or emergency department visits reported by care home staff have been reported as SAEs, if related and unexpected.

The RP/RP delegate is responsible for checking for relevant events throughout the duration of the intervention period. Any events meeting the criteria for seriousness (as defined in Table 10), unexpected (as defined in Section 15.6) and related (as defined in Section 15.5) must be recorded by the RP or delegate in the participant's care record and in the digital PenCTU Safety Reporting System **within 24 hours of the RP/delegate first becoming aware of the event**, even if not all information is available at the time of reporting.

For each SAE, the following information will be collected:

- Full details of the event, including a diagnosis
- Medical Dictionary for Regulatory Activities (MedDRA) coding (system organ class [SOC] and preferred term [PT])
- Event duration (start and end dates, if applicable)
- Action taken
- Outcome
- Seriousness criteria
- Causality (relatedness to the intervention/trial procedures) in the opinion of the RP/delegate
- Expectedness (whether the event would be considered anticipated)

Any change of condition or follow-up information should be entered on the digital SAE resolution form as soon as it is available or at least **within 24 hours of the information becoming available.**

All reportable SAEs will be followed up until resolution, stabilisation, or Sponsor satisfaction.

15.4 Assessing severity of serious adverse events

The RP or delegate should determine the severity of the AE as per the CI CTCAE (V5.0):

	Severity	Definition
1	*Mild*	Aware of sign/symptom but easily tolerated
2	*Moderate*	Discomfort enough to cause interference with usual activity
3	*Severe (or medically significant)*	Incapacitating, unable to work or perform usual tasks
4	*Life-threatening*	Risk of death at the time of the event, urgent intervention required
5	*Death*	Death related to AE

NOTE: to avoid confusion or misunderstanding the term "severe" is used to describe the intensity of the event, which may be of relatively minor medial significance, and is NOT the same as "serious" which is described in the safety definitions.

15.5 Assessing causality of serious adverse events

The RP (or authorised delegate) will assess the causal relationship between the SAE and trial participation.

- Not related: There is no evidence of a causal relationship between the event and trial participation.
- Related: There is evidence of a causal relationship between the event and trial participation i.e., a relationship cannot be completely ruled out.

The causality assessment should be completed by the RP (or delegate) within 3 calendar days of the event being reported.

15.6 Assessing expectedness of serious adverse events

As all reportable SAEs will have been deemed to be related to the study intervention or procedures, all reported SAEs should have an assessment of expectedness.

Any events **not** falling into one of the below criteria will be deemed **unexpected**:

- GI symptoms (i.e., diarrhoea, discomfort, bloating, constipation)
- Poorly controlled blood glucose exacerbated by ONS intake

The expectedness assessment is delegated to the RP (or delegate).

15.7 Onward reporting of SAEs

The CIs and Sponsor will be automatically notified of reported SAEs via email.

SAEs both suspected to be related to trial participation and unexpected as per the list in Section 15.6 (therefore all reportable SAEs), will be reported to the REC by the Sponsor or CI within 15 days of the CI becoming aware of the event.

15.8 Reporting urgent safety measures (USM)

If urgent safety measures are required, the CI or Sponsor will notify the REC via email within 3 days of the measures being implemented, setting out the reasons for the urgent safety measures and the plan for further action.

A substantial amendment covering the changes made as part of the USM will be submitted within 2 weeks of the notification to the REC.

If an USM is implemented at site, PenCTU should be notified immediately by emailing REFRESH.penctu@plymouth.ac.uk. The PenCTU will notify all participating sites within 24 hours of USM(s) being implemented.

15.9 Coding of adverse events

PenCTU will maintain a register of all recorded serious adverse events. Events entered into the eCRF will be coded by designated members of PenCTU staff using the MedDRA dictionary, +version 28.0. Events will be coded at two levels - the PT and SOC. The same version of the MedDRA dictionary will be used throughout the trial.

15.10 Responsibilities

RP / delegate:

- Record reportable SAEs in the digital PenCTU Safety Reporting System within 24 hours of becoming aware of the event.
- Perform seriousness, causality and expectedness assessments for reportable SAE.
- Provide further follow-up information to SAEs as soon as available.

CI / delegate:

- Assisting PenCTU in assigning MedDRA or Body System coding to all SAEs.
- Regular monitoring of the risk benefit profile of the study.

- Acknowledge receipt of all reported SAEs.

Sponsor: (NB where relevant these can be delegated to the CI or PenCTU)

- Central data collection and verification of SAEs according to the trial protocol onto a database.
- Reporting safety information to the CI or delegate for the ongoing assessment of the risk benefit profile.
- Reporting safety information to the independent oversight committees identified for the trial (DMEC and TSC) according to the Trial Monitoring Plan.
- To submit expedited reports to the REC where there is a related and unexpected SAE (all reportable SAEs in this trial).
- Notifying participating sites of related and unexpected SAEs.
- Assigning MedDRA or Body System coding to all SAEs.

TSC:

In accordance with the TSC Charter, periodically reviewing safety data and liaising with the DMEC regarding safety issues.

DMEC:

In accordance with the DMEC Charter, periodically reviewing overall safety data to determine patterns and trends of events, or to identify safety issues, which would not be apparent on an individual case basis. To facilitate this, line listings of SAEs will be reviewed at DMEC meetings.

16 STATISTICS AND DATA ANALYSIS

16.1 Sample size calculation

The target sample size is 90 care homes (clusters) and 1530 care home residents altogether (30 care homes and 510 residents in each of the three trial arms). We have estimated that a mean of 17 residents will be recruited per care home, based on recruiting care homes that have an average of 51 beds and that a third of residents are eligible for the trial.

The sample size is large enough to detect a difference of 0.35 standard deviation (SD) units on the EQ-5D-5L-proxy utility score at 6 months (primary outcome) between each of the two intervention arms (ONS and FF) and the usual care arm with 90% power at the 2-sided 5% level of significance. Assuming the SD of the EQ-5D-5L is 0.37[51] this difference is equivalent to a difference of 0.13 on the raw scale of the measure. For context, the mean change in England-specific EQ-5D-5L utility score resulting from changing the profile of responses on the EQ-5D-5L by one level (point) on one of the five dimensions (items) is 0.063[91]. On this basis, the raw difference we seek to detect (0.13) would be clinically meaningful. Our PPIE members confirmed that even a change of one level in one domain would represent a positive worthwhile improvement.

The sample size calculation is based on an intra-cluster (intra-care home) correlation coefficient (ICC) of 0.1 and a coefficient of variation of the cluster size of 0.35. The estimated ICC for the EQ-5D-5L utility from Logan et al[51] was 0.067 (ICC provided by personal communication with the trial statistician). The calculation allows for loss to follow-up of 1 care home in each trial arm; Stow[11] had 0 (0%) out of 6 care homes drop out at 6 months and Logan[51] had 2 (2%) out of 84 care homes drop out at 6 months and a further 3 (4%) at 12 months. The calculation also anticipates 5% loss to follow-up of residents (e.g., due to leaving the care home); Logan[51] reports that they recruited 1657 participants and 123 (7%) were lost to follow up for a variety of reasons at 12 months and 55 (3%) at 6 months, and, additionally, Stow[11,92] (feasibility trial) reported 5% (5/93) of individuals were lost to follow up at 6 months (moved and admitted to hospital with no planned return). Otherwise, we anticipate that the care home staff will complete a proxy report of the EQ-5D-5L for all residents.

We anticipate up to 30% mortality by the 6-month follow-up. This is based on the Stow[11,92] feasibility study which reported 25% mortality at 6 months. The Logan[51] reference we have used to support our loss to follow up estimates shows a 28% mortality rate at 12 months and 13% at 6 months. Residents who do not survive will be assigned an EQ-5D-5L utility score of 0, therefore the sample size is not inflated to account for mortality. As the measure is a proxy report by the care home staff, we do not anticipate missing data due to non-response.

The sample size calculation does not account for the correlation between baseline and 6-month follow-up and therefore the estimated power is likely to be conservative since baseline EQ-5D-5L will be adjusted for in the primary analysis.

A subsample of 270 participants (3 from each of the 90 care homes) will be assessed for nutrition intake (secondary outcome). Assuming up to 35% of these will not provide follow-up data due to mortality (30%) or other reason (5%), and that three of the 90 care homes drop out, this subsample is large enough to detect a mean difference of 100 kcals (smallest difference of interest) between trial arms with 90% power at the two-sided 5% level of significance. The SD and the ICC for nutrition intake are assumed to be 150 kcals and 0.1 respectively.

16.2 Planned recruitment rate

Ninety care homes will be recruited, targeting those with at least 51 residents. Based on a third of residents meeting the inclusion criteria, we anticipate that a mean of 17 residents per care home will be recruited. Thirty care homes will be recruited in each of the three cohorts of the study. It is estimated that one third of residents will be eligible and consent to take part.

16.3 Statistical analysis plan

The statistical analyses and health economic analyses will be fully prespecified in a joint SHEAP. The SHEAP will be signed off by the TMG, DMEC and TSC prior to the last follow-up. The trial will be reported in accordance with the CONSORT 2010 extension for cluster randomised trials[93].

16.3.1 Summary of baseline data and flow of residents

A CONSORT diagram will be used to summarise the flow of participating care homes (clusters) and residents through the trial. Participating resident and care home characteristics will be summarised using means and SDs (or medians and interquartile ranges) for continuous variables and numbers and percentages for categorical variables. Characteristics of participants will also be summarised, separately, for participants who do and do not provide follow-up data, by trial arm.

16.3.2 Primary outcome analysis

The main comparison for the primary outcome will be between trial arms (ONS versus routine care and FF versus routine care) and will be based on the intention-to-treat (ITT) principle with participants analysed according to the trial arm their care home was allocated to, undertaking a complete case analysis (i.e. residents are only included in the analysis if data are available). Missing data will not be imputed.

The primary outcome, EQ-5D-5L utility value at 6 months, will be compared using mixed effects (“multilevel”) linear regression models, reporting mean differences with 95% confidence intervals and p-values. This method allows for non-independence of responses of participants from the same care home cluster. Utility values will be derived from responses to the EQ-5D-5L questionnaire using the approach recommended by the NICE[67] at the time of analysis. Participants who do not survive to follow-up will be assigned an EQ-5D-5L utility value of zero from the date of death to the date that their final follow-up was due, in keeping with standard use of this measure. The analyses will be adjusted for key prognostic factors (e.g. baseline EQ-5D-5L), study cohort and including the factors on which the randomisation was balanced (i.e., region and number of residents recruited).

16.3.3 Secondary outcome analysis

Comparisons will be based on the ITT principle with participants analysed according to the trial arm their care home was allocated to, undertaking a complete case analysis. Missing data will not be imputed.

Continuous outcomes be compared using mixed effects ("multilevel") linear regression models, reporting mean differences with 95% confidence intervals and p-values, and binary outcomes will be compared using marginal logistic regression models using Generalised Estimating Equations with information sandwich ("robust") estimates of standard error, specifying an exchangeable correlation structure, reporting odds ratios with 95% confidence intervals and p-values. For each outcome, the intervention effect estimate will be adjusted for key prognostic factors, e.g. baseline value of the outcome under consideration, study cohort and including the factors on which the randomisation was balanced (i.e., region and number of residents recruited).

16.3.4 Subgroup analyses

Subgroup analyses will be undertaken using tests of interaction to investigate whether the effects of the interventions differ across categories defined by ethnic group, if a sufficient number of participants are recruited to the ethnic group categories. The SHEAP will contain full details of this and any other agreed subgroup analyses of interest. These analyses will be exploratory given their secondary nature and that the trial has not been powered to detect subgroup effects.

16.3.5 Interim analysis and criteria for the premature termination of the trial

There is no planned formal, comparative interim analysis for this trial. An internal pilot (Section 5.3, Table 5) will be used to make the decision to progress to the main trial. The progression recruitment criteria will be summarised descriptively.

16.4 Participant population

The primary analysis population will include all participants for whom the primary outcome can be derived (complete case) with the main comparison based on the ITT principle with participants analysed according to the trial arm their care home was allocated to.

In sensitivity analyses, for the primary outcome, survivor average causal effect analyses will estimate the effect of the interventions in the population that would have survived to follow-up regardless of which trial arm they were randomised to. Analyses will be based on complete cases.

As a result of mortality, most of the secondary outcomes will be based on only 70% of those recruited. For these, the analysis population will be defined as residents that survive to follow-up on an ITT basis to compare the trial arms.

16.5 Procedure(s) to account for missing or spurious data

Reasons for being unable to collect data during an assessment will be recorded on the electronic CRFs (eCRFs), where appropriate. eCRFs will be assessed for missing data by PenCTU and sites will be regularly chased for missing data. PenCTU will maintain a record of site compliance with eCRF completion. If data completion is poor, a monitoring visit may be scheduled (See Section 18 Monitoring, Audit and Inspection).

The eCRFs will include mandatory fields; if a form is saved without these fields being completed an automatic flag will be displayed to the user. Where questions may need to be left blank, options such as 'Not applicable' or 'Prefer not to say' will be available, to differentiate these from missing data. Validations will be written into the REDCap database, to raise queries with particular data field, such as flagging if the date of a visit does not correspond to the correct timepoint.

The PenCTU data manager will write a series of R scripts[94] to perform the following data tasks to aid data completeness, including checking overall completeness by field of all eCRFs, checking all visits have been recorded in a logical order and checking SAE forms have been completed within the

timeframe stipulated in Section 15 Safety Monitoring. The scripts will be run on a regular basis and any concerns will be raised individually with sites.

For data that are reported by proxy via care home staff we do not anticipate any missing data due to non-response and have allowed for some missing data due to residents moving care homes.

16.6 Economic evaluation

The economic evaluation will establish the resources required to deliver the ONS and fortified food interventions and will estimate intervention costs. We will conduct a full cost-effectiveness analysis (CEA), based on within-trial data collection, from the perspective of the NHS and Personal Social Services. We will also explore costs from a care home perspective and will consider the impact of each intervention on food waste; given the complex funding model for residential care, this will be presented as a cost-consequences analysis alongside the primary analysis.

The resources required to deliver each intervention will be assessed via participant-level case report forms, and discussion with the intervention developers and providers. This will include the purchase of ONS and fortified foods, staff time and training, documentation, and any equipment and consumables. Nationally recognised UK unit costs for health and social care services, including Unit Costs for Health and Social Care[95] and the National Schedule of NHS Costs[96], will be applied to these data. Where national costs are not available, costs will be identified in consultation with the intervention developers and providers.

Data on other health and social care resource use will be collected via a bespoke, proxy HCSUQ at 6-month and 12-month follow-up. The HCSUQ will be informed by previous resource use instruments and core items for resource use measures[97] and will be developed through input from the study SAG and PAG. It will include primary and community health care, secondary health care and contacts with social care professionals. The HCSUQs will be completed by the study fieldworkers, who will extract the relevant data from care home records. Unit costs will be applied to the resource use data, as described above.

The EQ-5D-5L Proxy Version 2[28] will be completed on behalf of residents at baseline, 6-month and 12-month follow-up. Participant-level health state values will be derived from EQ-5D-5L responses, in accordance with the approach recommended by NICE at the time of data analysis[67] and will be used to estimate quality-adjusted life-years (QALYs) for use as the primary economic endpoint.

We will follow the internationally recognised CHEERs guidelines for reporting cost-effectiveness studies.[98] Descriptive statistics will be used to summarise costs (by type of service) and QALYs. A regression model will be used to adjust for systematic differences between the three study arms that have not been accounted for by randomisation (as per the statistical analysis), and clustering by care home will be accounted for as a random effect. Analysis will be undertaken on an intention-to-treat basis and will include any residents who die before final follow-up. Incremental costs and incremental QALYs over 12 months will be used to estimate the cost-per-QALY for ONS and for fortified food, versus usual care, and incremental cost-effectiveness ratios (ICERs) will be presented. Cost-effectiveness planes and cost-effectiveness acceptability curves will be presented using the net benefit approach[99] to illustrate the probability that each intervention is cost-effective relative to the thresholds for adoption used by NICE. Sensitivity analyses will explore uncertainty, and a clear, policy-relevant presentation of findings will be provided.

17 DATA MANAGEMENT

Data management activities are summarised in this section. Detailed data management activities are described in a separate Data Management Plan (DMP).

17.1 Data collection tools

A REDCap database will be used to collect participant screening and outcome data, as well as to record safety events. It will be a web-based, fully validated system, compliant with MHRA guidance and ALCOA+ (attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring, available) principles. Data will be captured in accordance with the best principles of clinical data management and the relevant standard operating procedures on Clinical Data Management System Specification and Validation. PenCTU will be responsible for the database build and system validation. Inbuilt validation features will be utilised alongside post-entry monitoring, performed using validated R scripts to ensure data quality and completeness.

Data will be hosted externally by ARO on Microsoft Azure datacentres located within the UK (Liverpool, England). ARO are NHS DSP Toolkit compliant and hold ISO27001 and Cyber Essentials Plus certifications. Microsoft Azure datacentres are Service Organisation Control (SOC*) type 1 and 2 compliant. Data will be stored on hardware dedicated to PenCTU's instance of REDCap. All electronic data are regularly backed up and stored with a full audit trail. The electronic data capture forms and configuration of REDCap will be managed by PenCTU's information systems team. Requisite permissions and training required for data collection at any sites will be provided by PenCTU. Data Protection Impact Assessments, Data Sharing Agreements will be developed where appropriate.

17.2 Source Data

Source data will include participants' care records (e.g., for certain eligibility criteria and medical history), participant/consultee-completed documents (e.g. informed consent forms), worksheets provided by PenCTU and eCRFs. In the context of clinical care, investigator site staff must ensure that details of a resident's participation in the trial are recorded in the participant's health record. At a minimum, the participant's health record should be updated to include:

• Consent and eligibility for trial

• Dates of all trial visits and follow ups

• Serious adverse events

• Completion or discontinuation of trial

Source data should be compliant with ALCOA+. PenCTU will verify source data and source documents as stipulated in the trial monitoring plan (see Section 18). Trial data will be recorded on eCRFs.

The participating site should keep a record of all participants and all original signed informed consent forms. Any paper forms completed by site staff or participants should be retained in the investigator site file (ISF).

The care home and research team will ensure that the participant's identity is protected at every stage of their participation in the trial, according to the Caldicott principles. If any patient information needs to be sent to a third party the trial team will adhere to maintaining pseudo-anonymous participant parameters in correspondence.

17.3 Access to Data

Direct access to investigator site records will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits, and inspections, in line with participant consent.

17.4 Archiving

Following completion of trial data analysis, the Sponsor will be responsible for archiving the trial data and Trial Master File (TMF) in a secure location for at least 10 years after the end of the trial. PenCTU will prepare the TMF for archiving in accordance with the requirements of the Sponsor's SOP.

PenCTU will prepare a copy of the final dataset for archiving according to the requirements of their SOP, as well as copies of all electronic source data files.

At the end of the study, ISFs will be sent securely to PenCTU, where the nominated archivist will arrange for the documents to be archived in the UoP archive facility. The nominated archivist is the PenCTU QA Manager. Medical records containing source data or other trial related information should be labelled, physically or electronically, so as to ensure retention until the Sponsor gives authorisation to destroy. e.g., “Keep until dd/mm/yyyy” (where the date given is ten years after the trial closure).

18 MONITORING, AUDIT & INSPECTION

In accordance with PenCTU standard operating procedures for risk assessment and monitoring, a specific trial monitoring plan will be generated based on the PenCTU’s risk assessment, with input from the TMG. The monitoring plan will be signed off by the CIs and Sponsor before implementation.

PenCTU will perform ongoing central monitoring, outputs from which will be discussed by the TMG. Central monitoring will include close supervision of participant recruitment rates, attrition rates, data completeness (missing data), data quality (using range and consistency checks), protocol non-compliance, calendar checks (to identify deviations from follow-up schedules), consent process checks (through collection of completed consent forms) and appropriateness of delegated duties at investigator sites (through collection of site delegation logs). Central monitoring will be used to identify areas of potential poor performance at individual investigator sites. Monitoring might be initially conducted across all sites, and subsequently conducted using a risk-based approach that focuses, for example, on sites that have the highest enrolment rates, large numbers of withdrawals, or atypical (low or high) numbers of reported adverse events. Onsite monitoring will not be used routinely, but may be necessary if there are any concerns with sites.

The investigator(s) must ensure that source documents and other documentation for this trial are made available to study monitors, the REC or regulatory authority inspectors.

Independent audits may be conducted by the Sponsor, funder, or regulatory bodies. Site RPs, the CIs and the PenCTU will permit access to all records required by auditors to fulfil their audit duties.

19 PUBLIC AND PATIENT INVOLVEMENT

The involvement of residents, relatives/friends and care home staff is a key part of this trial, at all stages of the research process. PPIE informed the proposal and will continue to do so through the research delivery and dissemination activities. To summarise, the trial design has been informed by workshops and conversations with 40 care home staff, 10 relatives, 16 residents from 4 care homes in South West England (CQC rated good or outstanding) in rural, coastal and urban settings and a range of cultural, ethnic, socio-ethnic diversity and level of care dependency, with meals provide by on-site chef and outside caterers and using ONS. There are two public members as part of the research team, one has a family member living in a care home and the other is an experienced care home representative.

A PAG of 6-8 people (relatives/friends) will be actively involved during the whole trial (co-production of study documentation, lay summaries, interpret findings & guide dissemination). All PPIE activities will be undertaken in line with NIHR centre of Engagement and Dissemination payment guidance.

The project PPI co-applicant (Mr Aidan Foy) has lived experience expertise as a carer for relatives in two different care homes (both receiving a fortified diet with one receiving ONS for malnutrition). The role of the PPI co-applicant is to ensure that lived experience expertise of the topic being researched will inform and influence the project at all stages and at all levels. Mr Foy will be part of the PAG and the TMG. In being part of these two groups one of Aidan’s key roles is to ensure the insights from the

PAG contribute to and inform the decision-making processes of the TMG, ensuring lived experience expertise has real influence and remains at the heart of the project.

Training and support for the public contributors will be bespoke to support their individual training and support needs. The “Having A Voice In Research Course” provided by BU PIER is a co-designed, and co-delivered interactive course with members of BU PIER partnership with experience of being involved in research as public contributors with lived experience expertise. Aspects of this course will be tailored to meet any identified and arising training needs. It is envisaged there will be an emphasis on building confidence to really value their lived experience expertise, and to identify their support and access requirements to be able to use this expertise to influence and shape the project at all stages.

All public involvement activities will be supported, before, during and after each activity as best meets the needs of the public contributors. Support will be carried out by Dr Kate Jupp and can be group or individual, in person or remote, being flexible to meet individual needs and recognising needs are likely to fluctuate and or change depending on the activity and throughout the duration of the project.

19.1 Equity, Diversity, and Inclusion

We are committed to equity, diversity and inclusion (EDI) and have taken a proactive approach in ensuring that the research is inclusive, to reflect the diversity of the targeted population using ONS data (see Section 16.1). We will collect data on protected characteristics to ensure the research sample is representative of the older population living in care homes. We have included costs to enable us to maximise accessibility and inclusivity; all trial materials are designed using accessibility principles (such as large font to help understanding) and costs for translation where required. Public involvement will play a key role in ensuring that materials and processes are acceptable and accessible. We will draw on the NIHR INCLUDE Ethnicity Framework[56] and toolkit[87] to guide our proposed SWAP to enable us to increase participation of minority ethnic groups.

The co-leads are based in a Higher Education Institution (HEI); University of Plymouth and a GP practice; The Adam Practice) which have strong equity, diversity and inclusion policies and the research will be conducted in an environment which is completely transparent, free from bias and is open and accessible. Recruitment for any project-related posts will be carried out in line with existing equal opportunities policies and commitment to numerous initiatives related to equity and diversity including achieving Disability Confident status, signing the Mindful Employer charter. Our policies, procedures, guidance, and training framework uphold the commitments outlined in the Research Concordat to support research integrity, career development of researchers and the Horizon gender equality plan (i.e. Athena Swan) and improved representation, progression and success of minority ethnic staff and students (i.e., Race Equality Charter). We have developed a series of EDI principles based on the Humanising Framework[100-102] which has been discussed with our TMG. We will also undertake an Equality Impact Assessment in accordance with UKRI guidance[103] and the Humanising Framework which will be discussed with our TMG and TSC.

We will benefit from the leadership of Dr Camila Devis-Rozental as the EDI lead for the project.

20 ETHICAL AND REGULATORY CONSIDERATIONS

20.1 Research Ethics Committee (REC) review & reports

The CIs will obtain approval from the REC for the trial protocol, informed consent forms and other trial documentation (e.g., Resident Information Sheet). The Chief Investigators will ensure that this trial is conducted in conformity with relevant regulations and with the UK Policy Framework for Health and Social Care Research (2017), which have their basis in the Declaration of Helsinki.

Substantial amendments that require review by the REC will not be implemented until the REC grants a favourable opinion. Participating organisations have up to 35 days after REC favourable opinion to decide whether they can implement the substantial amendment in practice at sites. It is the sponsor’s responsibility to decide whether an amendment is substantial or non-substantial.

All correspondence with the REC will be retained in the TMF. The CIs/delegate will notify the REC of the end of the trial. If the trial is ended prematurely, the CIs/delegate will notify the REC, including the reasons for the premature termination. Within one year after the end of the trial, the CIs will submit a final report with the results, including any publications/abstracts, to the REC.

The University of Plymouth's Faculty of Health Research Ethics and Integrity Committee (FREIC) will also review the study.

20.2 Peer review

The trial was funded by NIHR through open competition after independent external peer review was conducted.

20.3 Regulatory Compliance

The trial will not commence until a favourable REC opinion has been obtained. Before any site can enrol patients into the trial, the CIs/RPs or delegates will ensure that appropriate approvals from participating organisations are in place.

For any amendment to the trial, the CIs or delegate, in agreement with the sponsor, will submit information to the appropriate body for them to issue approval for the amendment. The CIs or delegates will work with participating organisations so they can put the necessary arrangements in place to implement the amendment to confirm their continued support for the trial.

20.4 Protocol compliance

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 participant if they do not meet the eligibility criteria or restrictions specified in the trial protocol.

If a resident is offered the intervention (i.e., ONS) and declines, this will not be recorded as non-compliance. Non-compliance will only be noted in instances where the intervention was not offered by staff. Observational data may help identify such instances of non-compliance.

Non-compliance with the protocol will be captured on specific non-compliance report forms according to instructions provided by PenCTU and in accordance with PenCTU SOPs. Protocol non-compliance will be reviewed periodically by the TMG as part of central monitoring (see Section 19 Monitoring, Audit and Inspection), with the aim of identifying and addressing recurrent episodes of non-compliance. Protocol non-compliances which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

Each reported non-compliance is reviewed by the PenCTU Trial Manager. PenCTU staff must immediately inform the PenCTU Quality Assurance (QA) Manager if they believe that a serious breach has occurred (see below). Where the PenCTU Trial Manager and/or QA Manger believes that a non-compliance might constitute a serious breach, the Trial Manager should ensure that a completed non-compliance report form is provided to the Sponsor and CIs immediately (i.e., within 1 working day of first awareness).

20.5 Notification of Serious Breaches to GCP and/or the protocol

A "serious breach" is a breach which is likely to effect to a significant degree –

(a) the safety or physical or mental integrity of the participants of the trial; or
(b) the scientific value of the trial

Where a non-compliance meets the above criteria, PenCTU will immediately notify (i.e., within 1 working day of first awareness) the CI and Sponsor. The Sponsor will email a serious breach report to the REC within seven calendar days of becoming aware of the event. If the RP (or delegate) is unsure if the non-compliance meets these criteria, they should consult the Sponsor for further guidance.

Complete investigations of breaches will be fully documented, filed in the TMF and a copy provided to the Sponsor.

20.6 Data protection and patient confidentiality

All investigators and participating site staff must comply with the requirements of the UK Data Protection Act 2018 and the UK General Data Protection Regulation (GDPR) with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act and regulation's core principles.

Data will be collected and retained in accordance with the UK Data Protection Act 2018 and GDPR. The trial Sponsor is the Data Controller for the trial data. PenCTU is a Data Processor, centrally managing trial data generated at investigator sites. One of the CIs (Prof Mary Hickson) is the data custodian since data are stored on databases managed by the University of Plymouth.

Data including the number of residents screened, approached, and interested in taking part will be collected *via* a log completed by staff conducting screening. Investigator site staff will ensure that the participants' anonymity is maintained through protective and secure handling and storage of patient information in accordance with ethics approval.

Any paper-based data collection tools (e.g., worksheets and questionnaires) for capturing source data will remain at investigator sites. Investigator site staff will enter participant data into purpose designed data capture systems. Access to the system for all users (including PenCTU staff) is *via* a secure password-protected web-interface, with two-factor authentication. Each participant will be allocated a unique system-generated study number which will be related to site and recruitment number e.g., SC-YYYY (screening) and XXX-YYYY (after enrolment), where XXX denotes the site number and YYYY is the recruitment number. Participants will be identified in all trial-related documentation by their study number. Data collected and analysed during the trial will be pseudonymised by the use of this unique identifier. A record of trial participants' names and contact details and assigned trial numbers will be stored securely at the trial site and is the responsibility of the site RP and fieldworker.

Audio data from qualitative interviews/focus groups will be recorded either via Microsoft Teams or Zoom or using an encrypted digital audio recorder. Data collected will be stored on a secure University of Plymouth OneDrive folder using the participant's unique study number.

All data will be deleted from digital recorders as soon as it is transcribed. Audio recordings and transcribed data will only be accessible to the designated members of the qualitative evaluation team.

Transcription of audio recordings of interviews or sessions will only be carried out by members of the research team or collaborating universities.

20.7 Financial and other competing interests

The independent TSC committee members will sign a declaration form to disclose any financial or other competing interests including, but not limited to:

• any ownership interests that may be related to products, services or interventions considered

for use in the trial or that may be significantly affected by the trial

• commercial ties including, but not restricted to, any pharmaceutical, behaviour modification,

and/or technology company

• any non-commercial potential conflicts e.g. professional collaborations that may impact on academic promotion.

Declaration forms will be filed in the TMF.

RPs will be asked to sign a declaration as part of the model Non-Commercial Agreement.

20.8 Indemnity

This is a University of Plymouth sponsored trial. The University has in force a Public Liability Policy (see Zurich Municipal Insurance Policy), which is renewed annually on a rolling basis.

20.9 Amendments

If changes to the trial are requested, after discussing with the TMG, they must be discussed with the Sponsor, who is responsible for deciding if an amendment is required and if it should be deemed substantial or non-substantial. PenCTU staff will usually lead in amending trial documentation and in the preparation of the amendment, with support from the TMG as required.

Substantial amendments will be submitted to the REC for review and approval. The amendments will only be implemented after approval from relevant bodies as informed by the amendment tool, and from approvals from participating sites (unless they constitute an urgent safety measure). Non-substantial amendments will be notified to the relevant bodies as per the categorisation of the amendment tool.

Amended documents will be allocated a new sequential version number. Once approved by the regulatory bodies, this version will supersede any previous versions. The trial registry (ISRCTN) should be updated following each amendment.

Urgent safety measures will be implemented immediately, and the REC who issued the favourable ethical opinion will be notified via email by the Sponsor within 3 days. The email should detail the reason for the urgent safety measure and the plan for further action.

20.10 Post trial care

All participants will continue to receive the standard care for their condition and participation in this trial will not affect or delay this care.

20.11 Access to the final trial dataset

During the trial, the PenCTU data team will have access to the trial dataset. Other members of PenCTU and the wider study team will have restricted access to pseudonymised trial data. Access to the dataset will be granted to the Sponsor and host institution on request, to permit trial-related monitoring, audits, and inspections. Access will be overseen by the PenCTU Data Manager and Trial Manager. Access to the final dataset, and any interim datasets required, will be provided to the trial statisticians for analysis.

After the trial has been reported, the deidentified individual participant data that underlie the results will be available on request from the CI and Sponsor, along with supplementary files as required (e.g., data dictionaries, analysis code, etc.). Data will be shared with (or access to the data will be provided to) requesters whose proposed use of the data has been approved by the CI and Sponsor, under an appropriate data sharing agreement. It will not be possible to identify participants personally from any information shared. An anonymised dataset may be committed to University of Plymouth’s open access research repository PURE.

20.12 Researcher support

All individuals involved in collecting data, conducting interviews, focus groups, or observational research will be provided with appropriate support throughout the study. A process will be in place to allow individuals to debrief and decompress following research activities, particularly if they encounter potentially distressing or emotionally challenging situations. Where necessary, researchers will have the option to speak with an external support person to ensure their wellbeing is maintained.

21 DISSEMINATION POLICY

21.1 Dissemination policy

The data arising from the trial will be owned by the Sponsor. On completion of the trial, the data will be analysed and tabulated and a Final Trial Report prepared. This report will be submitted to the Trial Sponsor and Funder and will be publicly available. Participating investigators will not have rights to publish any of the trial data without the permission of the CI and Sponsor.

We will work with our public advisory group and research team to develop a dissemination plan and identify the best ways to disseminate our findings (project updates, interim and full trial findings) to practitioners, researchers, public and commissioners of services, policy makers and relevant older people's charities e.g. Malnutrition Task Force, Age UK, Alzheimer's Society, Dementia UK, Carers UK and NIHR research networks. We are already engaged with these bodies through our wider work around malnutrition in older people so have strong networks.

We will create a website platform for the project which will link with other university and stakeholder websites including National Care Forum, Devon Care Home Collaboration, Partners in Care, Hampshire Care Association, Solent Academy Care Home Partnership, West Midlands Care Association, Malnutrition Task Force, other national participating home care providers e.g. HC-One, Barchester Healthcare, Care UK, BUPA as well as UK and European Ageing Networks. The website will present project details, progress and be the main point of contact for outreach and communications. Social media will be used to complement the project website. We will take an inclusive approach to develop a publication policy, ensuring that all those involved in the research have opportunity to contribute to the publication process, as appropriate and to timely dissemination of the outputs.

We will discuss with the National Care Forum, our regional care home member organisations and the participating home care providers about how the findings could be shared e.g. as webinars, videos, in workshops, forums. Working with our PAG, we will also distribute plain English summaries of the findings as blogs & newsletters and disseminate via regional and national network meetings to engage with the care sector, as well as sharing summaries during Malnutrition Awareness and Nutrition and Hydration Awareness weeks.

We will discuss with our health and social care professional colleagues how best to disseminate the results; this will include publishing in professional magazines, blogs and newsletters and delivering presentations at conferences and forums aimed at these professionals e.g. BAPEN, Dietetics Today, RCSLT and Pharmacists Bulletin, Older People Specialist Group (BDA). We will engage with scientific audiences through presentations at academic conferences and regional events e.g. British Geriatrics Society, NIHR Applied Research Collaborations, NIHR RDN Ageing network meetings.

The key academic outputs will be high quality publications in peer-reviewed journals e.g. The Lancet Health Longevity, BMJ Open, Journal of Human Nutrition and Dietetics, Age and Ageing. Publications will include the protocol (registered on ISRCTN registry and updated regularly as appropriate and in line with instructions from the relevant NIHR secretariat/monitoring team), findings from the SWAP (to guide inclusive recruitment and trial design), process evaluation, and clinical and cost effectiveness findings. The results of the trial will be disseminated on ISRCTN in line with NIHR transparency policy.

All the journal articles will be available as open access and developed blogs, project newsletters and summaries will be accessible from stakeholder websites and signposted via the project website and social media posts.

The trial will be reported in accordance with relevant CONSORT Guidelines. All publications arising from this trial will acknowledge the Funder and a copy of all manuscripts will be provided to the Funder for review at the time of submission to a journal. However, the Funder does not have the right to revise any submission prior to publication. The trial protocol will also be submitted for open access publication to a peer-reviewed journal. A lay summary of the trial results will be produced and published on the PenCTU / University of Plymouth website. An anonymised participant level dataset will be produced and held within PenCTU.

Participants will not be identified in any publications.

21.2 Outputs

The project will produce co-designed outputs including manualised training for care home staff, new guidance, and resource materials as a free online tool (accessible from the project website) to use in future studies and by care home providers. The research team has previous experience of similar

developments as part of other externally funded projects with regard to intellectual property management with third parties e.g. https://www.bournemouth.ac.uk/research/projects/optimising-food-nutritional-care-people-dementia; https://www.plymouth.ac.uk/research/dietetics-and-health/covid-knowledge-hub. A collaborative agreement will be shared and agreed. There will be no commercial exploitation of the outputs. At the end of the project, an online workshop will be held to disseminate the findings to key stakeholders including the public, carers, health care professionals, charities, researchers, educators, commissioners, and policy makers. Designed infographic materials will also be produced to help share the key findings via social media and as posters at events and with the care home sites involved in the research.

21.3 Impacts of the research and further funding and support

For care home staff and providers

The outputs will reach care home providers *via* our partner organisations (National Care Forum and via regional care home member organisations) to build and extend existing skills and support the acquisition of new knowledge, approaches and attitudes with new training, access to resources. We anticipate that this will support them to adopt a strong commitment to improve nutritional care and the management and treatment of malnutrition for older residents, recognising the important role staff can play in this. For older people with malnutrition and their relatives/friends: Improving the management of malnutrition will help reduce deterioration in mental and physical health and wellbeing for older people, leading to the potential for improved quality of life, pleasure in eating, maintain independence for as long as possible, reduce carer burden and associated costs.

For NHS and social care

Older people who are at risk or are malnourished are often high users of NHS and social care services because of risk of increased complications, infections, GP visits, and hospital readmissions[22]. We would anticipate that effective provision of nutritional care for older people in care homes and improved management of malnutrition will reduce resource use (e.g. reduced hospitalisations, adverse events such as falls and infections that require NHS resources). Thus, as a successful definitive trial, we would expect the new knowledge and data produced to be adopted across integrated NHS and social care systems and impact evidence-based practice guidelines e.g. NICE, and national (e.g. Malnutrition Care Pathway) and regionally developed care pathways for managing malnutrition. This would be guided through the involvement of policy makers and commissioners on our Trial Steering Group, including Care Quality Commission. The findings and learning approach will also inform evidence-based education for the current and future nursing and Allied Health Professions workforce. We would also seek future NIHR funding to enable wider implementation, adoption and spread and to impact policy.

21.4 Authorship eligibility guidelines and any intended use of professional writers

Authorship of all manuscripts and papers relating to this trial will be determined according to the International Committee of Medical Journal Editors criteria. All members of the TMG who have contributed to trial design, management, analysis, and interpretation will be granted authorship of the Final Trial Report. The CI will retain lead author status on the Final Trial Report. There is no intention to use professional writers.

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