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REFRESH study: nutRition intervEntions For malnouRished oldEr adultS in care Homes - A parallel, superiority, three-arm cluster randomised controlled trial

Submission date 04/08/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 16/10/2025	**Overall study status** Ongoing	
Last Edited 24/10/2025	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims

Many older people living in care homes are at risk of malnutrition, which means they aren't getting the nutrients they need. This can lead to poor health, lower quality of life, and a higher chance of falls and infections. The REFRESH study will compare three approaches to nutritional care: fortified foods, supplement drinks, and usual care. Around 1,530 residents from 90 care homes will take part to help find out which approach works best to improve nutrition and quality of life.

Who can participate?

Participants will be older adults (65 years or over) with or at risk of malnutrition, living in a care home which has applied to take part and met certain care home inclusion criteria.

What does the study involve?

Once eligible care home residents (or consultees) have agreed to take part in the study, initial information will be collected (baseline data). Each care home will then be randomly placed into one of three groups. Residents will receive one of the following for 12 months:

• Oral nutritional supplements: Two ready-to-drink supplements each day between meals, alongside their usual diet.

• Fortified food: Meals, snacks and drinks made with extra protein, calories, vitamins and minerals, alongside their usual diet.

• Usual care: The care home will continue with their usual approach to nutrition for residents who are malnourished.

Further information will be collected at 6 months and again at 12 months.

What are the possible benefits and risks of participating?

We cannot guarantee there will be any benefits from taking part in the study as we do not know what the results will be. However, the participants' involvement will contribute to the development of new knowledge and understanding of malnutrition in care homes, which could

help to improve the care of older people in the future.
There is a chance that the oral nutritional supplements or the fortified food may cause the following:
- Gastrointestinal symptoms (i.e., constipation, bloating, nausea)
- Poorly controlled blood glucose (blood sugar levels that are too high or too low) in those with diabetes.
These effects may occur whichever group the participant is in, including usual care if these options are used as part of it. If necessary, the food or supplement which is thought to be the cause would be stopped.

Where is the study run from?
University of Plymouth (UK)

When is the study starting and how long is it expected to run for?
January 2025 to December 2028

Who is funding the study?
National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) Programme (UK)

Who is the main contact?
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Contact information

Type(s)
Principal investigator

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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
334241

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 58561, NIHR160348

Study information

Scientific Title
NutRition intervEntions For malnouRished oldEr adultS in care Homes (REFRESH)

Acronym
REFRESH

Study objectives

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)?

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.

Secondary objectives:
1. Evaluate the effects of ONS and FF compared to usual care on:
1.1. Dementia-specific Quality of Life (DEMQoL-CH) at 6 months post-randomisation
1.2. Nutritional status (Mini Nutritional Assessment (MNA)) at 6 months post-randomisation
1.3. Weight (kg) at 6 months post-randomisation
1.4. Dietary intake (3-day photographed food records and food record charts used to estimate nutrient content) at 6 months post-randomisation
1.5. Functional limitations (Modified Barthel Index (MBI)) at 6 months post-randomisation
1.6. Acceptability and adherence (3-day photographed food records and food record charts at 6 months post-randomisation)
1.7. Morbidity (antibiotic usage) at 6 months post-randomisation
1.8. Mortality (registered death records) at 6 months and 12 months post-randomisation
1.9. 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).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/10/2025, West Midlands – Coventry & Warwickshire Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8151; Coventryandwarwick.rec@hra.nhs.uk), ref: 25/WM/0154

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Each participating care home will be randomised into one of the following trial arms:

Oral Nutritional Supplement (ONS) Arm: Residents would receive two ready-to-drink ONS to be given at suitable points within the day between mealtimes, daily for 12 months. Residents will continue to receive meals and nutritional care according to the care home's usual routines.

Fortified Food (FF) Arm: Care homes would instigate a menu providing fortified food (usual food, drinks and snacks with added ingredients to increase nutrient density for participating residents) for 12 months. 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.). Residents will continue to receive nutritional care according to the care home's usual routines.

Care homes randomised to one of the above intervention arms will receive manualised training split into two levels: malnutrition awareness training and management of malnutrition training tailored to the allocated intervention. These care homes will be asked to appoint an 'in-house' nutrition champion to help disseminate information, promote, and embed the training during the trial, and support data collection.

Usual Care Arm: These care homes should manage malnutrition as they usually would.

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).

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Health-related quality of life (HRQoL) measured using EQ-5D-5L Proxy Version 2 at 6 months

Key secondary outcome(s))
1. Dementia-specific quality of life measured using (DEMQoL-CH) at 6 months post-randomisation
2. Nutritional status assessed using the Mini Nutritional Assessment (MNA) at 6 months post-randomisation
3. Weight (kg) measured at 6 months post-randomisation
4. Dietary intake measured using 3-day photographed food records and food record charts used to estimate nutrient content at 6 months post-randomisation
5. Functional limitations measured using the Modified Barthel Index (MBI) at 6 months post-randomisation
6. Acceptability and adherence measured using 3-day photographed food records and food record charts at 6 months post-randomisation
7. Morbidity measured using antibiotic usage at 6 months post-randomisation
8. Mortality measured using registered death records at 6 months and 12 months post-randomisation

9. EQ-5D-5L-proxy at 12 months post-randomisation
10. 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) at 6 and 12 months

Completion date
31/12/2028

Eligibility

Key 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 MUST
5. Able to obtain informed consent from the individual or a consultee based on the presumed will of an incapacitated adult

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 years

Sex
All

Key exclusion criteria
1. Fed via feeding tube
2. Already receiving nutrition support (ONS or fortified meals) on the advice of a healthcare professional (e.g. GP) and/or individualised dietetic advice
3. Active cancer treatment or recent major surgery
4. Considered by the care home staff to be approaching the end of life, where participation in the study would not be appropriate‡.
‡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).

Date of first enrolment
01/11/2025

Date of final enrolment

31/05/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Three Corners and Hill House
3 Greenway Road
Brixham
United Kingdom
TQ5 0LW

Study participating centre
Chestnut Lodge
166 Hendford Hill
Yeovil
United Kingdom
BA20 2RG

Study participating centre
Primley Court Nursing Home
13 Primley Park
Paignton
United Kingdom
TQ3 3JW

Study participating centre
Camelot House and Lodge
Taunton Rd
Wellington
United Kingdom
TA21 9HY

Study participating centre
Heron House
Heron Drive, Bishops Hull
Taunton

United Kingdom
TA1 5HA

Study participating centre
Hillside, Sheridan House
29 Douglas Avenue
Exmouth
United Kingdom
EX8 2HE

Study participating centre
Mulberry House
Brimley Lane, Bovey Tracey
Newton Abbot
United Kingdom
TQ13 9JS

Study participating centre
Mount Olivet Nursing Home
2 Great Headland Road
Paignton
United Kingdom
TQ3 2DY

Study participating centre
Lucerne House
Chudleigh Road, Alphington
Exeter
United Kingdom
EX2 8TU

Study participating centre
Kenwyn Care Home
Newmills Lane
Truro
United Kingdom
TR1 3EB

Study participating centre

West Eaton Nursing Home
Worcester Road
Leominster
United Kingdom
HR6 0QJ

Study participating centre
Summerdyne
Cleobury Road
Bewdley
United Kingdom
DY12 2QQ

Study participating centre
Cottage Christian
Granville Road
Newport
United Kingdom
TF10 7EQ

Study participating centre
Galanos House
Banbury Road
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CV47 2BL

Study participating centre
The Lawns
Main Road, Kempsey
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WR5 3NF

Study participating centre
Atholl House
98-100 Richmond Road
Wolverhampton
United Kingdom
WV3 9JJ

Study participating centre
Silver Birches
23 Tyne Close, Chelmsley Wood
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United Kingdom
B37 6QZ

Study participating centre
Greenfields Care Home
Liverpool Road
Whitchurch
United Kingdom
SY13 1SG

Study participating centre
The Gables Rest Home
18 Broomfield Road
Kidderminster
United Kingdom
DY11 5PB

Study participating centre
Robert Harvey House
Hawthorn Park Road
Handsworth Wood
Birmingham
United Kingdom
B20 1AD

Study participating centre
Avon View
Loring Road
Christchurch
United Kingdom
BH23 2GZ

Study participating centre
Trafalgar / Agincourt Care Home
207-209 Dorchester Road

Weymouth
United Kingdom
DT4 7LF

Study participating centre
Burwood Nursing Home
100 Dunyeats Road
Broadstone
United Kingdom
BH18 8AL

Study participating centre
Upton Bay Care Home
1 Hoyal Road
Poole
United Kingdom
BH15 4HY

Study participating centre
Chalgrove Care and Nursing Home
5-7 Westminster Road East
Branksome Park
Poole
United Kingdom
BH13 6JF

Study participating centre
Blenheim Care Home
17 Dunbar Road
Talbot Woods
Bournemouth
United Kingdom
BH3 7AZ

Study participating centre
Oakhill Mansions
College Park Drive
Westbury-on-trym
Bristol
United Kingdom
BS10 7QD

Study participating centre
Saville Manor / Waltham House
Saville Road, Stoke Bishop
Bristol
United Kingdom
BS9 1JA

Study participating centre
Somerhill Care Home
Little Somerford
Chippenham
United Kingdom
SN15 5BH

Study participating centre
St Teresa's Nursing Home
Corston Lane
Corston
Bath
United Kingdom
BA2 9AE

Sponsor information

Organisation
University of Plymouth

ROR
https://ror.org/008n7pv89

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository: After the trial has been reported, an anonymised dataset may be committed to University of Plymouth's open access research repository: https://pearl.plymouth.ac.uk/
The datasets generated during and/or analysed during the current study will be available upon request from the CIs and the Sponsor: After the trial has been reported, the de-identified individual participant data that underlies the results will be available on request from the Chief Investigators and the 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) requestors whose proposed use of the data has been approved by the CIs and Sponsor, under an appropriate data sharing agreement. It will not be possible to identify participants personally from any information shared. As part of consenting for the study, participants are asked to consent to the following clause 'I understand that the information collected about me may be used to support other research in the future and may be shared anonymously with other researchers.'

IPD sharing plan summary
Available on request, Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes