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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 [X] 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 16/11/2026	**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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Principal investigator

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Public, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
334241

Central Portfolio Management System (CPMS)
58561

National Institute for Health and Care Research (NIHR)
160348

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

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

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

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)
Resident

Healthy volunteers allowed
Yes

Age group
Senior

Lower age limit
65 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria as of 12/06/2026:

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‡.

‡Residents will be eligible if they have been:
1. Prescribed ONS short term (e.g. after a hospital stay) and have not yet been reviewed by a dietitian.
2. Prescribed ONS not specifically for malnutrition (e.g. for wound healing, haemodialysis).
3. Prescribed ONS by or on the recommendation of a health professional other than a dietitian (e.g. nurse or GP).
4. Discharged from dietetic care but are still on ONS.

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Previous key exclusion criteria as of 12/06/2026:

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
Hill House Nursing Home
Park Avenue
Brixham
England
TQ5 0DT

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

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

Study participating centre
Sheridan House
10c Douglas Avenue
Exmouth
England
EX8 2BT

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

Study participating centre
West Eaton House
Worcester Road
Leominster
England
HR6 0QJ

Study participating centre
Summerdyne Nursing Home
Cleobury Road
Wyre Hill

Bewdley
England
DY12 2QQ

Study participating centre
The Lawns Nursing Home
33 Main Road
Kempsey
Worcester
England
WR5 3NF

Study participating centre
Atholl House Nursing Home
98-100 Richmond Road
Compton
Wolverhampton
England
WV3 9JJ

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

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

Study participating centre
Waltham House
Stoke Park Road, Stoke Bishop
Bristol
England
BS9 1JF

Study participating centre
Three Corners
3 Greenway Road
Galmpton
Brixham
England
TQ5 0LW

Study participating centre
Valley Court
Valley Road
Cradley Heath
England
B64 7LT

Study participating centre
Elmwood
Swan Hill Road
Colyford
Colyton
England
EX24 6QJ

Study participating centre
Parkwood House
72-74 Exmouth Road
Stoke
Plymouth
England
PL1 4QJ

Study participating centre
Larkhall Springs Nursing Home
Swainswick Gardens
Larkhall
Bath
England
BA1 6TL

Study participating centre
Asher Care
120 Ashburton Road
Newton Abbot
England
TQ12 1RJ

Study participating centre
Arbour Walk
7-21 Hungerford Road
Bristol
England
BS4 5HU

Study participating centre
Davlyn House
41 Bull Lane
Brindley Ford
Stoke-on-trent
England
ST8 7QL

Study participating centre
Neville Williams House
8-14 Greenland Road
Selly Park
Birmingham
England
B29 7PP

Study participating centre
Resthaven CIO
15 Gussiford Lane
Exmouth
England
EX8 2SD

Study participating centre
Woodlands Quaker Home
434 Penn Road

Penn
Wolverhampton
England
WV4 4DH

Study participating centre
Seaview Haven
Oaktree Gardens
Highfield Road
Ilfracombe
England
EX34 9JP

Study participating centre
Fordingbridge Care Home
Station Road
Fordingbridge
England
SP6 1JW

Study participating centre
Katherine House
Cote House Lane
Westbury-on-trym
Bristol
England
BS9 3UW

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

Study participating centre
Tudor Court
18-20 Midvale Road
Paignton
England
TQ4 5BD

Study participating centre
Ashley Court
6-10 St Peters Road
Ashley Cross
Poole
England
BH14 0PA

Study participating centre
Forest Hill House Nursing Home
Rushall Lane
Corfe Mullen
Wimborne Minster
England
BH21 3RT

Study participating centre
Exmouth House
Long Causeway
Exmouth
England
EX8 1TS

Study participating centre
Mallands
Odle Hill
Abbotskerswell
Newton Abbot
England
TQ12 5NL

Study participating centre
Avon View
Loring Road
Christchurch
England
BH23 2GZ

Study participating centre
Gainsborough Care Home
53 Ulwell Road
Swanage
England
BH19 1LQ

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: Ater 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?
Protocol (other)	V4.0	12/03/2026	16/11/2026	No	No
Study website		11/11/2025	11/11/2025	No	Yes