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Malnutrition in care homes: a feasibility study

Submission date
11/04/2014

Recruitment status
No longer recruiting

Registration date
22/04/2014

Overall study status
Completed

Last Edited
23/10/2019

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Malnutrition increases risk of disease, delays recovery from illness and reduces quality of life. Care home residents are especially vulnerable, with an estimated 42% at risk. There is no agreed nutritional treatment for malnutrition. Techniques include food-based intervention and/or the use of prescribed oral nutritional supplements (ONS). It is unclear whether conventional food improves outcomes but there is growing evidence to support use of ONS. However, as conventional food is less expensive, some NHS trusts have developed stricter prescribing guidance to encourage 'food-first'. Care home residents are under-represented in research and evidence to guide best nutritional care is lacking.
This is an initial study to compare three approaches within an elderly care home population: food-based intervention, prescribed ONS intervention and standard care for malnutrition. The results will help design a larger study.

Who can participate?
Care homes that have received dietitian training.

What does the study involve?
The six care homes that have been identified will be randomly allocated to one of three groups: food-based intervention, ONS intervention or standard care. Residents who are malnourished or at risk of malnutrition will be eligible to participate. The Dietitian researcher will deliver the interventions, aiming to increase participant intake by 600kcal and 20-25g protein daily. Care homes allocated to standard care will continue to provide energy-enriched diets, in line with local guidance.

What are the possible benefits and risks of participating?
We consider this study to be low risk. The nutritional interventions being evaluated are well stablished and are currently in use to treat malnutrition in the care home population. Given their wide usage, unexpected adverse events are highly unlikely. Expected adverse events include the possibility of diarrhoea, bloating, nausea or satiety (gastrointestinal symptoms) on initiating ONS or a change in diet. Expected adverse events will be minimised as the dietary interventions will be delivered as per usual, standard practice to those that require them, by and under the control of a Registered Nutrition Support Dietitian. If any of the residents within the care homes allocated to the standard care home intervention experience a decline of nutritional status, they will be provided with dietetic intervention (food-based or ONS), after 6 weeks of standard care.

This follows local and national best practice guidelines and current, standard care within the local community setting. All of the care home residents that receive the allocated nutritional intervention will be at moderate or high risk of malnutrition. They may benefit from any of the nutritional interventions, if they prove to be effective at improving energy intake and anthropometry parameters. The information we get from this study will be used for a future larger study, which may help us to provide improved nutritional care for future care home residents with malnutrition. The findings will be shared with the local care home community.

Where is the study run from?
The study is being run from 6 privately run care homes (3 nursing and 3 residential) in Solihull Community (West Midlands).

When is the study starting and how long is it expected to run for?
December 2013 to September 2014.

Who is funding the study?
Investigator initiated and funded as part of Heart of England NHS Foundation Trust (UK)

Who is the main contact?
Miss Ruth Stow
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

R&D Project code: 2013102EM

Study information

Scientific Title
A cluster randomised feasibility study evaluating current dietary interventions in the treatment of malnutrition in care home-dwelling adults

Study objectives
To determine the feasibility and acceptability of running a full-scale cluster randomised trial comparing the efficacy of nutritional interventions for malnutrition, within care homes for the elderly.
Using questionnaires, self-reported scales, resident interviews and staff focus groups, we will assess the acceptability of the different dietary plans to both care home residents and staff, the willingness of care homes to randomise to the nutritional interventions, recruitment and retention rates, data collection processes and data completeness.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands - Edgbaston, 23/09/2013, ref. 13/WM/0390

Study design
Cluster randomised feasibility trial using a sequential, explanatory mixed method design. Open-label due to the nature of the nutritional interventions under investigation.

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Protein care energy malnutrition (PEM) within elderly care home residents

Interventions
Dietetic-led intervention arms: Dietitians currently use both food-based intervention and ONS intervention as treatment options for malnutrition within the care home setting.

1. Dietetic led food-based intervention will increase the daily calorie content of the diet by 600kcal and the daily protein content by 20-25g, alongside the standard care home diet for malnutrition, continued for 6 months. The content of the dietary intervention plan will follow locally agreed Nutrition Support guidelines.

2. Dietetic led ONS intervention will increase the daily calorie content of the diet by 600kcal and daily protein content by 24g, alongside the standard care home diet for malnutrition, continued for 6 months. The ONS intervention will use standard liquid sip feeds, in accordance with the local prescribing formulary and enteral feeding contract.

3. Standard, care home intervention arm: The current standard care home diet for malnutrition, without added dietetic intervention, will be delivered to residents for the 6-month period, in line with the training already provided to care home staff (including catering teams) by the Registered Dietitian. The purpose of the standard dietary intervention is to provide and encourage a calorie dense diet, which may be achieved through provision of small, frequent meals, recipe enrichment with additional calories and prompting and assistance from care home staff where required.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. The outcome measures collected within usual monitoring, such as change in energy intake and anthropometric parameters (weight, BMI, handgrip strength and MAMC) will continue to be collected for all residents with, or at risk of malnutrition that are placed onto a dietary plan.
2. A healthcare resource-usage questionnaire will be trialled by care home staff within this study to inform the development of a malnutrition specific instrument for the future trial.
3. For residents who have the capacity to consent to join the study, additional outcome measures will be collected, including: participant-reported quality of life (CO-OP Charts), health state (EQ-5D questionnaire), and participant rated appetite and dietary satisfaction (VAS tool).

Secondary outcome measures
Interviews with a sample of residents and focus groups with care home staff will complement the quantitative data collection by further exploring the feasibility and acceptability of the study design.

Overall study start date
15/12/2013

Completion date
30/09/2014

Eligibility

Key inclusion criteria
Local care home that has received dietitian training.
All care home residents that require dietary intervention for malnutrition will receive the randomly allocated dietary plan, provided they meet the following criteria:

1. With/at risk of Disease related malnutrition using the Malnutrition Universal Screening Tool (MUST)
2. Able to eat and drink
3. Registered with a Solihull GP and subsequently eligible for the provision of healthcare services provided by the Heart of England NHS foundation Trust (HEFT)

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
90-100

Key exclusion criteria
Residents will not receive the randomly allocated dietary plan if they:
1. Currently receive (or are likely to receive in the next 6 months) tube or parenteral nutrition
2. Currently receive nutrition support in the form of individualised dietetic advice or prescribed ONS
3. Have a known eating disorder or illness, which requires a therapeutic diet incompatible with fortification and/or supplementation. This may include but is not limited to, Galactosemia or known lactose intolerance, chronic renal disease requiring dialysis, poorly controlled diabetes, in receipt of active cancer treatment, or liver failure
4. Are on an end-of-life care pathway

Date of first enrolment
15/12/2013

Date of final enrolment
30/09/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nutrition Support Service
Birmingham
United Kingdom
B90 4LA

Sponsor information

Organisation
Heart of England NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded.

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/09/2015		Yes	No

Protocol article	protocol	01/12/2015		Yes	No
Results article	qualitative study results	19/07/2018	23/10/2019	Yes	No
HRA research summary			28/06/2023	No	No