

# Malnutrition in care homes: a feasibility study

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<b>Registration date</b> 22/04/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/10/2019	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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 established 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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**Contact details**

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## Additional identifiers

**Protocol serial number**

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

### **Study type(s)**

Treatment

### **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(s)**

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).

### **Key secondary outcome(s)**

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.

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Senior

### **Sex**

All

## **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**

United Kingdom

England

### **Study participating centre**

#### **Nutrition Support Service**

Birmingham

United Kingdom

B90 4LA

## **Sponsor information**

### **Organisation**

Heart of England NHS Foundation Trust (UK)

## **Funder(s)**

### **Funder type**

Other

### **Funder Name**

Investigator initiated and funded.

# Results and Publications

## 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?
<a href="#">Results article</a>	results	28/09/2015		Yes	No
<a href="#">Results article</a>	qualitative study results	19/07/2018	23/10/2019	Yes	No
<a href="#">Protocol article</a>	protocol	01/12/2015		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No