ISRCTN33287248 https://doi.org/10.1186/ISRCTN33287248

# Does the oral nutritional supplementation of undernourished older people after hospital discharge improve muscle function? A two centre double blind placebo controlled trial

**Submission date**
07/07/2005

**Recruitment status**
No longer recruiting

**Registration date**
21/10/2005

**Overall study status**
Completed

**Last Edited**
23/05/2018

**Condition category**
Nutritional, Metabolic, Endocrine

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

## Plain English summary of protocol

Background and study aims
Maintaining muscle strength in old age is very important since it is linked with walking and balance. Poor nutrition is associated with loss of muscle and reduced muscle function. It is known that providing extra nourishment can benefit undernourished older people while they are in hospital, but at present it is not known whether supplementing the diet after discharge from hospital would be also beneficial. The aim of this study is to find out whether giving extra nourishment improves muscle function in older people.

Who can participate?
Undernourished older people (age 70 and over) returning home after being in hospital with an acute illness

What does the study involve?
The study dietician takes some standard body measurements including weight and height. Participants are randomly allocated receive either two cartons (200ml each) per day of a milk-based supplement or to a similar drink which has minimal nutrients (placebo). A supply of these drinks is given free of charge one week after discharge from hospital and replenished by the study dietician at each visit. Handgrip and leg strength are measured twice while participants are in hospital. Assessing leg strength involves recording how long it takes to complete 10 full stands from a sitting position. On their day of discharge participants are given an accelerometer (a device the size of a matchbox worn on the waistband which measures how active they are) which they are asked to wear during waking hours for the next 7 days. This is collected by the dietician at the end of 7 days. The study dietician visits participants in their homes on three separate occasions over a 16-week period. On each occasion weight, handgrip and leg strength are measured. Two brief questionnaires are completed which look at basic activities associated with daily living and quality of life. A list of all food eaten in the 72 hours before the visit needs to be written down in the food diary provided. Each visit is likely to last for no more than 40 minutes.

What are the possible benefits and risks of participating?
Participants receiving the nutritional supplements receive extra nourishment that would not normally be part of usual care. Taking part in this study involves assessing muscle function and recording body weight which means that participants need to be able to stand unsupported. These procedures are very straightforward to do, may involve a little exertion but are painless and do not involve any risk.

Where is the study run from?
Ninewells Hospital & Medical School (UK)

When is the study starting and how long is it expected to run for?
February 2006 to July 2008

Who is funding the study?
Chief Scientist Office (UK)

Who is the main contact?
Prof. Marion McMurdo

# Contact information

### Type(s)
Scientific

### Contact name
Prof Marion McMurdo

### Contact details
Ageing and Health
Ninewells Hospital & Medical School
Dundee
United Kingdom
DD1 9SY

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
CZH/4/283

# Study information

### Scientific Title
Does the oral nutritional supplementation of undernourished older people after hospital discharge improve muscle function? A two centre double blind placebo controlled trial

## Study objectives
Added 23/05/2018:
Oral nutritional supplementation is associated with a reduction in disability in undernourished older people after hospital discharge

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Tayside Committee on Medical Research Ethics, 18/02/2005, ref: 05/S1401/05

## Study design
Randomised controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Home

## Study type(s)
Treatment

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

## Health condition(s) or problem(s) studied
Undernourished older people admitted with an acute illness

## Interventions
Complete liquid protein and energy supplement (400 ml/day) or matching liquid placebo with minimal protein and energy content over a 12 week period.

## Intervention Type
Supplement

## Phase
Not Specified

## Drug/device/biological/vaccine name(s)
Nutritional supplementation

## Primary outcome measure
1. Changes in muscle strength (handgrip dynamometry)
2. Changes in disability (Barthel index)

### Secondary outcome measures
1. Changes in lower limb muscle strength
2. Changes in weight
3. Changes in dietary intake (24 hour dietary recall)
4. Changes in daily physical activity levels (accelerometry)
5. Changes in health related quality of life (Euroquol)
6. Unplanned hospital readmissions

### Overall study start date
01/02/2006

### Completion date
30/07/2008

## Eligibility

### Key inclusion criteria
1. Age 70 years and over
2. Community dwelling
3. Admitted to hospital with an acute illness
4. Body mass index ≤24 kg/m^2
5. Mid-arm muscle circumference below the 10th centile and/or weight loss of 5% or more during hospital stay

### Participant type(s)
Patient

### Age group
Senior

### Sex
Both

### Target number of participants
320

### Key exclusion criteria
1. Chronic liver diease or renal failure
2. Nursing home residents
3. Cognitive impairment precluding informed consent
4. Dysphagia
5. Metastatic carcinoma or other terminal illness
6. Pathology such as inflammatory arthritis or stroke affecting non-dominant handgrip
7. Major surgery within one month

### Date of first enrolment
01/02/2006

### Date of final enrolment
30/07/2008

# Locations

**Countries of recruitment**
Scotland

United Kingdom

**Study participating centre**
**Ninewells Hospital & Medical School**
Dundee
United Kingdom
DD1 9SY

# Sponsor information

**Organisation**
University of Dundee (UK)

**Sponsor details**
Research & Innovation Services
University of Dundee
Dundee
Scotland
United Kingdom
DD1 9SY

**Sponsor type**
University/education

**ROR**
https://ror.org/03h2bxq36

# Funder(s)

**Funder type**
Government

**Funder Name**
Chief Scientist Office

**Alternative Name(s)**
CSO

### Funding Body Type
Government organisation

### Funding Body Subtype
Local government

### Location
United Kingdom

# Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan
The protocol is available from the authors on request but is not available online. Study data are available for non-commercial, bona-fide academic analyses in collaboration with the authors; decisions on data access will be made between the investigators and the Sponsor (University of Dundee). Participant consent for unrestricted sharing of individual participant data was not obtained. Contact for data sharing: Dr Catrina Forde (c.forde@dundee.ac.uk)

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/12/2009 | | Yes | No |
| Basic results | | 23/05/2018 | 23/05/2018 | No | No |