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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
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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
1. Changes in muscle strength (handgrip dynamometry)
2. Changes in disability (Barthel index)

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Senior

Sex
All

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
United Kingdom

Scotland

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

Sponsor information

Organisation
University of Dundee (UK)

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes