

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/10/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/05/2018	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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

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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 (Euroqol)
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 $\leq 24 \text{ kg/m}^2$
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 disease 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