

A randomised double-blind placebo-controlled study of energy, protein and micronutrients supplementation of elderly patients in active rehabilitation settings

Submission date 12/09/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2002	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/06/2011	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

577/484

Study information

Scientific Title

Acronym

FED Trial

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised double-blind placebo-controlled study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Nutritional status in the elderly

Interventions

Elderly patients referred for an active period of rehabilitation following an episode of acute illness are randomised to:

1. Normal hospital diet plus placebo, or
2. Normal hospital diet plus oral supplements for 6 weeks

Normal diet is what is normally provided to patients. All patients will have nutritional supplements or placebo prescribed in their drug charts. The supplement group will receive a

daily oral nutritional supplement 400 ml or more given daily at 15.00 and 20.00 hours in addition to the standard hospital diet. The composition of the supplement is such as to provide between 100 - 150% of the Reference Nutrient Intakes for a healthy old person for the following nutrients: carbohydrates, protein, fat, vitamins (A, C, D, E, B1, B2, B6, B12, folic acid, niacin, biotin and pantothenic acid), and minerals (potassium, magnesium, calcium, phosphorous, chloride, iron, zinc, iodine, copper, manganese and selenium).

Supplementation will continue for a period of 6 weeks. This will be either entirely in hospital or in the community also for patients discharged earlier than 6 weeks. For those discharged earlier than 6 weeks supplies will be given for patients to take in the community and they or their carers will be shown how to fill in food diary cards for the remaining period. The placebo will be identical to the supplement but will contain no protein or micronutrients and with a minimum calorie content in it to make it tasty and palatable to patients. Different flavours of supplements and placebo will be prepared and tested initially in a pilot study and those most liked by patients will be made available for patients to choose from.

Intervention Type

Supplement

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Nutritional supplements

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/2000

Completion date

01/01/2003

Eligibility**Key inclusion criteria**

Patients will be eligible for the study if they meet the following criteria:

1. Age 65 years, stable medical condition, referred for an active rehabilitation program
2. Able to swallow
3. Able to sign an informed written consent form

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

445

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2000

Date of final enrolment

01/01/2003

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Sheffield Institute for Studies on Ageing

Sheffield

United Kingdom

S5 7AU

Sponsor information**Organisation**

The Health Foundation (UK)

Sponsor details

90 Long Acre

London

United Kingdom

WC2E 9RA

+44 (0)20 7257 8000

info@health.org.uk

Sponsor type

Charity

Website

<http://www.pppfoundation.org.uk/>

ROR

<https://ror.org/02bzj4420>

Funder(s)

Funder type

Charity

Funder Name

The Health Foundation (UK)

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	01/07/2006		Yes	No