

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

<b>Submission date</b> 12/09/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/09/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 08/06/2011	<b>Condition category</b> 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

### Contact name

Dr SE Gariballa

### Contact details

Sheffield Institute for Studies on Ageing  
Community Sciences Centre  
Northern General Hospital  
Herries Road  
Sheffield  
United Kingdom  
S5 7AU  
+44 (0)114 271 5124  
s.e.gariballa@sheffield.ac.uk

## Additional identifiers

### Protocol serial number

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

## Study type(s)

Treatment

## 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(s)**

Not provided at time of registration

**Key secondary outcome(s)**

Not provided at time of registration

**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

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**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

United Kingdom

England

### Study participating centre

Sheffield Institute for Studies on Ageing

Sheffield

United Kingdom

S5 7AU

## Sponsor information

### Organisation

The Health Foundation (UK)

### ROR

<https://ror.org/02bj4420>

## Funder(s)

### Funder type

Charity

### Funder Name

The Health Foundation (UK)

## 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?
	results				

[Results article](#)

01/07/2006

Yes

No