

# Effect of a dietary intervention on Functional Immune sTatus in the elderly

**Submission date**  
24/05/2007

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
13/08/2007

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
05/11/2010

**Condition category**  
Nutritional, Metabolic, Endocrine

☐ Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

N05068

## Study information

### Scientific Title

**Acronym**

The FIT study

**Study objectives**

We hypothesise that:

1. There is a relationship between nutritional status, dietary intake and immune function in the elderly
2. Improving nutritional status will enhance immune function in the elderly

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approval received from the Barnsley Research Ethics Committee on the 10th October 2005 (ref: 05/Q2304/48).

**Study design**

Randomised, controlled, single centre trial

**Primary study design**

Interventional

**Study type(s)**

Quality of life

**Health condition(s) or problem(s) studied**

This study looks at immune function in healthy subjects

**Interventions**

Volunteers will be randomised to one of three intervention groups:

1. Dietary intervention: volunteers will be asked to consume a diet aimed at increasing the intake of fruit and vegetables (to five portions/day), fish (to two portions/week), and to increase consumption of wholemeal bread and nuts
2. Micronutrient supplement: vitamin C, beta carotene, zinc, selenium, vitamin E
3. Placebo

Each intervention will be for three months. Volunteers will be followed up for three months post-intervention.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

1. Innate and adaptive immunity, measured using:
  - 1.1. High-Sensitivity C-Reactive Protein (hSCRP)
  - 1.2. Natural killer cell cytotoxicity
  - 1.3. Neutrophil and monocyte oxidative burst and phagocytic activity

- 1.4. T-cell activation
- 1.5. Reponse to tetanus vaccine (administered at eight weeks)
2. Nutritional status, measured by:
  - 2.1. Plasma carotenoids
  - 2.2. Retinol
  - 2.3. Vitamin E
  - 2.4. Ascorbic acid
  - 2.5. Selenium
  - 2.6. Glutathione peroxidase
  - 2.7. Zinc
3. Number of days infection, measured using a self-reported infection diary

The primary and secondary outcomes will be measured at baseline, end of intervention and three months post-intervention, with the exception of the response to tetanus vaccine which is measured at 8 weeks and 12 weeks only (coinciding with tetanus vaccination and end of intervention).

#### **Key secondary outcome(s)**

1. Dietary intake and dietary change, measured using three-day food diaries
2. Physical activity, measured with the Community Healthy Activities Model Program for Seniors (CHAMPS) physical activity questionnaire
3. Quality of life, measured using the 36-item Geriatric Depression Scale (GDS36)
4. Body composition, measured by body weight, height, triceps skin-fold thickness

The primary and secondary outcomes will be measured at baseline, end of intervention and three months post-intervention.

#### **Completion date**

31/03/2009

## **Eligibility**

#### **Key inclusion criteria**

1. Men and women
2. Community based healthy volunteers
3. Aged 65 to 85 years
4. Living an active independent life
5. Low intake of fruit and vegetables (less than or equal to two portions per day)

#### **Participant type(s)**

Healthy volunteer

#### **Healthy volunteers allowed**

No

#### **Age group**

Senior

#### **Sex**

All

**Key exclusion criteria**

1. Hospitalised within past 12 months
2. Current or recent (within three months) users of micronutrient supplements
3. Have a Body Mass Index (BMI) less than 18 or more than 30
4. Have a special diet or about to embark on a weight loss diet
5. Have a malignancy or severe medical or psychiatric illness
6. Cannot understand or communicate effectively
7. Have insulin-dependent diabetes mellitus

**Date of first enrolment**

01/04/2006

**Date of final enrolment**

31/03/2009

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

Human Nutrition Unit

Sheffield

United Kingdom

S10 2JX

**Sponsor information****Organisation**

The University of Sheffield (UK)

**ROR**

<https://ror.org/05krs5044>

**Funder(s)****Funder type**

Government

**Funder Name**

Food Standards Agency (UK) (ref: N05068)

**Alternative Name(s)**

The Food Standards Agency, FSA

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

## 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?
<a href="#">Results article</a>	results	22/02/2010		Yes	No