ISRCTN45031464 https://doi.org/10.1186/ISRCTN45031464

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

Submission date	Recruitment status	[_] Prospectively registered
24/05/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/08/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/11/2010	Nutritional, Metabolic, Endocrine	

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

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 measure
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).

Secondary outcome measures
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.

Overall study start date
01/04/2006

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

Age group
Senior

Sex
Both

Target number of participants
216

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
England

United Kingdom

Study participating centre
Human Nutrition Unit
Sheffield
United Kingdom
S10 2JX

Sponsor information

Organisation
The University of Sheffield (UK)

Sponsor details
Research Office
Research Services
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Sponsor type
University/education

Website
http://www.shef.ac.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

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	22/02/2010		Yes	No