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School Nutrition to Improve Behaviour

Submission date	Recruitment status	[_] Prospectively registered
13/04/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/06/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/12/2017	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Background and study aims
A lack of long-chain omega 3 fatty acids, vitamins and minerals in the diet has been linked to antisocial behavior; correcting such deficiencies may therefore improve children's behaviour. We aimed to test the effects on behaviour of omega 3, mineral and vitamin supplements in UK adolescents.

Who can participate?
All year 10 pupils (male and female, aged 14 - 16 years) in the Robert Clack School will be asked to volunteer for the study.

What does the study involve?
Participants are randomly allocated to take either capsules containing the recommended intake of vitamins, minerals and omega 3 fatty acids, or identical looking and tasting placebo capsules, for 3 months. Blood samples are taken before and after supplementation and any changes in behaviour are measured using teacher rating scales together with school disciplinary records.

What are the possible benefits and risks of participating?
Participants' behaviour may improve. There are minimal risks.

Where is the study run from?
University of Oxford (UK).

When is the study starting and how long is it expected to run for?
May 2010 to November 2011.

Who is funding the study?
Esmee Fairbairn Trust (UK)

Who is the main contact?
Prof John Stein
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Contact information

Type(s)
Scientific

Contact name
Prof John Stein

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RCSP3

Study information

Scientific Title
Nutritional supplements to improve disadvantaged pupils' cognitive skills and behaviour: a double-blind randomised placebo-controlled trial

Acronym
SNIB

Study objectives
Can supplementation with capsules of vitamins, minerals and omega 3 fatty acids designed to bring levels up to recommended daily intakes significantly improve disadvantaged pupils' antisocial behaviour?

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West Research Ethics Committee pending as of 13/04/2010 (ref: 10/HO206/13)

Study design
Double-blind randomised placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
School

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Nutrition/antisocial behaviour

Interventions
3 months administration of capsules containing recommended intake of vitamins, minerals (1 capsule) and omega 3 fatty acids (2 capsules) or identical looking and tasting placebo capsules. Follow-up is for 3 months.

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Vitamins, minerals, omega 3 fatty acids

Primary outcome measure
Current primary outcome measure(s) as of 24/04/2012
Offences against disciplinary rules, recorded by the School Pupil Referral Unit and Learning Support Centre and other school discipline databases
Measured at:
Time 1: in the 12 weeks prior to randomisation

Previous primary outcome measure(s)
Offences against disciplinary rules, recorded by the School Pupil Referral Unit and Learning Support Centre

Measured at:
Time 1: week 0, before randomisation
Time 2: last week (12) of intervention

Secondary outcome measures
Current secondary outcome measure(s) as of 24/04/2012
1. Computerised measurements of changes in cognitive skills: reading spelling, short term memory, nonverbal intelligence, Teacher ADHD assessments.
2. Correlation of disciplinary and cognitive changes with changes in nutrient blood levels irrespective of whether allocated active or placebo

Previous secondary outcome measure(s)
1. Computerised measurements of cognitive skills: reading, spelling, mathematics, rapid visual processing, attention, impulsivity
2. Correlation of changes in participants' blood levels of essential micronutrients with changes in cognitive skills and antisocial behaviour

Measured at:
Time 1: week 0, before randomisation
Time 2: last week (12) of intervention

Overall study start date
01/05/2010

Completion date
30/11/2011

Eligibility

Key inclusion criteria
All year 10 pupils (male and female, aged 14 - 16 years) in the Robert Clack School will be asked to volunteer for the study

Participant type(s)
Patient

Age group
Child

Lower age limit
14 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Major medical disorders
2. Taking psychoactive medications expected to affect behaviour and learning

3. Taking vitamin supplements or fish oils already, or eating fish greater than 2 x week
4. Poor English

Date of first enrolment
01/05/2010

Date of final enrolment
30/11/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
Oxford
United Kingdom
OX1 3PT

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Clinical Trials and Research Governance
Rm 8, Manor House
Oxford
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United Kingdom
OX3 9DZ
+44 (0)1865 222757
heather.house@admin.ox.ac.uk

Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Esmee Fairbairn Trust (UK) (ref: 09-2343)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/01/2016		Yes	No