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Nutrition as a modifiable causal factor in anti-social behaviours

Submission date	Recruitment status	[X] Prospectively registered
05/01/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
06/01/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/05/2016	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

We have previously shown that better nutrition reduced offending in a prison and poor nutrition may thus be a cause of antisocial behaviour that we can do something about. This raises the possibility that for a great number of people, not only their health but also their ability to behave sociably could be improved by changing what they eat. This is not an area currently considered in standards of dietary adequacy and little is currently known about the best nutrient dosages required for brain function or behaviour. We will therefore carry out a larger study in 3 Young Offenders Institutes; we will administer vitamin, mineral and essential fatty acid supplements or placebo capsules to confirm our previous results and try to match the prisoners blood level changes in these nutrients with a range of behavioural measures.

Who can participate?

Volunteers from three institutions housing 1200 finally sentenced male prisoners aged 16 to 21 years.

What does the study involve?

Volunteers will take capsules containing vitamins, mineral and essential fatty acids or dummy (placebo) capsules. Volunteers will be randomly allocated to receive either the active capsule or placebo, and neither the volunteer nor the person giving them the capsule will know which one they are getting. Blood samples will be collected before and during supplementation to allow us to assess how changes in nutrient levels affect a range of behaviours including: violence, drug-related offences and incidents of self-harm. We will also match changes in blood levels with measures of attention, planning skills, impulse control and social interactions.

What are the possible benefits and risks of participating?

Improving nutrition should improve the health of the prisoners taking the active supplements. Since these are normal nutrients, adverse effects are highly unlikely. Those who dislike having blood taken will be free to decline.

Where is the study run from?

Department of Physiology, Anatomy and Genetics at Oxford University (UK)

When is the study starting and how long is it expected to run for?
The study started in March 2009 and is expected to run for 4 years.

Who is funding the study?
The Wellcome Trust (UK)

Who is the main contact?
Professor John F Stein
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Contact information

Type(s)
Scientific

Contact name
Prof John Stein

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
GR078667MA

Study information

Scientific Title
Nutrition as a modifiable causal factor in anti-social behaviours: a randomised, placebo controlled, double blind trial

Acronym
PINUP (PrIson NUtrition Project)

Study objectives
Supplements of vitamins, minerals and essential fatty acids will reduce anti-social behaviour in young offenders in prison.

Ethics approval required

Old ethics approval format

Ethics approval(s)
South East Research Ethics Committee, 11/09/2006, ref: 06/MREC01/47

Study design
Randomised placebo-controlled double-blind trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Anti-social behaviour in prison

Interventions
Food supplements (minerals, vitamins and essential fatty acids):
1. Forceval (Alliance Pharma plc): contains vitamin A (750 µg), vitamin D (10 µg), vitamin B1 (1.2 mg), vitamin B2 (1.6 mg), vitamin B6 (2 mg), vitamin B12 (3 µg), vitamin C (60 mg), vitamin E (10 mg), vitamin K1 (120 µg), biotin (100 µg), nicotinamide (18 mg), pantothenic acid (4 mg), folic acid (400 µg), calcium (100 mg), iron (12 mg), copper (2 mg), magnesium (30 mg), zinc (18 mg), iodine (140 µg), manganese (3 mg), potassium (4 mg), phosphorus (77 mg), selenium (50 µg), chromium (200 µg), molybdenum (250 µg). 1 capsule per day p.o. (by mouth).

2. Equazen: contains gamma linolenic acid (45 mg), eicosapentaenoic acid (EPA) (951 mg), docosahexaenoic acid (DHA) (147 mg), vitamin E (8.4 mg), magnesium (60 mg). 3 x 854 mg capsules daily by mouth.

Total duration of treatment: 4 months (maximum)
Total duration of follow-up: 1 month (for all treatment arms)

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Vitamin, mineral and essential fatty acid supplementation

Primary outcome measure
Governor's reports (of violence and other offences), measured after 4 months treatment.

Secondary outcome measures
1. Blood levels of micronutrients, measured after 4 months treatment
2. Cambridge Neuropsychological Test Automated Battery (CANTAB) measures of impulsivity, attention, measured after 4 months treatment
3. Heart rate variability changes, measured after 4 months treatment

Overall study start date
01/02/2009

Completion date
31/12/2012

Eligibility

Key inclusion criteria
16 - 21 year old male offenders in prison

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
1000

Key exclusion criteria
1. Chronic medical conditions
2. Psychotropic medication

Date of first enrolment
01/02/2009

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
Oxford
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OX1 3PT

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
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Sponsor type
University/education

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

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust (grant ref: 078667)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype

International 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
Available on request