# Nutrition as a modifiable causal factor in antisocial 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	<ul><li>Record updated in last year</li></ul>

# 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 john.stein@dpag.ox.ac.uk

# Contact information

# Type(s)

Scientific

#### Contact name

Prof John Stein

#### Contact details

Physiology, Anatomy and Genetics Parks Road Oxford United Kingdom OX1 3PT

# 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  $\mu$ g), vitamin D (10  $\mu$ g), vitamin B1 (1.2 mg), vitamin B2 (1.6 mg), vitamin B6 (2 mg), vitamin B12 (3  $\mu$ g), vitamin C (60 mg), vitamin E (10 mg), vitamin K1 (120  $\mu$ g), biotin (100  $\mu$ g), nicotinamide (18 mg), pantothenic acid (4 mg), folic acid (400  $\mu$ g), calcium (100 mg), iron (12 mg), copper (2 mg), magnesium (30 mg), zinc (18 mg), iodine (140  $\mu$ g), manganese (3 mg), potassium (4 mg), phosphorus (77 mg), selenium (50  $\mu$ g), chromium (200  $\mu$ g), molybdenum (250  $\mu$ g). 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).  $3 \times 854$  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 United Kingdom OX1 3PT

# Sponsor information

# Organisation

University of Oxford (UK)

# Sponsor details

Wellington Square
Oxford
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United Kingdom
OX1 3XP
+44 (0)1865 270011
richard.lewicki@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**

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