

# Older People and Enhanced Neurocognitive function study

<b>Submission date</b> 03/03/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 04/04/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/07/2015	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
NO5R0009

## Study information

**Scientific Title**  
Older People and Enhanced Neurocognitive function study

**Acronym**

OPEN

### **Study objectives**

Older people are at increased risk of vitamin B12 deficiency, which can lead to severe neurocognitive deficit (e.g., progressive weakness, vision and hearing loss, impairment in communication and co-ordination). The aim of the present study is to assess whether increased dietary intake of crystalline vitamin B12 will improve nerve function and cognitive function in older people with defined low vitamin B12 status. Demonstrating that vitamin B12 dependant nerve and cognitive function impairment is present even in individuals without clinical symptoms will have considerable public health significance.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Cambridgeshire 4 REC, 30/04/2008

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

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

Nerve and cognitive function

### **Interventions**

Daily nutritional supplement of 1 mg vitamin B12 versus placebo. The total duration of treatment is 12 months for both arms. Longer term follow-up may be the subject of a separate protocol.

### **Intervention Type**

Supplement

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Vitamin B12 supplementation

### **Primary outcome(s)**

Amplitude of tibial motor evoked responses and tibial nerve conduction velocity, measured at 12 months.

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

1. Cognitive function: immediate recall, prospective memory, letter search/cancellation, verbal fluency, symbol digit modalities, simple and choice reaction time
2. Timed up and go

3. Psychological health (mood) using the 30-item General Health Questionnaire (GHQ-30)
4. Height and weight
5. History of myocardial infarction (MI) and stroke (reported hospitalisation)

All outcomes measured at 12 months.

**Completion date**

01/11/2010

## Eligibility

**Key inclusion criteria**

1. Healthy volunteers
2. Aged 75 years and over, either sex
3. Defined low B12 status (greater than 107 pmol/l and less than 210 pmol/l)
4. No previous history of diabetes or dementia

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**Key exclusion criteria**

1. Pre-existing type I or type II diabetes at baseline
2. Pre-existing dementia at baseline
3. Currently consuming vitamin B12 on a daily basis
4. Mini-Mental State Examination (MMSE) score less than 24 at baseline screen
5. Very low B12 (below 107 pmol/l - Beckman Coulter assay)
6. B12 levels above 210 pmol/l
7. Anaemic
8. History of epilepsy
9. Those with implanted metallic devices such as a pacemaker
10. Alcoholics

**Date of first enrolment**

01/07/2008

**Date of final enrolment**

01/11/2010

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**London School of Hygiene and Tropical Medicine (LSHTM)**

London

United Kingdom

WC1E 7HT

## Sponsor information

**Organisation**

London School of Hygiene and Tropical Medicine (LSHTM) (UK)

**ROR**

<https://ror.org/00a0jsq62>

## Funder(s)

**Funder type**

Government

**Funder Name**

Food Standards Agency (UK)

**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	01/09/2015		Yes	No
<a href="#">Protocol article</a>	protocol	11/03/2011		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes