

Folate Activity Cognition Trial

Submission date 25/05/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 04/07/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/03/2008	Condition category Mental and Behavioural Disorders	<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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

The effects of physical activity and vitamin B supplementation on cognitive functioning and psychosocial health of older persons with mild cognitive impairment

Acronym

FACT

Study objectives

The aim of the study is to examine the effects of a walking programme and/or Folic Acid/B12/B6 supplementation on cognitive functioning and psychosocial health of older persons with mild cognitive impairment (MCI).

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study protocol was approved by the VU University Medical Center Medical Ethics Committee.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Mild cognitive impairment (MCI)

Interventions

Twice weekly brisk walking in a group at moderate intensity and/or daily supplementation with Folic Acid, vitamin B12 and B6.

Non-supplement groups receive a placebo supplement; non-walking groups will do stretching and relaxation exercises.

Intervention Type

Supplement

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Folic Acid, vitamin B12 and B6 supplementation

Primary outcome measure

Cognitive functioning.

Secondary outcome measures

1. Psychosocial health status
2. Physical activity
3. Physical fitness
4. Serum homocysteine levels

Overall study start date

01/09/2002

Completion date

30/09/2006

Eligibility

Key inclusion criteria

1. People aged 70 years or older
2. MCI according to the criteria of Petersen:
 - 2.1. Memory complaint
 - 2.2. Objective memory impairment
 - 2.3. Normal general cognitive function
 - 2.4. Intact activities of daily living
 - 2.5. Not demented
3. Recruited from the community

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

185

Key exclusion criteria

1. Diseases interfering with cognition
2. Unable to participate in moderate-intensity physical activity

Date of first enrolment

01/09/2002

Date of final enrolment

30/09/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

van der Boechorststraat 7

Amsterdam

Netherlands

1081 BT

Sponsor information

Organisation

Research Center on Physical Activity, Work and Health (The Netherlands)

Sponsor details

TNO-VUmc - Body@Work

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i.vanderleden@vumc.nl

Sponsor type

Research organisation

Website

<http://www.bodyatwork.nl/>

Funder(s)

Funder type

Research organisation

Funder Name

Body@Work (The Netherlands) - Research Center Physical Activity, Work and Health

Funder Name

The Netherlands Organisation for Applied Scientific Research (TNO) (The Netherlands) -VU University Medical Center (VUMC)

Funder Name

Fund for the Heart (Fonds voor het Hart) (The Netherlands)

Funder Name

Viatrix B.V. (The Netherlands)

Funder Name

Municipality of Alkmaar (Gemeente Alkmaar) (The Netherlands)

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?
Protocol article	Protocol	23/12/2005		Yes	No
Results article	Results	01/05/2008		Yes	No