ISRCTN19227688 https://doi.org/10.1186/ISRCTN19227688

Folate Activity Cognition Trial

Submission date	Recruitment status	[ ] Prospectively registered
25/05/2005	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/07/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/03/2008	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Marijke Jeanette Maidy Chin A Paw

Contact details
van der Boechorststraat 7
Amsterdam
Netherlands
1081 BT
+31 (0)20 4448203
m.chinapaw@vumc.nl

Additional identifiers

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.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
Cognitive functioning.

Key secondary outcome(s)
1. Psychosocial health status
2. Physical activity
3. Physical fitness
4. Serum homocysteine levels

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

Healthy volunteers allowed
No

Age group
Senior

Sex
All

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)

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
Viatris B.V. (The Netherlands)

Funder Name
Municipality of Alkmaar (Gemeente Alkmaar) (The Netherlands)

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?
Results article	Results	01/05/2008		Yes	No

Protocol article	Protocol	23/12/2005	Yes	No