Train the sedentary brain: move smart. The effects of an interactive cycling training on cognitive functioning in older persons with early stage dementia.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Dementia and amnestic conditions
Study type	Interventional

Summary

ID

NL-OMON42495

Source
ToetsingOnline

Brief title
Interactive cycling in dementia

Condition

- Dementia and amnestic conditions

Synonym
Dementia; Alzheimer Disease

Research involving
Human

Sponsors and support

Primary sponsor: Geriatrie

Source(s) of monetary or material Support: ZonMW Deltaplan Dementie Memorabel

Intervention

Keyword: Cognition, Dementia, Interactive cycling, Physical functioning

Outcome measures

Primary outcome

Our primary outcome measure is change in executive functioning, before and after the training intervention, in the interactive cycling group. Executive function will be measured with neuropsychological tests. Furthermore verbal and visual-spatial memory will be assessed.

Secondary outcome

Secondary outcome measures are physical functioning measured with performance-based tests, Brain Derived Neurothropic Factor (BDNF) measured via blood sample, prefrontal cortex activation measured with functional Near Infrared Spectroscopy (by fNIRS) and changes in activities of daily living (ADL), mood and quality of life, as measured by questionnaires

Study description

Background summary

There is no cure for dementia. Physical activity could be an alternative to medications in an effort to slow dementia-related cognitive decline. In healthy older subjects physical activity leads to improved cognition. In people with dementia the results are mixed. Recent research shows that exercise in combination with exposure to cognitive stimuli can lead to improved cognitive functioning in elderly with cognitive impairment. However further research is needed. In addition, it is unknown whether effects are moderated by APOEe4 status, the most important biological risk factor for dementie.

Study objective

Our aim is to investigate the cognitive effects of an interactive cycling training in early stage dementia patients (in comparison to an aerobic cycling training and a control group).

In addition we will investigate whether the effects of training are modified by APOEe4 carriers state.

We expect that interactive cycling leads to a greater improvement in executive functioning compared to an aerobic bicycle training. We expect stronger effects in APOEe4 carriers than in non-carriers.

Study design

The design is a single blinded RCT.

Intervention

The interactive cycling training consists of cycling on a home-trainer. During the cycling participants follow the route on a screen and have to conduct simple cognitive tasks. Participants will train 3 times a week for 12 weeks and are instructed to gradually increase their exercise frequency to 45 minutes per session. The aerobic cycling training consists of cycling on a stationary bike. Participants will also train 3 times a week for 12 weeks and are instructed to gradually increase their exercise frequency to 45 minutes per session. The intervention in the control group consists of flexibility exercises with the same duration and frequency.

Study burden and risks

The burden consists of participation in the intervention (27 hours) and measurements (approximately 5.5 hours) over a period of 24 weeks.
The in- and exclusion criteria are strict, e.g. no severe pulmonary or cardiovascular disease, to minimize the risk for the participant and avoid the presence of adverse events. Also, the interventions are supervised by well trained master students on a one-to-one basis, directly supervised by the physician-researcher, thereby increasing patient safety. With these strict measures we expect that there will be no extra risk involved in participation in the study. . For some of the participants in the cycling or interactive cycling group, especially those who were not practicing any kind of physical exercise prior to the study, there is a slight possibility that they might feel some muscle soreness and fatigue after training. However, the training will be customized on someone's individual capacities. The training will be performed at the location the participant prefers.
The tests are feasible and safe for older persons with dementia. If possible, the tests will be performed at the participants home. However, some tests need to be performed at the Radboudumc because of available material for testing

(for example, functional Near Infrared Spectroscopy (fNIRS)).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Diagnosis of dementia
Mini Mental State Examination (Folstein and Folstein 1975) score > 20
Clinical Dementia Rating (CDR) score 0.5 -1.0, and still capable to give informed consent
Having insufficient physical activity according to the ACSM guideline for older adults (maximum of 30 minutes five days a week moderate intensity)

Exclusion criteria

Wheelchair bound
Use of specifically dementia targeted nutritional supplements (e.g. Souvenaid) within the last 3 months
Cardiovascular problems that limit physical activity
Serious neurological or orthopedic disorder that limit physical activity
Diagnosis of severe depression, bipolar disorder or psychotic disorder (DSM-IV)
Current alcohol or drug abuse (DSM-IV)
Problems with the Dutch language
Severe hearing or visual problems not able to correct with the use of a hearing device/glasses

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-01-2016
Enrollment:	162
Type:	Actual

Ethics review

Approved WMO

Date:	04-08-2015
Application type:	First submission

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-09-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-01-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-02-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-07-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-03-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL52581.091.15