Passive exercise for an active brain

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

Summary

ID

NL-OMON46861

Source
ToetsingOnline

Brief title
Passive Exercise Active Brain

Condition

- Dementia and amnestic conditions

Synonym
Alzheimer Disease, Dementia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ZonMW Deltaplan Dementie Innovaties voor mensen met dementie en hun mantelzorgers,Vita Motion Technology

Intervention

Keyword: Cognition, Quality of Life, Therapeutic Motion Simulation, Whole Body Vibration

Outcome measures

Primary outcome

The main study parameter is the improvement or reduction in decline of quality

of life and physical functioning.

Secondary outcome

Secondary outcomes are cognitive functioning, need for care, care burden and

balance.

Study description

Background summary

Physical exercise is beneficial for quality of life and cognitive and physical functioning of people with dementia. In addition, cognitive functions can be positively influenced by means of physical exercise. However, physical exercise is not always feasible due to physical impairments or lack of supervision. This study aims to proof that an alternative for active exercise in the form of passive exercise in an multisensory environment is effective to influence quality of life and physical and cognitive functioning of people with dementia.

Study objective

The main objective of the study is to investigate the effects of three different passive exercise interventions (Therapeutic Motion Simulation (TMS), Whole Body Vibration (WBV) and a combination of TMS and WBV) on quality of life and physical daily functioning of people with dementia. The secondary objective is to investigate the effects of the three passive exercise interventions on cognitive functioning, need for care, care burden and balance.

Study design

The study design is a single-blind randomized controlled intervention study.

Intervention

In all three interventions a robotized exercise platform with chair (and

television screen) is used. During TMS the platform moves congruently with a movie on the screen. During WBV the platform vibrates with 30Hz. All three interventions have a duration of 6 weeks and a frequency of 4 times per week. Group 1 receives TMS during 10 minutes per session, group 2 WBV during 4 minutes per session, group 3 a combination of TMS and WBV during 10 minutes per session and the control groups receives normal care.

Study burden and risks

The interventions will be performed in the living environment of the participants. The visits are of short duration (interventions of 4-10 minutes per session), but the number of visits is considerably (27 visits including intervention and measurements). The interventions are generally experienced as pleasant and not as uncomfortable or tiring. For the participants with dementia, the measurements include a questionnaire, neuropsychological tests with tasks in which the participant has to respond to questions and three short balance tests. The interventions are therapeutic and safe . All sessions, interventions and measurements, are guided individually. Therefore, there are no risks associated with participation other than the normal risks of daily life. The experimental groups might benefit from the intervention by enhancement of quality of life and physical and cognitive functioning. For the control group no benefits are expected, but they may value the attention related to the measurements.

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

Diagnoses of dementia
Age 65 years or older
Low level of physical activity (no activity of minimally moderate intensity (>3METs) during 10 minutes continuously per day)

Exclusion criteria

Serious auditory disorders
Colour blindness
Excessive alcohol- or drug use
Serious progressive or terminal disease

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-11-2016
Enrollment:	196
Type:	Actual

Ethics review

Approved WMO Date:	25-10-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-10-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-01-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL58022.042.16

Study results

Date completed:	24-01-2019
Actual enrolment:	120