Improvement of engagement in physical activities and quality of life in dementia: a study into the (cost-)effectiveness of exergaming

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We want to study the effects and cost-effectivity with an randomised controlled trial in which we compare participants with dementia (and their informal caregiver) in daycentres which offer exergaming with participants in daycentres that offer...

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

Summary

ID

NL-OMON47912

Source
ToetsingOnline

Brief title
Exergaming project

Condition

- Dementia and amnestic conditions

Synonym
Alzheimer's disease, Dementia syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Embedded Fitness,Silverfit,ZonMw;stichting Dioraphte;Europese Unie - Marie Curie subsidie

Intervention

Keyword: Cost-effectiveness, Dementia, Exercise, Exergaming

Outcome measures

Primary outcome

The primary study parameter is the physical activity of the participants with dementia, which will be measured during the week of the three measuring moments. For each participant we will register in which physical activities he/she is engaging (how many a week, and for how long) in the daycarecentre and at home. The registration will be on paper. With regard to physical functioning, information will be gathered with a short physical test, the Short Physical Performances Battery (SPPB; Guralnik et al., 1994).

Secondary outcome

We will gather information about different secondary study parameters with interviews and tests:

Physical functioning. Information will be gathered with interview questions based on the Physical Activity Scale for the Elderly (PASE; Washburn et al. 1993) and a few items of the The Older Persons and Informal Caregivers Survey Minimum Dataset (TOPIC MDS).

Cognitive functioning. This will be measured with the Mini-Mental State Examination (MMSE; Folstein et al., 1975) and the Trail Making Test (Ashendorf

et al., 2008) during an interview.

Social Functioning. This will be measured with one item of the TOPIC MDS and one item of the ASCOT (Adult Social Care Outcome Kit; Netten et al., 2012) and this is part of the interview. Also, the personel of the daycentres will be asked to fill in one subscale of the Gedragsoverservatieschaal voor de intramurale Psychogeriatrie (GIP; Verstraten & van Eekelen, 1987), this is to measure the social functioning in the daycentre.

Behaviour and mood. Information about this will be gathered with the NeuroPsychiatryInventory (NPI-Q; Cummings et al., 1994). The 12 items of the translated and validated questionnaire (Kat et al., 2002) will measure the occurrence and nature of the neuropsychiatric symptoms during the past month. This will include depression, apathy, sleeping disorders etc. The informal caregiver will answer the questions of the NPI-Q.

Quality of life of the participants will be measured by the EQ5D-5L (EuroQol group, 2009), a short questionnaire. It measures mobility, self-care, daily activities, pain/discomfort, anxiety/depression and subjective evaluation of health. This list will also be used for the cost-effectiveness analysis.

To determine the fall incident rate we will ask the staff of the daycentre and the informal caregivers to register the incidents.

The level of motivation for exercising of the participants with dementia will be measured with the Intrinsic Motivation Inventory (Deci et al. 1994) during an interview. This list will give information about how participants rate their interest/enjoyment in the exercise and how much they value it.

The subjective burden of care of the informal caregivers will be measured with a few items of the TOPIC MDS, the Short Sense of Competence Questionnaire (SSCQ; Vernooij-Dassen et al. 1999) and the Positive Experience Scale (PES; De Boer et al., 2012). The SSCQ consist of 7 items with 5 possible answers. It will show the extent to which the informal caregiver feels able to care for the person with dementia. The PES consists of 8 items with 4 possible answers, which measures the positive experiences of care giving. The questions will be asked during an interview with the caregiver.

We will organise focus groups with the persons involved (participants with dementia, informal caregivers, staff and game providers) to measure the rate of approval of the physical activities and to discuss future possibilities.

Factors that are related to physical activities and playing games will be explored with a few individual questions, which will be answered by the participant with dementia, the caregiver and the personel of the daycentres. To measure the Body Mass Index of the participant with dementia, we will determine the height and weight during the first interview.

For the inventarisation of the costs of exergaming equipment, the form 'Costs and benefits of applied games' (Heuvelink e.a. 2014) will be used. This will be done in an interview with the staff of the daycare center at the end of the trial.

For the inventarisation of implementation aspects of exergaming the Measurement Instrument for Determinants of Innovations (MIDI-lijst) (TNO) will be used. This will be done in an interview with the staff of the daycare center at the end of the trial.

Study description

Background summary

Research shows that physical exercise can influence a persons level of fitness, functioning, health and general well-being in a positive way. Physical inactivity is related to negative health-outcomes, such as mortality, reduced well-being and social participation, and a influx in health related cost. Increasing evidence suggest that physical exercise has a positive effect on the physical, cognitive, emotional and social functioning of people with dementia.

Despite these benefits, it appears that people with dementia often are inactive. This could be because they often experience difficulties, for example orientation problems, that make it hard to do physical activities outside of their house. These difficulties can also be related to a lack of motivation and taking initiative.

Exergaming is an innovative way to perform physical exercises in virtual surroundings. The technology registers the movements of the player and this influences the game or the surroundings. There are various applications, for example cycling on a hometrainer where the digital environment on screen changes with your movements.

Exergaming is expected to be a playful way of exercising which will motivate people with dementia to engage in physical activities in a pleasant and save manner. They can maintain or improve their physical, cognitive, emotional and

social functioning.
In recent years various exergaming interventions have been developed. These are primarily used in daycentres, rehabilitation centres and nursing homes. Small studies which target people with dementia show that they like exergaming, that exergaming motivates them to exercise longer and that the videos sometimes evoke memories, which leads to mental activation. The workload of the staff was reduced, because the people with dementia were motivated to exercise.

These findings are promising, but there is no study yet that investigates the effects and cost-effectivity of exergaming in comparison with regular physical activities. We want to fill this void with the current project.

Study objective

We want to study the effects and cost-effectivity with an randomised controlled trial in which we compare participants with dementia (and their informal caregiver) in daycentres which offer exergaming with participants in daycentres that offer regular activities. The questions we want to answer are:

- Are persons with dementia in daycentres with exergaming more physically active than persons with dementia in daycentres without exergaming?
- In comparison to regular activities offered in daycentres, does exergaming have a positive effect on the physical, cognitive, emotional and social functioning and the quality of life on people with dementia? And does it have a positive effect on the burden of care as experienced by the informal caregivers?
- Do people with dementia enjoy the different exergaming activities and is this related to characteristics of the participant or the context?
- In comparison to regular activities in daycentres, is exergaming cost-effective for people with dementia?
- How do the persons involved think we can best apply the exergaming intervention for people with dementia?

If exergaming proves to be cost-effective, we hope to achieve that the exergaming intervention will be spread successfully. Our goal with this project is to motivate people with dementia to exercise more and cosequently will experience positive effects on their wellbeing and the quality of life. We also hope that this will have a positive effect on the burden of care experienced by their informal caregiver.

Study design

The study is a randomized controlled trial. We will (if possible) arrange blocks of centers that are similar to one another. Within the blocks centers will be randomly assigned to the experimental group (exergaming) or to the control group (regular activities). Interviews and tests will be scheduled at

the start of the study, after three and after six months.

Intervention

People with dementia who are assigned to the experimental group will participate in the exergaming intervention. The experimental intervention consists of interactive cycling in combination with a digital screen. The daycentres in the experimental group will purchase their own exergaming devices. They can decide which type of bicycle is the best fit for their clients and facilities of the centre.
The exergaming activities are open to visit for 5 times a week, during the 6 months of follow-up. The participants with dementia are asked to join the exergaming activity at least two times a week. The participants in the control group can join the regular activities in the daycentre.

Study burden and risks

Information will be gathered on three different occasions (at the start, after three and six months). Trained researchers will interview and test the participants. The participants with dementia in the experimental group will be asked to take part of the exergaming activities at least two times a week for six months.

Informal caregivers will be interviewed at the start of the study, after three and after six months. During the six months of the study, they will keep a diary in which they will register their use of health care facilities and their use of medicine. They will also register this for the person with dementia.

The exergaming intervention is developed to give elderly people a save and playful way to exercise. We expect that this has a positive effect on the wellbeing of the participant. However, the researchers will stay alert for any additional burden or risks for the participants and avoid disadvantageous situations. We expect that the risks for the participants are negligible.

Contacts

Public
Vrije Universiteit Medisch Centrum

Overschiestraat 57
Amsterdam 1062HN
NL
Scientific
Vrije Universiteit Medisch Centrum

Overschiestraat 57
Amsterdam 1062HN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Persons with mild to moderate dementia (indicator: MMSE between 24 and 10) who are expected to live in the community for at least six more months. ;The informal caregiver of the participant with dementia. He/she is willing to participate in interviews and is willing to keep track of the medical costs of themselves and the participant with dementia.

Exclusion criteria

Living in a nursing home, severe comorbidity, having a terminal disease. ;The informal caregiver is excluded if he/she isn't willing to participate in the research.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2017
Enrollment:	448
Type:	Actual

Ethics review

Approved WMO Date:	29-11-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-01-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-03-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-07-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-12-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-07-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	22-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL58227.029.16