Active+: Physical exercise and cognition

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21201

Source
Nationaal Trial Register

Health condition

Mobility limitations are defined as having a chronic condition (e.g. musculoskeletal and back disorder, COPD, rheumatism, osteoporosis, chronic heart disease) or other physical conditions (e.g. visual or hearing impaired) that impede.

Sponsors and support

Primary sponsor: Faculty of Psychology and Educational Sciences of the Open University Nederland
Source(s) of monetary or material Support: Hersenstichting and Open University

Intervention

Outcome measures

Primary outcome

Cognitive Functioning: Concept Shifting Test, Stroop Color Word, Auditory Verbal Learning Task

Secondary outcome

Cognitive Functioning: Letter Digit Substitution Test. Physical activity behavior (objectively: accelerometer; subjectively SQUASH). Also Quality of Life will be assessed with the SF-36 and

Activities of Daily Living with the Katz' ADL index.

Study description

Background summary

Research questions:

1) What are cognitive effects of the proven effective physical activity program 'Active+' in elderly with limited mobility?

2) How do type and intensity of physical activity, measured objectively by accelerometry, influence the magnitude of the cognitive effects?

Background: Although more and more evidence arises that physical activity (PA) has a positive effect on cognitive function (CF) of elderly people with mobility restrictions (ELM) (Colcombe & Kramer, 2013), there is still no suitable PA program that affects CF for ELM. Active + is a proven effective eHealth intervention that encourages moderate to vigorous PA in people over 50 (van Stralen, 2010; Peels, 2013; Peels, 2015). Participants will be given advice on the benefits of exercise, and get tips and examples of accessible exercises. Active+ does not impose behavior and does not organize activities itself. The intervention just motivates participants to get enough exercise and keep this level. The goal of this project is to understand the effects of the intervention on physical activity and CF. And to what extent the type and intensity of PA have an influence on the size of the cognitive effects.

Targetgroup: Inclusion criteria are: (a) age ≥ 65 (b) having mobility limitations; (c) able to read and speak Dutch (d) no brain disorder and/or condition that could influence cognitive functioning. Mobility limitations are defined as having a chronic condition (e.g. musculoskeletal and back disorder, COPD, rheumatism, osteoporosis, chronic heart disease) or other physical conditions (e.g. visual or hearing impaired) that impede mobility. This group was because it has hardly been studied, while it concerns a relatively large group in the Netherlands. Besides that, we expect that they also have positive effects from specific forms of physical activity on CF.

Design and power analysis: Phase 1: Project preparation: adapt Active+ to target group. Phase 2: Small scale feasibility test: 10 ELM and 4 intermediaries test Active+ materials and procedures. Phase 3: RCT: Active+ will be tested in a RCT with an intervention group

receiving Active+ (3 PA advises in 4 months) and a waiting list control group (access to Active+ after a year). A baseline measurement and post-tests (6 and 12 months after baseline) are conducted. In both the intervention group and the control group ± 3850 persons will be invited. We expect that 10% of the invited persons will participate. Next to that we expect that only 70 percent is eligible. Therefore we need to include 270 participants per group (G*power: ES=.3; power=.8; ICC=.01 and drop-out 30%). Fase 4: Analysis en completion project.

Measurements: Phase 2: Participants will answer questions about the materials and procedures. Phase 3: Participants will be visited at home during the measurements by the researcher. A cognitive test battery is assessed (primary: Concept Shifting Test, Stroop Color Words, Verbal Learning Task, secondary Letter Digit Substitution Test). This will take ± 40 minutes. They also receive an accelerometer that they wear for a week on their waist. They also receive a questionnaire containing the SQUASH, a validated questionnaire for measuring physical activity. Moreover, questions are asked on personal preferences and barriers because they are necessary for the forming of the advice. In addition, also Quality of Life as measured by the SF-36 and Activities of Daily Living with the Katz ADL index are assessed. Completing the questionnaire will take approximately 30 minutes.

Expected results: It is expected that Active + will improve CF of ELM by increasing the level of PA. Also the moderating and mediating pathways of PA on CF will be examined. The results of the study are displayed in English-language articles that will lead to a dissertation. The results will be presented at several (inter) national congresses.

Study objective

It is hypothesized that Active+ improves cognitive functioning in elderly with limited mobility through improvements in physical activity. As the literature is inconclusive on characteristics a PA program minimally needs to have in terms of type and intensity of PA, and whether type and intensity of PA matter, this study will make a detailed assessment of PA (type and intensity) and test moderating and mediating paths of PA on cognitive functioning.

Study design

All participants are measured at baseline and after 6 and 12 months.

Intervention

The research focuses on the effect of the Active + intervention on physical activity and cognitive function. The Active + intervention consists of several parts: (1) Active + intervention offers three computer-tailored physical activity advices (online or in writing) that aim to raise awareness of the participants amount of physical activity and motivates physical

activity with options for physical activity planning and monitoring of progress. The exercise advice is tailor-made, based on personal characteristics (e.g. age and physical complaints), the actual exercise behavior, and psychological determinants of physical activity behavior. (2) The intervention will be integrated into a website where additional information can be found, as well as a user forum, examples of physical activity exercises and a possibility to ask an expert questions. The intervention aims to raise awareness of the subject of his own (lack of) physical activity, and encourage them to increase physical activity and maintain it. Participants thus have the choice of what they pick up from the program and what they do with it. The waiting list control group receives access to the Active + program after a year.

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Eligibility criteria

Inclusion criteria

 age ≥ 65

 having mobility limitations (Mobility limitations are defined as having a chronic condition (e.g. musculoskeletal and back disorder, COPD, rheumatism, osteoporosis, chronic heart disease) or other physical conditions (e.g. visual or hearing impaired) that impede.)

 able to read and speak Dutch

Exclusion criteria

 no brain disorder and/or condition that could influence cognitive functioning or partaking in Active+.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2018
Enrollment:	540
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL6005
NTR-old	NTR6503
Other	Commissie Ethische Toetsing Onderzoek van de Open Universiteit : U2017/01979/FRO

Study results