Healthy Aging and Dementia.

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Older people with dementia who participate in a combined aerobic and strength training program will show larger effects on cognition, physical functioning, ADL functioning and social functioning in comparison with older people with dementia who...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22579

Bron
Nationaal Trial Register

Verkorte titel
HAD

Aandoening

Cognition (executive functioning and memory)
Physical functioning (aerobic capacity, strength, mobility and balance)
Activities of Daily Living
Affective/social functioning

Ondersteuning

Primaire sponsor: Universitair Medisch Centrum Groningen
Overige ondersteuning: Universitair Medisch Centrum Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The differences between neuropsychological test battery scores between pre-, post-, and

delayed post measurement are the main outcome parameters for this study.

Toelichting onderzoek

Achtergrond van het onderzoek

Title:
Healthy Ageing: Aerobic exercise, strength training and dementia.

Rationale:
Dementia presents a major public health problem that impacts people's ability to maintain cognitive, physical and social function. There are indications that physical activity can enhance cognition in older people with dementia. However, the number of studies is limited, the outcomes ambiguous and only studies with aerobic exercise programs were performed. This study focuses on the effects of combined strength and aerobic exercise in older people with dementia to evaluate the theory that there are stronger effects on cognition, physical functioning and ADL in comparison with an aerobic exercise program and controls.

Objective:
The objective is to investigate the effects of a combined strength and aerobic exercise program on cognition, physical functioning, social functioning and ADL.

Study design:
The study design is a randomized clinical trial. After pre-stratification on MMSE score, the participants will be randomized over three groups: combined strength and aerobic exercise, aerobic exercise only, control intervention (social visits). Measurements will take place, blinded for group, before the intervention (pretest), after the 10 weeks intervention (posttest) and at follow-up 10 weeks after the posttest.

Study population:
The study population consists of older people with moderate to moderate severe dementia (MMSE 10-22) aged > 65 years of age.

Intervention:
The intervention consists of a supervised physical exercise program which will be offered for 30 minutes a day, five days a week, during 10 weeks. The combined strength and aerobic group walk on 3 days per week and perform strength training on 2 days per week. The aerobic group will walk on 5 days per week. The controls receive social visits with the same frequency and duration.

Main study parameters/endpoints:
The main outcome parameters are cognition (memory and executive functioning), physical functioning, ADL and social functioning.

Doel van het onderzoek

Older people with dementia who participate in a combined aerobic and strength training program will show larger effects on cognition, physical functioning, ADL functioning and social functioning in comparison with older people with dementia who participate in an aerobic training program or a social visit group.

Onderzoeksopzet

1. Pre-measurement (T0);

2. 10 weeks intervention;

3. Post-measurement (T1);

4. 10 weeks no intervention;

5. Delayed post-measurement (T2).

Onderzoeksproduct en/of interventie

The supervised training programs will be offered for 30 minutes a day, 5 days a week, during 10 weeks. The combined strength and aerobic group will walk 3 days per week and perform exercises to increase leg strength for 2 days per week. The aerobic training group will walk 5 days per week. To control for social factors during the intervention, the control group will receive social visits with the same frequency and duration as the other groups. For all training programs, the participants will be guided individually by the PhD student or a well trained Master student Human Movement Sciences.

Strength training:

After a 5 minute walking warming-up period, 25 minutes of specific strength exercises will follow: Knee extensions (‘knee straightening’), plantar flexion ("toe standing"), hip abduction ("side lifts"), and hip extension ("back leg lifts").

Aerobic training:

Aerobic training consists of walking. Walks will be performed for 30 minutes per session and,

if necessary, moments of rest will be included.

Social visits:

The control group will receive social visits with the same frequency and duration as the combined exercise group and the aerobic exercise group.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. To look if the participant is mobile, the Timed Up & Go Test is assessed. The participant is included If he/she is able to perform this test with or without assistive device;

2. To investigate if the participant is able to perform neuropsychological tests and if he/she fits the population criteria, a Mini Mental State Examination is assessed. The participant is included if he/she scores between 10 and 22.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Wheelchair bound;

2. Have cardiovascular problems (e.a. severe high blood pressure or cardiac problems) that limit them from physical activity;

3. Have a history of alcoholism;

4. Have severe visual problems;

5. Have severe auditive problems;

6. Have problems with the Dutch language.

If the participant scores < 10 or > 22 on the MMSE or is not able to perform the Timed Up & Go Test he/she is excluded form the study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2010
Aantal proefpersonen:	153
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	31-03-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36410
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2145
NTR-old	NTR2269
CCMO	NL32037.042.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36410

Resultaten

Samenvatting resultaten
N/A