Bewegen, niet vergeten!

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22568

Source
Nationaal Trial Register

Brief title
COACH

Health condition

EN: Alzheimer's Disease, Inactivity, ApoE-e4, genetic vulnerability for Alzheimer's Disease
NL: ziekte van Alzheimer, dementie, inactiviteit, ApoE-e4 dragerschap, genetische kwetsbaarheid voor Alzheimer

Sponsors and support

Primary sponsor: Clinical Neuropscyhology section, Vrije Universiteit Amsterdam
Source(s) of monetary or material Support: ZonMw, Alzheimer Nederland

Intervention

Outcome measures

Primary outcome

Main outcome measure is cognitive function, measured with neuropsychological tests.

Secondary outcome

Secondary outcome measures are physical functioning measured with performance-based

field tests, IGF-1 and BDNF serum levels and ADLs, mood and quality of life, measured by questionnaires

Study description

Background summary

SUMMARY

In study 1 all participants are required to keep track of their daily activity by means of a pedometer during 2 consecutive weeks. All participants will be tested on cognitive functioning and physical fitness. In study 2 the participants in the experimental group participate in the COACH program, lifestyle training developed to increase daily physical activity. The COACH method consists of 5 individual coaching sessions directed at counselling the participants in reaching their personal activity goals. The sessions are scheduled periodically, spread over a period of 3 months, plus one follow up session after 3 extra months. Participants are required to keep track of their daily level of physical activity by means of a pedometer. Participants in the control condition receive a stretching and toning intervention. Physical fitness and cognitive functioning will be determined for all participants at the start and end of the intervention (after 4 months) and at the 3 month follow up.

Main study parameters/endpoints: Main outcome measure is cognitive function, measured with neuropsychological tests. Secondary outcome measures are physical functioning measured with performance-based field tests, IGF-1 and BDNF serum levels and ADLs, mood and quality of life, measured by questionnaires.

COUNTRY OF RECRUITMENT

The Netherlands

Study objective

Rationale: There is no cure for dementia. Physical activity could be an alternative to medications in an effort to slow cognitive decline In healthy elderly subjects physical activity leads to improved cognition.

Objective: Part 1: Main objective: Investigate the relation between level of physical activity

and cognition in healthy elderly and to examine the possible moderating effects of (Apolipoprotein E e4) APOE-e4 status, as well as IGF-1 and BDNF levels.

Part 2: Investigate the effect of an increase in daily physical activity as promoted by a lifestyle intervention in (inactive) APOE-e4 carriers and non-carriers on physical fitness and cognition and to examine the possible moderating role of APOE-e4 status, BDNF and IGF-1 levels.

The primary objectives of the study are:

(i) To investigate the relationship between the level of physical (in) activity and cognitive functioning

(ii) To assess whether the level of physical activity and cognitive functioning is lower in APOE-e4 carriers than in non-carriers.

(iii) To assess the increase in daily physical activity in inactive older people generated by the COACH method
(iv) To investigate whether an increase in daily physical activity leads to improved physical fitness and cognitive functioning

(v) To investigate whether an increase in daily physical activity leads to improved physical fitness and cognitive functioning in inactive older APOE-e4 carriers more substantially than in non-carriers

To identify the role of IGF-1 and BDNF as mediators in the effects of physical activity on cognition:

(vi) To study whether the increased physical activity elevates serum levels of IGF-1 and/or BDNF

(vii) To study whether the increased physical activity elevates serum levels of IGF-1 and/or BDNF more substantially in APOE-e4 carriers than in non-carriers.

(viii) To study whether elevated serum BDNF and/or IGF-1 levels mediate the effects of physical activity on cognitive function

The corresponding hypotheses of objectives (i) to (viii) are:
(1) Levels of physical activity and cognitive functioning are positively related

(2) APOE-e4 carriers display lower levels of physical activity and cognitive functioning than non-carriers

(3) The COACH method increases the level of daily physical activity in inactive older people.

(4) An increase in daily physical activity improves physical fitness and cognitive functioning.

(5) These effects are larger in APOE-e4 carriers.

(6) Increased physical activity results in elevated serum IGF-1 and BDNF levels.

(7) Increased physical activity results in elevated serum IGF-1 and BDNF levels, more substantially in APOE-e4 carriers than in non-carriers.

(8) There is a positive relation between increase of IGF-1 and/or BDNF levels and improvement of cognitive functioning, in APOE-e4 carriers as well as in non-carriers.

Study design

SCREENING

At the screening visit the in- and exclusion criteria are checked. Global cognitive functioning is assessed with the Mini Mental State Examination (MMSE) (Folstein et al., 1975), a brief 30 items questionnaire screening test sensitive to change. Functional mobility is assessed with the Timed Up and Go test Timed Up & Go test (TUG) (Podsiadlo & Richardson, 1991; Thomas & Hageman, 2003).
From those participants of whom information on ApoE genotype is not yet available saliva samples will be taken to measure APOE-e4.

BASELINE ASSESSMENT

Memory

1. Verbal Learning and Memory test (VLMT) (Lindeboom & Jonker, 1989). The 15 Word Test (15-WT) of the VLMT measures short and long term verbal episodic memory: direct recall, delayed recall and recognition. The scores are the number of correct words recalled.

2. Digit Span Forward (DSf) (Wechsler, 1955, 1987). The DSf measures attention and short-term verbal memory. A series of verbally presented digits are asked to be repeated. The number of digits increases by one digit every three trials. The score is the number of successful trials.

3. Verbal Fluency Test (VFT) (Snijders & Verhage, 1983). The VFT measures the ability to retrieve familiar information from the lexical memory. Also, executive functioning and working memory play an important role. The score is the number of words from a phonemic category (D,A,T) that participants can mention in 60 seconds.

4. Location Learning Test revised (LLTr) (Bucks & Willison, 1997; Kessels, Nys, Brands, & van Zandvoort, 2004). The LLTr measures spatial memory. The test consists of a stimulus card

with a 5×5 grid in which 10 everyday objects are presented at different locations. After exposure for 30 seconds, a blank array is used to cover the target array. Participants are handed 10 small cards with the target objects and asked to place each card at the correct location on the grid. The learning phase consists of five consecutive trials. After a delay the grid is shown again and participants are asked to place the cards at their correct locations from memory. Performance is measured in sum of errors and learning index reflecting the relative difference in performance between trials.

Executive functioning

5. Stroop colour-word test (Hammes, 1973). The Stroop colour-word test is a measure of selective attention and response inhibition. The test consists of three parts: the word task (read 20 names of colours printed in black), the colour task (name colour of 20 squares) and the color-word task (name ink color of 20 non-corresponding colour names). The time needed to complete the task is recorded.

6. Trail Making test (Reitan, 1958). The Trail Making Test measures visuomotor speed and attention (part A and B) and set-shifting (part B). In part A participants has to draw a line between encircled numbers, in part B they had to alternate between circles with numbers and letters (1-A, 2-B). The time to complete the tasks is recorded. The difference score (time part B minus time part A) is calculated as an additional measure of set-shifting. Lower scores indicate a better performance.

7. Digit Span Backward (DSb) (Wechsler, 1955, 1987). The DSb measures verbal working memory, distractibility and attention/ concentration. A series of digits have to be repeated in reverse order. The number of digits increases by one digit every three trials. The score is the number of successful trials.

8. Rule Shift Card Test, a subtest from the BADS (Wilson, Alderman, Burgess, Emslie, & Evans, 1996). This measure uses 21 non-picture playing cards and it assesses the ability to change from one pattern of responding to another. In the first part of the test, subjects are instructed to answer “Yes” to a red card and “No” to a black card. In the second part, subjects are instructed to respond “Yes” if the card which has just been turned over is the same color as the previous turned card and “No” if the color was different. These rules typed on a card, are left in full view throughout to reduce memory constraints. Time taken and number of errors are recorded in both parts. This test assesses flexibility and inhibition abilities, as well as rule learning. 9. Go/no-go task from the Frontal Assessment Battery (FAB) (Dubois, Slachevsky, Litvan, & Pillon, 2000; Wolters & van Laar, 2002). This test measures the participants’ ability to control impulsiveness. The participant is instructed to inhibit response that was previously given to the same stimulus e.g. not tapping when the experimenter taps twice.

Physical activity

1. The Short Physical Performance Battery (SPPB) (Hoeymans, Wouters, Feskens, van den Bos, & Kromhout, 1997). The SPPB includes standing balance (feet together, semi-tandem, tandem), 6 meter walking speed, and lower body strength (5 times sit-to-stand chair test). The SPPB is highly reliable in older adults (ICC=0.83-0.89) and has demonstrated a strong and consistent association with health status measures, regardless of socioeconomic and cultural differences.

2. Hand grip strength measured by the hydraulic JAMAR dynamometer (Bohannon, 2008; Härkönen, Harju, & Alaranta, 1993; Schmidt & Toews, 1970). Handgrip strength measurement by dynamometry is well standardized, and widely used as to estimate whole body strength due to the portability and practicality of grip dynamometry. Grip strength has been shown to be an important predictor of functional, psychological, social and cognitive health in aging (Bohannon, 2008; Taekema, Gussekloo, Maier, Westendorp, & de Craen, 2010). The procedure proposed by the American Hand Therapy Association will be followed (Fess, 1992). The participants are seated with the arm in adduction, the elbow flexed at 90°, the forearm in the neutral position and the wrist between 0 and 30 degrees of extension. The second handle position was used as per standard protocol. Three consecutive trials were performed with each hand, The mean of the three trials will be kept for the analyses.

3. Timed Up & Go test (TUG) (Podsiadlo & Richardson, 1991; Thomas & Hageman, 2003). The TUG measures functional mobility. The sitting participant rises from a chair, walks 3 meters, makes a turn, walks back and sits down in the chair again. Participants are allowed to use their hands while standing up. Walking devices are allowed. Two trials are performed and the average time is recorded.

4. Six Minute Walk test (6MWT) (Tappen, Roach, Buchner, Barry, & Edelstein, 1997). The 6MWT is an assessment for aerobic capacity (Rikli, Roberta E, Jones, 1998). The participant is instructed to walk as many times as possible in six minutes between two cones set 10 meters apart from each other. Walking devices are allowed and during the test the participant is allowed to take rests. The total walking distance is measured.

5. FICSIT-4 (Rossiter-Fornoff, Wolf, Wolfson, & Buchner, 1995). The FICSIT-4 measures static balance. The first three conditions are part of the SPPB (two feet parallel, semi-tandem, tandem). The last condition, single-leg stance, is added. Every stance has to be held for 10 seconds. During the test, 2 students stand at either side of the participant to ensure safety during the test. The total time of the performed positions is the outcome score.

Physical activity

1. Physical activity measured by the Digiwalker SW-200. The Digiwalker is a pedometer, a small lightweight wrist watch device that will be worn by the participants to quantify and monitor the number of steps each day. Any activities other than walking can be registered in a diary and converted (or in part 2 online on the MyCoach website) into number of steps. Participants in part 1 of the study or participants who do not have access to the internet at home will be given a paper diary to register their daily number of steps.

Other measures

Questionnaires

Level of physical activity, ADLs, mood and quality of life will be assessed by means of a questionnaire in an interview with the participants. The questionnaires will be administered in the same session as the physical tests but before the physical tests. In total, these questionnaires take approximately 20 minutes to administer.

1. Physical Activity Scale for the Elderly (PASE) (Schuit, Schouten, Westerterp, & Saris, 1997). The PASE is a questionnaire to assess level of physical activity.

2. Activities of Daily Living, mood, social activities, quality of life and care use are assessed with the corresponding subscales of the TOPICS-MDS (http://topics-mds.nl/).
3. Physical parameters: Blood pressure, weight, height and abdominal and hip circumference. These measures will take approximately 7 minutes to administer.

The interview + physical test battery and the cognitive test battery will be administered in one session.

(Invasive) measures of physiology

1. Blood samples of approximately 2,5 mL will be drawn once by a trained nurse to administer BDNF and IGF-1 serum levels.

Assessment of all measures listed under baseline assessment will take place in the second part of the study after the intervention (week 16) and at follow up (week 28). Satisfaction with the intervention program will be administered in the intervention group at posttest.

Intervention

INTERVENTION

The intervention studied is the COACH method, a 12 week pedometer based exercise counseling strategy, aimed at enhancing low-to-moderate daily physical activity. The method is based on the Motivational Interviewing Technique created by Miller and Rollnick (1991) and the goal setting theory developed by Locke and Latham (1990) both considered to be effective instruments for behavioral modification (Locke & Latham, 1990; Miller & Rollnick, 1991; Rubak, Sandbaek, Lauritzen, & Christensen, 2005). Six individual coaching sessions will be scheduled to guide the individual in assessing and obtaining personal activity goals. Five sessions are scheduled periodically, spread over a period of 4 months, plus one follow up session after 3 months. The coaching sessions are offered individually at the participants'

home by a coach trained by the CBO (Centrum voor Beweging en Onderzoek) Groningen, who developed the intervention method. Adjusting the counseling to personal goals and limitations increases the effectiveness of behavioral change paradigms (Bravata et al., 2007; Calfas et al., 1996). All coaching sessions in the trajectory of the participants will be performed by the same coach.

CONTROL

Participants in the control group receive 5 individually guided muscle toning and stretching sessions over a period of 4 months. At follow up 3 months after the end of the intervention the participants in the control group are offered 1 COACH session. They are, also required to keep track of their daily level of physical activity for 2 consecutive weeks in week 1 and 2 of study 1 and week 14 and 15 and week 26 and 27 of study 2. Participants in the control condition are offered 1 COACH session at the end of the study in week 28.

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, participants must meet all of the following criteria: age ≥ 55 years; able to perform the Timed Up & Go Test with or without assistive device, and a Mini Mental State Examination (Folstein, Folstein, & McHugh, 1975) score higher than 25. Both males and females will be included. In the second part of the study only those participants who display low levels of physical activity as measured in Part 1 of the study are recruited.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: wheelchair bound, cardiovascular problems that limit physical activity, epilepsy, presence of neurodegenerative disorder or focal neurological deficit, diagnosis of dementia or mild cognitive impairment, progressive or terminal disease, depression, history of alcoholism, severe visual problems, severe auditory problems and problems with the Dutch language.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2016
Enrollment:	266
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-06-2016
Application type:	First submission

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	NL5675
NTR-old	NTR5912
Other	METc VUmc: 2015.322 : ZonMw: NL53306.029.15

Study results

Summary results

n/a.