Differential physiological and cognitive effects of the COACH method in healthy elderly APOEe4 carriers and non-carriers

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Part 1: Main objective: Investigate the relation between level of physical (in)activity and cognition in healthy elderly and to examine the possible moderating effects of (Apolipoprotein E e4) APOEe4 status and IGF-1 and BDNF levels and blood…

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

Summary

ID

NL-OMON47735

Source
ToetsingOnline

Brief title
COACH

Condition

- Dementia and amnestic conditions

Synonym
cognitive function, decline of mental functions

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: ZonMw,Europese Unie

Intervention

Keyword: APOEe4, Cognition, IGF-1, Physical activity

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, blood metabolite concentrations and ADLS, mood and quality of life, measured by questionnaire.

Study description

Background summary

To delay or possibly offset cognitive decline increasing emphasis has been placed on the development of preventive strategies and identification of risk factors. The present study focusses on two well established risk factors for developing cognitive decline and Alzheimer dementia; genetic susceptibility and physical inactivity in healthy elderly. An important population of people at increased risk for developing dementia is carriers of the APOEe4 allele. Apolipoprotein E (APOE) is a cholesterol carrier that supports lipid transport and brain injury repair and is the strongest genetic risk factor for AD. Individuals carrying the e4 allele (14% of the population) have an increased risk of developing AD with younger age at onset.
Besides genetic susceptibility lifestyle appears to play a modifying role in the development of cognitive decline and dementia. Physical activity offsets the cognitive decline that occurs in late adulthood and diminishes the likelihood of developing dementia. APOEe4 carriers might be prone to physical inactivity. For this group increasing physical activity could offer protection against (future) cognitive decline.

Study objective

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

(in)activity and cognition in healthy elderly and to examine the possible moderating effects of (Apolipoprotein E e4) APOEe4 status and IGF-1 and BDNF levels and blood metabolite concentrations.
Part 2: Investigate the effects of an increase in physical activity generated by a lifestyle intervention in (inactive) APOEe4 carriers and non-carriers on physical activity level, physical fitness and cognition and to examine the possible moderating role of APOEe4 status and BDNF and IGF-1 levels and blood metabolite concentrations.

Study design

The design of study 1A is a cross sectional study. Study 1B is a single blind Randomized Controlled Trial.

Intervention

In part 2 of the study the participants in the experimental group participate in the COACH program, a lifestyle training developed to increase daily physical activity. The COACH method consists of 7 individual coaching session directed at counselling the participants in reaching their personal activity goals. The intervention for the control group consists of individual guidance in the stretching and toning of the muscles. The sessions are scheduled periodically, spread over a period of 6 months, plus one follow up session after 3 months. Participants in the experimental group are required to keep track of their daily level of physical activity by means of a pedometer.

Study burden and risks

The burden in study 1 consists of keeping track of daily activity by means of wearing a pedometer for 2 consecutive weeks and participation in assessment of cognitive (approximately 70 minutes) and daily functioning (approximately 20 minutes) and physical fitness (approximately 37 minutes). The researchers will contact participants twice by telephone to ask participants about their experiences with the pedometer. Total 240 minutes. Blood samples to determine levels of IGF-1 and BDNF and blood metabolite concentrations and saliva samoles to determine APOEe4 status will be taken once.

The burden in the second part of the study consists of participation in the intervention (8 coaching session of 45 minutes each = 6h) and assessment of cognitive (approximately 70 minutes) and daily functioning (approximately 20 minutes) and physical fitness (approximately 37 minutes) after a period of 6 months and follow up measurement after another 3 months (5 hours): approximately 10 hours and 30 minutes in total.

Participants in the experimental group will be guided towards a more active lifestyle which requires a daily increase in activity.

Participants in the experimental group are required to keep track of their daily level of physical activity by means of a pedometer.

Participants in the control group are required to keep track of their daily level of physical activity twice for 2 months by means of a pedometer. Participants in the control group will participate individually guided stretching and toning sessions (7 x 45 minutes) and one coaching session 45 min at follow up (6 hour) and in the assessment of cognitive (approximately 70 minutes) and daily functioning (approximately 20 minutes) and physical fitness (approximately 37 minutes) after a period of 6 months and at follow up measurement after another 3 months. Approximately 11 hours and 30 minutes in total. Blood samples to determine IGF-1 and BDNF serum levels will be taken at the end of the intervention and at follow up assessment. All activities in this study are self-chosen and lie within the range of normal activities of daily life. Participants are guided individually in finding suitable ways of improving their daily physical activity level.

Contacts

Public
Vrije Universiteit

Van der Boechorststraat 7-9
Amsterdam 1081
NL
Scientific
Vrije Universiteit

Van der Boechorststraat 7-9
Amsterdam 1081
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age * 55 years
- Males and females
- Able to perform the Timed Up & Go Test with or without assistive device
- Mini Mental State Examination (Folstein, Folstein, & McHugh, 1975) score higher than 25
- 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 and included

Exclusion criteria

- Weelchair-bound
- diagnosed with dementia or mild cognitive impairment
- diagnosed with a neurodegenerative disease
- diagnosed with a progressive or terminal disease
- diagnosed with serious cardiovascular disease, such as heart failure that limit physical activity
- epilepsy
- (history of) substance abuse
- (history of) major psychiatric illness (e.g. depression)
- severe visual or auditory problems
- insufficient proficiency of the Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-08-2016
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	12-10-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-03-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-06-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-08-2017
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:	14-02-2019
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	NL53306.029.15