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The PASSWORD Study – Promoting Safe Walking

Submission date	Recruitment status	[X] Prospectively registered
02/01/2017	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/01/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/06/2025	Signs and Symptoms	

Plain English summary of protocol

Background and study aims
A major task facing aging societies is to develop strategies to help older people to stay active. Among the most important means of doing so is the ability to walk safely in one's environment. Population based information shows that one-half of women and one-third of men aged 75 years and older find it difficult to walk 500 meters. Moreover, approximately 60% of women and one-third of men are unable to walk fast enough (>1.2 m/s) to cross the road during the green traffic light. Problems with walking are associated with poor health, lower participation in society and falls, the majority of which occur while walking. Walking is a complex process involving interaction of the nervous system, muscles and thinking (cognition), which all deteriorate with ageing. Therefore, activities requiring simultaneous physical and cognitive function are especially challenging for older people. The interplay between cognitive functions and walking suggest that both physical and cognitive training has potential for the prevention of walking difficulties in older people. The aim of this study is to investigate the potential benefits of a combined cognitive and physical training program on walking speed, cognition and falls compared to physical training alone.

Who can participate?
Older adults aged between 70 and 85 years who are living at home and have a sedentary lifestyle.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in a physical training program, which involves one to two sessions supervised sessions of 30 to 45 minutes per week of walking exercises and progressive resistance (to build strength) and balance training. Participants are also encouraged to complete exercises at home two to three times per week. Those in the second group take part in the same physical training program with the addition of a cognitive training program, which involves one to two 15 to 20 minutes per week. The cognitive training involves computer-based exercises for working memory (holding, processing, and manipulating information) and executive functions (a set of mental skills that help people to get things done). Participants in both groups complete the programs for a total

of 12 months. At the start of the study and then after six and 12 months, participants in both groups complete a number of assessments designed to assess their walking speed, cognition and whether they have had any falls.

What are the possible benefits and risks of participating?
Persons participating in the study will benefit for the participation as they have free access to training programs which have been shown to be beneficial for older people. There may be some risks in this type of physical training interventions. Outdoor walking exercises may increase falls among older populations. In this study, use of walking poles will be recommended during the walking exercises. Falls will be monitored on a monthly basis with diaries. If the program causes a significant increase in the amount of falls participants suffer, the programs will be adapted.

Where is the study run from?
University of Jyväskylä (Finland)

When is the study starting and how long is it expected to run for?
September 2016 to March 2020

Who is funding the study?
Suomen Akatemia (Finland)

Who is the main contact?
Professor Sarianna Sipilä
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
n:o 296843

Study information

Scientific Title
Promoting safe walking among older people: Physical and cognitive training intervention among older community-dwelling sedentary men and women

Acronym
PASSWORD

Study objectives
Primary study aim:
To investigate, in older community-dwelling sedentary men and women, the effects of a 12-month structured progressive physical and cognitive training program (PTCT) on walking speed and dual-task cost in walking speed compared to physical activity (PT) only.

Primary hypothesis:
1. The PTCT will induce significantly greater benefits on walking speed than the PT only. Dual-task cost is smaller after the PTCT intervention than after the PT-only intervention

Secondary study aims:
1. To investigate the effects of the PTCT program on rate of falls during 12-month intervention and a one-year follow-up in the target population compared to the PT only
2. To investigate the effects of the PTCT program on cognition in the target population compared to the PT only

Secondary hypotheses:
1. The rate of falls will be smaller among the PTCT group than the PT group during the intervention and a one-year follow-up.
2. The PTCT will induce significantly greater benefits on cognition than the PT only

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethical Commettee of Central Finland Health care District, 14/12/2016, ref: 11/2016

Study design
Single-centre single (assessor) blinded parallel-group randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Sedentary lifestyle, risk of mobility disability and falls, aging

Interventions
Participants are randomised to one of two groups using a computer-generated random allocation sequence of two-fold stratification by gender and age (70-74, 75-79, 80-85) with blocks of 20.

Physical Training (PT) group: Participants receive the multicomponent physical training (PT). This involves undertaking 1-2 supervised sessions of 30 to 45 minutes per week involving walking exercises and progressive resistance and balance training and home exercises. Each participant will attend once a week in supervised walking session. The target intensity will be 13 (moderate value) on the Borg scale. In addition, participants will be advised to walk on their own in order to attain in total 150 min per week by the end of the study. Supervised resistance and balance training will take place once a week in senior gyms. Each training session will include progressive balance training followed by progressive resistance training aiming to improve strength and power for the lower extremity muscles. The training will be performed by pneumatic resistance training machines with SmartCard Software which stores performed workload, sets, reps, and exercise time during each visit. In addition, participants will get a home exercise program including simple balance and functional exercises. The home exercises program is advised to be done 2-3 times/week.

Physical and Cognitive Training (PTCT) group: Participants receive the multicomponent physical training (PT) and a cognitive computer-based training (CT). This involves taking part in PT (as in Physical Training part) and 1-2 supervised cognitive training sessions of 15-20 minutes per week. Progressive cognitive training will include exercises on a computer which target working memory and different components of executive functions. In addition, participants are advised to perform computer-based cognitive exercises on their own 2 times a week.
A diary on all physical and cognitive home exercises will be kept on a daily basis.

A one year follow-up for participants in both groups takes place after the intervention period is complete (12 months) and it involves follow-up for falls with monthly falls calendar.

Intervention Type
Behavioural

Primary outcome measure
10-m maximal walking speed is measured by photocells at baseline, 6 and 12 months.

Secondary outcome measures
1. 6-min walking distance is measured by a stop watch at baseline, 6 and 12 months
2. Dual-task cost in walking speed is measured over a 20 m track with a visuospatial cognitive task at baseline, 6 and 12 months
3. Fall incidence is measured by monthly falls calendar during the intervention and 1 year follow-up there after
4. Executive functioning is measured using the stroop test and trail making A and B at baseline, 6 and 12 months

Other measures:
1. Overall health is assessed during nurses and physicians examinations (GDS, vision, orthostatic test, diseases and medication, resting EKG, blood samples for Hb, blood count, CRP, IGF-1, BDNF, metabolomics) at baseline and 12 months
2. Body composition is assessed using DXA at baseline and 12 months
3. Self-reported difficulty in walking outdoors, 500 m and 2 km is assessed using a questionnaire at baseline, 6 and 12 months
4. Life-space is assessed using a Life-space questionnaire at baseline, 6 and 12 months
5. Global cognitive function (CERAD total score) is assessed at baseline and 12 months
6. Verbal fluency is assessed using a verbal fluency test at baseline, 6 and 12 months
7. Injurious falls is assessed using a monthly falls calendar during the intervention and 1 year follow-up there after
8. Postural balance and lower extremity function is assessed using a Short Physical Performance Battery (SPPB) at baseline and 12 months
9. Level of physical activity is assessed through self-reporting and use of an accelerometer at baseline, 6 and 12 months
10. Fall-related self-efficacy is measured using the Fall-related self-efficacy (FES-I) questionnaire at baseline, 6 and 12 months
11. Sense of coherence (SOC) is measured by a SOC questionnaire at baseline and 12 months
12. Brain function is measured using Magneto Encephalon Graph recordings for a sub-group of 40 participants at baseline and 12 months

Added 08/11/2017:
13. Isometric knee extension and grip strength are measured at baseline and 12 months
14. Lower body extension power is measured using the Nottingham power rig at baseline and 12 months
15. Level of sedentary behavior is assessed through self-reporting and use of an accelerometer at baseline, 6 and 12 months
16. ADL and IADL are measured with a standardized questionnaire at baseline, 6 and 12 months
17. Emotional well-being is measured with the satisfaction with life scale, Diener 1989; Internationally reliable short form of the Positive and Negative Affect Schedule at baseline, 6 and 12 months, and personality is assessed with the Eysenck Personality Inventory, Floderus B. 1974, at baseline and 12 months and the NEO-Personality Inventory-3 (NEO-PI) at 12 months

Overall study start date
01/09/2016

Completion date
31/03/2020

Eligibility

Key inclusion criteria
1. Age 70 to 85 years
2. Community-dwelling
3. Sedentary lifestyle (modified 08/11/2017: sedentary or at most moderately physically active lifestyle)
4. Ability to walk 500 m without assistance (cane is allowed)
5. Willingness to participate
6. MMSE=>24

Participant type(s)
Healthy volunteer

Age group
Senior

Lower age limit
70 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
310

Total final enrolment
314

Key exclusion criteria
1. Unable or unwilling to give informed consent or accept randomization in either study group
2. Current consumption of more than 7 (women) or 14 (men) portions of alcohol per week
3. Another member of the household is a participant in the PASSWORD -study
4. Medical, psychiatric, or behavioral factors that in the judgment of the Principal Investigator may interfere with study participation or the ability to follow the intervention protocol
5. Underlying Diseases Likely to Limit Lifespan and/or Affect the Safety of the Interventions
6. Cognitive impairment (abnormal CERAD score) or disease affecting cognition (e.g. Altzheimers disease, MCI, dementia)
7. Severe arthritis (either osteoarthritis or rheumatoid arthritis)
8. Cancer requiring treatment in the past year, except for basalioma or cancers that have clearly been cured or in the opinion of the investigator carry an excellent prognosis (e.g., Stage 1 cervical cancer)
9. Lung disease requiring either regular use of corticosteroid pills or injections or the use of supplemental oxygen
10. Cardiovascular disease (including New York Heart Association Class III or IV congestive heart failure, clinically significant aortic stenosis, history or cardiac arrest, uncontrolled angina)
11. Severe parkinson's disease or other serious neurological disorder
12. Renal disease requiring dialysis
13. Type I or II diabetes with insulin medication
14. Epilepsy with regular medication and seizures during the last year

15. Stroke or cerebral haemorrhage with complications (e.g. hemiplegia)
16. Severe musculoskeletal pain; osteoporosis with fragility fracture history
17. Psychotic disorders (e.g. schizophrenia, bipolar disorder, severe depression)
18. Difficulty in communication with study personnel due to vision or hearing problems

Date of first enrolment
02/02/2017

Date of final enrolment
01/04/2018

Locations

Countries of recruitment
Finland

Study participating centre
University of Jyväskylä
Rautpohjankatu 8
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Sponsor type
University/education

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ROR
https://ror.org/05n3dz165

Funder(s)

Funder type
Government

Funder Name
Suomen Akatemia

Alternative Name(s)
Suomen Akatemia, Finlands Akademi, Academy of Finland, AKA

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Finland

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal in 2019-2020.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Sarianna Sipilä (sarianna.sipila@jyu.fi).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	15/09/2018	11/07/2019	Yes	No
Results article		01/07/2021	29/03/2021	Yes	No
Results article		13/10/2021	14/10/2021	Yes	No
Other publications	Accelerometer-measured and self-reported physical activity in relation to extraversion and neuroticism: a cross-sectional analysis of two studies.	29/07/2020	21/02/2023	Yes	No

Other publications	Participant characteristics associated with the effects of a physical and cognitive training program on executive functions	25/10/2022	21/02/2023	Yes	No
Results article	Effects of Physical and Cognitive Training on Falls and Concern About Falling in Older Adults: Results From a Randomized Controlled Trial	15/12/2021	21/02/2023	Yes	No
Results article	Personality traits and physical functioning: a cross-sectional multimethod facet-level analysis	24/11/2020	21/02/2023	Yes	No
Other publications	Changes in femoral neck bone mineral density and structural strength	30/10/2023	02/11/2023	Yes	No
Other publications	Subgroup analysis	06/02/2025	07/02/2025	Yes	No
Results article	Does personality moderate efficacy	10/02/2023	11/06/2025	Yes	No