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 sarianna.sipila@jyu.fi

Contact information

Type(s)

Scientific

Contact name

Prof Sarianna Sipilä

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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. Dualtask 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 followup 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 Jyvaskyla Finland 40700

Sponsor information

Organisation

University of Jyväskylä

Sponsor details

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Sponsor type

University/education

Website

https://www.jyu.fi/en

ROR

https://ror.org/05n3dz165

Funder(s)

Funder type

Government

Funder Name

Suomen Akatemia

Alternative Name(s)

Academy of Finland, Suomen Akatemia, Finlands Akademi, AKA

Funding Body Type

Government organisation

Funding Body Subtype

Research institutes and centers

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 |