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The effects of physical exercise training in combination with cognitive training on dual task costs of walking in elderly

Submission date
15/07/2011

Recruitment status
No longer recruiting

Registration date
10/08/2011

Overall study status
Completed

Last Edited
02/08/2016

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Walking difficulties can lead to loss of independence for older people. Treatment involves improving gait (the pattern of how a person walks). Previous studies have shown that physical exercise is effective and may reduce gait variability (the stride-to-stride fluctuations in walking). Treatment should preferably include strength training in combination with balance and coordination exercises. The aim of this study is to examine the effects of exercise training and combined exercise and cognitive (mental) training on the physical and cognitive functioning of community-dwelling or independent-living older adults.

Who can participate?
Adults aged over 65 who are able to walk 10 meters with or without support (cane or walking frame)

What does the study involve?
Participants are randomly allocated to receive either exercise training or both exercise and cognitive training. Gait is assessed before and after 12 weeks of training.

What are the possible benefits and risks of participating?
The risk of injury during exercise training and testing is low.

Where is the study run from?
Swiss Federal Institute of Technology Zurich (ETH Zürich) (Switzerland)

When is the study starting and how long is it expected to run for?
April 2011 to December 2013

Who is funding the study?
Swiss Federal Institute of Technology Zurich (ETH Zürich) (Switzerland)

Who is the main contact?
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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effects of physical exercise training in combination with cognitive training on dual task costs of walking in elderly: a two-groups pre-test post-test randomized controlled trial

Study objectives
This randomized controlled trial is designed to examine the effects of exercise training and combined exercise and cognitive training on the physical and cognitive functioning of community-dwelling or independent living older adults. We hypothesize that:
1. Both training groups will show significant improvements on measures of physical and cognitive functioning
2. The combined training group (exercise and cognitive training) will show greater walking function and cognitive improvements than the exercise-only training group

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Canton of Zurich Ethics Committee, 16/02/2011, ref: EK-ZH-Nr. 2011-0007/0
2. Canton of Bern Ethics Committee, 28/03/2011, ref: EK-BE-Nr. 031-11

Study design
Two-groups pre-test post-test randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Geriatrics related conditions

Interventions
1. Physical Exercise Training
1.1. Conventional Physical Gait Training: Both groups will perform 5-10 minutes warm-up exercises
1.2. Campbell developed a conventional gait training protocol, which is most likely the mainstay of many rehabilitation programs and validates physical therapists chosen interventions
1.3. This program is shown below and will be used in this study
1.4. Subjects are required to perform the exercise protocol two times a week
2. Sample Gait Protocol to be used in our study:
2.1. Progressive resistive exercises (PREs) to the hip extensors, abductors, knee flexors and extensors, ankle Dorsiflexors and plantarflexors on weight stack or pneumatic machines
2.2. One Legged Stance training
2.3. Tandem standing and walking
2.4. Walking on heels
2.5. Backward and sideward walking
2.6. Turns
2.7. Stepping over objects
2.8. Picking objects up
2.9. Stair climbing
2.10. Sit to stand transfers
2.11. Knee squats
2.12. Active range of motion (ROM) to the whole body
3. Cognitive Exercise Training
3.1. In addition to the physical gait training one group will receive cognitive training

3.2. As cognitive training we use the CogniPlus from Schuhfried. CogniPlus is a software package with which you can focus on the different cognitive areas you want to train
3.3. The training programs use realistic scenarios, making it easy for users to integrate the progress they have made into their everyday lives
3.4. The content of CogniPlus is closely linked to the Vienna Test System
3.5. With its ergonomically designed input panel and training programs that adapt to the progress made, clients find the system enjoyable and encouraging to use
3.6. The shared feature of all tasks is their adaptivity, that is, the task automatically increases in difficulty when the participant gets better at it, and also gets easier, when the performance drops again
3.7. The tasks of the training battery are suitable for target groups of different performance levels of people and differ in their demands and complexity
4. For the older adults aimed at in this study the following tasks will be used:
4.1. ALERT (Alertness): this program trains the alertness dimension of attention - the ability to temporarily increase and sustain the intensity of attention
4.2. SELECT (Selective Attention): this program trains selective attention - the ability to respond quickly to relevant stimuli and to suppress inappropriate responses
4.3. DIVID (Divided Attention): this Program trains divided attention - the ability to perform different tasks simultaneously
4.4. The computer keyboard is not always a suitable input medium for computerized therapy procedures
4.5. Therefore a special input panel that is large and robust enough to be used with confidence even by clients with significantly impaired or untrained motor control of the hand was developed

Intervention Type
Behavioural

Primary outcome measure
Gait was measured with a GAITRite instrumented walkway (CIR Systems, USA) before and after twelve weeks of training. The GAITRite system provided temporal (time) and spatial (distance) gait parameters via an electronic walkway connected to the serial port of a personal computer. The GAITRite walkway contained sensor pads encapsulated in a roll-up carpet with an active area of 7.3 m long. As the subject walked through the walkway, the sensors captured each footfall as a function of time and transferred the gathered information to a personal computer to process the raw data into footfall patterns. The GAITRite walkway was extended with a 2.5 meter carpet at the end and beginning of the active area to eliminate the effect of acceleration or deceleration and allow for steady state gait assessment. For each subject the relative dual task costs (DTC) of walking was calculated, as percentage of loss relative to the single-task walking performance, according to the formula DTC [%] = 100 * (single-task score - dual-task score) /single-task score

Secondary outcome measures
1. Physical performance:
The Expanded Timed Get-up-and-Go (ETGUG) test measures the overall time to complete a series of functionally important tasks. The ETGUG test is a sensitive and objective assessment of physical function.
2. Fear of falling:
The Falls Efficacy Scale International (FES-I) questionnaire was used as a measure of concern about falling to determine the transfer effects of training to activities of daily living. This scale assesses both easy and difficult physical activities and social activities with a scale of: 1 = not at all concerned, 2 = somewhat concerned, 3 = fairly concerned, 4 = very concerned.

3. Simple Reaction Time
These tasks are frequently used to measure psychomotor speed. Reaction time is assessed in milliseconds using a hand-held electronic timer and a light as the stimulus and depression of a switch by the finger and the foot as the responses. The light stimulus is located adjacent to the response switches and is bright (ie, supra-threshold) to ensure that the tests are not influenced by the subjects visual acuity. The timer has a built-in variable delay of 1 to 5 seconds to remove any cues that could be gained from the test administrator commencing each trial by pressing the start button. A modified computer mouse is used as the response box for the finger press task, and a pedal switch is used for the foot press task (Figs. 2A and 2B). Five practice trials are undertaken, followed by 10 experimental trials.
4. Postural Balance (SPPB)
The Short Physical Performance Battery (SPPB) is an objective assessment tool for evaluating lower extremity functioning in older persons. It was developed by the U.S.A. National Institute on Aging. The SPPB is composed of three timed tests: 3-meter walking speed, balance, and chair stand tests. Timed results from each test are categorized into 5-level variables ranging from 0 (worst performers) to 4 (best performers) according to well-established cut-points. The sum of the results from the three categorized tests (ranging from 0 to 12) is used for the analyses. This battery has been extensively validated, is predictive at the pre-clinical stage of later disability and has application in routine clinical settings in monitoring the functioning of older people. The standing balance portion requires participants to maintain a side-by-side, semi-tandem, and tandem stance for 10 seconds, with scores ranging from 0 to 4 (maximum score). The fastest time of two 4 m usual-pace walk attempts is used. The chair stands required participants to rise from a chair with arms across their chest for five repetitions. Categorical scores (range 04) for the 4 m walk and chair stands are based on timed quartiles previously established in a large population. Individuals unable to complete either task receive a score of 0. The sum of the three components comprises the final SPPB score with a possible range from 0 to 12 (12 indicating the highest degree of lower extremity functioning). The participants are tested within a single session that lasts about 10 minutes.
5. Executive Function (Trail Making A & B-Test) The Trail Making Test (TMT) provides information on visual search, scanning, speed of processing, mental flexibility, and executive functions. The TMT consists of two parts. TMT-A requires an individual to draw lines sequentially connecting 25 encircled numbers distributed on a sheet of paper. Task requirements are similar for TMT-B except the person must alternate between numbers and letters (e.g., 1, A, 2, B, 3, C, etc.). In Part B, participants are asked to connect circles containing numbers (from 1 to 13) or letters (from A to L) in an alternating numeric, alphabetical order (1-A-2-B-3-C, etc.). Errors must be corrected immediately and the sequence re-established. The test is terminated after 10 minutes even if it is not completed. The score on each part represents the amount of time required to complete the task. Performance on the TMT is a strong, independent predictor of mobility impairment, accelerated decline in lower extremity function, and death in older adults. The participants are tested within a single session that lasts about 5-10 minutes.
6. Cognitive Functioning: Vienna Test System The Vienna Test System (VTS) is known worldwide as a leading computerized psychological assessment tool. It is developed by Schuhfried Test Instruments. The use of the computer ensures the highest possible level of objectivity and precision and enables dimensions to be tested that could not be measured by traditional paper-and-pencil tests. In addition, the scoring of test results is guaranteed to be fast and accurate. For the older adults aimed at in this study the following test will be used:
WAF Perception and Attention Functions The following test of the Vienna Test System is linked to our cognitive exercise training program:
WAFG (Divided attention)
The respondent receives stimuli on two visual or rather one visual and one auditory canal. The respondents task is to observe, if one of the stimuli has changed two times in series.
For each of the WAF tests different test forms are available, enabling dimensions of attention to

be assessed under different presentation modalities. Thus the WAF tests systematically include sub-tests for visual, auditory and cross-modal presentation. In some subtests of the WAF test battery automated and controlled aspects of attention are measured separately; the stimuli either become more prominent because the intensity level is increased ("popping out"), or they become less prominent because their intensity is decreased and cognitively controlled "top down" processes are then required.

Overall study start date
01/04/2011

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Age over 65 years
2. Signed informed consent statement
3. Ability to walk 10 meters or more with or without walking frame

Participant type(s)
Healthy volunteer

Age group
Senior

Sex
Both

Target number of participants
140

Key exclusion criteria
1. Severe cognitive impairment (Mini-Mental State Examination below 22 points)
2. Rapidly progressive or terminal illness, acute illness or unstable chronic illness

Date of first enrolment
01/04/2011

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
Switzerland

Study participating centre

ETH Zurich
Zurich
Switzerland
CH-8093

Sponsor information

Organisation
Swiss Federal Institute of Technology Zurich (ETH Zürich) (Switzerland)

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Funder type
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Funder Name
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Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/12/2014		Yes	No