ISRCTN70130279 https://doi.org/10.1186/ISRCTN70130279

Effects of the six-month training on cognitive, physical performance, and daily physical activity in older adults

Submission date
17/05/2013

Recruitment status
No longer recruiting

Registration date
10/07/2013

Overall study status
Completed

Last Edited
10/07/2015

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The objective of this study is to find out which combination of physical and cognitive (mental exercises) training is most effective to increase physical and cognitive (mental) performance in older adults from 70 years of age. Moreover, the study examines the effects of the training on individuals daily physical activity patterns, frequency of falls, and symptoms of depression.

Who can participate?
People over 70 years of age, able to walk at least 20 meters with or without walking aids and living independently or in a community residence.

What does the study involve?
90 participants are randomly allocated to one of the three different training programs. Two training programs combine physical and cognitive training, whereas the third program consists of physical exercise only and acts as a control group.
Intervention group one (video-game dancing)
Intervention group two (dual-task walking)
Intervention group three (control group, treadmill walking)
Subjects practice for six months, two times one hour per week. Testing of physical and cognitive performance takes place before the training program, after three months of training, and at the end of the program (six months). Participants will be tested again one year after completion of the training.

What are the possible benefits and risks of participating?
Participants possibly benefit from increased physical and cognitive fitness after completing the training program. The risk of falls is not greater than in normal life of the elderly participants. Special attention is given to minimize the risk of falls while training. No other risks or side effects are expected.

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

of Human Movement Sciences and Sport. Testing and training takes place at the Geriatrics Clinic St.Gallen, Switzerland.

When is the study starting and how long is it expected to run for?
The study started in September 2012 and will run until April 2014 (including one-year follow-up testing). The recruitment of participants completed in October 2012.

Who is funding the study?
Swiss Federal Institute of Technology (ETH), Zurich and Institute of Human Movement Sciences and Sport, Switzerland

Who is the main contact?
MSc Patrick Eggenberger, PhD Student, ETH Zurich, Switzerland, Institute of Human Movement Sciences and Sport
patrick.eggenberger@hest.ethz.ch

Contact information

Type(s)
Scientific

Contact name
Dr Eling D. de Bruin

Contact details
ETH Zurich
Institute of Human Movement Sciences and Sport
HIT J 32, Wolfgang-Pauli-Strasse 27
Zurich
Switzerland
CH-8093

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effects of the six-month multimodal training intervention on cognitive, physical performance, and daily physical activity in older adults

Study objectives

Study part A (cognition and gait):
Combined physical and cognitive training (strength, balance, and virtual-reality video-game dancing) interventions can increase cognitive function (particularly attention) and gait parameters (particularly dual task cost of walking) to a greater extent than combined physical and cognitive training (strength, balance, and walking with memory tasks) and physical training alone (aerobic exercise, strength, and balance).

Study part B (aerobic performance and executive function):
Combined physical (aerobic exercise, strength, and balance) and cognitive training components, can increase measures of aerobic endurance performance [particularly heart rate variability (HRV) and heart rate recovery] to a greater extent than physical training (aerobic exercise, strength, and balance) alone. There is an association between HRV and executive function.

Study part C (prevention of falls and one year follow up):
Combined physical and cognitive training interventions, can decrease anxiety of falling and fall frequency to a greater extent than physical training (including aerobic exercise, strength, and balance) alone. One year after the six-month training intervention some selected physiological and cognitive measures are still elevated compared to pre-intervention level.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Canton of St.Gallen Ethics Committee (Switzerland), 03/09/2012, ref: EKSG 12/092

Study design
Single-centre three-groups pre-test, mid-test (three months), post-test (six-months) randomized controlled interventional trial with one-year follow-up testing

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Geriatrics related conditions of independent living and community dwelling in old adults

Interventions

Participants follow a six months guided training intervention. Training sessions take place twice weekly for one hour each session. Subjects are randomized into three groups with different training programs.

The participants of all three training groups will practice a basic training program consisting of strength and balance exercises. Strength exercises are performed using own body weight, small barbells, weight-wests, and resistive rubber-bands. The intensity of these exercises is increased progressively and performed with high movement velocity (power training). Participants are accustomed slowly to the exercises and are continuously monitored by the instructors.
1. Intervention group one (video-game dancing):
This group executes virtual-reality video-game dance training in addition to the strength and balance exercises. For the dance training, participants follow the step instructions (arrows) presented on a computer screen. Movements have to be carried out with the rhythm of the music. Participants are standing on a pressure-sensitive platform, which records right and false movements. For security reasons, participants hold on to ropes that are attached to the ceiling.
2. Intervention group two (dual-task walking):
This group also performs strength and balance exercises as a basic training program. Additionally, this group executes dual-task training with walking on a treadmill while doing memory exercises presented on a computer screen.
3. Intervention group three (control group, treadmill walking):
This group acts as a control group and does treadmill walking without any cognitive tasks, in addition to the basic strength and balance training.

Intervention Type
Behavioural

Primary outcome measure
1. Study part A (cognition and gait):
1.1 Test battery for cognitive function
1.2 Test for attention and concentration: age concentration test (AKT)
1.3 Processing speed: digit-symbols-test [revised Hamburg-Wechsler Intelligence Test for Adults (HAWIE-R)]
1.4 Memory: reproduce story [Wechsler Memory Scale-Revised (WMS-R)]
1.4.1 Memory: pair associate learning (IGD)
1.4.2 Working memory: executive control (IGD)
1.4.3 Short time memory: digit span forward/backward (WMS-R)
1.5 Fluid intelligence: Raven's matrices test
1.6 Attention: Trailmaking A and B test
2. Study part B (aerobic performance and executive function):
2.1. Heart-rate-variability, Six-minute walking test: Participants walk as far as possible within six minutes. Participants walk back and forth on a 30-meter track. Measures: walking distance; heart rate variability at rest, during the walk, and at recovery; heart rate recovery during five minutes after the walk
2.2. Executive function: Tests 1.2, 1.4.2, and 1.6 (see above)
3. Study part C (prevention of falls and one year follow up):
3.1. Falls: With a fall-diary, the frequency and severity of falls is assessed during the six months training phase and one year thereafter.
3.2. Fear of falling: The Falls Efficacy Scale International (FES-I) questionnaire is 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.

All measures are assessed pre-intervention, after three months, and after six months (post-intervention). Falls measures and some selected other measures are again assessed one-year post-intervention.

Secondary outcome measures
1. Study part A (cognition and gait):
1.1. Gait parameters are assessed with the GAITRite system (CIR Systems, USA). The GAITRite system provides temporal (time) and spatial (distance) gait parameters via an electronic walkway connected to the serial port of a personal computer. The GAITRite walkway contains sensor pads encapsulated in a roll-up carpet with an active area of 7.3m long. As the subject walks through the walkway, the sensors capture each footfall as a function of time and transfer the information to a personal computer.
2. Study part B (aerobic performance and executive function):
2.1. With the Short Physical Performance Battery (SPPB) the lower extremity functioning will be assessed. This test battery consists of a balance test, a 3-meter gait test, and a 5-chair-rise test. 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 SPPB was developed by the U.S.A. National Institute of Aging.
2.2. Body fat percentage and muscle mass is measured by means of bioelectrical impedance analysis (BIA). The leg-to-leg BIA system provides a simple and highly reproducible assessment for the body composition for groups.
3. Study part C (prevention of falls and one year follow up):
3.1. Daily physical activity is recorded using accelerometers (StepWatch, Orthocare Innovations, USA). These will be worn during one week. The StepWatch accelerometer can be used as a valid device to assess physical activity in community-dwelling older adults.
3.2. Using the geriatric depression scale (GDS) symptoms of depression are recorded. The German version of the GDS has a good validity and reliability.

Overall study start date
03/09/2012

Completion date
30/04/2014

Eligibility

Key inclusion criteria
1. Age over 70 years
2. Signed informed consent statement
3. Ability to walk at least 20 meters with or without walking aids
4. Independent living or community dwelling

Participant type(s)
Healthy volunteer

Age group
Senior

Sex
Both

Target number of participants
90

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
3. Alzheimer disease, dementia, or recent head injury

Date of first enrolment
03/09/2012

Date of final enrolment
01/10/2012

Locations

Countries of recruitment
Switzerland

Study participating centre
ETH Zurich
Zurich
Switzerland
CH-8093

Sponsor information

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

Sponsor details
Institute of Human Movement Sciences and Sport
HIT J 32, PD Dr. E.D. de Bruin
Wolfgang-Pauli-Strasse 27
Zurich
Switzerland
CH-8093

Sponsor type
University/education

Website
http://www.ibws.ethz.ch

ROR
https://ror.org/05a28rw58

Funder(s)

Funder type
University/education

Funder Name
Eidgenössische Technische Hochschule Zürich

Alternative Name(s)
ETH Zurich, ETH Zürich, Federal Institute of Technology Zurich, ETH Zürich (Eidgenössische Technische Hochschule Zürich), Eidgenössische Technische Hochschule Zürich (Switzerland), Eidgenössische Technische Hochschule Zürich (ETH), ethzurich, ETH

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Switzerland

Funder Name
Institute of Human Movement Sciences and Sport (Switzerland)

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