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EXERcise and changes in executive functions and pre-frontal BRAIN activity during walking

Submission date
13/12/2013

Recruitment status
No longer recruiting

Registration date
11/03/2014

Overall study status
Completed

Last Edited
13/03/2014

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
We are carrying out a study to test the effects of physical training with a video dance game on executive functions and frontal brain activity. Executive functions, a set of mental processes that helps connect past experience with present action, are used to perform activities such as planning, organizing, strategizing, paying attention to and remembering details. Our goal is to find the effects of the training programs on brain functions. The study's findings should help to improve the well-being of elderly and help prevent age-related changes in brain functioning.

Who can participate?
Men and women, aged over 70 years and able to walk independently for 10 minutes.

What does the study involve?
Participants will be randomly allocated to participate in one of two possible training programs. Group 1 receives a progressive dance video game training performed over 30 minutes, three times per week, on dance pads. The program lasts 8 weeks. Group 2 receives an intervention with progressive balance training and additional stretching exercises performed over 30 minutes, three times per week, on dance pads and the program lasts 8 weeks. At the beginning and end of the study, we will compare executive functioning and frontal brain activity while walking on a treadmill.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part but there should be benefits to elderly people in the future because the results of the study are likely to influence how fall prevention training should be designed.
The main risk of training is getting an injury because of increasing the difficulty of the exercise too quickly.

Where is the study run from?
The study has been set up by the Swiss Federal Institute of Technology in Zurich (Switzerland). Participants will be recruited in the city of St.Gallen, Switzerland and surrounding communities. Training intervention will take place in the Geriatrics Hospital St.Gallen.

When is the study starting and how long is it expected to run for?
Recruitment started in October 2013. Participants were enrolled on the study for a period of four months and the study completed in February 2014.

Who is funding the study?
Swiss Federal Institute of Technology (ETH) and Zurcher Kantonalbank (ZKB), Switzerland.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EKSG 13/089

Study information

Scientific Title
Pre-frontal brain activity during walking and executive functions following training: a functional near-infrared spectroscopy (fNIRS) study

Acronym
EXERBRAIN

Study objectives

We hypothesize that the prefrontal cortex will show changes in activation properties following a video-exergame training intervention in elderly.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical Ethics Committee of the Canton St. Gallen, Switzerland (EKSG 13/089)

Study design
Randomised 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Video-exergame training intervention in elderly

Interventions
Participants are randomised to one of two groups:
Intervention Group: Receives a progressive dance video game training performed during 30 minutes, three times per week, on dance pads. The program lasts 8 weeks.
Control Group: Receives an intervention with progressive balance training and additional stretching exercises for the same time period and with an equal frequency and training duration.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Near-infrared spectroscopic (NIRS) imaging to assess bilateral increase of oxygenated hemoglobin (oxyHb) in the prefrontal cortex during treadmill walking

Secondary outcome measures

1. Cognitive functioning (shifting, inhibition and updating): paper & pencil test / measured at baseline and three months
2. Short physical performance battery (SPPB): physical performance test / measured at baseline and three months

Overall study start date
01/10/2013

Completion date
28/02/2014

Eligibility

Key inclusion criteria
1. Aged 65 years or older
2. Living independently or in a retirement home
3. Being able to walk 10 minutes without a break on a treadmill
4. Being healthy (self-reported)
5. Having given written informed consent

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Individuals who reported more than one serious health complaint (e.g. recent heart attack, uncontrolled diabetes or uncontrolled hypertension)
2. Individuals who reported diagnosis of Alzheimer's disease, dementia, or recent head injuries

Date of first enrolment
01/10/2013

Date of final enrolment
28/02/2014

Locations

Countries of recruitment
Switzerland

Study participating centre
Inst.f.Bewegungswissenschaften und Sport
Zurich
Switzerland
8093

Sponsor information

Organisation
Swiss Federal Institute of Technology in Zurich (ETHZ) (Switzerland)

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Sponsor type
University/education

Website
http://www.ibws.ethz.ch/people/debruine/index

ROR
https://ror.org/05a28rw58

Funder(s)

Funder type
University/education

Funder Name
Zurcher Kantonalbank (Switzerland) within the framework of sponsoring of movement sciences, sports and nutritional sciences at the Swiss Federal Institute of Technology in Zurich (ETHZ) (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