

Effects of a motor-cognitive stepping exergame training in older adults

Submission date 06/06/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/06/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/10/2020	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Falls are a major problem in older adults. Maintaining balance during walking is not merely a motor task but also a cognitive task that involves attention, planning of a movement or constraining from it. To improve these aspects of postural control in older adults, researchers have developed a specific computer-based training program that combines specific stepping exercises with motivating gaming elements. The aim of this study is to determine whether this game-based exercise program is effective for improving stepping function in independently living older adults with moderate functional limitations.

Who can participate?

Community-dwelling adults over 60 years of age able to walk independently with or without a walking aid

What does the study involve?

Participants are randomly allocated to one of two groups (intervention group or control group). Both groups engage in weekly balance and strength exercises. During a ten-week period, individuals in the intervention group weekly receive exergame training aiming to improve stepping function. All participants complete an exergame assessment at the beginning of the study, at the end of the training period and ten weeks after the end of the training period.

What are the possible benefits and risks of participating?

Participants may benefit from improved dynamic postural control. Participating in the study is not associated with any specific risks.

Where is the study run from?

AGAPLESION Bethanien Hospital / Geriatric Centre of Heidelberg University (Germany)

When is the study starting and how long is it expected to run for?

March 2015 to January 2016

Who is funding the study?

AGAPLESION Bethanien Hospital / Geriatric Centre of Heidelberg University (Germany)

Who is the main contact?
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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
Nil known

Study information

Scientific Title
Effects of a motor-cognitive stepping exergame training in older adults: a randomized controlled trial

Study objectives
1. 10-week individual supervised exergame training improves dynamic postural control as assessed by specific internal exergame outcome parameters.
2. Effects of training on dynamic postural control as assessed by the specific exergame outcome parameters are sustained after the end of the intervention at 10-week follow-up.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 26/05/2015, Ethics Committee I of the Medical Faculty of Heidelberg University (Alte Glockengießerei 11/1, 69115 Heidelberg, Germany, Tel: +49 (0)6221 562646-0; Email: ethikkommission-I@med.uni-heidelberg.de), ref: S-242/2015

Study design

Single-center randomized controlled intervention trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

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

Geriatric related conditions

Interventions

Eligible participants are randomly assigned to the intervention or control group. Both groups engage in weekly strength and balance exercises. In the course of the trial individuals in the intervention group additionally receive a 10-session individual supervised exergame training with one session of 20 minutes per week.

The exergame intervention addresses the complex motor-cognitive demands of stepping. The exergame is performed on an interactive training device (Impact Dance Platform, Positive Gaming BV, BZ Haarlem, Netherlands) – a pressure sensitive plate connected by a USB port to a desktop computer and a screen and running with a game software created by Dividat® (Dividat AG, Schindellegi, Switzerland). Participants' step position and timing information of the stepping moment are tracked by contact sensors located within four pressure sensitive areas, each area marked with an arrow corresponding to the direction of the step. To play the game, participants are standing on the central section of the platform, feet closely parallel. Steps are cued by the squares, randomly moving from the central position to one of the four static squares. When executing the indicated steps, participants have to meet the point in time when a moving square is superimposed on a static one. The game includes ten levels, each of one-minute duration, split into two sub-sessions. In sub-session one progressive difficulty is achieved by increasing task speed, as well as by step directions involved in the level. Sub-session two additionally includes a randomly-presented task targeting inhibitory control: Participants have to restrain reaction when instead of a moving square a triangle appeared, and to react also to moving triangles if static squares switched to triangles. Completion criterion for both sub-sessions is set at

minimum 50 percent of successfully executed actions within the level. If the criterion is met, the participant moves to the next level.

Intervention Type

Device

Phase

Not Applicable

Primary outcome measure

Internal game parameters (reaction time [msec], game scores [scores]) measured using tailored assessment strategy at baseline (T1), after the intervention period (T2) and at 10-weeks' follow-up (T3)

Secondary outcome measures

Intervention adherence measured as percent attended sessions

Overall study start date

05/03/2015

Completion date

18/01/2016

Eligibility**Key inclusion criteria**

1. Aged 60 years or older
2. Cognitively intact, Mini-Mental State Examination (MMSE) score ≥ 24
3. Ability to walk independently with or without walking aid
4. Written informed consent
5. Adequate language level

Participant type(s)

Healthy volunteer

Age group

Senior

Sex

Both

Target number of participants

54

Total final enrolment

58

Key exclusion criteria

Uncontrolled or terminal neurologic, cardiovascular, metabolic or psychiatric disorder

Date of first enrolment

01/06/2015

Date of final enrolment

30/06/2015

Locations

Countries of recruitment

Germany

Study participating centre

AGAPLESION Bethanien Hospital /Geriatric Centre at the Heidelberg University

Rohrbacher Straße 149

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Sponsor information

Organisation

AGAPLESION Bethanien Hospital / Geriatric Centre of Heidelberg University

Sponsor details

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/040z4nv21>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

AGAPLESION Bethanien Hospital / Geriatric Centre of Heidelberg University

Results and Publications

Publication and dissemination plan

Publication of study results is planned.

Intention to publish date

01/07/2019

Individual participant data (IPD) sharing plan

As the study was not publicly funded, open access of the data was not planned and was therefore also not included in the study protocol. Consequently, it was also not a part of the ethical vote. Independent from open public data access, all scientific data in the research department is continuously open for potential formal external study evaluation. At the participant level, individual feedback concerning training results was provided for each participant as a benefit for study participation.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/09/2020	07/10/2020	Yes	No