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The positive effects of combined brain and body training in older adults

Submission date	Recruitment status	[_] Prospectively registered
11/01/2022	No longer recruiting	[X] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
14/01/2022	Completed	[X] Results
Last Edited	Condition category	[_] Individual participant data
13/12/2022	Other	

Plain English summary of protocol

Background and study aims
Preserving attention ability is of great concern to older adults who are motivated to maintain their quality of life as they age. Both mind and body fitness interventions have been tested in studies to assess maintenance and enhancement of attention abilities in seniors, and combining these approaches is a compelling strategy to improve mind and body health in a time- and resource-effective manner.
With this perspective, we created a closed-loop, motion-capture video game (Body-Brain Trainer: BBT) that adapts a player's cognitive and physical demands in an integrated approach, thus creating a personalized and cohesive experience across both domains.
The aim of this study is to find out if BBT could improve measures of attention and physical fitness in older adults.

Who can participate?
Seniors over the age of 55 years from the San Francisco Bay Area with normal or corrected-to-normal vision, had no history of stroke, traumatic brain injury, or psychiatric illness, not taking psychotropic, hormonal, or cardiovascular medications, no physical or mental conditions that may interfere with their daily activities (e.g., migraine headaches, substance abuse, neuropathy, and play less than 2-hours of video games per month).

What does the study involve?
Participants are randomized to play a game called 'BBT' or 'MBT'. Participants are asked to participate in this study 3 days a week for 8-weeks, with each day consisting of 9, 3-minute sessions, with training occurring at UC San Francisco. A research assistant will monitor participation and provide support and feedback during the BBT training, with the MBT training taking place at home (5x/week for 30min/day for 6 weeks). Prior to and after the intervention, participants will have specific cognitive and physiological measurements assessed, with certain measures repeated 1 year after the intervention as well.

What are the possible benefits and risks of participating?
There are no direct benefits or risks associated with participating in this study.

Where is the study run from?
University of California, San Francisco (USA)

When is the study starting and how long is it expected to run for?
January 2017 to March 2020

Who is funding the study?
University of California San Francisco Neuroscape Center (USA)

Who is the main contact?
Joaquin A. Anguera, Joaquin.anguera@ucsf.edu

Contact information

Type(s)
Principal Investigator

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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
Integrated cognitive and physical fitness training enhances attention abilities in older adults

Acronym
BBT-OA

Study objectives
Here we sought to evaluate the primary hypothesis of whether Body-Brain Trainer (BBT) could improve measures of attention and physical fitness in older adults (OA) beyond that of an expectancy-matched, active placebo control group.

We also interrogated the following secondary questions: what is the neural mechanism underlying positive cognitive effects, do any observed cognitive improvements persist one year later without booster training sessions, does BBT result in older adults achieving comparable levels to young adults on our primary outcome measure, and does this intervention affect other measures of cognitive control (working memory).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/01/2016, University of California, San Francisco Human Research Protection Program Institutional Review Board (UCSF Office of the Committee on Human Research, Box 1288 490 Illinois Street, Floor 6, San Francisco, CA 94143, USA; +1 415-476-1814; irb@ucsf.edu), ref: 10-04957

Study design
Interventional double-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Healthy aging

Interventions
Body-Brain Trainer (BBT): BBT is comprised of three modules, with each targeting a different aspect of cognitive control: visual search tasks for attention (with increasing distraction), spatial span/multiple object tracking tasks for working memory, and a task-switching paradigm targeting goal management/cognitive flexibility abilities. There are also three different tasks with ascending difficulty within each module, such that advancing to the next level engages a fresh challenge while maintaining interest (for example, a change from a spatial span condition

to a multiple object tracking condition with working memory demands). Comparable to our previous work using cognitive measures alone, here we integrate real-time adaptivity for both the cognitive and physical aspects of the gameplay. For each cognitive task, difficulty scales on a trial-by-trial basis, with a correct trial performed within a thresholding-determined response window leading to shorter response window by 10msec, and an incorrect trial leading to a lengthening of the response window by 30msec (thus, a 1"up"/3"down" staircase). These cognitive adaptive algorithms are designed to assure participants remain at an ~80% rate of accuracy, a level that is not too easy nor too hard, so that it is enjoyable and engaging. For the physical training, difficulty is tied to the demands associated with the distance an individual must travel for a given response and the amount of time allocated to complete this response. These movement-related aspects are directly responsive to whether heart rate is below/within /above a predetermined heart rate window to ensure a moderately intense workout that does not impede the ability to perform the cognitive task. For example, if one is playing the game below their assigned heart rate range, the software will automatically increase the distance that the participant must move to respond with their hands/feet on each trial until their heart rate is within the specified range. Training sessions are linked, such that the next session begins at the level attained at the end of the previous session. Participants are provided two types of feedback: 1) real-time feedback – indicating whether the participant successfully detected or classified the target and 2) punctuated feedback – participants advance through a series of "levels" that are reported at the beginning and end of each run.

Mind-Body Trainer (MBT): To mitigate any potential placebo effects brought on by participant expectations, a suitable active control condition based on participant predictions of potential training-related gains was identified. Specifically, a set of three commercially available iOS apps that were matched to the BBT program in terms of expectation of improvement on our cognitive outcome measures. Those apps were a language learning app (Duolingo; www.duolingo.com), a Tai Chi app (Tai Chi Step by Step; www.imoblife.net), and a logic games app (100 Logic Games; www.andreasabbatini.com/LogicGames.aspx).
For Duolingo, participants were given a choice of which language they wanted to learn from those available on the app. Within the app, a 10 min training time per day was set. During training, the app takes users through a series of modules that increase in difficulty and are only unlocked sequentially following completion of an earlier module. Modules are organized topically (e.g., Food, Animals, Phrases, etc.) and each module contains listening, speaking, vocabulary, and translation tasks and culminates with a topic quiz. At the end of each lesson the app provides a progress report showing learning "streaks" and the accumulation of "lingots" (Duolingo currency). These feedback features are meant to keep participants motivated.
For Tai Chi, users simply open the app and select from a series of modules that provide detailed and easy-to-follow instructions on how to perform many basic, intermediate, and advanced Tai Chi movements and is geared toward beginners with no Tai Chi experience. Each description can be read or listened to and is accompanied by an animation. Users were instructed to then practice the exercise themselves several times after each lesson. The logic games app is comprised of a series of "puzzle sets" that revolve around a particular theme and which get progressively more difficult as people advance. The puzzles are similar to the more well-known Sudoku puzzles, but provide a more engaging experience with colorful icons, unique rule sets for each theme, and increasing difficulty. For each puzzle, users are given a task (e.g., plant trees according to specific rules), a time limit, and several hints that they can unlock.

Participants are randomized to 'BBT' or 'MBT'. Randomization was performed using Microsoft EXCEL using the randomization function, using block size of 5.
Participants are asked to participate in this study 3 days a week for 8-weeks, with each day consisting of 9, 3-minute sessions, with training occurring at UC San Francisco. A research assistant will monitor participation and provide support and feedback during the BBT training,

with the MBT training taking place at home (5x/week for 30min/day for 6 weeks). Prior to and after the intervention, participants will have specific cognitive and physiological measurements assessed, with certain measures repeated 1 year after the intervention as well.

For Duolingo, the time was set internally in the app. For the other two apps, participants self-timed their training, and they recorded their time on a training log. All participants completed the MBT intervention at home using an iPad Mini 2 (iOS version 8.2; Apple) that was supplied by the UCSF Neuroscape Center. On the day they were given their iPad to begin training, participants were also provided an instructional binder with instructions on how to play, a calendar for recording notes and comments throughout their training experience, and were given e-mail support throughout the intervention period.

Intervention Type
Behavioural

Primary outcome measure
An objective behavioral measure of attention via a custom continuous performance task (CPT), comparable to the Test of Variables of Attention (TOVA), to assess vigilance without distraction (baseline, post-training and 1-year later).

Secondary outcome measures
1. Delayed recognition working memory paradigm designed to measure changes in participants' ability to maintain an accurate mental representation of items in working memory either in presence or absence of distracting or interfering information (baseline, post-training and 1-year later).

Exploratory outcome measures:
1. An objective neural measure of attention via a custom Filter Task designed to assess how well participants were able to identify targets in the presence of task-irrelevant information (baseline, post-training and 1-year later).
2. An objective measure of attention recording electroencephalography (EEG) during the CPT (baseline, post-training and 1-year later).
3. An objective measure of attention recording electroencephalography (EEG) during the Filter Task (baseline, post-training and 1-year later).
4. A physiological measure of fitness and health = Diastolic Blood Pressure (baseline, post-training).
5. A senior-specific measure of stability indicative of fall risk called the Limit of Stability Assessment (baseline, post-training).

Overall study start date
12/01/2016

Completion date
01/03/2020

Eligibility

Key inclusion criteria
All participants:
1. Had normal or corrected-to-normal vision,
2. Had no history of stroke, traumatic brain injury, or psychiatric illness,

3. Were not taking psychotropic, hormonal, or cardiovascular medications,
4. Did not have any physical or mental conditions that may interfere with their daily activities (e.g., migraine headaches, substance abuse, neuropathy.
5. Reported playing less than 2-hours of video games per month.
6. Were 55 years or older

Participant type(s)
Healthy volunteer

Age group
Senior

Sex
Both

Target number of participants
60

Total final enrolment
49

Key exclusion criteria
Did not meet the inclusion criteria with respect to age and listed health requirements for participation

Date of first enrolment
01/01/2017

Date of final enrolment
03/02/2019

Locations

Countries of recruitment
United States of America

Study participating centre
UC San Francisco - Neuroscape
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University/education

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ROR
https://ror.org/043mz5j54

Funder(s)

Funder type
Research council

Funder Name
Neuroscape Alliance

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/06/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request (Joaquin.Anguera@ucsf.edu).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		14/05/2014	13/01/2022	No	Yes
Protocol (preprint)		17/12/2021	13/01/2022	No	No
Results article		30/08/2022	13/12/2022	Yes	No