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GRADYS – computer simulation software with virtual reality elements for enhancement of cognitive functions in the elderly with healthy aging and with dementia diseases

Submission date
29/08/2019

Recruitment status
No longer recruiting

Registration date
10/09/2019

Overall study status
Completed

Last Edited
07/11/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Dementia is a syndrome (a group of related symptoms) associated with an ongoing decline of brain functioning. The aim of the study was to evaluate the effectiveness of VR-based cognitive training for older adults and to compare this effectiveness among older adults without cognitive impairment and with mild dementia.

Who can participate?
Adults aged 60 years or older with no cognitive impairment or with mild dementia.

What does the study involve?
Cognitive training with the use of GRADYS software – a computer game with elements of VR was used. It consists of eight sessions and lasts four weeks. The training program is preceded and followed by a cognitive assessment of processes corresponding to the modules of the game which aim to improve:
1. Attention
2. Memory
3. Language
4. Visuospatial processing.

What are the possible benefits and risks of participating?
Participation in the study is associated with possible benefits in cognitive functioning resulting from the training. All subjects were also diagnosed with their current cognitive status, including dementia screening tests. No financial benefits were provided for the participants.
The only inconvenience arising from participation in the study could have been the cybersickness - unwanted experiences associated with the use of VR headset (information leaflet in the attachment to the informed consent for participants, please find it attached). Participants experiencing serious cybersickness were excluded from further training.

Where is the study run from?
Kazimierz Wielki University Institute of Psychology, Poland

When is the study starting and how long is it expected to run for?
December 2015 to August 2016

Who is funding the study?
The National Centre for Research and Development, Poland

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
IS-1/004/NCBR/2014

Study information

Scientific Title
GRADYS – computer simulation software with virtual reality elements for enhancement of cognitive functions in the elderly with healthy aging and with dementia diseases

Acronym
GRADYS

Study objectives
1. Training using GRADYS game will result in an improvement in performance and reaching higher levels of the game difficulty in training modules.
2. The effect of the training will result in an improvement in the performance of standard cognitive measures.
3. Belonging to the group of non-demented and mildly demented older adults will differentiate the participants in terms of cognitive performance in pretest and in terms of training effects. The cognitive performance in pretest will be better in non-demented older adults. Training effects in both groups will be significant and positive, but in the group of non-demented older adults they will be greater.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/04/2016, Bioethics Committee of the Nicolaus Copernicus University in Toruń functioning at Collegium Medicum in Bydgoszcz (Komisja Bioetyczna Uniwersytetu Mikołaja Kopernika w Toruniu przy Collegium Medicum im. Ludwika Rydygiera w Bydgoszczy, ul. M. Curie Skłodowskiej 9, 85-094 Bydgoszcz; +48 52 585-35-63; komisja.bioetyczna@cm.umk.pl), ref: 320 /2016

Study design
Non randomised interventional pretest-posttest study design

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mild dementia

Interventions
There were two groups: non-demented and mildly demented older adults. Participants with mild dementia were recruited from patients of a geriatric clinic, from patients of a healthcare facility of the "Nowa Wspolna Droga" Association in Gniezno and through advertisement. Participants without cognitive impairment were recruited through advertisement.

VR-based cognitive training with the use of GRADYS game. The game contains 4 modules:
1. Attention
2. Memory
3. Language
4. Visuospatial processing

The training lasted 4 weeks, it comprised 8 individual training sessions, two per week. A single session lasted 45 minutes to one hour.

There are separate game scripts for four different cognitive domains: attention, memory, language, visuospatial processing. Each cognitive domain has its own gameplay, composed of several tasks involving the same cognitive function and forming a coherent storyline inspired by everyday life.

Attention: The tasks of the attention module were designed to activate selective and focused attention, sustained attention (vigilance), divided and alternating attention, and executive attention.
Example: On their way to the shop the player needs to cross the street, tramway tracks and a bike lane. To get to the other side of the street the player needs to mind the current traffic lights and the traffic on the road. When the difficulty level rises, the situation in the street gets more complicated and the number of elements that need to be taken into consideration when making the decision about crossing the street increases.

Memory: The tasks designed to stimulate memory functions concern short-term memory, long-term memory, and prospective memory.
Example: The player goes to the kitchen to prepare the salad. The recipe is displayed in the centre of the visual field for as long as the player needs to memorize all the ingredients. The number of the ingredients to memorize rises with the difficulty level of the game. To prepare the salad the player has to select the ingredients visible on the table. Once the salad is ready, the next task is to call a friend and give them the recipe.

Language: The tasks stimulating language functions are based on spoken and written text processing. To achieve this, one needs to activate phonological, spelling, semantic, and syntactic knowledge.
Example: The first task is to use an ATM machine. The player has to withdraw money and top up his phone account. To achieve this, they need to follow the instructions displayed on the ATM screen. The more difficult the game, the more complex the instructions provided to the player, and the more options to choose from on the screen.

Visuospatial processing:
The visuospatial modules in the game rely on visuospatial analysis, mental rotation, and visual search.
Example: The player needs to glue broken dish pieces together. On the desk, the player can see all parts that need to be glued together. Additionally, in the centre, the player can see in a different colour the piece that should be picked from the available ones and glued as the next one. To select the right piece the player has to mentally rotate it as the pieces on the desk are placed in a different position than the part being displayed in the centre. The complexity of the dish and hence the number of parts to glue together rise with the difficulty level.

Intervention Type
Behavioural

Primary outcome(s)
Cognitive abilities measured at baseline and at 8-weeks
1. Attention measured using: Digit Symbol from WAIS – R (PL); Colour trial test (CTT) – Adult version, d2 Test of Attention (indices: WZ – speed of processing, %B – percentage of errors, WZ-B – error-corrected speed of processing, ZK – ability to concentrate);
2. Memory measured using: Digit Span from WAIS – R (PL), Benton Visual Retention Test (BVRT), Rey Auditory Verbal Learning Test (AVLT), Famous Faces Test, Rey-Osterrieth complex figure test (ROCF) – delayed reproduction;

3. Language measured using: Verbal Fluency from ACE – III; Boston Naming Test (BNT);
4. Visuospatial processing measured using: Block Design from WAIS – R (PL), Rey-Osterrieth complex figure test (ROCF) – direct copying.

Key secondary outcome(s))
None

Completion date
30/09/2016

Eligibility

Key inclusion criteria
1. Polish citizens for whom Polish was a native language
2. 60 years or older
3. Cognitively healthy older adults: Mini-Mental State Examination score of 27-30
4. Older adults with mild dementia: Mini-Mental State Examination score of 19-23

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
99

Key exclusion criteria
1. Mental disorders
2. Serious somatic illnesses
3. Auditory and motor impairments preventing the use of the game peripherals
4. Taking medication disrupting cognitive functioning
5. Cybersickness

Date of first enrolment
01/12/2015

Date of final enrolment
01/08/2016

Locations

Countries of recruitment
Poland

Study participating centre
Kazimierz Wielki University
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Bydgoszcz
Poland
85-064

Study participating centre
Nicolaus Copernicus University in Toruń Ludwik Rydygier Collegium Medicum in Bydgoszcz
Jagiellońska 13-15
Bydgoszcz
Poland
85-067

Study participating centre
„Nowa Wspolna Droga" Association
Grudzińskiego 18A/8
Swarzędz
Poland
62-020

Study participating centre
Wyższa Szkoła Technologii Informatycznych w Warszawie (ang. The University of Information Technology in Warsaw)
Okopowa 59
Warszawa
Poland
01-043

Sponsor information

Organisation
The National Centre for Research and Development, Poland

ROR
https://ror.org/05pwfyy15

Funder(s)

Funder type
Government

Funder Name
Narodowe Centrum Badań i Rozwoju

Alternative Name(s)
National Centre for Research and Development, The National Centre for Research and Development, Polish National Center for Research and Development, National Center for Research & Development, NCBR, NCBiR, NCRD

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Poland

Results and Publications

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: Ludmiła Zając-Lamparska (lzajac@ukw.edu.pl); Paweł Izdebski (pawel@ukw.edu.pl) and Monika Wiłkość-Dębczyńska (monikawilkosc@gmail.com) in two weeks after request via e-mail. They will be available for scientist and for use in meta-analyses and / or systematic reviews. The raw data and/ or descriptive statistics will be provided without personal data of study participants (only anonymous data or aggregated data). This is consistent with the informed consent was obtained from all individual participants included in the study (all subjects gave written informed consent in accordance with the Declaration of Helsinki; if the participants with mild dementia had a legal guardian, the legal guardian gave written informed consent in accordance with the Declaration of Helsinki).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/10/2017	30/08/2019	Yes	No
Results article	results	01/01/2017	30/08/2019	Yes	No
Results article	results	27/11/2019	02/12/2019	Yes	No

Study website	Study website	11/11/2025	11/11/2025	No	Yes