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Computerized cognitive training and whole-body cryotherapy and health-related psychological factors in seniors

Submission date
31/03/2021

Recruitment status
No longer recruiting

Registration date
06/09/2022

Overall study status
Completed

Last Edited
06/09/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Computerized cognitive training (CCT) and whole-body cryotherapy (WBC) are non-drug interventions aimed at improving cognitive performance and also non-specific psychological factors which may have an impact on healthy behaviours. The aim of this study is to evaluate the effect of CCT and WBC on health-related psychological factors in seniors.

Who can participate?
Community-dwelling seniors aged 65 and over with normal or mildly impaired cognition recruited from community centers supporting education (i.e., library, computer labs, discussion clubs)

What does the study involve?
Participants are allocated to CCT, CCT and WBC, or to standard stimulation.
Computerized cognitive training (CCT) includes nine sessions, each lasting 90 minutes. Each session is supervised by a certified trainer in accordance with the instructions. Attendance is checked for each session. Each session is supervised and monitored by an independent researcher to ensure that the course of the session is in accordance with the protocol. Each session is attended by small groups of 10 to 15 people. The program utilized for CCT is Mind Academy® from Formsoft® (Wroclaw, Poland), educational software created to improve the mental capacity of the elderly. The training program is created under the guidance of psychologists and recommended by lecturers of psychology at SWPS in Wroclaw as well as by clinical psychologist practitioners. It has been disseminated among institutions that used psychoeducational programs, for individual recipients and care homes for elderly people. The level of the cognitive exercises is adapted to the current level of participants' cognitive function and includes cognitive functions tasks such as immediate and delayed memory, attention, processing speed, reaction time, visuospatial skills, and flexibility.
Participants in the CCT and WBC group undergo 10 WBC sessions in 2 weeks (Monday-Friday, excluding weekends). Sessions consist of short exposures (2-3 minutes) to extremely low temperatures (-110°C to -130°C). A liquid nitrogen-cooled cryotherapy chamber is used. The intervention is under the supervision and care of professional staff, and each participant is

examined by a physician who measures their blood pressure before each WBC session. Five to six participants undergo WBC at the same time, and they are required to wear minimal clothing.

What are the possible benefits and risks of participating?
CCT is a method of improving cognitive performance which may have a non-specific effect on psychological variables (cognitive, emotional and behavioral aspects), leading to changes in strategies of coping with cognitive deficits. The results of the study may enable the introduction of the interventions into treatment.
The interventions could improve the psychological disposition of the participants, i.e. optimism-pessimism, life satisfaction, self-esteem, mood and quality of life, as well as cognitive performance. No adverse health effects are expected.

Where is the study run from?
Wroclaw Medical University (Poland)

When is the study starting and how long is it expected to run for?
December 2017 to May 2019

Who is funding the study?
Investigator initiated and funded

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
Trial ID: 1

Study information

Scientific Title
Synergetic effects of computerized cognitive training and whole-body cryotherapy – a controlled pre-post study

Acronym
CCTWBTPF

Study objectives
In the group of senior volunteers participating in computerized cognitive training (CCT), the researchers want to assess the psychological variables that have a potential impact on their pro-health behavior, and also observe whether the addition of whole-body cryotherapy (WBC) to computerized cognitive training (CCT) will affect these variables.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/12/2017, Bioethical Commission of the Wroclaw Medical University (50-367 Wrocław, ul. Pasteura 1, Poland; +48 (0)71 784 10 14, +48 (0)48 71 784 17 10; bioetyka@umed.wroc.pl), ref: KB-780/2017

Study design
Prospective pre/post controlled single-blind parallel-group study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Prevention of dementia in older adults (aged 65+ years)

Interventions
A prospective, pre/post controlled, single-blind trial, parallel-group study is conducted. The study is not randomized due to the fact that the participants voluntarily agree to participate in one of the two groups or the control group (active group) with standard stimulation. Participants are assigned to groups taking into account their decision, physical condition, and possible medical contraindications to WBC, i.e., with CCT (n = 32). Participants who don't meet the standard contraindications to WBC and are willing to participate in it are assigned to the CCT and WBC group (n = 33), and other people are enrolled into the control group (CG, n = 25).

Computerized cognitive training (CCT) (Mind Academy® from Formsoft®, Wroclaw, Poland) program is an educational software created to improve the mental capacity of the elderly. The training program was created under the guidance of psychologists and recommended by lecturers of psychology at SWPS in Wroclaw and clinical psychologist practitioners. It is disseminated in institutions that use psychoeducational programs, for individual recipients and care homes for elderly people.

The level of the cognitive exercises is adapted to the current level of participants' cognitive function and include tasks of cognitive functions as immediate and delayed memory, attention, processing speed, reaction time, visuospatial skills, and flexibility. The sessions are conducted according to a specific schedule and include the following modules:
1. Discussion of homework, carried out together in a group
2. Theoretical part in the form of transferring knowledge about the functioning of the brain, specific cognitive functions and learning strategies
3. Own work with a computer using tasks that stimulate cognitive functions
discussion of group tasks and common tasks performed in small groups or in the whole group tasks (stimulating cognitive and interpersonal functions)
4. Discussion of planned homework
5. Summary of the training session
Additionally, the participants did home assignments (twice a week, 90 minutes each) to motivate them to independent precognitive activity and enhance transferring of the acquired skills from training to everyday life.

The cognitive training includes nine sessions, each lasting 90 minutes. Each session is supervised by a certified trainer in accordance with the instructions. Attendance is checked at each session. Each session is supervised and monitored by an independent researcher to ensure that the course of the session is in accordance with the protocol. Each session is attended by small groups of 10 to 15 people and takes place in the Lower Silesian Public Library in Wroclaw. CCT is a cognitive method of improving cognitive performance which may have a non-specific effect on psychological variables that create specific attitudes (cognitive, emotional and behavioral aspects), leading to changes in strategies of coping with cognitive deficits.

Whole-Body Cryotherapy (WBC)
The participants undergo 10 WBC sessions in 2 weeks (Monday-Friday, without the weekends); the sessions consisted of short, cyclic exposures (2-3 minutes) to extremely low temperatures (-110°C to -130°C). A liquid nitrogen-cooled cryotherapy chamber (CR 2002) is used. The intervention is under the supervision and care of professional staff, and each participant is examined by a physician who measures their blood pressure before each WBC session. Each WBC takes place in the medical company Creator Sp. z o.o. in Wrocław. Five to six participants would

undergo WBC at the same time, and they are required to wear minimal clothing (shorts and a t-shirt), gloves, a headband (or a beanie) as well as a mask covering the mouth and nose, knee-high socks and dry shoes (e.g. wooden).

Intervention Type
Mixed

Primary outcome measure
1. Level of dispositional optimism, defined as generalized expectations of positive events measured using the Revised Life Orientation Test (LOT-R) at T1: before intervention (CCT) or (CCT+WBC), T2: 9 weeks (immediately after intervention)
2. Level of sense of self-efficacy, defined as successful coping, adaptation to stressful events in life measured using the General Self-Efficacy Scale – Schwarzer (GSES) at T1: before intervention (CCT) or (CCT+WBC), T2: 9 weeks (immediately after intervention)
3. Level of cognitive judgments of life satisfaction, defined as subjective well-being and satisfactory quality of life measured with the Satisfaction With Life Scale (SWLS) at T1: before intervention (CCT) or (CCT+WBC), T2: 9 weeks (immediately after intervention)
4. Mood and degree of depressive symptoms measured using Geriatric Depression Scale (GDS-30) at T1: before intervention (CCT) or (CCT+WBC), T2: 9 weeks (immediately after intervention)

Secondary outcome measures
Cognitive status assessed using Montreal Cognitive Assessment (MoCA) test at T1: before intervention (CCT) or (CCT+WBC), T2: 9 weeks (immediately after intervention)

Overall study start date
29/12/2017

Completion date
23/05/2019

Eligibility

Key inclusion criteria
1. Written informed consent
2. Age ≥65 years
3. Cognitively healthy volunteers and with mild cognitive impairment (MCI) (scores in the Montreal Cognitive Assessment Scale (MoCa), score range: 0-30, cut-off points for norm: >26, 26-30 for MCI)
4. Basic computer knowledge

Participant type(s)
Healthy volunteer

Age group
Senior

Sex
Both

Target number of participants

111

Total final enrolment
95

Key exclusion criteria
1. Inability to understand questions and written information (presence of any type of severe visual, hearing or motor deficits)
2. Any psychiatric or neurological diagnosis (alcohol and drug abuse, psychosis, suicidal thoughts)
3. Standard contraindications to WBC

Date of first enrolment
01/08/2018

Date of final enrolment
30/12/2018

Locations

Countries of recruitment
Poland

Study participating centre
Lower Silesian Public Library
Rynek 58
Wroclaw
Poland
50-116

Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/01qpw1b93

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
30/05/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other