ISRCTN14524472 https://doi.org/10.1186/ISRCTN14524472

The effect of psychological interventions on mental function in the elderly

Submission date 08/08/2020	**Recruitment status** No longer recruiting	[ ] Prospectively registered
		[ ] Protocol
Registration date 12/08/2020	**Overall study status** Completed	[ ] Statistical analysis plan
		[ ] Results
Last Edited 12/08/2020	**Condition category** Mental and Behavioural Disorders	[ ] Individual participant data
		[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The world population is ageing and one of the consequences of ageing is cognitive decline (decreases in memory, attentional ability, processing speed, problem solving and planning). A decrease in these cognitive abilities can lead to poorer quality of life in elderly, losing social connections, struggling in day to day life challenges and etc. To address these issues many interventions in recent years are presented both for public use and use in professional settings. We are planning to compare three interventions in this study and see which one has the best effect on the cognition of the elderly and has the most lasting effect. The interventions that we are going to investigate are Loving Kindness Mediation (LKM; a type of mindfulness), Computerized Cognitive Training (CCT; also known as brain fitness) and Multiple Exemplar Training (MET; based on Relational Frame Theory, which is a theory to explain how human language and thought process works).

Who can participate?
Retired elderly aged between 65 and 75 years.

What does the study involve?
Participants must pass the screening The Addenbrooke's Cognitive Examination-III (ACE-III). Participants are randomly allocated to four groups. Three of them are experimental groups (LKM, CCT and MET) and one control group with no treatment. They will be tested for cognitive baseline. The CCT and MET experimental groups will be given a specific software for training which they can use in the home and the LKM group training given a script and audio file of Loving-kindness meditation that they must practice at home. After 8 weeks of training, the participants are asked to be tested for cognitive changes as the post-test. They will be tested after another six months for follow up results to check if there is any changes from post-test cognitive results.

What are the possible benefits and risks of participating?
All the participants in experimental groups will benefit from training and once the experiment is done the control group and the experimental group will receive the most effective intervention. and there are no side effects or risk reported for the interventions of this study.

Where is the study run from?
Kharazmi University of Tehran (Iran)

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

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Amir Etemadi
Etemadi.a.sh@gmail.com

Contact information

Type(s)
Scientific

Contact name
Mr Amir Etemadi Shams Abadi

ORCID ID
https://orcid.org/0000-0001-6143-9680

Contact details
Dept of clinical psychology
Faculty of Psychology
Kharazmi University of Tehran
Tehran
Iran
1418664114
+98 (21) 88329220-3
etemadi.a.sh@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2603869

Study information

Scientific Title

Comparing the efficacy of multiple exemplar training, cognitive training & loving-kindness meditation on enhancing the executive functions and psychological wellbeing of elderly

Acronym
MET LKM CCT elderly

Study objectives
As the world's population ages, the number of people suffering from cognitive decline and dementia is increasing. One of the most important consequences of aging is cognitive decline. This growing age group emphasizes the need for fast, effective, and low-cost solutions to reduce age-related cognitive decline. in this study we aim to compare the three interventions on elderly groups and compare the results both after the treatment and after six month as follow up study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/01/2020, Kharazmi University Research Ethics Committee (Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran; +98-21-81455618; ethics@behdasht.gov.ir), ref: IR.KHU.REC.1398.043

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Quality of life

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
Cognitive decline

Interventions
There will be three intervention groups and one control group.

CCT: One of the tools to address cognitive decline is cognitive training. This intervention typically relies on activating and stimulating brain neural circuits. Neuroplasticity is achieved during repetitive exercises that allow participants to perform cognitive operations that are

slightly above their current ability threshold. Numerous studies support its use in age-related cognitive decline. the computerized version of cognitive training will be used, The CCT protocol will be provided to the subjects as interactive software and will be presented in 16 sessions over 2 months. In this software, a set of cognitive games is presented to the individual and the subject should practice them in each session for 30 - 45 minutes. these exercises are feedback based and the subject's answers and times are recorded.

LKM: the second intervention that we are planing to investigate is LKM. Mindfulness is defined as the awareness of the moment to moment and without judgment of what we are experiencing internally or externally. Among all the different types of meditation, the most studied meditations are focused-attention meditation (FAM), open-monitoring meditation (OMM), and loving-kindness meditation (LKM). Love-kindness-kindness meditation includes elements from both FAM and OMM meditation. Loving-Kindness is a form of meditation that involves benevolence, along with the repetition of the phrase such as: "I wish all beings to be happy" to cultivate a sense of selfless love. The LKM experimental group will be given complete information about mindfulness and how to do it, and there will be instructions for performing love-kindness-kindness meditation both in script and audio file. This type of meditation involves the repetition of a set of phrases that are addressed first to the individual, then to others and acquaintances, and finally to all human beings and beings. For example, when meditating on oneself, one repeats phrases such as, "I wish I was safe from all dangers, I wish I was happy and at peace, and I wish I was free from suffering." This set of phrases is done in a 20-minute session consisting of the following sections: 4 minutes of self-directed phrases, phrases for a friend for about 5 minutes, for a family member for 5 minutes, and finally for all humans and living things for 6 minutes.

MET: Another intervention that will be investigated in this research is Multiple Exemplar Training (MET). Multiple exemplar training (MET) is the process of teaching specific behavioral responses by exposing the organism to different stimuli in different contexts to control stimulus responses and modify behavior. In addition to shaping day to day events, the MET protocol has also found useful in shaping communication skills. MET is based on relational frame theory (RFT). The MET protocol is interactive software that is designed in 16 stages and five levels and the subject is asked to practice in 16 sessions of 30 - 45 minutes for eight weeks. After registering in the software and entering the required information, the individual enters the page where the stages are located. At the beginning of each stage, instructions are shown to the individual according to which he should perform the exercises of that stage.

Control group: no treatment (waiting list) unique ID will be assigned to each participant and using the PASS software, subjects will be randomly assigned to three experimental and one control groups.

Intervention Type
Mixed

Primary outcome measure
1. Attention is measured using Stroop test at baseline, 2 months and 8 month
2. Problem solving is measured using Tower of Hanoi at baseline, 2 months and 8 month
3. Working memory is measured using The digit span backward test, 2 months and 8 month
4. Processing speed is measured using Digit symbol substitution test, 2 months and 8 month
5. Cognitive flexibility is measured using Trail Making Test, 2 months and 8 month

Secondary outcome measures

Psychological well-being measured using Ryff Scales of Psychological Well-Being at month 8

Overall study start date
04/07/2017

Completion date
04/02/2020

Eligibility

Key inclusion criteria
1. Age 65 - 75 years
2. Living in Tehran
3. Having at least a high school degree
4. Vital

Participant type(s)
Healthy volunteer

Age group
Senior

Sex
Both

Target number of participants
100 (25 in each group)

Key exclusion criteria
1. Using drugs or other cognitive enhancement meth
2. Suffering from psychological disorders
3. Cognitive impairment
4. Serious health condition
5. Alcohol and drug abuse

Date of first enrolment
20/05/2019

Date of final enrolment
04/02/2020

Locations

Countries of recruitment
Iran

Study participating centre

Tehran University
North Kargar st.
Tehran
Iran
1418664114

Sponsor information

Organisation
Kharazmi University

Sponsor details
Tehran
Tehran
Iran
1418664114
+98 (21) 88329220-3
international@khu.ac.ir

Sponsor type
University/education

Website
http://khu.ac.ir/portal/faces/public/portal

ROR
https://ror.org/05hsgex59

Funder(s)

Funder type
University/education

Funder Name
Kharazmi University

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Iran

Results and Publications

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

Intention to publish date
30/11/2020

Individual participant data (IPD) sharing plan
The datasets gathered and analysed during the current study will be stored in a publicly available repository (www.osf.io, SPSS data will be shared in this domain after publishing the article. the data will be available for every researcher for research purposes. the data are anonymous and there's no mention to personal data of the participants.

IPD sharing plan summary
Available on request