Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Nov 2026

The impact of computer-based cognitive training intervention on the quality of life among elderly people: A randomized clinical trial

Protocol summary

Study aim

The aim of this study is to determine the efficacy of computer-based cognitive training intervention on the quality of life of more than 60 year old community-dwelling elderly in Tehran by controlling the effects of probable variables affecting relationship between cognitive functions and quality of life.

Design

The Parallel Group Stratified Randomized Clinical Trial of 52 participants, with blinded analyzer of data enrolled between June 5st to July 21th 2017 and followed for 3 months.

Settings and conduct

The subjects were 60-year-old and above people who were selected from three health centers in west of Tehran. Participants were assigned to two groups by health center's secretary , 26 in the intervention and 26 in the control group.The intervention group attended 12 sessions of a cognitive intervention schedule twice a week. The 45 minute sessions implemented the attentive rehabilitation of attention and the memory (ARAM) software application. the person who analyzed data was blinded.

Participants/Inclusion and exclusion criteria

The elderly which obtain the Mini Mental State score of 22 and higher and have no self-report history of psychological or neurodegenerative diseases was entered into the intervention.

Intervention groups

The intervention group attended 12 sessions of a cognitive intervention schedule twice a week. The 45 minute sessions implemented the attentive rehabilitation of attention and the memory (ARAM) software application. ARAM is a part of Neurocognitive Joyful Attentive Training Intervention that has been designed as a tool for cognitive rehabilitation.The participants who assigned to the control group were participated in educational workshops about age related cognitive changes and cognitive disorders.

Main outcome variables

Primary outcome of the study was Quality of Life which assessed before and three months after the intervention.

General information

Reason for update

Entering final results of study and explaining changes which was happen during the study

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122731602N1**
Registration date: **2017-06-21, 1396/03/31**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-03, 1398/09/12**
Update count: **1**

Registration date

2017-06-21, 1396/03/31

Registrant information

Name
Leila Kazazi
Name of organization / entity
University of Social Welfare and Rehabilitation Sciences
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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-06-05, 1396/03/15

Expected recruitment end date
2017-07-21, 1396/04/30
Actual recruitment start date
2017-06-05, 1396/03/15
Actual recruitment end date
2017-07-21, 1396/04/30
Trial completion date
2017-10-21, 1396/07/29

Scientific title
The impact of computer-based cognitive training intervention on the quality of life among elderly people: A randomized clinical trial

Public title
The efficacy of cognitive training intervention on the quality of life of older people
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Eligible participants were older adults aged 60 years and above. Eligible participants were elderly who were able to communicate in Persian Older adults required at least four years of education to respond the items on the Mini Mental State Examination (MMSE) test. Eligible participants achieved a MMSE score ˃21 and a clock drawing test score ≥ 4.
Exclusion criteria:
The diagnoses of a disease which could lead to extreme cognitive or functional decline, such as a stroke in the previous 12 months or end stage cancer Individuals with dementia and Parkinson disease Individuals with uncorrected visual or auditory impairment. Individuals with subjective complaints of memory impairment
Age
From **60 years** old to **100 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **52**
Actual sample size reached: **51**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants were assigned to two groups using Balance blocked randomization, 26 in the intervention and 26 in the control group. Educational level and depression were considered as two potential confounding variables by considering existing evidence .Thus, a stratified randomized design was implemented to control the potentially confounding effect of these two binaries. Four randomizing sequences were used (the combination of depression and low educational level, depression and high educational level, high educational level without depression and low educational level without depression) and the participants were divided in either the intervention or control group based on this different strata. Finally pulled data was analyzed.
Blinding (investigator's opinion)
Single blinded
Blinding description
According to the nature of the intervention, the participants could not be blinded in the process of intervention, so the person who analyzed data was blinded to the allocated into the intervention or control groups.
Placebo
Not used
Assignment
Parallel
Other design features
In this study, the stratified design randomization will be used. Considering of depression(y/n) and educational status(diploma/academic education) as a dual- state variables, we will design 4 different randomization tables and samples will allocated into intervention and control group based on these variables. Finally data of this tables will be pooling, so we could control the effect of confounder variables.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of University of Social Welfare and Rehabilitation Sciences
Street address
Koodakyar de, Daneshjou Blvd, Evin
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Province
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Postal code
1985713834
Approval date
2016-08-10, 1395/05/20
Ethics committee reference number
IR.USWR.REC.1395.88

Health conditions studied

1

Description of health condition studied
Age-related cognitive decline
ICD-10 code
R41.8
ICD-10 code description
Other and unspecified symptoms and signs involving cognitive functions and awareness

Primary outcomes

1

Description
Quality of life
Timepoint
Before intervention and immediately after intervention and 3 months later
Method of measurement
Quality of life questionnaire (SF- 36)

Secondary outcomes

1

Description
cognitive function
Timepoint
June 5st to July 21th 2017
Method of measurement
It was measured basically by the Iranian version of MMSE . The specific domain of the cognitive function was assessed by Wisconsin card sorting test, the Stroop test, the N back test and the go/no-go test

Intervention groups

1

Description
Intervention group: In Intervention group, after an evaluation session by assessing with cognitive function and quality of life instruments, participants are trained by ARAM app through 10 45-minute sessions, 2 times per week. Then they will be reassessed in the 12th session. Attentive rehabilitation of attention and memory (ARAM) is a software application that is a part of Neurocognitive Attentive Training Intervention as cognitive rehabilitation intervention. These tasks have different kinds of task in which the level of difficulty are graded and increased based on responses. Grading is based on the number of flanker stimuli, velocity of presented stimuli, number of goal stimuli and changing task rule.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Ekbatan health center
Full name of responsible person
Farzane Mohebi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of University of Social Welfare and Rehabilitation Sciences
Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice Chancellor for research of University of Social Welfare and Rehabilitation Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
University of Social Welfare and Rehabilitation Sciences

Full name of responsible person
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Position
PhD of Gerontology

Latest degree
Ph.D.

Other areas of specialty/work
Geriatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available