Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jun 2026

The effect of the cognitive stimulation program based on the Improvecog model on the cognitive functions of the elderly with chronic obstructive pulmonary disease

Protocol summary

Study aim

The aim of the present study is to examine the effectiveness of cognitive stimulation program based on the cognitive improvement model on information processing speed, visuospatial working memory, and cognitive failures among elderly individuals with chronic respiratory diseases.

Design

A randomized controlled clinical trial is being conducted on 25 patients, including a control group.

Settings and conduct

This study is carried out in Imam Reza (AS) clinic in Shiraz city. The experimental group will receive the model-based cognitive stimulation therapy program (ImproveCog) during 12 weeks (one 90-minute session per week). During this period, the control group does not receive any intervention.

Participants/Inclusion and exclusion criteria

The inclusion criteria for participating in the study include: Age: Elderly individuals aged 65 to 80 years, Diagnosis of chronic respiratory obstruction. The exclusion criteria for exiting the study are: Having a serious or chronic physical illness, having a psychological disorder, using psychiatric drugs, using any other type of psychological intervention at the same time as conducting the research.

Intervention groups

The experimental group consists of elderly individuals with chronic respiratory obstruction who receive a cognitive stimulation program based on the improvecog model in the current study. The control group also consists of elderly individuals with chronic respiratory obstruction, but they do not receive any intervention.

Main outcome variables

information processing speed; visuospatial working memory; cognitive failures

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230902059332N1**
Registration date: **2023-11-13, 1402/08/22**
Registration timing: **prospective**

Last update: **2023-11-13, 1402/08/22**
Update count: **0**

Registration date

2023-11-13, 1402/08/22

Registrant information

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Name of organization / entity
Shahid Bahonar University of Kerman
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-15, 1402/08/24

Expected recruitment end date

2024-01-08, 1402/10/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of the cognitive stimulation program based on the Improvecog model on the cognitive functions of the elderly with chronic obstructive pulmonary disease

Public title
The effect of cognitive stimulation program on the cognitive functions of the elderly with chronic obstructive pulmonary disease

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Being 65 to 80 years old Having a definitive diagnosis of chronic obstructive pulmonary disease by a lung specialist Literacy in reading and writing Adequate visual and auditory abilities to complete questionnaires, perform tasks, and cognitive exercises Adequate speech ability for communication Adequate motor ability (able to walk without assistance and perform personal tasks) Regular attendance capability for sessions

Exclusion criteria:
Having a severe or other chronic physical illness that prevents participation in the study Concurrent diagnosis of other respiratory diseases Shortness of breath during the study to the extent that the participant cannot complete the session Presence of a psychiatric disorder Use of psychiatric medications Use of any other psychological intervention during the study Withdrawal from the study and more than two absences from intervention sessions.

Age
From **65 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **25**

Randomization (investigator's opinion)
Randomized

Randomization description
Random assignment of the elderly will be done based on their educational status. The samples will be placed in two groups (intervention (use of cognitive stimulation program) and control group) using stratified random block method (in order to match the groups in terms of education level (sub-diploma, diploma, associate and bachelor) The method of allocating the samples to two groups is that by considering the four educational classes (sub-diploma, diploma, associate and bachelor), 4 classes are formed. Within each class, 4 random blocks are used to assign patients to Two groups A (intervention) and group B (control) will be used. For this purpose, a list of blocks will be written first and numbers will be assigned to them, and the order of these blocks will be randomly determined by Excell software.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Ethics Committee of Shahid Bahonar University of Kerman, Department of Psychology.

Street address
Imam Khomeini Highway, Pajoohesh Square, Shahid Bahonar University of Kerman.

City
Kerman

Postal code
7616913439

Approval date
2022-11-15, 1401/08/24

Ethics committee reference number
IR.KMU.REC.1402.265

Health conditions studied

1

Description of health condition studied
Chronic obstructive pulmonary disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Cognitive failures score in Broadbent questionnaire

Timepoint
Measuring cognitive failures before and after the study (pre-test and post-test stage)

Method of measurement
Broadbent Cognitive failures Questionnaire

2

Description
Information processing speed score in digit symbol test

Timepoint
Measuring the information processing speed before and after the study (pre-test and post-test stage)

Method of measurement
The Symbol Digit Modalities Test (SDMT)

3

Description
The score in the visuospatial test of corsi block
Timepoint
Measuring visuospatial working memory before and after the study (pre-test and post-test stage)
Method of measurement
the visuospatial test of corsi block

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For the intervention group, the cognitive stimulation program based on the cognitive improvement model will be held in 12 sessions, each session lasting 90 minutes, and one session will be held every week. The program of each session will be different from the previous session, which creates motivation and interest in the elderly to continue the treatment. This intervention includes a wide range of interesting cognitive activities such as physical activities, presenting songs and identifying and classifying sounds, talking about childhood and their jobs in youth and adulthood, talking about the taste and value of food, talking about It includes current issues and news, related word games, orientation and classification of objects.
Category
Rehabilitation

2

Description
Control group: No intervention
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Specialty and Subspecialty Clinic
Full name of responsible person
Dr. Mohammad Ali Qayomi
Street address
Shiraz, Namazi Square, next to blood transfusion, specialized and super-specialized clinic of Imam Reza (A.S.).
City
Shiraz
Province
Fars
Postal code
7134814734
Phone
+98 71 3212 7001
Fax
+98 917 482 9657
Email
emamreza@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
No sponsors
Full name of responsible person
No sponsors
Street address
No sponsors
City
Shiraz
Province
Fars
Postal code
No sponsors
Phone
+98 86 7055 0321
Email
nosponser@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
No sponsors
Proportion provided by this source
1
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Bahonar University of Kerman
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Fateme Moradi
Position
PhD student in psychology
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be 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
Not applicable
Data Dictionary
Not applicable