

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Sep 2026

Effectiveness of cognitive-behavioral therapy with treatment based on compassion and Intellectual-Motor Exercises on elderly,s plasma lipoproteins, executive functions, psychological syndrome, and sleep quality

Protocol summary

Study aim

Evaluation of the effectiveness of cognitive-behavioral therapy with treatment based on compassion and Intellectual-Motor Exercises on elderly,s plasma lipoproteins, executive functions, psychological syndrome, and sleep quality

Design

An intervention design Individuals are randomly assigned to four groups based on matching scores and assigned to each code. They are randomly assigned to one of three experimental groups and one control group to form three experimental groups and one control group. There are 15 people in each group, and for each person in that group, there will be one person in each of the other 3 groups.

Settings and conduct

the study will be in Neshat Elderly day care center in Mashhad. intervention and control groups with non-blinding random assignment of selection and training will be applied.

Participants/Inclusion and exclusion criteria

participants should have at least 60 years old , no major cognitive deficits or Alzheimer,s disease willingness to participate in study The number of points required for the cognitive ability screening tests . Having any major psychological disorder The lack of high cholesterol (LDL outside 130 and 100) (HDL for women less than 60 and for men less than 40)

Intervention groups

Intervention group 1, cognitive-behavioral therapy combined with compassion-based therapy and cognitive-motor activities. Members first receive cognitive-behavioral therapy and then compassion-based therapy for both cognitive-behavioral activities, including sudoku activities, along with simple motor activities such as lifting the arms and moving the legs once a week. Intervention group 2, behavioral therapy combined with

compassion-based therapy

Main outcome variables

elderly. psychological syndrome. sheep quality. blood cholesterol. cognitive behavioral therapy. compassion focused treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191012045065N1**

Registration date: **2021-01-04, 1399/10/15**

Registration timing: **retrospective**

Last update: **2021-01-04, 1399/10/15**

Update count: **0**

Registration date

2021-01-04, 1399/10/15

Registrant information

Name

Anahita Kashmari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3761 5377

Email address

anahita.kashmari1347@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-21, 1398/08/30

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of cognitive-behavioral therapy with treatment based on compassion and Intellectual-Motor Exercises on elderly,s plasma lipoproteins, executive functions, psychological syndrome, and sleep quality

Public title

Effectiveness of cognitive-behavioral therapy with treatment based on compassion and Intellectual-Motor Exercises on elderly,s plasma lipoproteins, executive functions, psychological syndrome, and sleep quality

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

participants should have at least 60 years old , no major cognitive deficits or Alzheimer,s disease willingness to participate in study

Exclusion criteria:

The number of points required for the cognitive ability screening tests . Having any major psychological disorder The lack of high cholesterol (for LDL outside 130 and 100) and (HDL for women less than 60 and for men less than 40)

AgeFrom **60 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

Selected individuals are tested for research based on the test scores scores . then all study individuals are performed randomly in four peer groups . Then everybody in the group finds a code of interest. As from the no 1 to no 15 in one group, from the number 16 to No 30 hn another group ,from no 31 to no 45 in next group and from no 46 to no 60 in last group. Finally , each group was assigned randomly in one of the three experimental groups (the experimental group no1 ; the experimental group no 2, the experimental group no 3) and one control group (group no 4) . in such a way that there are hundreds of thousands of people per person in the screening test scores of the same group in the other three groups .

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**

Ethics committee of Birjand university of medical sciences.

Street address

Birjand University of Medical Sciences. Ghafari st

City

Birjand

Province

Razavi Khorasan

Postal code

09717853577

Approval date

2019-05-01, 1398/02/11

Ethics committee reference number

IR.BUMS.REC.1398.003

Health conditions studied**1****Description of health condition studied**

psychological syndrome

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

high cholesterol level

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

plasma lipoproteins,

Timepoint

one week before the intervention started and one week after the end of interventions .

Method of measurement

by blood test

2

Description

executive functions,

Timepoint

one week before the intervention started and one week after the end of interventions .

Method of measurement

Behavior Rating Inventory of Executive Function (BRIEF)

3

Description

psychological syndrome(anxiety and depression)

Timepoint

one week before the intervention started and one week after the end of interventions .

Method of measurement

General Anxiety Inventory (GAI) and General Depression Scale for older persons

4

Description

sleep quality

Timepoint

one week before the intervention started and one week after the end of interventions .

Method of measurement

Pittsburgh Sleep Quality Index (psqi)

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group : They first receive cognitive - behavioral training , and on compassion Focused Therapy. during the ten - minute session , twice in the week with, behavioral cognitive functions include activities such as puzzles , and simple activities such as lifting the hands and legs per week

Category

N/A

2

Description

Intervention group: Group B :Cognitive-Behavioral Therapy with Compassion Focused Therapy. they received cognitive - behavioral therapy and then continuing the treatment based on compassion in two sessions per week , twice per week

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Nesht day care of elderly center

Full name of responsible person

Mrs Hamideh Safaryan

Street address

No. 255, Next to the Kalantari4, Shahid Kalantari Blvd

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Phone

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neshatdaycare@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Fatemeh Shahabi Zadeh

Street address

Azad University of Birjand, End of Ghafari Aven

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Birjand

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Anahita Kashmari

Position

Student

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The research has not been done yet

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available