# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Comparison of the Effectiveness of Humor Therapy and Cognitive Rehabilitation on Agitation, Apathy, Cognitive and Memory Function in Patients with Mild Cognitive Impairment (MCI)

### Protocol summary

**Study aim**
Determining the effectiveness of humor therapy on Agitation, Apathy, Cognitive and Memory Function in Patients with (MCI)and comparing it with the effectiveness of cognitive rehabilitation

**Design**
Clinical trial with control group, with parallel groups, randomized, on 45 patients, simple random

**Settings and conduct**
This study is conducted at Kahrizak Institute in Alborz Province.

**Participants/Inclusion and exclusion criteria**
Seniors over 65 years of age Entry criteria: elderly resident with MCI, ability to speak Non-entry criteria: No psychiatric medications, no hearing problems

**Intervention groups**
Cognitive Rehabilitation Intervention: Cognitive Rehabilitation Guide includes strategies and techniques. Compiled at Trinity College Dublin and the Alzheimer's Society of Ireland by Kelly and O'Sullivan (2015). Humor Therapy Intervention: Seven Humor Skills designed by McGhee (2004). A control group that does not receive any intervention during the study process. Only pre-tests and post-tests will be taken from them.

**Main outcome variables**
Apathy; Agitation; cognitive and Memory Function

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20201012049009N1**
Registration date: **2020-12-10, 1399/09/20**
Registration timing: **retrospective**

Last update: **2020-12-10, 1399/09/20**
Update count: **0**

**Registration date**
2020-12-10, 1399/09/20

**Registrant information**

**Name**
Zahra Fereidouni Valashejerdi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-07-22, 1399/05/01

**Expected recruitment end date**
2020-09-22, 1399/07/01

**Actual recruitment start date**
2020-09-22, 1399/07/01

**Actual recruitment end date**
2020-09-22, 1399/07/01

**Trial completion date**
2020-09-26, 1399/07/05

**Scientific title**
Comparison of the Effectiveness of Humor Therapy and Cognitive Rehabilitation on Agitation, Apathy, Cognitive and Memory Function in Patients with Mild Cognitive Impairment (MCI)

**Public title**
The effect of humor therapy and cognitive rehabilitation on mild cognitive impairment

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

elderly residents home mild cognitive impairment The ability to speak

**Exclusion criteria:**

No psychiatric medications No hearing problems

**Age**

From **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **45**

Actual sample size reached: **45**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The randomization process is performed www.randomization.com the site. In order to hide random allocation, random sequence sealed envelope is used. In this way, the sample size of 45 people, the envelope is prepared by the reception officer of the center and each of the random sequences created on a card is recorded and the cards are placed in the envelopes in order, in order to maintain the random sequence, the numbering is done on the external surface of the envelopes in the same order. Based on the order of entry of eligible participants into the study, one of the envelopes is opened and the assigned group of the participant is revealed and during this time the researcher and participants are not aware of the allocation of the experimental and control 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 Islamic Azad University of Tonekabon

**Street address**

No. 98, Valfajr 4, Pirouzi Alley, Motahari St.

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**Approval date**

2020-11-19, 1399/08/29

**Ethics committee reference number**

IR.IAU.TON.REC.1399.050

## Health conditions studied

### 1

**Description of health condition studied**

Mild Cognitive Impairment (MCI)

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

Total number less than 24 in Montreal Cognitive Assessment-Basic (MoCA-Basic)

**Timepoint**

Before the intervention, after the intervention, two months after the intervention

**Method of measurement**

Total score in Montreal Cognitive Assessment-Basic (MoCA-Basic),

### 2

**Description**

Total score in Cohen-Mansfield Agitation Inventory

**Timepoint**

Before the intervention, after the intervention, two months after the intervention

**Method of measurement**

Total score in Cohen-Mansfield Agitation Inventory

### 3

**Description**

Total score in apathy Martin's inventory

**Timepoint**

Before the intervention, after the intervention, two months after the intervention

**Method of measurement**

Total score in apathy Martin's inventory

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group1: Stages of humor training Educational content relied on the seven steps of

fostering Paul McGui's sense of humor (2004). The program includes the effect of humor on life, examining the sense of humor of the members of the group from their point of view, theories about humor and discussion of ways of enhancing the spirit of humor, teaching humor skills, practicing jokes, benefits and types of humor, exposure to resistances and direct guidelines on how to use humor in the living environment and in times of crisis. At the end of each session, assignments were determined and each session started with discussions about the assignments performed.The humor skills training program was divided into meetings: the first session: familiarity with the rules of the group, discussing of learning this skill as a positive defense mechanism and its impact on social interactions and physical health. The humor skills training program was divided into meetings: the first session, familiarity with the rules of the group, discussion of the concept and benefits of humor, the necessity of learning this skill as a positive defense mechanism and its impact on social interactions and physical health. Second session: Identifying the uniqueness of people's humor style, discussion, modeling and behavioral exercises such as funny imaginary dialogue with the other person and practicing it.Session 3: Practicing laughter, using the discussion method, activating the child inside and ten minutes of laughter without reason and expressing feelings. Session 4: The ability to play with words, to say jokes and riddles, to teach specific skills of humor, to use alternative. words as jokes. Session 5: Seeking satirical awares in everyday life, such as taking notes of any funny events among your or others' funny experiences, patterning and and ten minutes of laughing without reason and expressing feelings.Session 6: Learning to laugh at oneself, using the method of drawing your cartoon, laughing at the members together, practicing countering group inhibitions, and ten minutes of laughing without reason and expressing feelings. Session 7: The use of humor at the height of tension and discomfort, discussing the style of humor in stressful and fearful situations, teaching the patterns of humor application in these situations to the people of the group.Session 8: Summing up and exchanging experiences, applying the skills learned during this period and reviewing its effect. A summary of the training program and reviewing its effects on the group members and evaluating the program. Session 9: Post-test stage and re-implementation of questionnaires

**Category**

Behavior

### 2

**Description**

Intervention group: Session 1: Familiarity with group rules, discussion of learning these skills and cognitive rehabilitation exercises as strategies and techniques to improve memory and increase one's recall and its impact on one's daily life, as well as social interactions.Session 2: Teaching the basics about memory and recall, verbal repetition and continuous processing Session 3: Dual cognitive support: illustration and memory enhancement, errorless learning. Session 4: Teaching Recall Strategies: Mnemonics, Cueing. Session 5: Continuation of Recall Strategies Training: Chunking, Loci Method, Spaced Retrieval Session 6: Specific interventions including face-name Recall: face accompaniment of face - names of familiar members of the group through their photographs.Session 7: Story Recall, List/Object Recall.Session 8: Procedural Memory, practice and repetition with the aim of mastering the task.Session 9:Additional Support, Auxiliary programs and techniques including memory aids.Session 10: Adaptation to the individual's living environment, relaxation training.

**Category**

Behavior

### 3

**Description**

Control group: Control group: do not receive any intervention.

**Category**

Behavior

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Kahrizak Institute of Alborz Province

**Full name of responsible person**

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Research Branch of Tonekabon Islamic Azad University

**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**
Research Branch of Tonekabon Islamic Azad University

**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**
Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
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Zahra Fereidouni Valashejerdi
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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**
Not applicable

**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to

make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable