

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### The effect of participation in cognitive leisure activities on life satisfaction and memory status in the elderly

#### Protocol summary

##### Study aim

Determining the effect of participation in cognitive fun activities on life satisfaction and memory status of the elderly

##### Design

.Randomized clinical trial with control group, on 80 elderly people

##### Settings and conduct

The study population is 80 elderly people living in Kahrizak sanatorium in Alborz province. After obtaining a research permit from the ethics committee of the School of Nursing, Midwifery and Rehabilitation, the researcher will introduce himself to the Kahrizak Alborz Charity Center and select 80 elderly people who meet the criteria to enter the research from the list of elderly people living there.

##### Participants/Inclusion and exclusion criteria

1. No cognitive impairment by AMT tool (score below 6 indicates cognitive impairment.)
2. History of living in a nursing home for 6 months
- 3.No mental problems based on medical records and the opinion of the psychiatrist.
4. Lack of experience of grief or acute emotional problems in the last 6 months according to the ward psychologist
5. The ability of sight and hearing and speech to communicate
- 6.The elderly in the age range of 60 to 90 years

##### Intervention groups

Playing puzzles and word formation with letters for 12 weeks on individual days for 1 hour in the research environment and the elderly in groups of 2 to 3 people will be held in the form of lectures, questions and answers and discussions.

##### Main outcome variables

Life satisfaction level and memory status

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20210302050557N1**

Registration date: **2021-07-15, 1400/04/24**

Registration timing: **retrospective**

Last update: **2021-07-15, 1400/04/24**

Update count: **0**

##### Registration date

2021-07-15, 1400/04/24

#### Registrant information

##### Name

Tahere Ahmadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3620 5446

##### Email address

tahereahmadi.1375@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2021-04-22, 1400/02/02

#### Expected recruitment end date

2021-05-10, 1400/02/20

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of participation in cognitive leisure activities on life satisfaction and memory status in the elderly

#### Public title

The effect of participation in cognitive leisure activities on life satisfaction and memory status in the elderly

#### **Purpose**

Prevention

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

The elderly in the age range of 60 to 90 years No cognitive impairment by AMT tool (score below 6 indicates cognitive impairment.) History of living in a nursing home for 6 months No mental problems based on medical records and the opinion of the psychiatrist 5. Lack of experience of grief or acute emotional problems in the last 6 months according to the ward psychologist 6. The ability of sight and hearing and speech to communicate

##### **Exclusion criteria:**

Having an acute illness during study Hospitalization and non-participation in the program for 2 consecutive sessions Personal reasons for leaving the study

#### **Age**

From **60 years** old to **90 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

- Participant
- Investigator
- Data analyser

#### **Sample size**

Target sample size: **80**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

Samples are classified by random sampling method, based on age and gender, are divided into two groups of test and control (40 people in each group, 20 men and 20 women). The method of random allocation will be classified in such a way that the elderly will be divided into two groups based on their gender, men and women, and then each group will be divided into three age groups: ages 60-69, 70-79 and 80+. According to the two sex groups and the three age groups, we will have a total of six classes. Random allocation for the control and intervention group will be done in a simple random manner in each of these six classes and random allocation will be done using SPSS software.

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

In this study, the participants are aware of the participation, drawbacks and benefits of this study. After filling informed consent form, The participants and their families will be blind toward randomized allocation. Moreover, the researcher and the one who collects and analyzes the data will be blind too.

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

#### **Secondary Ids**

empty

#### **Ethics committees**

##### 1

##### **Ethics committee**

###### **Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

###### **Street address**

No. 1, Poursina St, Qods St, Enghelab St

###### **City**

Tehran

###### **Province**

Tehran

###### **Postal code**

1415665881

##### **Approval date**

2021-04-22, 1400/02/02

##### **Ethics committee reference number**

IR.TUMS.FNM.REC.1400.011

#### **Health conditions studied**

##### 1

##### **Description of health condition studied**

Life satisfaction and memory status

##### **ICD-10 code**

##### **ICD-10 code description**

#### **Primary outcomes**

##### 1

##### **Description**

Life satisfaction

##### **Timepoint**

Before the intervention, after the intervention and 3 months after the intervention

##### **Method of measurement**

Elderly Life Satisfaction Questionnaire (LSI)

##### 2

##### **Description**

Memory status

##### **Timepoint**

Before the intervention, after the intervention and 3 months after the intervention

##### **Method of measurement**

Wechsler memory test

#### **Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

The intervention includes performing cognitive puzzle fun activities and word formation with letters, which will be performed for 30 months on individual days for 1 hour, each intervention for 30 minutes.

#### Category

Prevention

### 2

#### Description

Control group: People in the control group do not receive any intervention and are placed on a waiting list to be rehearsed at another time.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kahrizak Charity Institution of Alborz Province

##### Full name of responsible person

Dr. Afshin Vejdani Roshan

##### Street address

Saheb Al-Zaman Street

##### City

Mohammad Shahr

##### Province

Alborz

##### Postal code

31845167

##### Phone

+98 26 3630 9171

##### Email

pr@kahrizakcharity.com

##### Web page address

<https://kahrizakcharity.com/kahrizak-charity-hospital-in-alborz-province>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr. Mohamadali Sahraian

##### Street address

6th Floor, Central Building, Qods St, Keshavarz Blvd

##### City

Tehran

##### Province

Tehran

##### Postal code

1417613151

##### Phone

+98 21 6405 3334

##### Email

vcr@tums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Tehran University of Medical 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

Tehran University of Medical Sciences

##### Full name of responsible person

Tahere Ahmadi

##### Position

Master degree student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

##### Street address

No. 1, Hadith Alley 4, Tabatabai St., Meshkin Dasht, Karaj

##### City

Tehran

##### Province

Tehran

##### Postal code

3177959374

##### Phone

+98 26 3620 5446

##### Email

tahereahmadi.1375@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Tahere ahmadi

##### Position

Master student of geriatric nursing

##### Latest degree

Bachelor

**Other areas of specialty/work**

Nursery

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Tahere ahmadi

**Position**

Master student of geriatric nursing

**Latest degree**

Bachelor

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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**

There is no more information

**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