

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

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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

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3177959374

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+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

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Tehran University of Medical Sciences

Full name of responsible person

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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