

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The Effect of group play therapy on depression and loneliness among the elderly

Protocol summary

Study aim

the Effect of Group play Therapy on Depression and Loneliness in the Elderly

Design

This study was a clinical trial study. The population of this study was 60 elderly patients aged 60 years and older who were referred to Daneshamooz and Sadaf health centers in Mashhad. Individuals based on the goal will be included in the study, then Then randomly and based on the Random numbers Divided In both intervention and control groups. Pre-test is done in both groups then play therapy sessions are conducted in the intervention group in 12 sessions.

Settings and conduct

two health centers that named Daneshamooz and Sadaf

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 60 and above; willingness to participate in the study; ability to communicate with the researcher; Obtaining a score of at least 7 from a short-cognitive questionnaire; lack of visual and hearing impairment; non-use of antidepressants during the study; absence of acute and chronic disabling diseases and lack of mental disorders; minimal depression ; feeling lonely. Exclusion criteria: Refuse to participate in the study and collaborate with the researcher; Missing more than 3 sessions at meetings; The deaths of research units; Acute illness or hospitalization during the study.

Intervention groups

The subjects were randomly assigned to control and intervention groups. Pre-test is done in both groups, Then the play therapy sessions in the intervention group are 12 sessions and 2 sessions per hour each week. members are organized in groups and groups of 10 people. The control group uses the central service (Organizing Senior Education Classes; Domestic doctor and general practitioner visits; Perform periodic laboratory test; Perform specialist Psychological actions and so on) of the center. After the end of the

intervention, post-test is done in both groups.

Main outcome variables

Depression Loneliness

General information

Reason for update

Record the actual date of recruitment date and Trial completion date

Acronym

IRCT registration information

IRCT registration number: **IRCT20170619034650N1**

Registration date: **2018-01-02, 1396/10/12**

Registration timing: **prospective**

Last update: **2020-09-25, 1399/07/04**

Update count: **1**

Registration date

2018-01-02, 1396/10/12

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3621 3673

Email address

jameif1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-05, 1396/10/15

Expected recruitment end date

2018-02-15, 1396/11/26

Actual recruitment start date

2018-01-05, 1396/10/15

Actual recruitment end date

2018-02-15, 1396/11/26

Trial completion date

2018-02-15, 1396/11/26

Scientific title

The Effect of group play therapy on depression and loneliness among the elderly

Public title

The Effect of group play therapy on depression and loneliness among the elderly

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria:: Age 60 and above; willingness to participate in the study; written consent for participation in the research; ability to communicate with the researcher; Obtaining a score of at least 7 from a short-cognitive questionnaire; lack of visual and hearing impairment to an extent that causes activity impairment; non-use of antidepressants during the study; absence of acute and chronic disabling diseases such as kidney disease, cancer, and insufficiency Heart failure and lack of mental disorders; minimal depression (obtaining a score of at least 5 from the depression scale of the elderly); feeling lonely (obtaining a score of at least 21 from the loneliness scale.

Exclusion criteria:

Exclusion criteria: Refuse to participate in the study and collaborate with the researcher; Missing more than 3 sessions at meetings; The deaths of research units; Acute illness or hospitalization during the study.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals based on the goal will be included in the study, then Then randomly and based on the Random numbers Divided In both intervention and control groups

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The games in the study are under the supervision of a game therapist

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mashhad University of Medical Sciences

Street address

Danesh Salamat Shahrak, Between Shahid Al Shahidi Sq. And Shahid Javan Sq., Shahid Fakouri Blvd., Mashhad, Iran

City

mashhad

Province

Razavi Khorasan

Postal code

99191-91778

Approval date

2017-11-23, 1396/09/02

Ethics committee reference number

IR.MUMS.REC.1396.248

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

loneliness

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

depression

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

Depression

Timepoint

Before and after the end of the intervention

Method of measurement

Geriatric depression scale

2**Description**

Loneliness

Timepoint

Before and after the end of the intervention

Method of measurement

Loneliness questionnaire (UCLA ver3)

Secondary outcomes

1

Description

social support

Timepoint

before and after the intervention

Method of measurement

social support scale by kasidi

Intervention groups

1

Description

Intervention group: Intervention 1 is as follows: the play therapy sessions in the intervention group are 12 sessions and 2 sessions per hour each week. members are organized in groups and groups of 10 people. The first session is a general introduction and description of the activities, explaining the goals of the research and the duties of each person during the intervention and The next sessions will be based on the scheduled schedule.

Category

Lifestyle

2

Description

Control group: The control group uses the central service (Organizing Senior Education Classes; Domestic doctor and general practitioner visits routinely and periodically; Perform periodic laboratory test; Perform specialist Psychological actions) of the center. No specific action is taken in this group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad No. 1 Health Center

Full name of responsible person

Amini Naser

Street address

Vakil Abad Boulevard, between Vakil Abad 66 and 68, Mashhad

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000

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Email

Aminin1@mums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Vice chancellor for research; Islami Saeed ; University of Medical Sciences

Street address

Danesh Salamet Shahrak, Between Shahid Al Shahidi Sq. And Shahid Javan Sq., Shahid Fakouri Blvd., Mashhad, Iran

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vcresearch@mums.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Jamei fateme

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Mashhad University of Medical Sciences, Faculty of Nursing and Midwifery, Daneshgah street, Mashhad

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

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Web page address

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

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