

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effect of participating in support groups on relocation stress syndrome(RSS) in residents of nursing homes

Protocol summary

Study aim

Determine the effect of participating in support groups on relocation stress syndrome in residents of nursing homes

Design

Randomized clinical trial with control group, community and practical based, parallel groups, blinded outcome assessment, randomized

Settings and conduct

The study environment is Kahrizak nursing home. The research community is the elderly living in the Kahrizak nursing home who will be selected based on entry criteria. A researcher-made demographic information questionnaire, and Depression, anxiety and loneliness questionnaires, will be completed for both groups at the beginning of the study. Support group meetings for the intervention group will be held for 6 sessions and each session will be held for 1 hour and 2 times a week. After 4 weeks from the last support group meeting, the questionnaires are completed again. At the end, the tools for the control group will also be completed, then the results will be compared.

Participants/Inclusion and exclusion criteria

Entry requirements: 1.Duration of stay up to 1 year 2. No cognitive disorder 3. Ability for visual and verbal communication 4.No mood disorders. No entry condition: 1.Unwillingness to continue participating in the study 2.Lack of participation at support group meetings in 2 sessions 3.Beginning of the cognitive disorder during the study 4. An important incident (such as divorce, death of loved ones, financial bankruptcy ...) during the last year

Intervention groups

There is an intervention group and a control group. At first, the required explanations for the research are given to the samples and informed consent will be obtained. In this study, the final sample size will be 30 people per group and a total of 60 people. The intervention group will attend the support group meetings.

Main outcome variables

Depression Anxiety Loneliness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170812035647N3**

Registration date: **2018-07-16, 1397/04/25**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-16, 1397/04/25**

Update count: **0**

Registration date

2018-07-16, 1397/04/25

Registrant information

Name

Sarieh Poortaghi

Name of organization / entity

Tehran University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-21, 1397/03/31

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of participating in support groups on relocation stress syndrome(RSS) in residents of nursing homes

Public title

Effect of support groups on relocation stress syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The elderly living in a nursing home whose length of stay at that center is at most 1 year There is no recognized cognitive impairment (such as Alzheimer's, dementia, delirium, etc.) Being able to communicate verbally and eye contact There is no history of mood disorders based on expert diagnosis

Exclusion criteria:

Unwillingness to continue participating in the study Non-attendance at support group meetings in 2 sessions Beginning of the cognitive disorder during the study In one year, an important incident (such as divorce, death of loved ones, financial bankruptcy ...) has occurred in life

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting the prototype, individuals will be assigned to the intervention and control groups based on the case number and using the random number table

Blinding (investigator's opinion)

Single blinded

Blinding description

To collect data from a research collaborator using unknowing type groups Also, the statistics specialist and participants in the research will also be unaware

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

School of Nursing Midwifery ,Tehran University of Medical Sciences,Nosrat st. Tohid sq. Tehran I.IRAN 141973317

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Province

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Approval date

2017-11-03, 1396/08/12

Ethics committee reference number

IR.TUMS.FNM.REC.1396.3870

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32.0

ICD-10 code description

Major depressive disorder, single episode, mild

2

Description of health condition studied

Anxiety Disorders

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Depression

Timepoint

Before the intervention and 4 weeks after the intervention

Method of measurement

Geriatric depression scale

2

Description

Anxiety

Timepoint

Before the intervention and 4 weeks after the intervention

Method of measurement

Geriatric anxiety scale

3

Description

Loneliness

Timepoint

Before the intervention and 4 weeks after the intervention

Method of measurement

University of California at Los Angeles Loneliness scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Desired tools included researcher-made demographic questionnaire and geriatric depression scale(GDS), geriatric anxiety scale(GAS) And the shortened form of UCLA (ULS) University of California, Los Angeles , will be completed at the beginning of the study for both groups. The support groups will hold for 6 sessions and each session for 1 hour and 2 times a week.The first session will focus on the familiarization and expression of goals. At the next sessions, according to the goals, the researcher will initially provide the group members with information on each of the topics discussed, including depression, anxiety and loneliness.Then the people in the group will share their experiences and individual ways of dealing with it ,In the meantime, the researcher addresses the problems raised during the meeting, while the elderly are discussing and discussing emotional support among each other, to provide scientific and practical solutions And uses the experience of a successful counterpart in relation to the subject. After 4 weeks from the last support group meeting, the questionnaires are completed again. At the end, the tools for the control group will be completed and the results will be compared.

Category

Lifestyle

2

Description

Control group: Depression, anxiety and loneliness questionnaires will be completed before the beginning of the study for the control group. During the study, the group will not receive intervention. After the end of the intervention in the intervention group, the questionnaires will be completed again for the control group and then the results will be compared.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kahrizak Charity Foundation

Full name of responsible person

Dr Mohammadreza Hakimzadeh

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Dr. Hakim Zade Blvd,end of Kahrizak,after Behesht Zahra,Qom old road ,Kahrizak,Tehran,Iran

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Web page address

http://kahrizak.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Deputy of Research of Tehran University of Medical Sciences

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Deputy of Research ,Central Organization of the University,Corner of Quds Street,Keshavarz Blvd,Tehran

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Web page address

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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

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

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Person responsible for general inquiries

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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

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