

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6105 4209

##### Email address

s-poortaghi@sina.tums.ac.ir

##### 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

##### City

Tehran

##### Province

Tehran

##### Postal code

141973317

#### 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

##### Street address

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

##### City

Tehran

##### Province

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##### Postal code

1575633411

##### Phone

+98 21 5652 5804

##### Fax

+98 21 8834 5620

##### Email

info@kahrizak.com

##### 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

##### Street address

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

##### City

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##### Province

Tehran

##### Postal code

1417653761

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+98 21 8163 3623

##### Email

rmo@tums.ac.ir

##### Web page address

https://www.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

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## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Seyedeh Sahar Ghaderi  
**Position**  
Student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
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School of Nursing Midwifery ,Tehran University of  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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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