

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effectiveness of Group Reality Therapy on Anxiety and Depression of Iranian Family Caregivers of the Elderly with Multiple Chronic Conditions: A Randomized Controlled Trial Study

#### Protocol summary

##### Study aim

The effectiveness of group reality therapy on anxiety and depression of family caregivers of the elderly with multiple chronic conditions

##### Design

Randomized controlled trial with pre and post-test design, with two experimental and control groups, without blinding, the allocation of family caregivers in two experimental (reality therapy) and control groups (without intervention) is done by block random assignment method.

##### Settings and conduct

Two health centers and outpatient clinics of three government hospitals are the sampling sites. After obtaining informed and written consent from eligible samples, family caregivers are divided into experimental (A: implementation of reality therapy intervention) and control groups (B: without intervention) using block random allocation method.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Caring for an elderly family member with multiple chronic illnesses for at least three months, Age 18-60 years Exclusion criteria: Participate in any other related research on geriatric care over the past two years, Inability to take care of oneself and perform daily activities

##### Intervention groups

Reality therapy is implemented for the experimental group; While no intervention is carried out for the control group. After completing the intervention in the the experimental group and and collecting the questionnaires in both groups, in order to observe moral considerations, the reality therapy package will be provided to the control group. The researcher devised the content of this intervention based on choice theory and based on reality therapy techniques and Dr. William Glasser's reality therapy book translated by Dr. Ali

Sahebi, reviewing the studies of reality therapy and under the supervision of a doctor of psychology.

##### Main outcome variables

Anxiety Depression

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210920052525N1**

Registration date: **2021-10-23, 1400/08/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-10-23, 1400/08/01**

Update count: **0**

##### Registration date

2021-10-23, 1400/08/01

##### Registrant information

##### Name

Sahar Malmir

##### Name of organization / entity

Nursing Department, Faculty of Medical Science,  
Tarbiat Modares University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 66 3330 9193

##### Email address

s.maleh@modares.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-10-02, 1400/07/10

##### Expected recruitment end date

2021-10-30, 1400/08/08

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The Effectiveness of Group Reality Therapy on Anxiety and Depression of Iranian Family Caregivers of the Elderly with Multiple Chronic Conditions: A Randomized Controlled Trial Study

**Public title**

The Effectiveness of Group Reality Therapy on Anxiety and Depression

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Caring for an elderly family member with multiple chronic illnesses for at least three months Age 18-60 years Willingness to participate in the study Having literacy Being able to communicate and use a smartphone

**Exclusion criteria:**

Participate in any other related research on geriatric care over the past two years Inability to take care of oneself and perform daily activities Having a severe mental disorder that requires medication

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization: Step 1: Random sequence generation: Considering that the researchers of this study tend to have all sample groups with equal sample size, they used restricted randomization. In the present study, the method used in this type of randomization in order to create a balance in the number of samples assigned to each of the studied groups is block randomization. The placement of family caregivers of the elderly with several chronic diseases in two groups of intervention (reality therapy) and control (without intervention) was done by block random allocation method. The method of assigning 50 eligible samples to two groups of 25 is as follows: the method of 4 random blocks is used to assign family caregivers to the four groups studied. To do this, first write a list of blocks and assign numbers to them {(1) AABB- (2) ABAB- (3) ABBA- (4) BBAA- (5) BABA- (6) BAAB}. Then, using a table of random numbers, 13 random numbers between 1 to 6 are created and

according to the mentioned numbers, the relevant block is selected and a random sequence is formed as a sequence of letters A and B (letter A for the test group and letter B for the control group). Step 2: Concealment of random allocation: To perform a random sequence on the study participants, Sequentially numbered, sealed, opaque envelopes are used. In such a way that the assigned group is not specified before the individual is assigned; A number of envelopes are prepared and each of the random sequences created is recorded on a card and the cards are placed inside the envelopes in order. In order to maintain a random sequence, envelopes are numbered in the same way on the outer surface of the envelopes. Finally, the lids of the letter envelopes are glued and placed inside the boxes, respectively. At the beginning of the registration of participants, one of the envelopes of the letter is opened and the assigned group of the participant is revealed, according to the order of entry of the eligible participants. Step 3: Execute the random allocation process: The student examines the participants in terms of inclusion and exclusion criteria in the study and registers them in the study. However, the person who assigns the participants to the groups will not be involved in the intervention and data collection of the participants.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committees of Tarbiat Modares University

**Street address**

Tehran, Jalal AleAhmad, Nasr, Tarbiat Modares University

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713116

**Approval date**

2019-05-07, 1398/02/17

**Ethics committee reference number**

IR.MODARES.REC.1398.045

**Health conditions studied**

## 1

### Description of health condition studied

Multiple Chronic Conditions

### ICD-10 code

### ICD-10 code description

## Primary outcomes

## 1

### Description

Anxiety

### Timepoint

Before intervention and after intervention (End of a month)

### Method of measurement

Depression, Anxiety and Stress Questionnaire (DASS-21)

## 2

### Description

Depression

### Timepoint

Before intervention and after intervention (End of a month)

### Method of measurement

Depression, Anxiety and Stress Questionnaire (DASS-21)

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: Reality therapy intervention is done for a period of one month in the form of group training and twice a week. The sessions are conducted by the researcher (PhD student in nursing) and PhD in psychology on family caregivers in the intervention group with the aim of reducing their anxiety and depression. Topics of 8 sessions of reality therapy include "environment and assessment; providing information and flipping; explaining and understanding anxiety based on choice theory and reality therapy; familiarity with depression based on choice theory and the sacrifice triangle; communication skills training as a deterrent External control and its destructive effects mean anxiety and depression; communication skills (internal control and general behavior machine); intelligent planning (SMART PLAN); WDEP process to solve the problem.

### Category

Other

## 2

### Description

Control group: They do not receive any intervention and only receives health and medical care that is specific to

the elderly from medical centers or health centers. These cares include: health advice about caring for the chronic diseases of the elderly, how to take medication, medical visits.

### Category

N/A

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Out patient of Ashayer hospital

#### Full name of responsible person

Babak Hadian

#### Street address

Lorestan, Khorramabad, Enghelab Street, Ashayer hospital

#### City

khorrarnabad

#### Province

Lorestan

#### Postal code

68169 33132

#### Phone

+98 66 3323 6402

#### Fax

#### Email

shohadahospital@lums.ac.ir

## 2

### Recruitment center

#### Name of recruitment center

Outpatient clinic of Shahid Madani Hospital

#### Full name of responsible person

Babak Abdolkarimi

#### Street address

Lorestan, Khorramabad, Imam Hossein Square, Shahid Beheshti St. (Khairabad), Shahid Ayatollah Madani Hospital

#### City

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#### Province

Lorestan

#### Postal code

6814713115

#### Phone

+98 66 3341 9123

#### Email

madanihospital@lums.ac.ir

## 3

### Recruitment center

#### Name of recruitment center

Shahid Rahimi Hospital Outpatient Clinic

#### Full name of responsible person

Saeed Rahimi

#### Street address

Lorestan, Khorramabad, Azadi Square, Mojahedin St.,

not far from Safavid Bridge, Shahid Seyed Fakhreddin  
Rahimi Hospital

**City**  
Khorramabad  
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Lorestan  
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**Email**  
rahimihospital@lums.ac.ir

#### 4

##### **Recruitment center**

**Name of recruitment center**  
Urban Health Center  
**Full name of responsible person**  
Ramin Khosravifar  
**Street address**  
East Goldasht, Karim Khan Zand Square  
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+98 66 3343 7794  
**Email**  
publicrelation@lums.ac.ir

#### 5

##### **Recruitment center**

**Name of recruitment center**  
Health Unit  
**Full name of responsible person**  
Mehrdad Hosseinpour  
**Street address**  
Not reached Imam Hossein Square, Patio Gol Alley,  
Shaghayegh  
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## **Sponsors / Funding sources**

#### 1

##### **Sponsor**

**Name of organization / entity**  
Tarbiat Modares University  
**Full name of responsible person**

Yaghoub Fathollahi

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Tehran, Jalal Al-Ahmad, Nasr Bridge  
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Tehran  
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1411713116  
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**Email**  
fatollahi@modares.ac.ir

##### **Grant name**

**Grant code / Reference number**

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

##### **Title of funding source**

Tarbiat Modares University

**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**  
Tarbiat Modares University  
**Full name of responsible person**  
Sahar Malmir  
**Position**  
Phd Nursing Student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Alavi Street  
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6813963658  
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saharmalmir93@gmail.com

## **Person responsible for scientific inquiries**

##### **Contact**

**Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

Hassan Navipour

**Position**

Assistant Professor of Nursing Management

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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Tehran, Jalal Al-Ahmad, Nasr Bridge

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naviporh@modares.ac.ir

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+98 66 3330 9193

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saharmalmir93@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The data obtained in relation to the target population of this study are related to demographic information and the two main outcomes of the study, namely anxiety and depression, which are reported anonymously and as a result of the analysis of the findings.

**When the data will become available and for how long**

Access period starts from 1401

**To whom data/document is available**

Researchers in the field of nursing and psychology All health care providers Nursing politicians

**Under which criteria data/document could be used**

Reference to the researchers of this study

**From where data/document is obtainable**

Send a message to saharmalmir93@gmail.com

**What processes are involved for a request to access data/document**

Data is sent after obtaining permission from the supervisors

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

Sahar Malmir

**Position**

Phd Nursing Student

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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Alavi Street

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**Province**

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**Postal code**