

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

Khorramabad

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

Province

Lorestan

Postal code

6813816314

Phone

+98 66 3333 6143

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

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Phone

+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

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Phone

+98 66 3340 8786

Email

m.h.khorramabad @lums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Yaghoub Fathollahi

Street address

Tehran, Jalal Al-Ahmad, Nasr Bridge

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 2009

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

City

Khorramabad

Province

Lorestan

Postal code

6813963658

Phone

+98 66 3330 9193

Email

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

Street address

Tehran, Jalal Al-Ahmad, Nasr Bridge

City

Tehran

Province

Tehran

Postal code

111-14115

Phone

+98 21 6657 0089

Email

naviporh@modares.ac.ir

6813963658

Phone

+98 66 3330 9193

Email

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

Street address

Alavi Street

City

Khorramabad

Province

Lorestan

Postal code