Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the Effect of Reality Therapy on the Anxiety and Stress of Family Caregivers of Stroke Patients

Protocol summary

Study aim
Determining the Effect of Reality Therapy on the Anxiety and Stress of Family Caregivers of Stroke Patients
Design
Quasi-experimental Randomized Controlled Trial on 82 Family Caregivers of Stroke Patients
Settings and conduct
In this study,After obtaining the required permits family caregivers of patients who have the desire to participate and meet the inclusion criteria will be selected through the convenience sampling method, and they will be randomly allocated in control and intervention groups. Reality therapy skills will be taught face-to-face in 8 sessions at the 9th Dey Hospital in Torbat Heydarieh city. for the intervention group. After the end of the study, the skills taught to the intervention group will be provided to the control group during 8 training sessions.
Participants/Inclusion and exclusion criteria
Inclusion Criteria: 1- To have the ability to understand and speak Persian. 2- Have the physical ability for interview and complete the questionnaire. 3- Absence of known mental illness 4- hearing health to participate in reality therapy sessions
Intervention groups
In this study, reality therapy skills will be taught face-to-face in 8 sessions for the intervention group. After the end of the study, the skills taught to the intervention group will be provided to the control group during 8 training sessions.
Main outcome variables
Anxiety and Stress

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240526061900N1**
Registration date: **2024-06-15, 1403/03/26**
Registration timing: **prospective**

Last update: **2024-06-15, 1403/03/26**
Update count: **0**
Registration date
2024-06-15, 1403/03/26

Registrant information
Name
Reza Vafaei
Name of organization / entity
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Iran (Islamic Republic of)
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+98 56 3239 5000
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rezavafaei935@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-07-22, 1403/05/01
Expected recruitment end date
2024-08-22, 1403/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the Effect of Reality Therapy on the Anxiety and Stress of Family Caregivers of Stroke Patients

Public title
Investigating the Effect of Reality Therapy on the Anxiety and Stress of Family Caregivers of Stroke Patients
Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

To have the ability to understand and speak Persian. Have the physical ability for interview and complete the questionnaire. Absence of known mental illness hearing health to participate in reality therapy sessions

Exclusion criteria:

Impaired verbal and non-verbal communication suffering from mental illness

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **82**

Randomization (investigator's opinion)

Randomized

Randomization description

The random block method will be as follows: 1)The size of each block will be 6. 2)All possible balanced combinations will be written with 3 control cases and 3 intervention cases. (20 combinations) 3)Blocks are randomly selected to allocate each 30 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 committee of Birjand University of Medical Sciences

Street address

Ghafari Blvd.,Birjand University of Medical Sciences

City

Birjand

Province

South Khorasan

Postal code

9717853076

Approval date

2024-05-26, 1403/03/06

Ethics committee reference number

IR.BUMS.REC.1403.066

Health conditions studied

1

Description of health condition studied

Cerebrovascular Accident

ICD-10 code

G46.4

ICD-10 code description

Cerebellar stroke syndrome

Primary outcomes

1

Description

Anxiety

Timepoint

Before Starting the Intervention and After Completing the Intervention

Method of measurement

Beck Anxiety Questionnaire

2

Description

Stress

Timepoint

Before Starting the Intervention and After Completing the Intervention

Method of measurement

Tjomas Stress Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, reality therapy skills will be taught face-to-face in 8 sessions for the intervention group. The educational content for each session is determined under the supervision of a mental health specialist, and each training session will be presented in 30 minutes.

Category

Rehabilitation

2

Description

Control group: After the end of the study, the skills taught to the intervention group will be provided to the control group during 8 sessions. The educational content for each session is determined under the supervision of a mental health specialist, and each training session will be presented in 30 minutes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
9th Dey Hospital of Torbat Heydarieh
Full name of responsible person
Dr.Zahra Nikfarjam
Street address
Kashani Blvd.,9th Dey Hospital
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Dr. Masoud Yousefi
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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
Birjand 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
Birjand University of Medical Sciences
Full name of responsible person
Reza Vafaei
Position
Nurse
Latest degree
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Other areas of specialty/work
Nursery
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Baesd on Ethical Issues
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available