Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effectiveness of human givens therapy on psychological distress and quality of life of the elderly living in a nursing home

Protocol summary

Study aim
Determining the effectiveness of human givens Therapy on reducing anxiety, stress, and depression in elderly residents of nursing homes and determining the effectiveness of human givens Therapy on improving the physical, cognitive, social and self-care dimensions and life satisfaction and improving sexual issues and reducing depression and anxiety dimensions of quality of life Elderly residents of nursing homes

Design
The sample size is 30 people. Random assignment to intervention and control groups, simple randomization, individual, manual selection.

Settings and conduct
A semi-experimental study with a pre-test and post-test, along with a control group and the effectiveness of human deposit therapy on the scores of the components of psychological disturbance and the quality of life of the elderly living in Ghamar bani hashem nursing homes.

Participants/Inclusion and exclusion criteria
The elderly living in nursing homes aged between 60 and 75 years,Literacy for reading and writing,Not receiving medical and psychological treatments during the last six months

Intervention groups
Seven treatment sessions for human givens, once a week and the duration of each session is 45 minutes،The control group does not receive any intervention.

Main outcome variables
psychological distress ؛ quality of life

General information

Reason for update

Acronym
HGT

IRCT registration information
IRCT registration number: **IRCT20230105057059N1**
Registration date: **2023-05-06, 1402/02/16**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-06, 1402/02/16**
Update count: **0**

Registration date
2023-05-06, 1402/02/16

Registrant information

Name
Masoumeh Kalantarabharpour

Name of organization / entity
The University of semnan

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-21, 1402/02/01

Expected recruitment end date
2023-06-19, 1402/03/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of human givens therapy on psychological distress and quality of life of the elderly living in a nursing home

Public title
The effectiveness of human givens therapy on

psychological distress and quality of life

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Literacy for reading and writing Age range from 60 to 75 years

Exclusion criteria:

receiving medical and psychological treatments during the last six months

Age

From **60 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization,individual,manual selection.The list of seniors who meet the entry criteria will be numbered and the test group will be completed by lottery, and then the lottery will be done again to complete the proof group.

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 semnan University ofMedical Sciences

Street address

Floor 13,Block A,Ministry of Health &Medical Education Headquarters,Between Zarafshan&South Falamak,Qods Town

City

Tehran

Province

Tehran

Postal code

1467664961

Approval date

2022-12-26, 1401/10/05

Ethics committee reference number

IR.SEMUMS.REC.1401.253

Health conditions studied

1

Description of health condition studied

Psychological distress

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Quality of life

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

psychological distress

Timepoint

Before the start and after the end of therapy

Method of measurement

kessler psychological distress questionnaire scale k10

2

Description

quality of life

Timepoint

Before the start and after the end of therapy

Method of measurement

the LEIPAD standard quality of life questionnaire for the elderly

Secondary outcomes

empty

Intervention groups

1

Description

Seven treatment sessions for human givens, once a week and the duration of each session is 45 minutes.Therapy sessions are done in groups. The content of the sessions includes establishing therapeutic communication, assessing the condition and severity of the disorder, examining and evaluating emotional needs and their role in the occurrence of disturbance. Providing the task of identifying needs such as the need for security. Investigating the unsatisfied needs of every elderly person, how emotions arise due to exposure to stimuli with mental patterns, presenting the task of identifying the motivating stimuli, paying attention to inherent resources such as (empathy, past memories, dreaming of the thinking mind, etc.), investigating the

irrational thoughts of the elderly, analyzing General information with the approach of hope and optimism and analysis of the way of satisfying individual needs and resources in the nursing home and creating a new story for living and thinking in different and successful ways.

Category
Treatment - Other

2

Description
Control group:They do not receive intervention

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghamar bani hashem care center for the elderly

Full name of responsible person
Abolghasem Khatibzade

Street address
Shahid mofatteh First of Ave ,Shohada Sq,Damghan Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
The University of semnan

Full name of responsible person
Hossein ehsani

Street address
Mahdishar Facualty of psychologyand Educational sciences,Darban Ave,Mahdishar Town

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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
The University of semnan

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
The University of semnan

Full name of responsible person
Masoumeh Kalantarabharpour

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Psychology

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Person responsible for updating data

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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
Not applicable

Data Dictionary
Not applicable