

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

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

#### Protocol summary

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

#### 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

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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3526 3555

##### Email address

m.kalantar.a@semnan.ac.ir

#### Design

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

#### 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

#### 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.

#### Scientific title

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

#### 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

#### Public title

The effectiveness of human givens therapy on

#### 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**

psychological distress and quality of life

IR.SEMUMS.REC.1401.253

## 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 of Medical 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

## 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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mkabharpour@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

The University of semnan

**Full name of responsible person**

Hossein ehsani

**Street address**

Mahdishar Faculty of psychologyand Educational sciences,Darban Ave,Mahdishar Town

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**Email**

Psychology@semnan.ac.ir

**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 scientific inquiries****Contact****Name of organization / entity**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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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