

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of therapeutic reality on the anxiety of the death of the elderly

Protocol summary

Study aim

Determining the Effect of Therapeutic Reality on Death Elderly Anxiety (General Objective)

Design

Clinical trials with community-based control group with parallel groups have not been blinded. Two-step randomized, first step: selecting cluster randomized cluster-managed nursing homes. Second stage: Selection of elderly people eligible for Simple random method
Sample size: 44 people

Settings and conduct

The place of research is nursing homes covered by Shemiran's well-being. At first, random cluster sampling of 5 elderly homes was selected from nursing homes of well-being and then entered into each cluster of eligible elders and randomly divided into two groups of intervention and control. The sample number is 44 people. Then, the demographic questionnaire and death anxiety for the elderly are completed. Then, real-life therapy is delivered as a lecture for 8 sessions, every 2 weeks for each session, 90 minutes for each session. During this period, the control group will receive no training. After completing the meetings, the Templer questionnaire will be completed again for both groups.

Participants/Inclusion and exclusion criteria

Entry requirements : 1- To receive a score of 8 to the Templar death anxiety questionnaire 2. Be alert and able to speak Persian. 3. No severe physical and psychological illness. 4. Hearing problems. 5. Miles to participate in research. Non-arrival conditions: Earning a score below 8 from Templar's Death Anxiety Inventory

Intervention groups

Intervention group: Reality Therapy Education Control group: no training.

Main outcome variables

By the difference of the points obtained before and after the education of the reality of the treatment, the effect of training will be determined.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190105042237N1**
Registration date: **2019-01-17, 1397/10/27**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-17, 1397/10/27**

Update count: **0**

Registration date

2019-01-17, 1397/10/27

Registrant information

Name

Monir Ghaffari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4435 5194

Email address

monir20ghaffari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-10, 1397/10/20

Expected recruitment end date

2019-02-09, 1397/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of therapeutic reality on the anxiety of the

death of the elderly

Public title

The Effect of Therapeutic Reality on Death Anxiety

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Be alert and able to speak Persian. Severe physical and emotional illness. Do not have hearing problems. Willing to participate in research.

Exclusion criteria:

Co-operative in another psychotherapy

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 44

Randomization (investigator's opinion)

Randomized

Randomization description

At first, five houses are selected randomly from nursing homes, then clustered, elderly eligible and randomly assigned to two groups of intervention and control.

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, Islamic Azad University of Medical Sciences, Tehran, Iran

Street address

No.8;11 Alley; Aasgari Street; Shahrn

City

Tehran

Province

Tehran

Postal code

1478739557

Approval date

2018-03-06, 1396/12/15

Ethics committee reference number

IR.IAU.TMU.REC.1396.316

Health conditions studied

1

Description of health condition studied

Death Anexity

ICD-10 code

F41

ICD-10 code description

Other anxiety disorders

Primary outcomes

1

Description

People who have a Templar death anxiety score above 8.

Timepoint

Death anxiety measurement before and after intervention

Method of measurement

Templar death anxiety inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First, the purpose of the study is explained and then two demographic and Templar death anxiety questionnaires will be completed by the researcher for the elderly. Then the treatment of reality therapy will be delivered as a lecture for the intervention group for 8 sessions, 2 sessions per week each 90 minutes each session. . These sessions are guided by the principles of the theory of therapeutic reality so that the initial sessions of the members are familiar with each other and the rules of the training course and the statement of the objectives of the sessions are emphasized. In the following sessions, the outline of the theory of therapeutic reality, including life in the present, basic human needs, accountability, successful work, planning to achieve the goals and behavioral techniques is taught. After completing the sessions, the Templar questionnaire will be completed for individuals, and the impact of training will be determined by differentiating the scores obtained before and after the reality therapy.

Category

Behavior

2

Description

Control group: First, the purpose of the study is explained and then two demographic and Temple death anxiety questionnaires are completed for the subjects. This group does not receive any training. After 4 weeks, the Templar questionnaire will be completed again and

the results will be reviewed by the intervention group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shemiranat Welfare

Full name of responsible person

Naji Yalali

Street address

Rashid Yasemi Street; Valiaasr Avenu

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1968713111

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Research Associate, Faculty of Nursing, Azad University of Tehran (Dr. Nekavand)

Street address

Zargande Street; Shariaati Street

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1916893813

Phone

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Fax

+98 21 2260 0714

Email

iautmu@iautmu.ac.ir

Web page address

http://www.iautmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad 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

Islamic Azad University

Full name of responsible person

Shirin Hejazi

Position

Professor

Latest degree

Master

Other areas of specialty/work

Nursery

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Zargande Street; Shariaati Street

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Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Monir Ghaffari
Position
Student
Latest degree
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Web page address
<http://www.iautmu.ac.ir>

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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

After being unidentified, information about the Death Anxiety Score and the impact of education can be shared

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers working in academia and academia

Under which criteria data/document could be used

Just in order to know the result of the research

From where data/document is obtainable

Tehran, Shariati St., Zargandeh St., Tehran, Islamic Azad University of Medical Sciences, Tehran, Iran. 1-library, Mr. Ismaili 2- Send an email to the research director, Ms. Hejazi Postal code: 1916893813 Mailbox: 19395/1495 Phone: 22006660 Email: iautmu@iautmu.ac.ir

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

1- Referral to the library unit of Islamic Azad University of Medical Sciences of Tehran 2- Send an email to the research director, Ms. Hejazi

Comments