

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of employees' humorous intervention on the severity of stress, anxiety, and depression among the elderly living in the nursing home

Protocol summary

Study aim

- 1- Determination and comparison of stress among the elderly in the intervention group before and after training
- 2- Determination and comparison of stress among the elderly of the control group at the first and second stages of the assessment
- 3- Determining and comparing anxiety among the elderly of the intervention group before and after training
- 4- Determination and comparison of anxiety among the elderly of the control group at the first and second stages of the assessment
- 5- Determination and comparison of depression among the elderly of the intervention group before and after training
- 6- Determination and comparison of depression among the elderly of the control group at the first and second stages of the assessment

Design

A randomized clinical trial with a control group with a sample size of 60 people

Settings and conduct

The sample size in this study was 30 in each group. In this research, 30 elderly people living in Tohid nursing home were considered as an intervention group and 30 elderly people in the Farzanegan nursing home were considered as control group.

Participants/Inclusion and exclusion criteria

In this study, having a willingness to cooperate in the study, having full consciousness, having the vision, hearing and speaking ability, and satisfaction of families for the participation of the elderly were considered as criteria for entry and significant incidence of mental disorders and being in the chronic phase of lung disease as Non-entry criteria.

Intervention groups

In this study, the intervention included employee humor training, presented by the researcher. Humor training was conducted for 7 sessions of one and a half hours. The control group did not receive an intervention.

Main outcome variables

Stress, anxiety, and depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190207042652N1**

Registration date: **2019-02-15, 1397/11/26**

Registration timing: **retrospective**

Last update: **2019-02-15, 1397/11/26**

Update count: **0**

Registration date

2019-02-15, 1397/11/26

Registrant information

Name

Tannaz Taheri Gharagzlu

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8848 8065

Email address

t.taheri43@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-05, 1397/03/15

Expected recruitment end date

2018-07-16, 1397/04/25

Actual recruitment start date

2018-06-05, 1397/03/15

Actual recruitment end date

2018-07-23, 1397/05/01

Trial completion date

2018-10-02, 1397/07/10

Scientific title

The effect of employees' humorous intervention on the severity of stress, anxiety, and depression among the elderly living in the nursing home

Public title

The effect of employees' humorous intervention on the severity of elderly's stress, anxiety and depression in the

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Having a willingness to collaborate and participate in the study
Not having a significant incidence of mental disorders
Not being in the chronic stage of lung disease
Having full consciousness
Having vision, hearing and speaking ability
Satisfaction of and his/her family for the participation in the study

Exclusion criteria:

Unwillingness of the elderly or their families to continue cooperation after the start of the research
Elder's death or leaving the nursing home
Facing with acute pulmonary and cardiac problem during research
The onset of psychiatric medications affecting consciousness during the study period

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Actual sample size reached: 60

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, samples were selected from two nursing homes. A total of 30 elderly residents in each nursing home were selected based on inclusion criteria. Then, randomly, the elderly of one of the nursing homes were considered as an intervention group and the other as a control group. In this regard, the name of each of the nursing homes was written on a piece of paper and placed in a dish. Then it was determined that the first extracted paper was the intervention group and the other paper the control group. By random extraction of the first paper, it was determined the intervention group and then the control 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 on Biomedical Research, Islamic Azad University, Faculty of Medicine

Street address

خیابان دکتر شریعتی، خیابان شهید خاقانی، خیابان عطاری مقدم، بن بست دانش

City

Tehran

Province

Tehran

Postal code

1936893813

Approval date

2018-05-05, 1397/02/15

Ethics committee reference number

IR.IAU.TMU.REC.1397.020

Health conditions studied**1****Description of health condition studied**

Stress, anxiety, and depression

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Stress

Timepoint

Before the intervention begins and immediately after it is completed

Method of measurement

Depression, Anxiety, Stress Scale (DASS)

2**Description**

Anxiety

Timepoint

Before the intervention begins and immediately after it is completed

Method of measurement

Depression, Anxiety, Stress Scale (DASS)

3**Description**

Depression

Timepoint

Before the intervention begins and immediately after it is completed

Method of measurement

Depression, Anxiety, Stress Scale (DASS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, the intervention included the humor training which was presented by the researcher during 7 sessions of an hour and a half.

Category

Behavior

2

Description

Control group: The control group participants received no intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tohid Nursing Home Complex

Full name of responsible person

Behrouz Hosseini

Street address

NO.137, Zahedi Alley, West Nosrat St, Tohid Sq, Tehran.

City

Tehran

Province

Tehran

Postal code

1457763181

Phone

+98 21 6694 2151

Email

Info@tohidsara.com

2

Recruitment center

Name of recruitment center

Farzanegan Nursing Home Complex

Full name of responsible person

Mojtaba Moazen

Street address

NO.11, Bahman pass way, Fifth St, Front of Laleh Hospital, Simaye-E- Iran St, Shahrak-e-Garb

City

Tehran

Province

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Postal code

1464213321

Phone

+98 21 8808 0304

Email

info@farzanegan.org.ir

Web page address

http://farzanegan.org.ir/contact

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Mehrandokht Nekavand

Street address

Khaghani St, Shariati St, Tehran

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1916893813

Phone

+98 21 2200 6660

Email

mnakavand@hotmail.com

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

Tannaz Taheri Gharagzlu

Position

Master of Sciences in Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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No.1271, Tehran international residential tower, Hakim and Sheikh Bahaei intersection

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Person responsible for scientific inquiries

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Master
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All information are shareable after non-identifiable people

When the data will become available and for how long

Available in 2019

To whom data/document is available

Faculty members and academic researchers

Under which criteria data/document could be used

Scientific use with source mention

From where data/document is obtainable

Vice-chancellor for research of Islamic Azad University,
Tehran Medical Branch

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

Apply to the Vice-chancellor for research of Islamic Azad University, Tehran Medical Branch

Comments