

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

The effect of emotion release technique on sleep quality and mental health of the elderly

Protocol summary

Study aim

Determining the effect of emotion release technique on sleep quality and mental health of the elderly

Design

Samples will be selected from people over 60 years old. After evaluating the elderly, the samples will be selected based on inclusion and exclusion criteria. The subjects of the intervention group perform EFT technique for 6 days, twice a day and each time for 20 minutes. Follow-up of EFT will be done daily by phone. The control group will not receive any intervention.

Settings and conduct

First, the city is divided into three regions: north, south and center, and then from each region, three health centers are randomly selected as clusters, and then the elderly are randomly selected from the list of names of these centers

Participants/Inclusion and exclusion criteria

Inclusion criteria 1) Age 60-70 years 2) Having insomnia based on the sleep quality questionnaire score (score higher than 5 Pittsburgh scales) Exclusion criteria 1) Lack of cooperation during the intervention 2) Use of benzodiazepines and other sedatives and hypnotics during the study

Intervention groups

Samples will be selected from people over 60 years old. After evaluating the elderly, the samples will be selected based on inclusion and exclusion criteria. The participants of the intervention group perform EFT technique for 6 days, twice a day and each time for 20 minutes. This technique is taught to the elderly in person so that the person can do it himself. Follow up daily EFT by phone Will be done. The control group will not receive any intervention. And after performing the research steps, this group will be trained in EFT. The samples of the control group will not receive any intervention.

Main outcome variables

Sleep quality and mental health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210626051707N1**

Registration date: **2021-12-01, 1400/09/10**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-01, 1400/09/10**

Update count: **0**

Registration date

2021-12-01, 1400/09/10

Registrant information

Name

Habib Zaheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3324 1473

Email address

habibzaheri4060@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-21, 1400/08/30

Expected recruitment end date

2021-12-21, 1400/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of emotion release technique on sleep quality and mental health of the elderly

Public title
The effect of emotion release technique on sleep quality and mental health of the elderly

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Age 60-70 years Insomnia based on sleep quality questionnaire score (score above 5 Pittsburgh scales)
 Dont have a serious physical and mental illness Dont have a cognitive deficits (score less than 7 on the Cognitive Status Questionnaire (AMT) Abbreviated mental test Dont have a drug addiction Dont have a wounds in the areas of energy channels
Exclusion criteria:
 Lack of cooperation during the intervention Use of benzodiazepines and other sedatives and hypnotics during the study getting severe physical and mental illness during the study Occurrence of unfortunate events such as mourning and loss of elderly loved ones during research

Age
From **60 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
According to the inclusion and exclusion criteria, people enter the study. In order to equalize the distribution of two important confounders of age and sex, classes based on these two variables are described as "age group 60 to 65 years / age group 65 to 70 years / age group 70 to 75 years / age group 75 to 80 years" and The "male / female class" is created and then randomly divided into two groups of treatment and control in a balanced way (Block Randomization)The size of each block is 4 items, so that 6 different combinations of 4 blocks are created and are selected randomly by placing the blocks. Using this method, the sample size in the two study arms will be equal (balance) and the difference between the two groups in terms of sample size will be equal to a maximum of half a block (two people).

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

Lorestan Medical Sciences Ethics Committee

Street address

Lorestan, Khorramabad, Lorestan University of Medical Sciences, Campus Kamalvand, Vice Chancellor for Research and Technology

City

Khorram Abad

Province

Lorestan

Postal code

381351698

Approval date

2021-03-12, 1399/12/22

Ethics committee reference number

IR.LUMS.REC.1399.365

Health conditions studied

1

Description of health condition studied

Elderly

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

sleep quality

Timepoint

Assessment of sleep quality scores before the intervention will be on the last day of the intervention and one month after the intervention

Method of measurement

Based on the Pittsburgh Standard Questionnaire

Secondary outcomes

1

Description

mental health

Timepoint

Before the intervention, it will be on the last day of the intervention and one month after the intervention

Method of measurement

Based on the DASS standard questionnaire

Intervention groups

1

Description

Intervention group: In this clinical trial, after obtaining the approval of the ethics committee and the necessary permits from the Vice Chancellor for Research and Technology of Lorestan University of Medical Sciences, the intervention will begin and samples will be collected. Then, with informed consent, seniors with inclusion criteria will complete demographic information questionnaires, the Pittsburgh Sleep Quality Scale, and the Short Cognitive Status Scale. Sampling method in this study is a multi-stage method including cluster and random. They are randomly selected from the list of names of these centers. It should be noted that the list of elderly people with files in health centers after receiving administrative and legal steps, will be received from each center and samples will be selected from people over 60 years. After evaluating the elderly, samples based on inclusion criteria and Exits are selected. The intervention group performs EFT technique for 6 days, twice a day for 20 minutes each time. This technique is taught to the elderly in person so that the person can do it himself. This technique will be taught individually to the elderly. EFT follow-up will be done daily by telephone.

Category

Behavior

2

Description

Control group: The control group does not receive any intervention. After performing the research steps, this group is trained in EFT. The samples of the control group do not receive any intervention and after the intervention, the EFT technique, if desired, These people will be trained. The EFT technique will be performed according to the EFT guide

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Nasser Khosrow Comprehensive Health Service Center

Full name of responsible person

Saman Hatami

Street address

Khatam Al-Anbia Street, above the emergency intersection on the right in front of Haft Store

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habibzaheri4060@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Ebrahim Falahi

Street address

km 5 Road of Khorram Abad - Boroujerd - opposite to the Kahrizak village- Integrated Lorestan Medical Sciences Khoramabad, Lorestan, Iran

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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

Khoram-Abad University of Medical Sciences

Proportion provided by this source

10

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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Habib Zaheri

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available