

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Emotional Freedom Technique (EFT) on Sleep Quality and Anxiety of Elderly

Protocol summary

Study aim

The effect of emotion freedom technique on sleep quality and anxiety in the elderly

Design

This study is a type of clinical trial in Shiraz. participants of this study fall into two groups: intervention and control (40 people per group).

Settings and conduct

This study is a single blind clinical trial with a control group. Samples were selected based on the inclusion criteria, , Using the randomized block allocation method with a block size of 4 equal to two AABB groups are randomly divided, each group is 40 people and a total of 80 people are considered. The person assessing the consequences is unaware of the allocation of individuals in the groups. The study site will be in Pishgam physiotherapy clinic in shiraz, satarkhan Blvd.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age over 60 years, Patients with sleep disorders and anxiety according to the sleep quality and anxiety questionnaire, Absence of cognitive and motor disorders. Exclusion Criteria: History of using psychotropic or psychiatry drugs, As well as suffering from pain pain before the intervention.

Intervention groups

Intervention group: Intervention will performed in 8 sessions (twice a week for four weeks) for 15 minutes. In each session, participants are asked to rate their level of mental distress. Sequence of striking points, first the point of the karate stick and then the meridian point (head difference), between the eyebrows, both sides of the eyes, under the eyes, under the nose, under the lips, two claws in the chest, under the arms (below the armpit) The index finger, thumb, middle finger, and little finger are taught. These steps will be repeated during 8 sessions. Control Group: No intervention will be performed in the control group.

Main outcome variables

Anxiety and Sleep Quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180923041101N3**

Registration date: **2021-04-16, 1400/01/27**

Registration timing: **prospective**

Last update: **2021-04-16, 1400/01/27**

Update count: **0**

Registration date

2021-04-16, 1400/01/27

Registrant information

Name

Majid Najafi Kalyani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4251

Email address

najafikalyani@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-19, 1400/01/30

Expected recruitment end date

2021-09-21, 1400/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Emotional Freedom Technique (EFT) on Sleep Quality and Anxiety of Elderly		(day 1 and final day after 8 week), and does not know the allocation of the groups.	
Public title	The Effect of Emotional Freedom Technique (EFT) on Sleep Quality and Anxiety of Elderly	Placebo	Not used
Purpose	Education/Guidance	Assignment	Parallel
Inclusion/Exclusion criteria		Other design features	
Inclusion criteria:	Age 60 years and older Absence of mental illness or use of psychiatric and psychiatric drugs Patients with sleep and anxiety disorders according to the Sleep and Anxiety Quality Assessment Questionnaire Absence of cognitive and motor disorders	Secondary Ids	empty
Exclusion criteria:	Pain before the intervention due to illnesses that prevents the intervention Lack of literacy to complete the questionnaires and understand the process of work	Ethics committees	
Age	From 60 years old	1	
Gender	Both	Ethics committee	
Phase	3	Name of ethics committee	Research Ethics Committee Shiraz University of Medical Sciences
Groups that have been masked	Outcome assessor	Street address	Zand St
Sample size	Target sample size: 80	City	Shiraz
Randomization (investigator's opinion)	Randomized	Province	Fars
Randomization description	After selection of participants based on the inclusion criteria, the random allocation method in this study will be the permutation block method, where A represents the person receiving the intervention and B represents the person who does not receive the intervention. This method is performed by considering 4 blocks so that the total number of 4 permutations is equal to 6. Then, using a table of random numbers and assigning code zero to 9 to each of the permutations (ABAB code 0, BABA code 1, AABB code 2, BBAA code 3, BAAB code 4 and ABBA code 5 to 9), a random list of 60 The desired consisting of 20 blocks of 4 ($4 * 20 = 80$ total number of samples) is generated and the order of assignment to each of the samples participating in the study is determined. How to use the table of random numbers is that the starting point is selected randomly and 20 numbers from zero to 9 are selected randomly (row or column) and the permutation assigned to each number is noted. (The order of placement of shifts next to each other will be from left to right) and how to allocate a total of 80 people to two groups A and B will be determined. (40 people in each group). These steps are performed using random allocation software.	Postal code	71348-14336
Blinding (investigator's opinion)	Single blinded	Approval date	2020-05-05, 1399/02/16
Blinding description	In this study, the evaluator of outcome are kept blind to the type of intervention. In this way, the outcome evaluator fills the questionnaire in the appointed time	Ethics committee reference number	IR.SUMS.REC.1399.352
		Health conditions studied	
		1	
		Description of health condition studied	Sleep quality, Anxiety
		ICD-10 code	
		ICD-10 code description	
		Primary outcomes	
		1	
		Description	Sleep Quality
		Timepoint	Day 1 and 35
		Method of measurement	Pittsburg Inventory
		2	
		Description	Anxiety
		Timepoint	Day 1 and 35
		Method of measurement	Speilberger's Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention sessions are performed in 8 sessions (twice a week for four weeks) in the morning for 15 minutes while the elderly person is sitting on a chair. The technique is that at the beginning of each session, participants are asked to rate their level of mental distress on a scale of 1 to 10, with 1 indicating the lowest and 10 the highest level of distress. The statement confirming the acceptance of this mental disorder is repeated 3 times. For example, "Even if I have this problem, I accept myself deeply and completely", this phrase is different for each person. Sequence of striking points, first the point of the karate stick and then the meridian point (head difference), between the eyebrows, both sides of the eyes, under the eyes, under the nose, under the lips, two claws in the chest, under the arms (below the armpit) The index finger, thumb, middle finger, and little finger are taught, and participants are asked to repeat the affirmative phrase when tapping the point of the meridian and the karate stick. And then point 9 - Gammot and turning the eyes to communicate with the two hemispheres of the brain along with whispering favorite music is taught. These steps will be repeated during 8 sessions.

Category

Behavior

2

Description

Control group: A group on which no intervention will be made.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Pishgam Physiotherapy Clinic

Full name of responsible person

Habibollah Lari

Street address

Sattar Khan St

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3626 1192

Email

h_lari@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Poost Foroosh

Street address

Zand St, Shiraz, Iran.

City

Shiraz

Province

Fars

Postal code

71348-14336

Phone

+98 71 3235 7282

Fax

+98 71 3212 2430

Email

vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Shiraz University of Medical Sciences

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

Shiraz University of Medical Sciences

Full name of responsible person

Zahra Shakibavand

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Zand St

City

Shiraz

Province
Fars
Postal code
13119-71936
Phone
+98 71 3647 4254
Email
nadia1374.ns@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Majid Najafi Kalyani
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Namazee St
City
Shiraz
Province
Fars
Postal code
3119-171936
Phone
+98 71 3647 4251
Fax
Email
najafikalyani@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Majid Najafi Kalyani
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work

Nursery
Street address
Namazee St
City
Shiraz
Province
Fars
Postal code
3119-171936
Phone
+98 71 3647 4251
Fax
Email
najafikalyani@sums.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

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

Analyzed data can be shared after completion of the study as an article.

When the data will become available and for how long

Start of access period 6 months after publication of results.

To whom data/document is available

All of the researchers in Medical Sciences Universities.

Under which criteria data/document could be used

Analysis of data based on statistical software.

From where data/document is obtainable

Dr. Majid Najafi Kalyani

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

Sending request, permission from Ethic Committee, sending data.

Comments