

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The effectiveness of emotional freedom technique(EFT) on sleep disorders of elderly in adult Day-Care Centers

Protocol summary

Study aim

Determining the effect of emotional Freedom technique on sleep disorders in elderly of day care centers in Babol

Design

This study is based on two experimental and control groups. The study population consisted of two groups of 25 each the elderly live in the Day Care Center. Questionnaires were completed before the intervention, after finishing it, and will be performed by the researcher 1 month after the intervention.

Settings and conduct

This study is based on two experimental and control groups. The study population consisted of two groups of 25 each the elderly live in the Day Care Center. This is conducted for 6 weeks, 2 sessions per week and each session for 30-45 minutes. At the beginning of the interventions, for both test and control groups, first a training session with pamphlets it will be done.

Participants/Inclusion and exclusion criteria

Samples from elderly people over 60 years old who visit day care centers and have problem in sleep quality score will be selected. Elderly people with cognitive impairment, severe hearing loss, severe anxiety, severe depression and severe pain and, substance user, or if they are unwilling to cooperate and miss more than 1 meeting, will be excluded.

Intervention groups

The intervention group includes 25 elderly people who receive a 6-week intervention emotional freedom technique. The control group includes 25 elderly people who receive sleep health education in one session.

Main outcome variables

Quality sleep, sleepiness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170725035278N2**

Registration date: **2020-12-13, 1399/09/23**

Registration timing: **retrospective**

Last update: **2020-12-13, 1399/09/23**

Update count: **0**

Registration date

2020-12-13, 1399/09/23

Registrant information

Name

Samaneh Pourhadi

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3219 0560

Email address

s.pourhadi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-11, 1398/08/20

Expected recruitment end date

2020-05-04, 1399/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of emotional freedom technique(EFT) on sleep disorders of elderly in adult Day-Care Centers

Public title

The effectiveness of emotional freedom technique(EFT) on sleep disorders of elderly

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Elderly people over 60 years Sleep quality score greater than 5 or sleepiness score greater than 10

Exclusion criteria:

Elderly with cognitive impairment Severe hearing disorders Severe Anxiety Severe Depression Smoking and alcohol Lack of cooperation and absence from more than one meeting

Age

From 60 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Babol University of Medical Sciences

Street address

No. 2, Modarres 21, Modarres St., Babol, Mazandaran Province

City

Babol

Province

Mazandaran

Postal code

4714933757

Approval date

2019-11-24, 1398/09/03

Ethics committee reference number

IR.MUBABOL.HRI.REC.1398.246

Health conditions studied

1

Description of health condition studied

sleep disorders

ICD-10 code

G47.9

ICD-10 code description

Sleep disorder, unspecified

Primary outcomes

1

Description

Sleep quality

Timepoint

Before intervention, immediately and one month after intervention

Method of measurement

Pittsburgh Sleep Quality Questionnaire

2

Description

Sleepiness

Timepoint

Before intervention, immediately and one month after intervention

Method of measurement

Epworth Sleepiness Questionnaire

Secondary outcomes

1

Description

Quality of Life

Timepoint

Before intervention, immediately and one month after intervention

Method of measurement

Quality of Life Questionnaire Control, Autonomy, Self-realization, Pleasure-19

2

Description

Anxiety

Timepoint

Before intervention, immediately and one month after intervention

Method of measurement

Geriatric Anxiety Inventory

3

Description

Depression

Timepoint

Before intervention, immediately and one month after

intervention
Method of measurement
Geriatric Depression Scale

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Avayemehr@yahoo.com

Intervention groups

1

Description

Intervention group: The Emotional Freedom Technique for 6 weeks, 2 sessions per week and 30-45 minutes per session.

Category

Behavior

2

Description

Control group: will receive sleep hygiene training in one session.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Daily Hamrah Salamat Center

Full name of responsible person

Samad Izadi

Street address

No. 101, Baharan 26, Western Belt, Babol

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Recruitment center

Name of recruitment center

Avaye Mehr Daily Center

Full name of responsible person

MehrasaMirza Babazade

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Feyzie 7, Next to the Karimnezhad Hall, Mirza Koch Khan Boulevard, Shahid Bazaz Square, Babol

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Phone

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Reza Ghadimi

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Vice chancellor for research, Babol University of Medical Sciences ,Ganj Afroz Street

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s_ghoreishi68@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Seyedeh Sahar Ghoreishi

Position

Master of Science Student of Geriatric Health

Latest degree

Bachelor

Other areas of specialty/work

Audiology

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable