Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Oct 2026

The effect of foot reflexology on anxiety in patients undergoing electroconvulsive therapy and complications after it, a clinical trial study

Protocol summary

Summary

The aim of this study is to determine the effect of foot reflexology massage on anxiety, pain and amnesia among psychiatric patients admitted and candidate for electroconvulsive therapy. In clinical trial, 68 electroconvulsive therapy candidate patients who are not in the acute phase of psychosis are divided into two groups, experimental (34 individuals) and control (34 individuals) by Using the random number selected and assigned to two groups of intervention and control. Assigned to random sequence generation method will be performed by a table of random numbers by excel software. For intervention group in workroom, foot massage will be performed three times a week by the researchers and help female researchers in the morning shifts and when will not interfere with the round section (visit time, occupational therapy). Massaging the soles of the feet will be done as three times a week by the researcher and female assistant researcher in the morning shifts and when will not interfere with the round section (visit time, occupational therapy). reflexology mesaage will be done 3 times a week, each session lasts 40 minutes for 1 week, and for each foot massage is done for 20 minutes which includes 10 minutes for foot basic message, and the other 10 minutes of massage is related to anxiety and relaxation areas. Allocated patients in the intervention group, reflexology using with olive oil will be carried out without the using of gloves, and in the control group, Only the patient's feet will be anointed with olive oil. The outcome variables are anxiety, amnesia and pain.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015080623525N2**
Registration date: **2016-04-28, 1395/02/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-04-28, 1395/02/09

Registrant information

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Name of organization / entity
Tabriz University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Tabriz University of medical sciences

Expected recruitment start date

2015-12-27, 1394/10/06

Expected recruitment end date

2016-06-09, 1395/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot reflexology on anxiety in patients undergoing electroconvulsive therapy and complications after it, a clinical trial study

Public title

The effect of foot massage on agitation in patients undergoing electroconvulsive therapy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: candidated for ECT by a psychiatrist؛ no history of eclectroconvulsive therapy؛ males and females with age of 18 years and over؛ lack of foot problems such as ulceration and scarring؛ Desiring to participate in the study؛ Be alert and aware؛ Lack of drug addiction and non-drug treatment of sleep the night before eclectroconvulsive therapy؛ lack of an underlying medical condition (having diabetes, hypothyroidism, Hypethyroidism, electrolyte disorders, neuromuscular diseases)؛ lack of perceptional disorders and impaired reality testing (hallucinations and delusions)؛ the absence of anxiety disorder؛Inform the doctor about the procedure on the patients؛ getting consent from protector of patient؛ no acute problems vision due to interference by filling out the Visual Analog Scale for Pain (VAS Pain). Exclusion criteria: Patients who for any reason do not have the desire to continue working؛ patients in the acute phase of psychosis (hallucinations and delusions)؛ absence of more than one session in the process of intervention

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz university of medical sciences

Street address

Golghasht Ave,

City

Tabriz

Postal code

Approval date

2015-11-09, 1394/08/18

Ethics committee reference number

TBZMED.REC.1394.842

Health conditions studied

1

Description of health condition studied

Anxiety,Amnesia and pain

ICD-10 code

F41.9

ICD-10 code description

Anxiety NOS

Primary outcomes

1

Description

Anxiety

Timepoint

Before and immediately after the intervention

Method of measurement

Spilberger Questionnare

Secondary outcomes

1

Description

Amnesia

Timepoint

Thirty minutes after electroconvulsive therapy

Method of measurement

Galveston- Orietation-Amnesia-Test

2

Description

Pain

Timepoint

Fifteen minutes after electroconvulsive therapy

Method of measurement

Numeric Pain scale

Intervention groups

1

Description

intervention group: Massaging the soles of the feet will be done as three times a week by the researcher and female assistant researcher in the morning shifts and when will not interfere with the round section (visit time, occupational therapy). reflexology mesaage will be done 3 times a week, each session lats 40 minutes for 1 week, and for each foot massage is done for 20 minutes to 10

minutes for foot basic message, and its 10 minutes of massage areas is related to anxiety and relaxation. Allocated patients in the intervention group, reflexology using with olive oil will be carried out without the using of gloves.

Category

Treatment - Other

2

Description

Only the patient's feet will be anointed with olive oil.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Educational and Treatment Psychiatric center

Full name of responsible person

Hossein Namdar Areshtanab

Street address

Razi Educational and Treatment Psychiatric center, Elgoli road

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rashidi

Street address

University Ave, Tabriz University of Medical Sciences

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty