

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 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

###### Name

Hossein Namdar Areshtanab

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3479 6770

###### Email address

namdarh@tbzmed.ac.ir

##### 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: candidates for ECT by a psychiatrist: no history of electroconvulsive 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 electroconvulsive therapy: lack of an underlying medical condition (having diabetes, hypothyroidism, Hypothyroidism, electrolyte disorders, neuromuscular diseases): lack of perceptual 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 Questionnaire

## **Secondary outcomes**

### **1**

#### **Description**

Amnesia

#### **Timepoint**

Thirty minutes after electroconvulsive therapy

#### **Method of measurement**

Galveston- Orientation-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 message 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 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**

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**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

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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**

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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Saeed Alinezhad machiani

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Masters student

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**Web page address****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*