# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

13 Oct 2026

## The effect of reflexology on post- electroconvulsive thrapy on severity of pain in depressed patients referring to educational-treatmant Razi psychiatric center of Urmia in 2018

## Protocol summary

**Study aim**
The Effect of Reflexology on Post- Electroconvulsive thrapy on severity of Pain in depressed patients

**Design**
Assignment of patients to the intervention and control groups will be done in a gendered and randomized manner, and a total of 26 people will be in each group.

**Settings and conduct**
Control of pain intensity in patients referring to Razi Educational-treatment Psychiatric Center, Urmia, Iran

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: age: 18-65 years old; having one of the types of depression that requires the ECT; absence of clear anomalies in the organs; conscious willingness and consent to participate in the study; not being affected by underlying diseases such as diabetes, hypothyroidism, hypoparathyroidism, musculoskeletal disorders; failure to understand perception and disturbance in clear realism; no history for anxiety disorders; no acute vision problems; earn score 3 or higher on a visual scale assessing pain; receive reflexology; no drug addiction or drug intake before the study; receive the drug at least 4 hours before the intervention. Exit criteria: no collaboration to receive intervention; illness and delirium creation in patient; cancellation of patients for continuation of study; sensitivity to touch.

**Intervention groups**
In the intervention group, the massage will be performed using odorless olive oil without gloves. After the initial heating of the target member, it will push the reflection points of the head and muscles in the hands and feet (middle finger and thumb) using a special stick and finally use a thumb for the solar network for 2 minutes will be pressed. All steps will be performed within 20 minutes. After 10 minutes, the severity of pain in the intervention group will be measured using the visual instrument of pain.The control group will be given routine care.

**Main outcome variables**
Severity of pain

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20161116030926N1**
Registration date: **2018-09-08, 1397/06/17**
Registration timing: **prospective**

Last update: **2018-12-01, 1397/09/10**
Update count: **1**

**Registration date**
2018-09-08, 1397/06/17

**Registrant information**

**Name**

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 44 3275 4961

**Email address**
alilu@umsu.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2018-09-14, 1397/06/23

**Expected recruitment end date**
2018-12-14, 1397/09/23

**Actual recruitment start date**
empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of reflexology on post- electroconvulsive thrapy on severity of pain in depressed patients referring to educational-treatmant Razi psychiatric center of Urmia in 2018

**Public title**

The effect of reflexology on post- electroconvulsive thrapy on severity of pain in depressed patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Age: 18-65 years old Having one type of depression (based on documentation of the case and psychiatrist's opinion) that requires ECT Patient is not in the acute phase of psychosis Patient with obvious anomalies in the organs Patient has a willing and informed consent to participate in the study Patient with underlying diseases such as diabetes, hypothyroidism, hypoparathyroidism, musculoskeletal disorders Patient at the time of intervention with perceptual impairment and disorder The patient does not have anxiety disorders according to the diagnosis of the psychiatrist The patient has no acute visual problems. (Due to interference with the filling of the numerical scale of pain) Score 3 or higher on the visual scale of pain assessment No previous massage has been performed Drug addiction or drug intake before the study Not using the drug for at least 4 hours before the intervention

**Exclusion criteria:**

The patient does not have the necessary cooperation to receive the intervention Intervention causes illness and delusions in the patient Patient disclaims continuation of the study for any reason The patient is allergic to the touch and the inability to tolerate massage in the area

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **56**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Assignment of patients to intervention and control groups will be done in a gendered and randomized manner. For this purpose, in two separate and distinct bags, in sex (male or female), the number 14, number one and 14, number two, which are written on the cardboard parts. , Each patient extracts one of the numbers from the bag of his sexual group. Each patient who succeeds in making the number one in the intervention group and each patient who leaves the number two in the control group Will take. At the end of the lottery, fourteen female patients in the intervention group and fourteen female patients in the control group as well as fourteen male patients in the intervention group and fourteen male patients in the control group will be placed.

**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**

Urmia University of Science & Technology Ethics Committee

**Street address**

Urmia University of Medical Sciences,

**City**

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**Province**

West Azarbaijan

**Postal code**

5714783734

**Approval date**

2018-08-27, 1397/06/05

**Ethics committee reference number**

IR.UMSU.REC.1397.171

## Health conditions studied

### 1

**Description of health condition studied**

Severe depression without symptoms of psychosis

**ICD-10 code**

F32.2

**ICD-10 code description**

Severe depressive episode without psychotic symptoms

## Primary outcomes

### 1

**Description**

Severity of pain

**Timepoint**

Measure the severity of pain before the intervention and after the intervention

**Method of measurement**

Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: After initial heating, the head will press the reflection points of the head and muscles in the hands and feet (mid-thumb and middle finger) using a reflexology stick (stick) with gentle pressure and without pain, and eventually 2 minutes using the thumb to initially press the solar network at the border between the upper third and middle of the foot of the foot in the area where the foot is folded up when the foot is bent, initially fixed for 2 minutes. And then will be given a rotational massage. The pressure applied is to the extent that the upper third of the fingers of the researcher is white and the patient will feel the pressure, but will not feel pain. All of these steps will be performed within 20,

**Category**
Treatment - Other

**2**

**Description**
Control group: Get routine for pain control

**Category**
N/A

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Educational-Treatmant Razi Psychiatric Center of Urmia

**Full name of responsible person**
Maryam Ali ashraf jodat

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
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**Full name of responsible person**
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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**
Oroumia 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**

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**Position**
masters student

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Master

**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**
Not applicable
**Informed Consent Form**
No - There is not 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**
Not applicable
**Data Dictionary**
Not applicable