Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Nov 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)

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+98 44 3275 4961

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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

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Maryam Ali Ashraf Jodat

Position

masters student

Latest degree

Master

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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