

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of foot reflexology massage on pain and anxiety of male patients after abdominal surgery

Protocol summary

Summary

This study is going to be administered with the aim of determining the effect of foot reflexology massage on pain and anxiety of male patients after abdominal surgery in selected instructive hospitals of Tehran. The study will be quasi-experimental before and after which will be contain three groups of control, placebo, and intervention. The study population will consist of male patients who had an abdominal surgery. A sample size of 30 patients will be considered for each of the three groups. Sampling will initially based on objective and After selecting participants based on inclusion criteria, they randomly will be assigned to three groups: control, placebo, and intervention. Inclusion criteria: age between 15 to 60 years old; lack of analgesics before intervention; full consciousness after surgery; getting the minimum score of pain intensity from three and more base on the visual analogue scale; Lack of the experience of using foot reflexology massage; and exclusion criteria: lack of desire to continue cooperation in the study; tenderness or massage; and spinal anesthesia. The intervention will be done by the researcher in one session without using cream or conditioner for 30 minutes (each leg 15 minutes) for certain areas in all regions of the foot and abdominal surgery due to surgical site to reduce pain and anxiety in the leg and Immediately after the massage, 10 minutes, and 24 hours after the end of the massage, the pain and anxiety of patient would be measured and recorded.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016053128200N1**

Registration date: **2016-07-04, 1395/04/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-07-04, 1395/04/14

Registrant information

Name

Abolfazl Rahimi Zarchi

Name of organization / entity

Tehran University of Social Welfare and Rehabilitation Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2218 0085

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ab.rahimi@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Social Welfare and Rehabilitation Sciences

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot reflexology massage on pain and anxiety of male patients after abdominal surgery

Public title

The effect of foot reflexology massage on pain and anxiety

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: admitted for abdominal surgery; Age between 15 to 60 years old; lack of analgesics before intervention having; healthy feet, especially the soles of them; getting the minimum score of pain intensity from three and more base on the visual analogue scale; full consciousness after surgery; Lack of addiction to drugs, alcohol and...; Lack of sensory and motor derangement according to the doctor's opinion or the existent information in the document or the patient saying itself; Lack of fever and skin diseases according to the doctor's opinion or the existent information in the document or the patient saying itself; Lack of hearing disorders according to the doctor's opinion or the existent information in the document or the patient saying itself; Lack of any physical and mental disorder except recent surgery according to the doctor's opinion or the existent information in the document or the patient saying itself; Lack of the experience of using foot reflexology massage; Lack of Chronic pain in other parts of the body (migraine, low back pain and ...) according to the doctor's opinion or the existent information in the document or the patient saying itself; Exclusion criteria: addiction diagnostic to drugs, alcohol, etc. After the inclusion; spinal anesthesia; lack of desire to continue cooperation in the study; tenderness or massage; any intervention process because the person is unable to tolerate or pursue

Age

From **15 years** old to **60 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Simple random

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Social Welfare and Rehabilitation Sciences

Street address

Kodakyar Avenue, Daneshjo Blvd., Evin, Tehran

City

Tehran

Postal code

1985713834

Approval date

2015-05-24, 1394/03/03

Ethics committee reference number

IR.USWR.REC.1394.31

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

R10.0

ICD-10 code description

Acute abdomen

2

Description of health condition studied

anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

pain

Timepoint

immediately before intervention- immediately after invention- 10 minutes after intervention- 24 hours after intervention

Method of measurement

visual analog scale

2

Description

anxiety

Timepoint

immediately before intervention- immediately after invention- 10 minutes after intervention- 24 hours after intervention

Method of measurement

Spielberger anxiety inventory

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention group: to relieve the pain of experimental group, foot reflexology massage is used and narcotic drugs as well if necessary. The intervention of experimental group includes foot reflexology massage which is done by the researcher after training and receiving the certification of reflexology performance from massage Art Institute of Iran. Foot reflexology massage is done without using cream or conditioner for 30 minutes (15 minutes per foot) in certain areas of abdominal surgery on foot. Then immediately after intervention, ten minutes later, and 24 hours later the intervention, the severity of pain and anxiety is measured.

Category

Placebo

2

Description

Control group: for control group, analgesic drugs in necessary situations and usual care are done. There is no intervention in control group, but just in time parallel with the experimental group, its severity of pain and anxiety is measured.

Category

Placebo

3

Description

Placebo group: for the placebo group, a simple massage on the foot is done and analgesic drugs as well if necessary. The severity of pain and anxiety of patients is measured immediately before the intervention. Then a 30 minute massage movements not the real massage runs in the sole of the patient's foot. These pressures are not on the surgical parts of the patient, then immediately, ten minutes and 24 hours after the end of the massage, the intensity of pain and anxiety is measured.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Ms. Jafary- Bachelor of Nursing

Street address

Imam Khomeini Hospital Complex, The western end of Keshavarz Boulevard, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tehran University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Doctor Mohammad Ali Hosseini

Street address

Kodakyar Avenue, Daneshjo Blvd., Evin, Tehran

City

Tehran

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 of Tehran University of Social Welfare and Rehabilitation 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

Tehran University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Abolfazl Rahimi Zarchi

Position

Nursing Graduate Student

Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Doctor Mohammad Ali Hosseini

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Associate Professor- Postdoctoral knowledge transfer from the University of Technology Sydney, Austr

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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