# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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

**Email address**

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**
**Street address**
Kodakyar Avenue, Daneshjo Blvd., Evin, Tehran
**City**
Tehran
**Postal code**
1985713834

**Phone**
+98 21 2218 0085
**Fax**
+98 22180109
**Email**
amozesh@uswr.ac.ir
**Web page address**
http://www.uswr.ac.ir

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
University of Social Welfare and Rehabilitation Sciences
**Full name of responsible person**
Doctor Mohammad Ali Hosseini
**Position**
Associate Professor- Postdoctoral knowledge transfer from the University of Technology Sydney, Austr
**Other areas of specialty/work**
**Street address**
kodakyar Ave., daneshjo Blvd.,Evin
**City**
Tehran
**Postal code**
1985713834
**Phone**
+98 21 2218 0085
**Fax**
+98 22180109
**Email**
amozesh@uswr.ac.ir
**Web page address**
http://www.uswr.ac.ir

## Person responsible for updating data

**Contact**
**Name of organization / entity**
University of Social Welfare and Rehabilitation Sciences
**Full name of responsible person**
Abolfazl Rahimi Zarchi
**Position**
Nursing Graduate Student
**Other areas of specialty/work**
**Street address**
kodakyar Ave., daneshjo Blvd.,Evin
**City**
Tehran
**Postal code**
1985713834
**Phone**
+98 21 2218 0085
**Fax**
+98 22180109
**Email**
amozesh@uswr.ac.ir
**Web page address**
www.uswr.ac.ir

## 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*