

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effect of reflexology on pain and sleep disorder in older women whit abdominal surgery

Protocol summary

Summary

The main objectives of the project: to determine the effect of reflexology (reflexology) on sleep disorders and pain in elderly women undergoing abdominal surgery study design: experimental clinical trial, non-random sampling, a control group and test centers. The study population consisted of older women undergoing abdominal surgery form. Inclusion criteria; exposure to abdominal surgery due to surgical incision and duration of surgery, the point 5 of the tool above the PSQI, no interference or foot deformity, no diabetes, grade 7 and older versions of Persian short test cognitive status, their ability to report pain. Exclusion criteria of the study; the lack of cooperation or death of the elderly, less than two days of hospital discharge after surgery, the risk of malignancy associated with any surgery, the patient needs to be hospitalized in the intensive care unit. A sample of 80 elderly women undergoing abdominal surgery case study is reflexology massage. Since Intervention: Intervention Reflexology in the morning (an hour after breakfast) and evening (one hour before bedtime) in the second and third day of surgery and for 20 minutes each will be conducted by the researcher. Primary Outcome: Reflexology intervention in reducing sleep disorders and pain affects older women undergoing abdominal surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016010325625N2**

Registration date: **2016-01-24, 1394/11/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-24, 1394/11/04

Registrant information

Name

Azadeh Kheiri

Name of organization / entity

Iran University of Medical Science

Country

Iran (Islamic Republic of)

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+98 000000

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kheiri.a@tak.iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Iran University of Medical Sciences

Expected recruitment start date

2016-01-20, 1394/10/30

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of reflexology on pain and sleep disorder in older women whit abdominal surgery

Public title

Reflexology effect on sleep disorders and pain after abdominal surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria for the study; Operation of the surgical

incision in the abdomen, according to the length of time of operation, the point 5 of the tool above the PSQI, no disturbance or deformation of the foot (corn, burning feet, amputations and skin diseases), The lack of a history of drug use or psychiatric disorders, absence of diabetes, lack of severe visual-auditory disorders, addiction to alcohol and drugs, having a fracture, graft and wound infections , Mini-Mental State Examination scores Persian versions 7 and above, the ability to self-report pain Exclusion criteria of the study; Lack of cooperation or death of the elderly, less than two days of hospital discharge after surgery, not wanting to continue to participate in the study, any risk of malignancy associated with the surgery, the patient needs to be hospitalized in intensive care unit.

Age

From **60 years** old to **80 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Sampling method in this study consecutively (targeted) will be. So that patients Inclusion criteria for the study were randomly coin toss in the hospital as one of the two groups are or control.

Secondary Ids

1

Registry name

Secondary trial Id

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of the Iran University of Medical Science

Street address

Between the intersection of sheikh fazlolahe nouri st. and shahid chamran st., Toward the west of Shahid Hemmat Highway, Iran University of Medical Science, Tehran, Iran

City

Tehran

Postal code

7396144859

Approval date

2015-08-05, 1394/05/14

Ethics committee reference number

IR.IUMS.REC.1394.9211580203

Health conditions studied

1

Description of health condition studied

Sleep disorder

ICD-10 code

G47

ICD-10 code description

Disorders of initiating and maintaining sleep [insomnias]

2

Description of health condition studied

Pain

ICD-10 code

R10

ICD-10 code description

Severe abdominal pain (generalized)(localized)(with abdominal rigidity)

Primary outcomes

1

Description

Improving in sleep quality

Timepoint

Half an hour before the intervention and the fourth day of surgery

Method of measurement

Pittsburgh Sleep Quality Index

2

Description

Pain relief

Timepoint

Half an hour before the intervention and the fourth day of surgery

Method of measurement

Visual Analog Scale

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups**1****Description**

intervention group; Reflexology in the morning(one hour after breakfast) and evening (one hour before bedtime) in the second and third day of surgery and for 20 minutes each will be conducted by the researcher.

Category

Other

2**Description**

The control group; did not receive special treatment than the routine care of surgery.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hazrate Rasoul educational-medical center related to IUMS

Full name of responsible person

Azade kheiri

Street address

Hazrate Rasoul educational-medical center, At the corner of the Mansouri St, Niayesh St, Sattarkhan district, Urban area 2, Tehran, Iran

City

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2**Recruitment center****Name of recruitment center**

Firouzgar educational-medical center related to IUMS

Full name of responsible person

Azade kheiri

Street address

Firouzgar educational-medical center, Karimkhan zand St. to Beh-Afarin St., Vali Asr Square, Tehran, Iran Tehran

City

tehran

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Vice Chancellor of Research- Iran University of

Medical Science

Full name of responsible person

Dr Seyed Ali Javad Mousavi

Street address

The fifth floor of headquarters,Iran University of Medical Science, Between the intersection of sheikh fazlolahe nouri st. and shahid chamran st., Toward the west of Shahid Hemmat Highway

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 of Research- Iran University of Medical Science

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**

Faculty of Nursing and Midwifery, Iran University of Medical Science

Full name of responsible person

Azade khriri

Position

Student / M.Sc.

Other areas of specialty/work**Street address**

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

Faculty of Nursing and Midwifery, Iran University of

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Full name of responsible person

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Ph.D / Associate Professor

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Other areas of specialty/work

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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