

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The Impact of foot massage on anxiety before and after hysterectomy

Protocol summary

Summary

1 -The main goal: The effect of foot massage on anxiety before and after hysterectomy 2 - Study design: The clinical study, 2 groups (intervention and control) the randomly selected 3 - Interventions: The intervention (massage) once a day, 20 minute foot massage is done that started one day before surgery to 2 days after surgery to continue. In the control group patients in parallel with a time massage intervention group, research on the bedside will be present in the two groups before and 30 minutes after the massage Questionnaire Anxiety addition, Berger by researcher will be completed as well as vital signs, including: pulse, respiration and bp is measured and recorded. 4 - Main Outcomes: Outcomes are measurable anxiety and vital sign. Inclusion Criteria: At least literate; not having the surgery except oophorectomy; hysterectomy to benign compliant until study time; No history of foot massage; After gaining consciousness; At least one day before surgery and 2 days after surgery in the hospital; For long term (more than one month), tranquilizers, pain or anxiety drugs such as inderal is not received; Lack of drug addiction; No known diseases as diabetes, heart disease, mental disorders, movement disorders, impaired vision, hearing; having a healthy part of legs Exclusion criteria: Severe complications after surgery, such as bleeding, infection, need for care in the intensive care unit; Lack of access to experimental conditions during the study (compliant and discomfort and ...); Lack of patient consent to continue participation in the study

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201301196284N5**
Registration date: **2013-05-18, 1392/02/28**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-05-18, 1392/02/28

Registrant information

Name

Maryam Modarres

Name of organization / entity

Tehran university of Medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Tehran University of Medical Sciences

Expected recruitment start date

2013-01-24, 1391/11/05

Expected recruitment end date

2013-05-31, 1392/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Impact of foot massage on anxiety before and after hysterectomy

Public title

Effect of foot massage on anxiety before and after hysterectomy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: At least literate; not having the surgery With the exception of oophorectomy; hysterectomy to benign compliant until time study; No having history of foot massage; After gaining consciousness; At least one day before surgery and 2 days after surgery in the hospital; For long term (more than one month, tranquilizers, pain or anxiety drugs such as inderal is not received; Lack of drug addiction; No known diseases as diabetes, heart disease, mental disorders, movement disorders, impaired vision, hearing; having a healthy part of legs. Exclusion criteria: Severe complications after surgery such as bleeding, infection, need for care in the intensive care unit; Lack of access to experimental conditions during the study (for example discomfort and ...); Lack of patient consent to continue participation in the study.

Age

From **20 years** old to **85 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

no

Secondary trial Id

no

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Tehran university of Medical sciences

Street address

sixth floor,central organization of university, edge of Qods street, keshavarz blvd, Tehran

City

Tehran

Postal code

Approval date

2012-07-11, 1391/04/21

Ethics committee reference number

668 /130/91/5

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

f40-f41-f4

ICD-10 code description

Neurotic, stress-related and somatoform disorders

Primary outcomes

1

Description

Anxiety

Timepoint

Before and 30 minutes after the first intervention, before and 30 minutes after the second intervention, before and 30 minutes after the third intervention, one week after hysterectomy

Method of measurement

Anxiety by STAI anxiety questionnaire measures .

2

Description

Vital sign

Timepoint

Before and 30 minutes after the first intervention, before and 30 minutes after the second intervention, before and 30 minutes after the third intervention

Method of measurement

vital signs, including blood pressure through mercury sphygmomanometer in millimeters of mercury and pulse through touch radial arterial of hand for 1 minute and respiratory through movement chest for 1 minute.

Secondary outcomes

1

Description

Age patient

Timepoint

Before first intervention

Method of measurement

Demographic information questionnaire

2

Description

Patient job

Timepoint

Before first intervention
Method of measurement
Demographic information questionnaire

3

Description
Patient husband job
Timepoint
Before first intervention
Method of measurement
Demographic information questionnaire

4

Description
Income
Timepoint
Before first intervention
Method of measurement
Demographic information questionnaire

5

Description
Patient education
Timepoint
Before first intervention
Method of measurement
Demographic information questionnaire

6

Description
Patient husband education
Timepoint
Before first intervention
Method of measurement
Demographic information questionnaire

7

Description
Marital status
Timepoint
Before first intervention
Method of measurement
Demographic information questionnaire

8

Description
Number of children
Timepoint
Before first intervention
Method of measurement
Demographic information questionnaire

9

Description
Menopause status
Timepoint
Before first intervention

Method of measurement
Demographic information questionnaire

10

Description
Anesthesia method
Timepoint
Before second intervention
Method of measurement
Operation questionnaire

11

Description
Surgery method
Timepoint
Before second intervention
Method of measurement
Operation questionnaire

12

Description
Hysterectomy reason
Timepoint
Before first intervention
Method of measurement
Demographic information questionnaire

13

Description
Duration of disease diagnosis
Timepoint
Before first intervention
Method of measurement
Demographic information questionnaire

14

Description
Surgery history
Timepoint
Before first intervention
Method of measurement
Demographic information questionnaire

15

Description
Hospitalization
Timepoint
Before first intervention
Method of measurement
Demographic information questionnaire

16

Description
The amount of medication to reduce pain
Timepoint
First and second day after surgery
Method of measurement

Intervention groups

1

Description

In control group patients during the massage in intervention group, attended the bedside for 20 minutes and create rapport addition, Berger anxiety questionnaire before and 30 minutes after the intervention is completed. One week after surgery for following again berger state questionnaire with patient by the researcher calling is completed.

Category

Other

2

Description

In patient intervention group foot special massage done. In this massage base of the palm, the palm and fingers to movement rubbing, rotation, pull, grasping, push and flexing in different part (both sides of foot, the narrow foot, toe, heel, edge toe, fingers, between fingers, the dorsal surface of the foot, the inner edge of edge of the foot, the up surface of the foot) used. The general movement of the ankle and toes done . The massage is a 3 step, 20 movement in each specialized massage movement are carried out on the patient legs. This massage during 20 minutes done (each foot 10 minutes). This intervention one day before surgery and first, second postoperative day is performed on patients once a day in the intervention group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariate and Valeasr hospitals of Tehran

Full name of responsible person

Zohre Maryami

Street address

faculty of nursing and midwifery, beginning of the Nosrat street, Tohid square, Tehran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Tehran University of Medical Sciences

Full name of responsible person

Dr Akbar Fotuhi

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sixth floor, central organization of university, edge of Qods street, Keshavarz blvd, 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 Medical 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

Nursing-Midwifery university

Full name of responsible person

Maryam Modarres

Position

Phd student in Medical education

Other areas of specialty/work

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Other areas of specialty/work

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City

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