Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Maryam Modarres
Name of organization / entity
Tehran university of Medical sciences
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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,centeral 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/د

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 questionaire

2

Description
Patient job

Timepoint

Before first intervention
Method of measurement
Demographic information questionaire

3

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

4

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

5

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

6

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

7

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

8

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

9

Description
Menopause status
Timepoint
Before first intervention
Method of measurement
Demographic information questionaire

10

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

11

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

12

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

13

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

14

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

15

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

16

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

Recorded in milligrams per questionnaire Surgery

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 questionaire 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 foots, 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
Tehran

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

Street address
sixth floor,centeral 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

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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