Comparison of impact of Foot Reflexology Massage and Bensone Relaxation on severity of pain after cesarean section

Protocol summary

Summary
The objective of this clinical trial is to compare the effects of foot reflexology massage and Benson relaxation on reducing pain after Caesarean section. The study population was women undergoing cesarean section in the Baqiyatallah hospital. Ninety participants were randomly assigned to foot reflexology massage, Benson relaxation, or control groups. In the foot reflexology massage group, patients were placed in a comfortable position and both feet are massaged for ten minutes. In the Benson relaxation group after providing completely calm and quiet environment, the patients were asked to follow instructions and explanations of cassette operation during the implementation period to maintain their focus on relaxation for twenty minutes. Pain was evaluated immediately after reflexology massage and Benson relaxation. The control group did not receive any type of intervention and only intensity of pain was measured after twenty minute interval. The interventions were done twice a day for two days with 6-8 hours interval.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT138904124299N1
Registration date: 2010-08-29, 1389/06/07
Registration timing: retrospective

Last update:
Update count: 0
Registration date
2010-08-29, 1389/06/07

Registrant information
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Recruitment status
Recruitment complete
Funding source
Baqiyatallah University of Medical Sciences

Expected recruitment start date
2006-09-20, 1385/06/29
Expected recruitment end date
2006-11-07, 1385/08/16
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of impact of Foot Reflexology Massage and Benson Relaxation on severity of pain after cesarean section

Public title
Impact of Foot Reflexology Massage and Benson Relaxation on pain
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: having middle and higher levels of pain, no sensory or motor disorder
Exclusion criteria: Unwillingness to participate or continue
Age
From 26 years old to 55 years old
Gender
Female

Phase
N/A
Groups that have been masked
None
Sample size
Target sample size: 90
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: empty

### Ethics committees

1
- **Ethics committee**
  - **Name of ethics committee**: Baqiatallah University of Medical Sciences
  - **Street address**: Araj Square, Aghdasieh
  - **City**: Tehran
  - **Country**: Iran (Islamic Republic of)
  - **Postal code**
  - **Approval date**
  - **Ethics committee reference number**: 301

### Health conditions studied

1
- **Description of health condition studied**: Pain
- **ICD-10 code**: R52.0
- **ICD-10 code description**: Acute pain

### Primary outcomes

1
- **Description**: Intensity of pain
- **Timepoint**: pre and post intervention
- **Method of measurement**: pain scale 1-10

### Secondary outcomes
- empty

### Intervention groups

1
- **Description**: In the foot reflexology massage group, patients were placed in a comfortable position and both feet are massaged for ten minutes, twice a day for two days with 6-8 hours interval
  - **Category**: Other

2
- **Description**: In Benson relaxation group after providing completely calm and quiet environment and minimizing environmental stimulation a sound player and a cassette were given to the patients. The patients were asked to follow the instruction and explanations of the cassette consisting breathing exercises, twice a day for two days with 6-8 hours interval.
  - **Category**: Other

3
- **Description**: The control group did not receive any type of intervention and only intensity of pain was measured after twenty minute interval.
  - **Category**: Other

### Recruitment centers

1
- **Recruitment center**
  - **Name of recruitment center**: Baqiatallah Hospital
  - **Full name of responsible person**: Jamileh Mokhtari
  - **Street address**: Araj Square, Aghdasieh
  - **City**: Tehran
  - **Country**: Iran (Islamic Republic of)

### Sponsors / Funding sources

1
- **Sponsor**
  - **Name of organization / entity**: Baqiatallah University of Medical Sciences
  - **Full name of responsible person**: Hossein Majedi
  - **Street address**: Sheikh Bahaii, Vanak
  - **City**: Tehran
  - **Country**
Iran (Islamic Republic of)

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Baqiatallah 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
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Person responsible for updating data

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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