

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparison the effect of skin to skin contact and music during skin to skin contact on maternal state anxiety in cesarean section unit

Protocol summary

Summary

This study evaluates effects of non pharmacologic methods comprising skin to skin contact (SSC) and music during SSC on maternal state anxiety in cesarean section unit in Akbarabadi Educational-Health center. In a randomized controlled trial, 90 Iranian women 20-40 years old with term and singleton pregnancy who will be scheduled for cesarean section repeat, under spinal anesthesia, will be recruited in three groups (30 women in each group). Two hours after operation, pain relief drugs will be prescribed as a routine care for all women. Post operative pain will be evaluated by visual analog scale (VAS). If $VAS \leq 3$, Maternal state anxiety will be measured by using the State-Trait Anxiety Inventory (STAI) Scale (Spielberger). Interventions will be done for mother-infant dyads in intervention groups as 30 min SSC or music during SSC and control group will be received routine care only. Six hours later, if $VAS \leq 3$, maternal state anxiety will be measured by using the Spielberger Scale again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138808092324N4**

Registration date: **2009-10-31, 1388/08/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-10-31, 1388/08/09

Registrant information

Name

Maryam Keshavarz

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4365 1813

Email address

keshavarz@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

School of Nursing and Midwifery, Iran University of Medical Sciences

Expected recruitment start date

2009-07-29, 1388/05/07

Expected recruitment end date

2009-08-22, 1388/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of skin to skin contact and music during skin to skin contact on maternal state anxiety in cesarean section unit

Public title

Skin to skin contact with or without music and maternal state anxiety

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: healthy Iranian women 20-40 years old with term and single pregnancy and History of cesarean section, under spinal anesthesia in current Surgery, no history of Neonatal death, pain score by visual analog Scale (VAS) ≤ 3 . Exclusion criteria: Unwilling to continue study, existing medical or surgical problem during

intervention and before filling the second questionnaire, VAS >3 before filling the second questionnaire, infant sever crying during intervention or before filling the second questionnaire.

Age

From **20 years** old to **40 years** old

Gender

Female

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

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Nursing and Midwifery, Iran University of Medical Sciences

Street address

Rashid Yasami St. Valiasr Ave

City

Tehran

Postal code

19964

Approval date

empty

Ethics committee reference number

1323575

Health conditions studied

1

Description of health condition studied

maternal state anxiety in cesarean section unit

ICD-10 code

O82.0

ICD-10 code description

Delivery by elective caesarean section

Primary outcomes

1

Description

mathernal state anxiety

Timepoint

six hours after intervention

Method of measurement

State-Trait Anxiety Inventory (STAI) Scale (Spiel Berger)

Secondary outcomes

empty

Intervention groups

1

Description

Skin to skin contact, 30 min

Category

Prevention

2

Description

Music, 30 min

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Akbarabadi treatment & education center

Full name of responsible person

Maryam Keshavarz

Street address

Molavi street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nursing and Midwifery, Iran University of Medical Sciences

Full name of responsible person

Maryam Keshavarz

Street address

School of Nursing and Midwifery, Iran University of Medical Sciences, Rashid Yasami St. Valiasr Ave, P.P. Box: 19395-4798

City

Tehran

Grant name

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

Yes

Title of funding source

Nursing and Midwifery, Iran 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**

School of Nursing and Midwifery, Iran University of Medical Sciences

Full name of responsible person

Maryam Keshavarz

Position

MSc in midwifery - academic member

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

School of Nursing and Midwifery, Iran University of Medical Sciences, Rashid Yasami St. Valiasr Ave.

City

Tehran

Postal code

19964

Phone

+98 21 8247 1406

Fax

+98 21 8879 3805

Email

keshavarz@ium.ac.ir , m_keshir@yahoo.com

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

School of Nursing and Midwifery, Iran University of Medical Sciences

Full name of responsible person

Maryam Keshavarz

Position

MSc in midwifery - academic member

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

School of Nursing and Midwifery, Iran University of Medical Sciences, Rashid Yasami St. Valiasr Ave.

City

Tehran

Postal code

19964

Phone

+98 21 8247 1406

Fax

+98 21 8879 3805

Email

keshavarz@iums.ac.ir , m_keshir@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

School of Nursing and Midwifery, Iran University of Medical Sciences

Full name of responsible person

Maryam Keshavarz

Position

MSc in midwifery - academic member

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

School of Nursing and Midwifery, Iran University of Medical Sciences, Rashid Yasami St. Valiasr Ave.

City

Tehran

Postal code**Phone**

+98 21 8247 1406

Fax

+98 21 8879 3805

Email

keshavarz@iums.ac.ir , m_keshir@yahoo.com

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