

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Effect of multisensory stimulation room on pain of delivery intensity, Childbearing self-efficacy and Breastfeeding self-efficacy in one of selected hospital in Tehran University of Medical Sciences 1389.

Protocol summary

Summary

Objectives: To determine and compare efficacy the active phase of labor pain, breastfeeding in 24 hours, 10 days and six weeks after delivery in women with two method of stimulating multiple senses and normal delivery. Design: This study is clinical trial. The mothers are selected random room. After permitting letter from the Ethics Committee and research deputy in Tehran University with referring to one of selected hospitals. Participants including eligibility criteria: fifty women in relaxation room and fifty women the delivery room, as the control group. Intervention: aquarium, fish, Lavender or peach oils, with shining different shapes and soft music. Main outcome measures variables: pain intensity, efficacy delivery and breastfeeding. Data of individual characteristics and obstetric history included 10 questions. Lowe self efficacy questionnaire which has been two stages, first efficacy consists of 15 questions and second expectation in the active phase and Dennis breastfeeding efficacy questionnaire with 14 item Likert scale of five categories at 24 hours, 10 days and six weeks after delivery, which is filled by mothers. Content validity of instruments by 8 faculty members and Cronbach's alpha reliability of the questionnaire before starting work as a pilot sample of 20 people will be This number will not be part of the sample size. To coordinate the arrival of two chi-square test for the variables of inferential statistics, such as t test, Fisher and Mann-Whitney was used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810203034N1**
Registration date: **2011-07-19, 1390/04/28**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-07-19, 1390/04/28

Registrant information

Name

Mansoureh Jamshidimanesh

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2010-02-20, 1388/12/01

Expected recruitment end date

2011-05-22, 1390/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of multisensory stimulation room on pain of delivery intensity, Childbearing self-efficacy and Breastfeeding self-efficacy in one of selected hospital in Tehran University of Medical Sciences 1389.

Public title

Effect of multisensory stimulation room on pain of delivery intensity, Childbearing self-efficacy and Breastfeeding self-efficacy in one of selected hospital in Tehran University of Medical Sciences 1389.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1- not problem for cesarean (CPD, fetal distress,...) 2-asthmatic mother exclusion criteria: 1- When samples cancel research study 2- if every abnormal configuration present that it necessary for cesarean section in active phase then mother leave the study.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

Ethics Committee School of Nursing and Midwifery,
Tehran University of Medical Sciences

Street address

Tohid SQ East Nosrat Ave

City

Tehran

Postal code

Approval date

empty

Ethics committee reference number

1536772

Health conditions studied

1

Description of health condition studied

delivery

ICD-10 code

O80.9

ICD-10 code description

Single spontaneous delivery, unspecified Spontaneous delivery NOS

Primary outcomes

1

Description

pain of delivery intensity

Timepoint

active phase labour

Method of measurement

Childbearing self-efficacy of questionnaire

2

Description

Childbearing self-efficacy

Timepoint

active phase labour and second stage

Method of measurement

Childbearing self-efficacy of questionnaire

3

Description

Breastfeeding self-efficacy

Timepoint

24 hour,10 days and 6 weeks after delivery

Method of measurement

Breastfeeding self-efficacy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention groups: designing labour room, seting up fish pool, lighting to wall, aromatherapy,relaxing music

Category

Other

2

Description

nothing control groups

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar Abadi Hospital

Full name of responsible person

Mahnaz Kalati

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr Akbar footohoi

Street address

Tehran University of Medical Sciences Keshavarz Bolivar, Qhods Ave, Central office

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, 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Nursing and Midwifery, Tehran University of Medical Sciences

Full name of responsible person

Mansoureh Jamshidimanesh

Position

MSc Midwifery, Master of Science

Other areas of specialty/work

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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