Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of multisensory stimulation room on pain of delivery intensity, Childbearing self-efficacy and Breastfeeding selfefficacy 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

Iran University Faculty of Nursing & Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 21 4365 1811

Email address

delshad2@iums.ac.ir

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 selfefficacy 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
Scool 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

Street address
Scool of Nursing and Midwifery, Tehran University of Medical SciencesTohid SQ East Nosrat Ave Tehran, Iran

City
Tehran

Postal code

Phone
+98 2166927171222

Fax

Email
jamshidimanesh@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Scool of Nursing and Midwifery, Tehran University of Medical Sciences

Full name of responsible person
Mansoureh Jamshidimanesh

Position
Midwifery, Master of Science

Other areas of specialty/work

Street address
Scool of Nursing and Midwifery, Tehran University of Medical Sciences Tohid SQ East Nosrat Ave Tehran, Iran

City
Tehran

Postal code

Phone
+98 2166927171222

Fax
+98 21 6690 4252

Email
jamshidimanesh@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