Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effect of Accompanying Midwife and Non-Midwife on the degree of Aanxiety and Labor Pain in Primipara Women

Protocol summary

Study aim

The main objective: Comparison of the Effect of Midwife and Non-Midwife on Reduction of Anxiety and Labor Pain in Primipara Women Dedicated Objectives: 1. Determine the Degree of Anxiety in Intervention groups (with Midwife and Non-Midwife) and Control before and after Intervention 2. Determination of Pain in Intervention groups (with Midwife and Non-Midwife) and Control before and after Intervention 3. Comparison of Anxiety level in Intervention groups (with Midwife and Non-Midwife) and Control before and after Intervention 4. Comparison of Pain in Intervention groups (with Midwife and Non-Midwife) and Control before and after Intervention 5- Comparison of Anxiety level in two groups of Intervention with Midwife and Non-Midwife 6. Comparison of Pain Score in two groups of Midwives and Non-Midwives Practical purposes: If the Presence of a Companion is Effective in Reducing the amount of Anxiety and in the Delivery of PrimiParous Women, the results will be decided by the Maternity wards of the province and the related Hospital Committees in order to be Included in the Protocols for Pain Relief.

Design

This Randomized, Triple Randomized Clinical Trials Study was Conducted on 120 Pregnant Nursing Mothers who had entered the study. Samples were Randomly assigned to three Intervention groups with Midwife and Non-Obstetric Intervention along with a Control group (Routine Care), Randomized Block-Type Random Block Size. Sample Size using the statistical formula and according to Previous Studies and Consideration The Maximum standard deviation of Women's Anxiety score at departure from the Delivery room is 16.04 and the type 1 error is 0.05, the Study Power is 0.90, and the Effect Size of 0.35, with the help of the software G Power A total of at least 108 samples are needed, Considering that there is a probability of dropping about 10% of samples in a total of 120 People, and in each group, 40 People are enrolled and each Participant is assigned a Code.

Settings and conduct

Block of Delivery in Abhar Abdol and Omid Hospitals and the Type of Randomized Clinical Trial of Three groups and random block type with equal block size

Participants/Inclusion and exclusion criteria

Inclusion criteria: -Iranian Native-Born Women -Sunnis 15-40 Years Old -The Pregnancy is between 37Weeks and 42 Weeks -Have a Live Embryo, Monocular and without Major Anomalies -Cephalic display and Normal weight 4000 2500 -Presence of Labor Contractions, Dilatation 3-4 cm, proper Pelvic Position Output metrics: - The presence of Acute and Chronic Psychiatric NeuroPsychiatric and Anxiety Recorded in the case and use of a Special Psychic Disorder - Having a history of Acute and Chronic Pain, such as Migraine and Appendix, etc. Recorded in the case Having an Indication of Cesarean Section such as history of Surgery on the Uterus, Placenta Pervia, Head and Pelvic Misalignment, Preeclampsia,Cervicellacae Cervix history, Fetal Distress and Partial Early Retirement Use of Analgesic in the last 8 hours - History of Blood Pressure, Gestational Diabetes and Other underlying Illnesses Registered in the case - History of Alcohol Addiction, Smoking and Drug use - Unwilling to Participate in Research

Intervention groups

The Two Intervention groups (with Midwife and Non-Midwife) and the Control group, the Midwife Intervention group, who, in addition to Routine Childbirth Care, from the Active Phase of Labor until two hours after Delivery, a Midwife (Obstetric midwife) is permanently associated with Zao, and Psychological Support Zao does. The Second Intervention group, in addition to Routine Nursing Care, is a Familiar Companion and Selects a Mother who has at least one Normal Delivery from the Onset of the Active Phase of Labor to two hours after giving Birth to Zao and Provides Psychological Support to Zao. The Control group that receives Routine Childbirth Care.

Main outcome variables

Independent variable: Accompanied Midwife, Untimely Companion Dependent variable: Anxiety and Labor Pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20171111037380N1**
Registration date: **2018-09-11, 1397/06/20**
Registration timing: **retrospective**

Last update: **2018-09-11, 1397/06/20**
Update count: **0**
Registration date
2018-09-11, 1397/06/20

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 28 3323 7267
Email address
darvishizahra45@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-11-16, 1396/08/25
Expected recruitment end date
2018-01-15, 1396/10/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effect of Accompanying Midwife and Non-Midwife on the degree of Aanxiety and Labor Pain in Primipara Women

Public title
Comparison of theAccompanying Midwife with Non-Obstetrician at Birth
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Iranian Native-Born Women Sunnis 15-40 Years Old The Pregnancy is between 37 Weeks and 42 Weeks Have a Live Embryo, Monocular and without major Anomalies Cephalic display and Normal weight 4000- 2500 Presence of Labor Contractions, Dilatation 3-4 cm, proper Pelvic Position
Exclusion criteria:
- The Presence of Acute and Chronic Psychiatric Neuropsychiatric and Anxiety Recorded in the case and use of a Special Psychic disorder - Having a History of Acute and Chronic Pain, such as Migraine and Appendix, etc. Recorded in the case Having an Indication of Cesarean Section such as history of Surgery on the Uterus, Placenta Pervia, Head and Pelvic Misalignment, Preeclampsia, Cervicellacae Cervix, Fetal Distress and Partial Early Retirement Use of Analgesic in the last 8 hours - History of Blood Pressure, Gestational Diabetes and Other Underlying Illnesses Recorded in the case - History of Alcohol Addiction, Smoking and Drug use - Unwilling to Participate in Research
Age
From **15 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
The first-stage sampling method is available from among primiparous women who come to the hospital for delivery. In the second stage, randomly assigned blocks were divided into three intervention groups 1 and 2 and control group. To select the samples, the sealed envelopes used by the statistic consultant and the researcher and those who do the sampling do not know the contents of the envelopes, on the envelopes numbered from one to twenty six. At each sampling time, each sample picks up a number, which, after opening the envelope, is based on the contents of the envelope, the sample is in one of the intervention groups 1 and 2, or controlled.
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 in Biomedical Research of Qazvin University of Medical Sciences
Street address
Qazvin University of Medical Sciences، Bahonar Blvd
City
Qazvin
Province
Qazvin
Postal code

3419759811

Approval date

2017-10-25, 1396/08/03

Ethics committee reference number

IR.QUMS.REC.1396.302

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

O99.3

ICD-10 code description

Mental disorders and diseases of the nervous system complicating pregnancy, childbirth and the puerperium

2

Description of health condition studied

Labor Pain

ICD-10 code

047.9

ICD-10 code description

-Complications of labour and delivery

Primary outcomes

1

Description

Improve Satisfaction

Timepoint

At the end of the Intervention

Method of measurement

Checklist

2

Description

Duration of the Active Phase First and Second Stages of Labor

Timepoint

From the onset of the Active Phase (3-4 cent) to Baby Delivery

Method of measurement

Partograph

Secondary outcomes

1

Description

Anxiety

Timepoint

Before Entering the Study, After Entering the Study in Dilatation 3-4, 8-10 and Postpartum

Method of measurement

Spilberger's Explicit and Secret Anxiety Questionnaire

2

Description

Labuor Pain

Timepoint

Before Entering the Study, After Entering the Study in 3-4 centuries Dilatation, 5-7 cm and the Second Stage of Labor

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

Intervention group 1: Intervention group 1 with Midwife. In this group, a Midwife who has completed a Physiological Delivery and is a member of the Midwifery Counseling and Counseling Center Provides Supportive Care from the Pregnant Mother. These behaviors include: Emotional Support [Encouraging the Mother to Make Statements such as the Nature of the Pain, the Effect of Pain intensity on the progress of Labor and the touch, and Maternal Massage, answers to Mothers' questions about the progress and Delivery success, Essential Education During Labor and Delivery (Breathing, Correct Positioning at different stages, ...), Physical Support (Help to Change Position, Accompaniment The Person has been in need of Moving and getting out of bed). This Midwife has no Involvement in Labor Control and Delivery.

Category

Behavior

2

Description

Intervention group2: The intervention group 2 is associated with Non-Emergency. In this group, a Companion who has at least One Successful Natural Delivery has the choice of Mother at All Stages of Labor, Childbirth, and Postpartum Birth, and Emotional and Physical Supportive Behaviors such as Speaking and Encouraging, Moving, and Massage Back.

Category

Behavior

3

Description

Control group: The Control group has No Companions and Routine Care is Provided by Doctors and Obstetricians.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان امدادی ابهر و بیمارستان امید ابهر

Full name of responsible person
Masoumeh Darvishi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Qazvin University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Dr. Zainat Jorabchi

Position
Associate

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
The total potential data can be shared after unidentifiable people
When the data will become available and for how long
Start the access period from 1398
To whom data/document is available
For researchers working in academic institutions, applied applications in medical universities
Under which criteria data/document could be used
For scientific research and for use in hospitals
From where data/document is obtainable
Qazvin University of Medical Sciences
What processes are involved for a request to access data/document
With reference to the scientific site of Qazvin University of Medical Sciences
Comments