Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of self-hypnosis effect on fear and pain of normal delivery in primiparous women

Protocol summary

Study aim
Determination of self-hypnosis effect on fear and pain of normal delivery in primiparous women

Design
Controlled clinical trial, with a parallel group, randomized by blocking method with sample size of 70 patients.

Settings and conduct
The present clinical trial will be done in Ommolbanin hospital in Mashhad. After taking a written informed consent, persons will be placed in 2 groups based on random allocation with blocked method. The control group will receive only routine prenatal cares. Intervention group receive mentioned intervention in addition prenatal cares. Self-hypnosis education is done by researcher. Fear of childbirth will be measured before self-hypnosis education in 37th week of pregnancy, after ending two training self-hypnosis education sessions and cervix dilatation: 8-10 cm by Wijma Delivery Expectancy/Experience Questionnaire A and Delivery Fear Scale. Also pain of delivery will be measured by visual scale of pain (VAS).

Participants/Inclusion and exclusion criteria
Age:18-35 years old; Primiparous; Gestational age: 36-37 weeks; Not having depression, anxiety, stress; Having average and high level of hypnotic susceptibility; Having average and high level of fear of childbirth.

Intervention groups
The Intervention group will receive two training sessions of 15-20 minutes self-hypnosis education in 37-38th weeks of pregnancy in addition to usual prenatal cares. Audio file (15-20 minutes) of pain and fear control dialogues derived from sessions will be recorded by mother’s mobile phone and will be given to the pregnant woman in which listening and practicing self-hypnosis twice a day at home (morning and afternoon) until delivery time and then doing it at delivery.

Main outcome variables
Assessment fear of childbirth after self-hypnosis education in 38 week Assessment fear of childbirth in active phase of labor. Assessment of labor pain scale in active phase of labor.

General information

Reason for update

Acronym
SHFP

IRCT registration information
IRCT registration number: **IRCT20190129042538N1**
Registration date: **2019-10-22, 1398/07/30**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-22, 1398/07/30**
Update count: **0**

Registration date
2019-10-22, 1398/07/30

Registrant information

Name
Batool Kamalimanesh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-22, 1398/03/01

Expected recruitment end date
2019-12-21, 1398/09/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of self-hypnosis effect on fear and pain of normal delivery in primiparous women

Public title

Effect of self-hypnosis on fear and pain of normal delivery

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age: 36-37 weeks Willingness to have a normal delivery Having moderate to high degree of hypnotic susceptibility

Exclusion criteria:

Having high risk pregnancy Having psychological disorders including depression, anxiety, stress Having clinical fear (scoring greater than 85 points according to Wijma Expectancy/Experience Delivery Questioner type A)

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Study samples were divided into intervention and control groups by using Microsoft Excel computer program. The samples categorized into A and B groups.In this study, we used from quadruple blocks. All of quadruple blocks listed as AABB, ABBA, ABAB, BBAA, BAAB, BABA, and numbered from 1 to 6. Then randomly will be generated all of the numbers 1 through 6 and allocated them to the nominated blocks accordingly and then put them together.

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

Ethic committtee of Mashhad University of Medical Sciences

Street address

Ibne Sina Street, Crossroads Doctora, School of Nursing and Midwifery

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2019-03-05, 1397/12/14

Ethics committee reference number

IR.MUMS.NURSE.REC.1398.005

Health conditions studied

1

Description of health condition studied

Fear of Childbirth

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Pain of Labour

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Score fear of childbirth (The Wijma Delivery Expectancy/Experience questionnaire A and Delivery Fear Scale)

Timepoint

Before training self-hypnosis in 37 week and after training self-hypnosis in 38 week by The Wijma Delivery Expectancy/Experience Questionnaire A, Evaluation fear of childbirth by Delivery fear scale in Cervical dilation 8-10 cm

Method of measurement

The Wijma Delivery Expectancy/Experience Questionnaire A, Delivery fear scale

2

Description

Pain of Labour

Timepoint

Cervical dilation: 8-10 cm

Method of measurement

Visual Analog Scale

Secondary outcomes

1

Description
Fear of childbirth
Timepoint
Two hours after delivery
Method of measurement
The Wijma Delivery Expectancy/Experience Questionnaire B

2

Description
Pain of labour
Timepoint
Cervical dilation: 4-5 cm
Method of measurement
Visual Analog Scale

3

Description
Childbirth Satisfaction
Timepoint
Two hours after delivery
Method of measurement
Mackey Childbirth Satisfaction Rating Scale

Intervention groups

1

Description
Intervention group will receive two training sessions of 15-20 minutes self-hypnosis education in 37-38th weeks of pregnancy in addition to usual prenatal cares. Audio file (15-20 minutes) of pain and fear control dialogues derived from sessions will be recorded by mother's mobile phone and will be given to the pregnant woman in which listening and practicing self-hypnosis twice a day at home (morning and afternoon) until delivery time and then doing it at delivery.
Category
Other

2

Description
Control group received routine prenatal care.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ommolbanin hospital
Full name of responsible person
Fatemeh Tara
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Ayatolah Bahjat Street, Mashhad, Khorasan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Presidentoffice@mums.ac.ir
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http://www.mums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Batool Kamalimanesh
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be 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