

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 2081

Email address

kamalimaneshb961@mums.ac.ir

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 committee 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

Street address

Ayatolah Bahjat Street, Mashhad, Khorasan

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3223 1061

Fax

+98 51 3223 1444

Email

p.relations@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Saeid Eslami

Street address

Daneshgah Str.

City

Mashhad

Province

Razavi Khorasan

Postal code

1394491388

Phone

+98 51 3841 2081

Fax

+98 51 3841 3006

Email

Presidentoffice@mums.ac.ir

Web page address

<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

Midwifery

Street address

Daneshgah str.

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 2081

Fax

+98 51 3841 3006

Email

Kamalimaneshb961@mums.ac.ir

Web page address**Fax**

+98 51 3841 3006

Email

Moradim@mums.ac.ir

Person responsible for updating data

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

Midwifery

Street address

Daneshgah Str.

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 2081

Email

B.kamalimanesh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Maryam Moradi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Daneshgah str.

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 2081

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