

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effectiveness of focused solution brief counseling on anxiety and labor pain intensity in nulliparous women

Protocol summary

Study aim

Determining effectiveness of focused solution brief counseling on anxiety and labor pain intensity in nulliparous women

Design

Clinical trial with control group, with parallel group, no blinding, randomized, on 110 patients, to randomize from the website
<https://www.sealedenvelope.com/simple-randomiser/v1/lists> and the 4-block method is used

Settings and conduct

Location of the maternity ward of Hakim Hospital in Neishabour, For mothers of the intervention group, in addition to routine care, the researcher will conduct a Solution Focused Brief Counseling based counseling session individually for 45 to 60 minutes. For mothers of the control group, only routine care is provided. The anxiety test is completed by the Spilberger Questionnaire after counseling for both groups in two steps, in dilatation of 5 and 8 and 10 centimeter of cervical.

Participants/Inclusion and exclusion criteria

Pregnancy age 37 to 41 weeks Fetal health in the first trimester ultrasound examination The pregnant mother has no special medical or midwifery problems Wanted pregnancy No entry condition: History of psychotherapy or mental illness Addiction to cigarettes or drugs and alcohol Having a history of recurrent miscarriage and infertility Taking anti anxiety and anti depressant drugs The onset of labor pains

Intervention groups

Intervention group: provide solution focused brief counseling before the onset of labor pains in nulliparous women in addition to receiving routine in the delivery block control group: receiving routine in the delivery block

Main outcome variables

Anxiety level in nulliparous women: intensity of labor pain

General information

Reason for update

Acronym

SFBT

IRCT registration information

IRCT registration number: **IRCT20200513047431N1**

Registration date: **2020-07-28, 1399/05/07**

Registration timing: **retrospective**

Last update: **2020-07-28, 1399/05/07**

Update count: **0**

Registration date

2020-07-28, 1399/05/07

Registrant information

Name

Mahdieh Mohiti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4261 0816

Email address

mohitim1390@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-22, 1399/03/02

Expected recruitment end date

2020-07-23, 1399/05/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of focused solution brief counseling on anxiety and labor pain intensity in nulliparous women

Public title

The effectiveness of focused solution brief counseling on anxiety and labor pain intensity in nulliparous women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnancy age 37 to 41 weeks Fetal health in the first trimester ultrasound examination The pregnant mother has no special medical or midwifery problems Wanted pregnancy

Exclusion criteria:

History of psychotherapy or mental illness addiction to cigarettes and drugs and alcohol Have a history of recurrent miscarriage and infertility Taking anti anxiety and anti depressant drugs The onset of labor pains

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: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the website <https://www.sealedenvelope.com/simple-randomiser/v1/lists>, and with the help of the methodological consultant , the allocation sequence is generated. The 4-block method is used to create the allocation sequence. Within each block half of the intervention people and half as a control are considered. White envelopes are used to hide the sequence. In this way each sequence is placed inside a white envelope and the envelopes are placed side by side and envelopes are numbered. An envelope is opened for each person in the order in which they enter the study and assigned to the desired group. Participants are not blind because they are trained . After the intervention the questionnaires are completed by a person who is not aware of their group. The information analyst is also not aware of the group of the people.

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 of Shahroud University of Medical Sciences

Street address

No. 28,Khayyam 25 Alley.,Khayyam Ave.,Farhangian Town

City

Neyshabour

Province

Razavi Khorasan

Postal code

9318733333

Approval date

2020-05-15, 1399/02/26

Ethics committee reference number

IR.SHMU.REC.1399.048

Health conditions studied

1

Description of health condition studied

Anxiety and labor pain intensity

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

Anxiety level in nulliparous womens

Timepoint

Anxiety assessment before intreviewtion begins and after consuling in dilatations 5 and 8 cm of services of services

Method of measurement

Questionnaire Spielberger State-trait Anxiety Inventory

Secondary outcomes

1

Description

Labor pain intensity

Timepoint

Before intervention and after intervention in dilatation 5, 8,10 cm cervics

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

Intervention group: Perform short-term focus counseling before labor pains begin. single session counseling is a solution oriented approach for mothers who have not attended childbirth preparation classes during pregnancy and they have anxiety. For the mothers of the intervention group in addition to the routine care of the ward the researcher conducts one session Solution Focused Brief counseling for 45 to 60 minutes .it is done individually. Solution Focused Brief counseling is a strengths based model. With different techniques and reminders of exceptions .it helps pregnant mothers to recognize their abilities and overcome their anxiety during childbirth. Techniques used: Immediate relaxation or abdominal breathing. Riding on the wave of terror. Education Autogenic. Technique Just because. Mindfulness. Fan 12345. Courage ladder.

Category

Behavior

2

Description

Control group: Get routine care of the ward but they do not receive advice

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Hakim hospital

Full name of responsible person

Mohiti Mahdieh

Street address

Basige Squ.

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Razavi Khorasan

Postal code

9318633333

Phone

+98 51 4263 8001

Email

mohitim1390@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Emamiyan Mohammad Hasan

Street address

Hafta Tir Squ.

City

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Province

Semnan

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3614773947

Phone

+98 23 3239 5054

Fax

+98 23 3239 5009

Email

info@shmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Mahdieh Mohiti

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

No.28, 25 Khayyam Alley ., Khayyam Ave. ,
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mahdieh Mohiti

Position

Student

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Person responsible for updating data

Contact

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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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The effectiveness of focused solution brief counseling on
anxiety and labor pain intensity in nulliparous women

When the data will become available and for how long

From september 1399

To whom data/document is available

All persons

Under which criteria data/document could be used

Contact the researcher by email

From where data/document is obtainable

Mohiti Mahdieh.mohitim1390@gmail.com,
00985142638001

What processes are involved for a request to access data/document

First an email will be sent then a phone call and ten days
later the data will be emailed

Comments