

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Effectiveness of Cognitive Behavioral Therapy and Haptonomy on fear of childbirth, Birth Experiences and postpartum depression in Nulliparous Pregnant Women: A Randomized Controlled Clinical Trial

Protocol summary

Study aim

Determine the effect of cognitive behavioral therapy (CBT) and haptonomy on fear of childbirth, birth experience and postpartum depression in nulliparous pregnant women

Design

A RCT with 3 parallel groups, non-blind will be conducted on 99 women at gestational age of 24-28 weeks. The participants will be assigned into three groups by blocked randomization and the allocation ratio of 1:1:1.

Settings and conduct

Sampling will be done in 4 health complexes of Tabriz. The fear of childbirth, depression and their preferred type of delivery will be measured in 24-28 weeks. At 35-37 weeks, fear of birth and their preferred type of delivery will be measured. One month after delivery, fear, childbirth experiences and postpartum depression and type of delivery will be assessed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Primiparous women aged 18-45 years at gestational age of 24-28 weeks, Fear of birth score above 65 based on Wijma. Exclusion criteria: History of psychological disorders, Known fetal abnormality, Unplanned pregnancies, History of participating in physiological birth classes, History of recurrent miscarriages, Pregnancy with artificial reproductive techniques.

Intervention groups

In CBT group, from 24-28 weeks, counseling about introducing thought, feeling and behavior cycle, and relaxation will be offered once a week in 8 sessions. In haptonomy group, communication techniques will be taught in 5 sessions including positive feelings towards pregnancy, methods of labor pain control, and helping to change the mind. The control group will receive routine pregnancy care.

Main outcome variables

Mean score of fear of childbirth, birth experience and postpartum depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170506033834N9**

Registration date: **2022-01-02, 1400/10/12**

Registration timing: **prospective**

Last update: **2022-01-02, 1400/10/12**

Update count: **0**

Registration date

2022-01-02, 1400/10/12

Registrant information

Name

Roghayeh Nourizadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3479 6770

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-05, 1400/10/15

Expected recruitment end date

2022-08-11, 1401/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Cognitive Behavioral Therapy and Haptonomy on fear of childbirth, Birth Experiences and postpartum depression in Nulliparous Pregnant Women: A Randomized Controlled Clinical Trial

Public title

Effectiveness of Cognitive Behavioral Therapy and Haptonomy on fear of childbirth, Birth Experiences and postpartum depression in Nulliparous Pregnant Women: A Randomized Controlled Clinical Trial

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Primiparous women aged 18-45 years Gestational age of 24-28 weeks Fear of childbirth score above 65

Exclusion criteria:

History of mental disorders according to the mother statement Known fetal abnormalities Unplanned pregnancy History of participating in physiological birth classes History of recurrent miscarriages or pregnancies with artificial reproductive techniques

AgeFrom **18 years** old to **45 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **99****Randomization (investigator's opinion)**

Randomized

Randomization description

Participants randomly using RAS software through stratified random blocking based on high and severe fear with 6 and 9 blocks into three groups with a ratio of 1:1:1 (in Each group 33 people) will be assigned. The allocation type will be written on paper and numbered in consecutive opaque envelopes (Allocation Concealment). The envelopes will be opened sequentially by the person not involved in the sampling.

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 Tabriz University of Medical Sciences

Street address

Faculty of Nursing and Midwifery, South Shariati Street

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Tabriz

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East Azarbaijan

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5138947977

Approval date

2021-11-01, 1400/08/10

Ethics committee reference number

IR.TBZMED.REC.1400.678

Health conditions studied**1****Description of health condition studied**

Postpartum depression

ICD-10 code

O90.6

ICD-10 code description

Postpartum mood disturbance

2**Description of health condition studied**

Fear of childbirth

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Fear of childbirth score

Timepoint

Before the intervention in 24-28 gestational week, 35-37 weeks of pregnancy and one month after delivery

Method of measurement

Wijma delivery expectancy/experience questionnaire (versions of A & B)

2**Description**

Childbirth experience score

Timepoint

One month after delivery

Method of measurement

Childbirth Experiences Questionnaire version 2.0(CEQ-2.0)

3

Description

Postpartum depression

Timepoint

Before the intervention in 24-28 weeks and one month after delivery

Method of measurement

Edinburgh Postpartum Depression Scale (EPDS)

Secondary outcomes

1

Description

Preferred delivery type

Timepoint

Before the interventions at gestational age of 24-28 weeks and again in 35-37 weeks.

Method of measurement

Ask the mother about preferred delivery type

2

Description

Method of delivery

Timepoint

One month after delivery

Method of measurement

Medical record

Intervention groups

1

Description

Intervention group 1: In the group of cognitive-behavioral intervention from the 24- 28 weeks, counseling in groups of three to six people in eight sessions (combination of face-to-face and online sessions) will be held and each session will be for 45 to 60 minutes, once a week. The content of counseling mainly includes teaching the process of pregnancy and childbirth, expressing the benefits and harms of vaginal birth and cesarean section, teaching the birth stages and process, identifying thoughts, introducing thought, feeling and behavior cycle, providing coping exercises and prevention of inappropriate behaviors and thoughts, training distraction technique, training abdominal breathing, relaxation and Kegel exercises, training in the technique of changing mental images and training to deal with the return of previous behaviors and attitudes.

Category

Behavior

2

Description

Intervention group 2: In haptonomy group, communication techniques will be taught from 24 to 28 gestational week, in groups of 3 to 6 people in 5 sessions, a combination of face-to-face and online sessions, each session lasting 45-60 minutes, once a

week. The content of intervention mainly includes strengthening positive feelings and attitudes towards pregnancy, identifying worries about pregnancy and childbirth and helping to solve fears and worries, teaching communication methods such as talking to the fetus, observing and touching Abdomen, attention to fetal movements and training fetal movement counting, advice to name the fetus , teaching various methods of controlling labor pain, showing the effect of pregnancy hormones on anatomical changes of the pelvis, helping to change the mind with understanding the pregnancy process and Delivery and evaluation of the birth schedule.

Category

Behavior

3

Description

The control group will receive only routine prenatal care.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Eram health center

Full name of responsible person

Roghaiyeh Nourizadeh

Street address

Almahdi Street, region 8, Eram Town

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Web page address

2

Recruitment center

Name of recruitment center

Bavafa health center

Full name of responsible person

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Infront of Asad-Abadi hospital, Bahar Street

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Recruitment center

Name of recruitment center

Asad-Abadi health center

Full name of responsible person

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Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Parviz Shahabi

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Zahra Alivand

Position

Master student of counseling in midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Roghaiyeh Nourizadeh

Position

Ph.D in Reproductive Health

Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more data

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Roghaiyeh Nourizadeh

Position

Ph.D in reproductive health

Latest degree

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Other areas of specialty/work

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