

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the Effect of Mindfulness-based Art therapy and Routine Care on Severe Fear of Childbirth in Nulliparous Women

Protocol summary

Study aim

To determine the effect of mindfulness-based art therapy (MBAT) on severe fear of childbirth in primiparous women: a randomized controlled clinical trial

Design

A randomized controlled clinical trial, phase 3, on 58 nulliparous pregnant women (with a 20% drop). The random function of Excel software will be used for randomization.

Settings and conduct

The research community is primiparous women who go to health centers, clinics, and private clinics in Sari for prenatal care. In the first stage, eligible pregnant women will announce their readiness through advertisements that will be shared in the centers. The W-DEQ-A and the entry checklist for these individuals will be sent online. In women who get a score of 66 or higher and have other inclusion criteria, the researcher will introduce herself and explain the research objectives by sending an SMS. Due to the nature of the intervention, it will not be possible to keep the participants and the researcher responsible for the intervention blind during the intervention process. Therefore, in order to control the detection bias, the blinding process will be performed on the people who are responsible for collecting information and analyzing data.

Participants/Inclusion and exclusion criteria

Inclusion: Nulliparous Women with singleton pregnancy, Gestational age 28-26 weeks and W-DEQ-A score from 66 to 100; With written consent Exclusion: High-risk pregnancy; Getting pregnant through assisted reproductive techniques; Receive other treatments to control anxiety and fear

Intervention groups

The intervention group will receive a MBAT that will be performed in 8 sessions in women with a gestational age of 26-28 weeks and in groups. women in the control group will receive routine prenatal care. After completing the last questionnaire, a brief MBAT session will be held

for the control group.

Main outcome variables

Fear of childbirth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160619028528N5**

Registration date: **2021-11-28, 1400/09/07**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-28, 1400/09/07**

Update count: **0**

Registration date

2021-11-28, 1400/09/07

Registrant information

Name

Zeinab Hamzehgardeshi

Name of organization / entity

Mazandaran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 7342

Email address

z.hamzehgardeshi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Mindfulness-based Art therapy and Routine Care on Severe Fear of Childbirth in Nulliparous Women

Public title

The Effect of Mindfulness-Based Art therapy on Sever Fear of Childbirth in Nulliparous Women: A randomized controlled clinical trial

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Nulliparous Women Gestational age 28-26 weeks Wijma Delivery Expectancy Questionnaire (W-DEQ-A) score from 66 to 100 Single pregnancy Living together with a spouse Iranian nationality Persian language Having a written consent to participate in the research

Exclusion criteria:

High-risk pregnancy Getting pregnant through assisted reproductive techniques Repeated abortion experience (2 times or more) History of psychiatric illness (schizophrenia, bipolar disorder, and major depression) or get it at the time of the study by self-report or registration in the medical record Use of psychiatric drugs (such as antidepressants, anti-anxiety and anti-psychotic drugs), drug abuse, alcohol and psychotropic drugs Chronic physical illness (diabetes, cardiovascular disease, kidney disease, self-report or registration in the medical record) Receive other treatments or participate in other interventions (types of interventions including behavioral therapy, cognitive-behavioral therapy, psycho-education, etc.) to control stress, anxiety and fear

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: 58

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked random allocation method will be used for random assignment of samples to two intervention groups (mindfulness-based art therapy) and control group (routine care). For this purpose, quadruple blocks will be considered. The six blocks may be TCTTCC, CTTC, CTCT, CCTT, TCTC, TCCT, with T being for the intervention group and C for the control group. The randbetween function in Excel will be used to randomly

select blocks. Production numbers will be between 1 and 6 and will be selected based on the production number of the desired block and all 4 samples will be assigned to the intervention and control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of the intervention, it will not be possible to keep the participants and the researcher responsible for the intervention blind during the intervention process. Therefore, in order to control the blinding bias at the evaluator level (detection bias), the blinding process will be performed on the people who are responsible for collecting information and analyzing data.

Placebo

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mazandaran University of Medical Sciences

Street address

Moallem Square, Vice Chancellor for Research and Technology, Mazandaran University of Medical Sciences

City

Sari

Province

Mazandaran

Postal code

48178-57344

Approval date

2021-10-02, 1400/07/10

Ethics committee reference number

IR.MAZUMS.REC.1400.505

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

Fear of childbirth in nulliparous women

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

Fear of childbirth

Timepoint

At the time of enrollment - immediately after the intervention - one month after the intervention

Method of measurement

Wijma Delivery Expectancy/ Experience Questionnaire (W-DEQ-A)

Secondary outcomes

1

Description

Childbirth self-efficacy

Timepoint

At the time of enrollment - immediately after the intervention - one month after the intervention

Method of measurement

Iranian Childbirth Self-Efficacy Inventory (ICBSEI-36)

2

Description

Mindfulness

Timepoint

At the time of enrollment - immediately after the intervention - one month after the intervention

Method of measurement

Five Factor Mindfulness Questionnaire (FFMQ)

3

Description

Preferred childbirth method

Timepoint

At the time of enrollment - immediately after the intervention - one month after the intervention

Method of measurement

Socio-demographic-fertility Characteristics

4

Description

Treatment (Intervention) Adherence

Timepoint

One month after the intervention

Method of measurement

3 criteria for adherence to the intervention: the number of mindfulness-based art therapy sessions that women participate in the intervention group, the number of participants who do their homework and the number of participants who complete the questionnaires completely.

5

Description

Treatment (Intervention) Satisfaction

Timepoint

One month after the intervention

Method of measurement

Satisfaction Visual Analog Scale

Intervention groups

1

Description

Intervention group: The intervention is mindfulness-based art therapy, which will be performed by a Master of Midwifery Counseling in 8 sessions in women with a "gestational age" of 26-26 weeks. Group meetings are held for 4 weeks (2 sessions per week). Each session will take 90 minutes. The groups will be 3-5 people. The research team includes a reproductive health specialist, a reproductive epidemiologist, a psychiatrist, a clinical psychologist, an art therapist, and a graduate student in midwifery counseling who will assist in the design and implementation of the protocol. The content of the program of the present research sessions is as follows: 1. Familiarity with mindfulness technique, exploring the relationship between mind and body and understanding pregnancy and the existence of a child 2. Recognizing and accepting their feelings by focusing on feelings about childbirth and child 3. Recognizing and understanding the feelings and perceptions about the birth process 4. Recognizing and understanding the feelings towards the baby 5. Recognizing and understanding the feelings and perceptions about parenting 6. Recognizing and understanding the feelings and perceptions towards the delivery room and staff 7. Recognizing perceptions related to the person's self-confidence and abilities, recognizing obstacles in order to help him on the journey to delivery 8. Recognizing and understanding the feelings and perceptions of the person Life after childbirth. Content validity of the protocol of this 8-session program will be reviewed by relevant experts (psychiatrist, psychologist, art therapist, reproductive health specialist, gynecologist). In these sessions, techniques of painting, collage and working with clay or dough will be used. The tools used in this research include painting supplies such as paper, crayons, watercolors and pastels, and collage supplies such as cardboard, pieces of fabric, newspapers, magazines, photographs, disposables, glue and clay or dough. Exercises are also considered as homework. This protocol is implemented practically in Iran and its effect on the study outcome (fear of childbirth) will be calculated through indicators such as the Effect Size index.

Category

Treatment - Other

2

Description

Control group: Women in the control group will receive routine prenatal care (Prenatal periodic visits). After completing the last questionnaire (four weeks after the intervention), in order to enjoy the benefits of the study, a mindfulness-based art therapy session will be held for the control group participants and their possible questions about fear of childbirth will be answered.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sari health centers, Private clinics in Sari

Full name of responsible person

Zeinab Hamzehgardeshi

Street address

Nasibeh Nursing and Midwifery Faculty, Vesal Street,
Amir Mazandarani Boulevard

City

Sari

Province

Mazandaran

Postal code

4843163181

Phone

+98 11 3336 7342

Fax

+98 11 3336 8915

Email

Z.hamzehgardeshi@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Majid Saeedi

Street address

Moalem Street, Vice chancellor for research

City

Sari

Province

Mazandaran

Postal code

48431-63181

Phone

+98 11 4443 4210

Email

majsaeedi@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Kosar Miraei Mohammadi

Position

Student (MSc)

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Piroozi Alley 12, Piroozi St., Taleghani Blvd.

City

Sari

Province

Mazandaran

Postal code

48187-68977

Phone

+98 11 3310 6053

Email

kosarmohammadi1371@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Zeinab Hamzehgardeshi

Position

Associated Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Nasibeh Nursing and Midwifery Faculty, Amir
Mazandarani Street

City

Sari

Province

Mazandaran

Postal code

48431-63181

Phone

009833367342

Fax

+98 11 3337 8915

Email

z.hamzehgardeshi@mazums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Kosar Miraei Mohammadi

Position

Student (MSc)

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Piroozi Alley 12, Piroozi St., Taleghani Blvd.

City

Sari

Province

Mazandaran

Postal code

48187-68977

Phone

+98 11 3310 6053

Email

kosarmohammadi1371@gmail.com

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