

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Oct 2026

The effect of midwife-led counseling on fear of childbirth in fathers

Protocol summary

Study aim

The effect of midwifery counseling on fear of childbirth in fathers

Design

This study is a randomized controlled clinical trial with a blinded strain. Research community: Fathers with a pregnant spouse of 24-27 weeks covered by selected health care centers or family physician sites and earn a severe and higher score based on the Fear of Childbirth Scale that designed in Iranian fathers. Randomization: Randomized block assignment (using computer software and quadruple block selection) will be divided into two groups of 25 members, intervention and control groups.

Settings and conduct

Sampling will be done at health center in Sari. In the intervention group, the counseling program on the Skyroom has been able to. The control group will receive an individual training session after completing the last post-test questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnancy age of 24-27 weeks in spouse-Reading and writing literacy-Intense score of fear of childbirth-Consent to participate in the research
Exclusion criteria: Suffering from depression, anxiety and stress-Participate in any educational and counseling programs related to pregnancy-Use of psychiatric drugs-History of hospitalization in the psychiatric ward

Intervention groups

Intervention group: Six 60-90 minute sessions (two sessions a week) in group of 25 people on the Skyroom, by a master's degree student in counseling of midwifery under the supervision of the research team.
Interventions: Includes providing information on pregnancy and childbirth, Empowering fathers to deal with irrational thoughts, Attempts to explain the origin of fear of childbirth, Problem Solving and Relaxation Control group: They will receive one individual training session after completing the last post-test questionnaire.

Main outcome variables

Fear of childbirth

General information

Reason for update

Due to the outbreak of Covid disease and the subsequent ban on crowds, the intervention changed from face-to-face classes to virtual classes in the Skyroom space. According to the research team, following the change in the form of intervention, the number of sessions, the time of intervention and the number of people in each group also changed.

Acronym

IRCT registration information

IRCT registration number: **IRCT20150608022609N6**
Registration date: **2019-12-04, 1398/09/13**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-29, 1399/11/10**

Update count: **2**

Registration date

2019-12-04, 1398/09/13

Registrant information

Name

Zohre Shahhosseini

Name of organization / entity

Mazandaran University of Medical Science, Nasibe School Of Nursing and Midwifery

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-21, 1398/08/30

Expected recruitment end date

2020-02-19, 1398/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of midwife-led counseling on fear of childbirth in fathers

Public title
The effect of midwife-led counseling on fear of childbirth

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Pregnancy age 24-27 weeks in spouse Severe and higher childbirth fear score (Based on a Father's Fear of Childbirth Scale) Literacy for reading and writing Consent to participate in the research
Exclusion criteria:
Suffering from depression, anxiety and stress based on the Depression, Anxiety and Stress Scale-21 (DASS-21) Participate in any educational and counseling programs related to pregnancy and childbirth up to six months before and during the study Use of psychiatric drugs (current or history of use) Hospitalization history in the psychiatric ward

Age
No age limit

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done as a randomized block assignment. In this method, given that there are two intervention and control groups, quad blocking will be employed, in which each block will be two in the intervention group and two in the control group. Then the software will give us the different modes that these four people can come together. For example, the first two people who enter the study may both fall into the intervention group either fall into the control group or the first into the control group and the second into the intervention group or the first person in the intervention group and the second in the control group. Thus, based on the software output, these 50 individuals will be assigned to one of the intervention or control groups.

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 Mazandaran University of Medical Sciences

Street address

Deputy of Research and Technology of Mazandaran University of Medical Sciences, Moalem Square

City

Sari

Province

Mazandaran

Postal code

4816715793

Approval date

2019-09-30, 1398/07/08

Ethics committee reference number

IR.MAZUMS.REC.1398.899

Health conditions studied

1

Description of health condition studied

Fear of childbirth

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

fear of childbirth

Timepoint

Pre-intervention, immediately and one month after intervention

Method of measurement

Father's Fear of Childbirth Scale

Secondary outcomes

1

Description

self efficacy

Timepoint

Before the intervention, immediately and one month after the intervention

Method of measurement

General self-efficacy scale

2

Description

Selective delivery type

Timepoint

Before the intervention, immediately and one month after the intervention

Method of measurement

In the form of a question

3

Description

Satisfaction with the intervention

Timepoint

immediately and one month after the intervention

Method of measurement

Visual Analog Scale: Satisfaction

Intervention groups

1

Description

Intervention group: In the intervention group, 6 sessions of 60-90 minutes (two session per week) will receive interventions (Includes providing information on pregnancy and childbirth, Teaching the concept of rational and irrational thoughts and empowering fathers to deal with irrational thoughts, Attempts to explain the origin of fear of childbirth, Problem Solving and Relaxation) in a group of 25 members in the Skyroom.

Category

Behavior

2

Description

Control group: Will receive routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Sari health centers

Full name of responsible person

Aghil Barzegar

Street address

Sari County Health Center, Amir Mazandaran St, Shahband St, Sari, Mazandaran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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Deputy of Research and Technology of Mazandaran University of Medical Sciences, Moallem Square, Moallem Avenue

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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

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

Seyedeh Fatemeh Ghaffari

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Zohreh Shahhosseini
Position
PhD in Reproductive Health
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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