

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Evaluation of online prenatal education's effect on fear of child birth in primigravid women

Protocol summary

Study aim

Evaluation of online prenatal education's effect on fear of child birth in primigravida women, Gorgan 2021

Design

randomized Clinical trial with with control group, parallel groups, community-based and pragmatic, one-blind

Settings and conduct

This study will be conducted in health centers in Gorgan City. pregnant women will be Randomized into two groups. In this study, because the researcher himself randomizes the samples and intervenes, she cannot be blind. However, the participants are not aware of their position in the control and intervention group, so the study is one-sided blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: primigravid women, low-risk pregnancies and gestational age 20-24 weeks, willingness to participate in the study exclusion criteria: History of mental or anxiety disorder, use of any sedatives or medications related to anxiety disorders, infertility history, need for intensive care during pregnancy, drug addiction

Intervention groups

intervention group: This group will receive online pregnancy training in accordance with the wijma Fear of childbirth Package. control group: This group will receive online pregnancy training in accordance of ministry of health protocol Package.

Main outcome variables

Fear of child birth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180408039229N3**

Registration date: **2021-06-17, 1400/03/27**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-17, 1400/03/27**

Update count: **0**

Registration date

2021-06-17, 1400/03/27

Registrant information

Name

Narjes Sadat Borghei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3254 9718

Email address

dr.borghei@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-12, 1400/03/22

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of online prenatal education's effect on fear of child birth in primigravid women

Public title

Evaluation of online prenatal education's effect on fear of child birth in pregnant women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

primigravid women low-risk pregnancy gestational age between 20-24 weeks willingness to participate in the study

Exclusion criteria:

History of mental or anxiety disorder use of any sedatives or medications related to anxiety disorders infertility history need for intensive care during pregnancy drug addiction

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: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization Method: block Randomization Random unit: Individual For random assignment of samples to the intervention and control groups, the quadratic block method with permutations (AABB-ABAB-ABBA-BABA-BAAB-BBAA) will be used. A represents the intervention group and B represents the control group. The blocks are randomly selected without placement and the samples will be assigned to groups according to their permutations.

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 Golestan University of Medical Sciences

Street address

Golestan University of Medical Sciences, Hyrcan Boulevard, beginning of Shisht Kola Road, Deputy of Research and Technology., Gorgan

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2020-05-10, 1399/02/21

Ethics committee reference number

IR.GOUMS.REC.1400.042

Health conditions studied

1

Description of health condition studied

Prenatal education class

ICD-10 code

F40.233

ICD-10 code description

Fear of injury

Primary outcomes

1

Description

Fear of child birth

Timepoint

the beginning and after intervention

Method of measurement

Wijma Delivery Expectancy/Experience Questionnaire (W-DEQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group will receive pregnancy training in accordance with the Wijma Delivery Expectancy/Experience Questionnaire Fear Package. These trainings will be done in eight sessions of 40 minutes, weekly and online.

Category

Behavior

2

Description

Control group: This group will receive pregnancy training in according to the protocol of the Ministry of Health as prenatal education Package. These trainings will be done in eight sessions of 40 minutes, weekly and online.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Gorgan Health Centers

Full name of responsible person

Elnaz pooralijani

Street address

Gorgan's Health Center., Razi St., Gorgan

City

Gorgan

Province

Golestan

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4914819971

Phone

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Email

puraliyanielnaz@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Dr Mohammadreza Honarvar

Street address

Golestan University of Medical Sciences, Hyrcan
Boulevard, beginning of Shisht Kola Road, Deputy of
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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

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Elnaz pooralijani

Position

Master's student in midwifery counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Golestan University of Medical Sciences, Hyrcan
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Narjes sadat borghei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Elnaz pooralijani

Position

Master's student in midwifery counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Email

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

No decision has been made yet

When the data will become available and for how long

Six months after the article was published

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

the part of Data for similar research can be used
scientifically and with reference. To access the data, they
can send a message to the email address of
Correspondent Author.

From where data/document is obtainable

Correspondent Author

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

Applicants can send a message to the correspondent's
email and finally receive a response within a week.

Comments