Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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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

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gorgan University of Medical Sciences
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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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Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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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