Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of Online childbirth preparation classes on Perceived stress in pregnant women covered by comprehensive health centers in Saveh during the corona pandemic

Protocol summary

Study aim

Determining the effect of childbirth preparation classes on stress levels of pregnant women covered by comprehensive health centers in Saveh during the corona pandemic

Design

The sampling method is stratified random. Thus, from 7 centers in Saveh, a number of samples will be selected according to the number of available files. The number of cases in 7 centers is 116,120,178,201,212,255,214, respectively. Therefore, according to the number of files of each center and the above relations, 6, 8, 10, 12, 12, 14, 12 will be randomly selected and entered into the study, respectively. The sample size is 74 people.

Settings and conduct

Classes are held online according to the class schedule in physiological childbirth courses of the Ministry of Health. Location of Saveh city and Chamran center

Participants/Inclusion and exclusion criteria

Inclusion criteria Age 20-35 years, gestational age 19 to 22 weeks, willingness to participate in research, single pregnancy, no previous history of attending classes, no history of mental illness, no history of hypertension and diabetes, no systemic diseases, no History of abortion and symptoms threatening abortion. Exclusion criteria Mother's dissatisfaction Not attending 3 sessions of childbirth preparation classes

Intervention groups

Before the first session of the classes, the questionnaires will be completed by the control and experimental groups and then the classes will be held in 8 sessions of 1.5 hours for the experimental group (due to the lack of conditions for face-to-face classes online and through the program. Skyroom is held). After the sessions, the questionnaires are completed again by both experimental and control groups.

Main outcome variables

If classes reduces stress in the covid19 pandemic. this method can be used to control stress and stress complications in pregnancy and childbirth.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220424054637N1**
Registration date: **2022-07-22, 1401/04/31**
Registration timing: **registered_while_recruiting**

Last update: **2022-07-22, 1401/04/31**
Update count: **0**

Registration date

2022-07-22, 1401/04/31

Registrant information

Name

Sara Heydari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 4241 4105

Email address

mahhaid1371@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-07, 1401/04/16

Expected recruitment end date

2022-09-07, 1401/06/16

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Online childbirth preparation classes on Perceived stress in pregnant women covered by comprehensive health centers in Saveh during the corona pandemic

Public title
The effect of Online childbirth preparation classes on Perceived stress in pregnant women
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Age20-35 years Gestational age 19 to 22 weeks Willingness to participate in research Single pregnancy No previous history of attending classes No known history of mental illness No increase in blood pressure and diabetes in the mother's previous and current pregnancy No systemic diseases Absence of history of abortion and symptoms threatening abortion
Exclusion criteria:
Maternal dissatisfaction with further research Not attending 3 sessions of maternity preparation classes by the mother
Age
From **20 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
The sampling method is stratified random. Thus, from 7 centers in Saveh, a number of samples will be randomly selected and entered into the study according to the number of available cases of pregnant women. According to the available statistics, there are 1296 cases of pregnant women in 7 centers and the number of cases in 7 centers is 116,120,178,201,212,255,214, respectively. Therefore, according to the number of files in each center and the above relations, 6, 8, 10, 12, 12, 14, 12 will be randomly selected and entered into the study, respectively. After selecting 74 pregnant women to be assigned to the experimental and control groups, a simple random method without placement will be used, with 37 red papers for assigning the experimental group and 37 blue papers for assigning the control group, and a total of 74 papers entering the container. It is poured and by completely random selection of each participant without returning the papers to the desired container, equal allocation is made to the two groups of test and control. In order to prevent bias, the process of randomization and selection of papers will be done by the personnel of each center and the researcher will not interfere in this stage and the relevant personnel will not know the desired color for assigning each group and thus any bias will be prevented. Due to group training and prevention of any bias, selected pregnant mothers from centers 1, 2 and 5 will enter the intervention group and the rest will be in the control group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethics of Qazvin medical university
Street address
bahonar
City
Qazvin
Province
Qazvin
Postal code
3419759811
Approval date
2021-12-11, 1400/09/20
Ethics committee reference number
400000045

Health conditions studied

1

Description of health condition studied
stress during pregnancy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
on Perceived stress in pregnant women
Timepoint
before the trial and after trial
Method of measurement
cohen perceived stress scale (pss)-Corona Disease Anxiety Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Online childbirth preparation classes based on national protocol will be perform for case group
Category
N/A

2

Description
Control group: they will receive routine care
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
comprehensive health centers in Saveh
Full name of responsible person
Mojtaba Zokaee
Street address
Taleghani1, Madar square
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Markazi
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3918698786
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Doctor Seyed Mahdi Mirhashemi
Street address
Bahonar st
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Province
Qazvin
Postal code
3419759811
Phone
+98 28 3333 6001
Fax
+98 28 3332 4970
Email
medicine@qums.ac.ir
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Sara Heydari
Position
student
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Information on the main outcome is unpublishable
When the data will become available and for how long
The access period starts from 1402
To whom data/document is available
It will be available to both researchers and industry professionals
Under which criteria data/document could be used
The data is sent without revealing the identity of the people
From where data/document is obtainable
Sara Heydari Contact number: 09361742070 Postal code: 3918847835 mahaid1371@gmail.com
What processes are involved for a request to access data/document
Documents are sent in the form of photos and via email
Comments