

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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:**

Age 20-35 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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+98 86 4222 2080

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+98 86 4222 6653

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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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Qazvin

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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 scientific inquiries

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Person responsible for updating data

Contact
Name of organization / entity
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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