

# 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

#### City

Saveh

#### Province

Markazi

#### Postal code

3918698786

#### Phone

+98 86 4222 2080

#### Fax

+98 86 4222 6653

#### Email

mahhaid1371@gmail.com

## 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

#### City

Qazvin

#### 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

Midwifery

#### Street address

Andarzgoo 5 th ave , Saveh

#### City

Saveh

#### Province

Markazi

#### Postal code

3918847835

#### Phone

+98 86 4241 4105

#### Email

mahhaid1371@gmail.com

## Person responsible for scientific 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**  
Midwifery  
**Street address**  
Andarzgoo 5th .Saveh  
**City**  
Saveh  
**Province**  
Markazi  
**Postal code**  
3918847835  
**Phone**  
+98 86 4241 4105  
**Email**  
mahhaid1371@gmail.com

## Person responsible for updating data

**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**  
Midwifery  
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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