Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of the online child birth preparation classes on anxiety and the quality of life of pregnant women during COVID_19 pandemic

Protocol summary

Study aim
The effect of the online child birth preparation classes on anxiety and the quality of life of pregnant women during covid-19 pandemy

Design
This research is a randomised clinical trial with two control and intervention group.50 pregnant women are selected randomly in each group.No blinding is done.

Settings and conduct
This research is a randomised clinical trial in Arash hospital.100 pregnant women are allocated to control and intervention group randomly.8 online educational sessions about birth preparation are held for intervention group.Control group receives just routine prenatal cares.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Gestational age between 20 weeks to 30 weeks Access to the virtual space Primary educations Not attending in virtual and attendance birth preparation courses in current pregnancy Non inclusion criteria: Preterm delivery suffering from mental disorders and depression before and during pregnancy suffering from fetal and maternal health threatening diseases

Intervention groups
Intervention group:50 eligible pregnant women reffering to the prenatal clinic of Arash hospital are selected as intervention group.8 online educational sessions are held. Control group:50 eligible pregnant women reffering to the prenatal clinic of Arash hospital are selected ascontrol group.Thi group receives just routine prenatal cares and after post test ، educational sessions are held for them.

Main outcome variables
Anxiety-Quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190713044192N2**
Registration date: **2020-11-21, 1399/09/01**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-21, 1399/09/01**
Update count: **0**

Registration date
2020-11-21, 1399/09/01

Registrant information

Name
Zohreh Maleki

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 3348 4604

Email address
iris_decor_group@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-21, 1399/09/01

Expected recruitment end date
2021-01-20, 1399/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of the online child birth preparation classes on anxiety and the quality of life of pregnant women during COVID_19 pandemic

Public title

The effect of the online child birth preparation classes on pregnant women during COVID_19 pandemic

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age between 20 weeks -30 weeks Access to virtual space Primary education Not attending in virtual and attendance child birth preparation courses in current pregnancy

Exclusion criteria:

Preterm delivery suffering from psychological disorders and depression befor and during pregnancy suffering from health threatening diseases in fetus and mother

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research، systematic randomization is applied.Pregnant women who are reffered to prenatal clinic are asked to enroll if they are interested in .For determining the counting distance ، the number of enrolled women is divided to intended cases of the research .For choosing the first case، a number from 1 to 10 is selected randomly.This number is allocated to the first case.other cases are selected based on the counting distance till 100 cases are selected.A number is selected from 1 to 100. If this number is even، all the even numbers will be selected as intervention group and odd numbers will be selected as control group.

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 Tehran university of medical science

Street address

Ghods street -Enghelab square

City

Tehran

Province

Tehran

Postal code

3439123900

Approval date

2020-09-15, 1399/06/25

Ethics committee reference number

IR.TUMS.FNM.REC.1399.098

Health conditions studied

1

Description of health condition studied

Anxiety and quality of life

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Score of Spielberger State-Trait questionnaire

Timepoint

Before the intervention and four weeks after the intervention

Method of measurement

Spielberger State-Trait questionnaire

2

Description

Score of Quality of life questionnaire

Timepoint

Before the intervention and four weeks after the intervention

Method of measurement

Quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this research the intervention group consists of 50 eligible pregnant women reffering to the prenatal clinic of Arash hospital.After pretest، 8 virtual educational sessions about child birth preparation is held، Educational sessions are held every 3 days. Each session takes about 2 hours and the content is taught through power point، lecture and video.The content consists of introduction، anatomical and physiological changes in pregnancy، personal health، adaption to pregnancy changes، breathing techniques and relaxation، nutrition، mental health، painless delivery ،

postpartum and neonate health.

Category

Other

2

Description

Control group: In this research the control group consists of 50 eligible pregnant women reffering to the prenatal clinic of Arash hospital.This group just receives routin prenatal cares and after post test، educational sessions are held.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash hospital

Full name of responsible person

Farnaz Farnam

Street address

Baghdarnia street- Farjam street- Tehranpars

City

Tehran

Province

Tehran

Postal code

1854213265

Phone

+98 21 7788 3288

Email

hos_arash@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammadali Sahraeian

Street address

Ghods street- Enghelab Ave

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 6405 3334

Email

tums_edu@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Farnaz Farnam

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Tohid square- Facaulty of Midwifery and Nursing

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6692 4411

Email

f_farnam@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Farnaz Farnam

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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+98 21 6692 4411

Email

f_farnam@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Zohre Maleki

Position

Midwife

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Tohid square-Facaulty of Midwifery and Nursing

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 935 736 0033

Fax

Email

z_maleki63@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Participant s informations are secret.

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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The final result will be accessible as an article on the accepted journal.

When the data will become available and for how long

No limited timespan

To whom data/document is available

No limitation

Under which criteria data/document could be used

Applying the result of this research is permissible just in cases of citations.

From where data/document is obtainable

For receiving data and documents، send an e-mail to this address:z_maleki63@yahoo.com

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

Sending e-mail for requesting access to the data and document

Comments