

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Effectiveness of online positive psychology counseling on psychological well-being of nulliparous pregnant women participant in childbirth preparation classes

Protocol summary

Study aim

Effectiveness of online positive psychology counseling on psychological well-being of nulliparous pregnant women participant in childbirth preparation classes

Design

The study is a two arm parallel group randomized trial without blinding on 74 eligible nulliparous pregnant women . convenience sampling method and Random Allocation software is used for randomization.

Settings and conduct

Research population: pregnant women referring to comprehensive health centers in Farsan city. Positive psychology intervention is conducted online by the second researcher, under the supervision of the first, third and fifth researchers. Childbirth preparation classes are held routinely in health centers.

Participants/Inclusion and exclusion criteria

Inclusion: Iranian nationality. Age 18 - 40 years. Nulliparity. Gestational Age 16 - 24 Week. Single fetus. Literacy for reading and writing. Interested in participate in childbirth preparation classes. Having Smartphone with licensed virtual software. Internet access. Voluntary willingness to participate in research. Exclusion: History of infertility. High risk pregnancy(hypertension, vaginal bleeding, diabetes, thyroid disorders, placenta previa, fetal anomalies and...) The occurrence of unfortunate events in the past six months, such as the death of loved ones, accidents, divorce and... Self-reported drug abuse by the pregnant woman or her husband. Having a history or being treated for psychiatric disorders.

Intervention groups

The control group participates in 8 weekly sessions of face-to-face childbirth preparation classes at health centers. In addition to the above class, the intervention group also participates in 8 weekly online positive counseling sessions.

Main outcome variables

Mean score of psychological well- being

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230212057395N1**

Registration date: **2023-03-18, 1401/12/27**

Registration timing: **prospective**

Last update: **2023-03-18, 1401/12/27**

Update count: **0**

Registration date

2023-03-18, 1401/12/27

Registrant information

Name

Seyedehbatoul Hashemibabaheidari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3324 7726

Email address

sb.hashemibabaheidari@stu.ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-09, 1402/01/20

Expected recruitment end date

2023-08-11, 1402/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of online positive psychology counseling on psychological well-being of nulliparous pregnant women participant in childbirth preparation classes

Public title

Effectiveness of online positive psychology counseling on psychological well-being of nulliparous pregnant women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Iranian nationality Age 18 - 40 years Nulliparity Gestational Age 16 - 24 week Single fetus Literacy for reading and writing. Interested in participate in childbirth preparation classes Having Smartphone with licensed virtual software Internet access Voluntary willingness to participate in research

Exclusion criteria:

History of infertility High risk pregnancy(hypertension, vaginal bleeding, diabetes, thyroid disorders, placenta previa, fetal anomalies and...) The occurrence of unfortunate events in the past six months, such as the death of loved ones, accidents, divorce and ... Self-reported drug abuse by the pregnant woman or her husband Having a history or being treated for psychiatric disorders

Age

From **18 years** old to **40 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

74 nulliparous pregnant women are selected based on the entry and exit criteria as convenience sampling method from the comprehensive health centers of Farsan city and the covered bases. Then they are divided into two groups of 37 people, positive counseling + childbirth preparation training (intervention group) and childbirth preparation training alone (control group) by a biostatistics specialist using simple randomization method and random number sequence with online randomization software (using the site www.random.org/sequences).

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 Shahid Sadoughi University of Medical Sciences

Street address

Bahonar Square, Yazd

City

Yazd

Province

Yazd

Postal code

8916189165

Approval date

2023-03-01, 1401/12/10

Ethics committee reference number

IR.SSU.REC.1401.106

Health conditions studied**1****Description of health condition studied**

Psychological well- being

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Measurement of mean score of psychological well- being in two groups

Timepoint

Measurement of the well-being variable at the beginning of the study (before the start of the intervention) and the eighth week (end of the intervention) and the twelfth week (follow-up) from the start of the study in two groups

Method of measurement

Ryff's Scales of Psychological Well-being

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: Pregnant women in this group participate in 8 weekly 90-minute sessions of routine birth preparation classes, which are held face-to-face in

groups of 8 to 10 people. These classes are conducted by trained midwives in health centers according to the protocol of the Ministry of Health. The contents of the sessions include anatomy of the reproductive system, nutrition during pregnancy, mental health of pregnant women, danger signs in pregnancy, benefits of natural childbirth, non-pharmacological pain relief methods, stages of labor, postpartum care and newborn health care. In addition, exercises to strengthen the skeletal-muscular system, breathing exercises and relaxation methods are taught that mothers should practice at home. At the beginning of each session; mothers should report how much they did their homework in the previous week.

Category

Behavior

2

Description

Intervention group: Pregnant women in this group, like the control group, participates in 8 weekly 90-minute sessions of face-to-face childbirth preparation classes that are established in health centers according to the protocol of the Ministry of Health. In addition, they also participate in online positive psychology training classes in groups of 12 to 15 people according to Seligman and Rashid's protocol in 8 weekly sessions of 90 minutes. These classes are conducted under the supervision of a psychologist consultant and by a senior student of counseling in midwifery who has completed the above course. The content of the sessions includes explaining positive psychology, identifying strengths, expressing the role of positive feelings and emotions in increasing well-being, gratitude and forgiveness, focusing on the topic of hope and optimism, positive relationships, fascination and meaning in life. Each session has home practices, mothers are asked to do their practice before the next session and report the amount of practice in a virtual way in private.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Farsan health centers

Full name of responsible person

Azam Khoshbin

Street address

Bouali Ave

City

Yazd

Province

Yazd

Postal code

8916877443

Phone

+98 35 3824 1754

Email

azamkhoshbin@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amin Salehi Abargouei

Street address

Alam Square, Medical Sciences Campus, Yazd

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8916978477

Phone

+98 35 3149 2229

Fax

Email

abargouei@ssu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Azam Khoshbin

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Midwifery

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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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Full name of responsible person
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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

All personal data of study participants can be shared after unidentifying.

When the data will become available and for how long

After results publication.

To whom data/document is available

The data will be available to researchers working in academia and academia, and people in the industry can apply for it.

Under which criteria data/document could be used

Scientific usage.

From where data/document is obtainable

azamkhoshbin@gmail.com

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

One Week after receiving requested email.

Comments