Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effectiveness of prenatal self-care training application in Covid 19 pandemic on quality of life, depression, corona anxiety and fear of childbirth in pregnant women

Protocol summary

Study aim
Determining the effectiveness of pregnancy self-care training application in Covid epidemic 19 on quality of life score, depression, coronary anxiety and fear of childbirth in pregnant women

Design
Clinical trial with control group, with parallel groups,No blinding,Random allocation using block randomization

Settings and conduct
From the list of health centers, two centers are selected as available and divided into two groups using random allocation (blocking).Intervention group B: will receive a free pregnancy self-care application that has 8 training sessions, according to the instructions of the Ministry of Health. Control group A: will receive 5 text messages per day related to pregnancy self-care through WhatsApp for one month.The SF-36 Quality of Life Questionnaire, DASS21 Depression, Corona Alipour Anxiety and Harman's Fear of Childbirth will be sent before and immediately after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria Gestational age less than 20 weeks, maternal age 15-49 years, informed consent, internet access, possibility of making phone calls, first or second pregnancy, literacy, having a smartphone, exclusion criteria: not receiving and implementing training, no Completion of questionnaires with miscarriage, major stress, Corona

Intervention groups
The application intervention group receives pregnancy training which has 8 training sessions and they are advised not to share the application with other people and their ambiguities in the field of application in WhatsApp are answered. Control group They receive 5 text messages related to pregnancy training daily for one month through WhatsApp (150 text messages in total). Before and after the end of the one-month training course, the questionnaires are sent and received again.

Main outcome variables
quality of life, depression,Corona anxiety and fear of childbirth

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210531051457N1**
Registration date: **2021-06-27, 1400/04/06**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-27, 1400/04/06**
Update count: **0**

Registration date
2021-06-27, 1400/04/06

Registrant information

Name
Masuomeh Fayazi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3258 2844

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seyedehmasuomeh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-22, 1400/04/01

Expected recruitment end date
2021-07-01, 1400/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of prenatal self-care training application in Covid 19 pandemic on quality of life, depression, corona anxiety and fear of childbirth in pregnant women

Public title

Evaluation of the effectiveness of prenatal self-care training application in Covid 19 pandemic on quality of life, depression, corona anxiety and fear of childbirth in pregnant women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age less than 20 weeks maternal age 15-49 years informed consent to participate in research after hearing research goals and programs Internet access and messengers possibility of making telephone calls to pregnant mother first or second pregnancy, Having literacy in Persian waned pregnancy not having any physical or mental illnesses according to the mother not having a fetus with abnormalities not getting a high score of anxiety or depression from the questionnaires not having a history of infertility Having a smartphone

Exclusion criteria:

Failure to receive and perform training failure to complete questionnaires at any stage of the research abortion major stress during the intervention such as death of a relative person or spouse or child with corona heart disease

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

First, 2 centers are randomly selected from the list of urban health centers. One center for the intervention group and one center for the control group will be non-random sampling (available) and for random allocation of samples to each of the two intervention and control groups, 4 variable blocks will be used. In this way, first 6 possible modes of 4 blocks (BBAA, BABA, ABBA, BAAB, AABB, ABAB) are listed and each block is assigned a number from one to six. Then a number between one to 6 is randomly selected and then individuals are assigned to the test group (B) and control (A) based on the block corresponding to the selected number. This continues until the sample size is completed.

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 Committee of Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences

City

Gonabad

Province

Razavi Khorasan

Postal code

9156137374

Approval date

2021-06-02, 1400/03/12

Ethics committee reference number

IR.GMU.REC.1400.028

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Quality of Life

ICD-10 code

ICD-10 code description

3

Description of health condition studied

Corona anxiety

ICD-10 code

ICD-10 code description

4

Description of health condition studied

Fear of childbirth

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Quality of life score in two groups
Timepoint
At the beginning of the intervention and immediately after the end of the study
Method of measurement
Global Health Quality of Life Standard Questionnaire sf-36

2

Description
Depression score
Timepoint
At the beginning of the intervention and immediately after the end of the study
Method of measurement
Depression Questionnaire dass-21

3

Description
Corona Anxiety Score
Timepoint
At the beginning of the intervention and immediately after the end of the study
Method of measurement
Corona Anxiety Questionnaire Ahmad Alipour

4

Description
Fear of childbirth score
Timepoint
At the beginning of the intervention and immediately after the end of the study
Method of measurement
Harman Maternity Fear Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Pregnancy self-care application, which is designed according to the instructions of the Ministry of Health during pregnancy, and is very comprehensive, is provided to people for free and the ambiguities in WhatsApp are answered.
Category
Behavior

2

Description
Control group: A group is formed in WhatsApp and 5 text messages related to pregnancy education are provided to people daily for one month.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Gonabad Urban Health Center Number One
Full name of responsible person
Acram ajam
Street address
Gonabad Health Center number one
City
Gonabad
Province
Razavi Khorasan
Postal code
9156137374
Phone
+98 51 3258 2844
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info@gmu.ac.ir

2

Recruitment center
Name of recruitment center
Gonabad Urban Health Center No. 2
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gonabad University of Medical Sciences
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Grant name

Grant code / Reference number

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

Title of funding source
Gonabad 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
Gonabad University of Medical Sciences
Full name of responsible person
Roghaieh Rahmany
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to

make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available