Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of an educational intervention based on the preced model on the quality of life of pregnant women referring to the health centers of Arak city during the COVID-19 pandemic.

Protocol summary

Study aim
Study on the effect of educational intervention based on precede model on the quality of life in pregnant women referring to health centers in Arak duration of pandemic COVID-19

Design
Clinical trial work for control group with parallel groups, without blinding, with simple randomization based on the entry list is performed on 120 mothers of 12 to 24 weeks.

Settings and conduct
Standardized questionnaire is completed by the samples and then based on this assessment and determination of their quality of life score, test group is trained in field of increasing the quality of life. The control group receive routine care. There is no case of blinding.

Participants/Inclusion and exclusion criteria
Healthy expectant mothers in the second trimester of pregnancy in Arak, who are not infected with COVID and do not have mental and physical diseases affecting the quality of life, who have access to the social network with a smartphone, will be invited to participate in the study. The exclusion criteria include the mother's unwillingness to participate in the study is migration from Arak city or suffering from mental and physical diseases affecting the quality of life during pregnancy, not actively participating in face-to-face or non-face-to-face training sessions during the training intervention.

Intervention groups
Educational interventions will be presented to the case group in offline and online educational sessions based on the lesson plan. One month later, the intervention effect will be evaluated. The control group received education and routine care of the health system.

Main outcome variables
Quality of life, predisposing factors, reinforcing factors, enabling factors, behavioral goals

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220707055407N1**
Registration date: **2022-07-20, 1401/04/29**
Registration timing: **registered_while_recruiting**

Last update: **2022-07-20, 1401/04/29**
Update count: **0**

Registration date
2022-07-20, 1401/04/29

Registrant information

Name
Akram Hamzehlouyan

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 86 3222 6948

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-11, 1400/12/20

Expected recruitment end date
2022-07-21, 1401/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of an educational intervention based on the preced model on the quality of life of pregnant women referring to the health centers of Arak city during the COVID-19 pandemic.

Public title
Investigating the effect of an educational intervention based on the Persed model on the quality of life of pregnant women during the Corona pandemic
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant mothers in the second trimester of pregnancy living in the city of Arak, whose pregnancy is registered in the electronic file Do not have covid Do not have any high-risk pregnancy or mental and physical diseases affecting the quality of life based on the mother's health record Have a smartphone and have access to social networks
Exclusion criteria:
Unwillingness to participate in the study Migration from the city of Arak Suffering from mental and physical diseases affecting the quality of life during pregnancy Lack of active attendance in face-to-face or non-face-to-face training sessions during the training intervention
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
The list of pregnant mothers from 12 to 24 weeks covered in Arak urban health centers was prepared from the Sib system, 120 mothers were selected and 60 of them were randomly assigned to the intervention group and 60 to the control group. According to the order of entering the Excel list. In all ten research centers, the names of the first people entering the control group and the rest were included in the test 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 Arak University of Medical Sciencesl Sciences
Street address
alamolhoda bolivar،Arak medical university
City
Arak
Province
Markazi
Postal code
3818146851
Approval date
2021-12-05, 1400/09/14
Ethics committee reference number
IR.ARAKMU.REC.1400.252

Health conditions studied

1

Description of health condition studied
covid-19
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Quality of life variable score
Timepoint
Before starting the intervention and after the intervention
Method of measurement
A standard researcher-made questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
In addition to routine trainings, standard trainings in 2 online sessions and 4 offline sessions, a pamphlet and 15 educational poster files sent in the WhatsApp group related to the research are presented to this group.
Category
Behavior

2

Description
Control group: They receive routine training in the health

system.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak urban health centers

Full name of responsible person

Khorsandi Mahboobeh

Street address

Faculty of Health, Golestan, Mustafa Khomeini town,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Drkhorsandi Mahboobeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for updating data

Contact

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ahamzehlouyan@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
Individual data is not allowed to be published
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
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Only part of the data related to the main outcome can be shared
When the data will become available and for how long
Access period starts 6 months after publication
To whom data/document is available
Health care workers and researchers in the field of health education
Under which criteria data/document could be used
The questionnaire will be shared in the target group for the use of the applicants and to repeat the research
From where data/document is obtainable
To receive documents, refer to the responsible author
What processes are involved for a request to access data/document
By sending an email, the researcher-made questionnaire will be sent to the applicant within a week.
Comments