

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

**Investigating the effect of an educational intervention based on the precede 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)

##### Phone

+98 86 3222 6948

##### Email address

ahamzehlouyan@yahoo.com

#### 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 Sciences| 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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+98 86 3366 6234

**Email**

khorsandi.mahboobeh@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Alireza Kamali

**Street address**

Sardasht, Basij Square

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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

**Street address**

Faculty of Health ,Mustafa Khomeini settlement,  
Golestan district

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Position**

Professor

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Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Hamzehlouyan Akram

**Position**

student

**Latest degree**

Master

**Other areas of specialty/work**

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**Province**

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3814135959

**Phone**

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**Email**

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**