

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of educational intervention based on precede model on the performance of mothers with infants in preventive behaviors of middle ear infection

Protocol summary

Study aim

The effect of educational intervention based on precede model on the performance of mothers with infants in preventive behaviors of middle ear infection

Design

Training case including intervention and control groups. One-blind, SPSS software was used on 88 mothers with infants for randomization.

Settings and conduct

This study is performed in Arak health centers on mothers with infants who are registered in the apple system. The study is done in two stages: cross-sectional and intervention. The type of intervention will be educational.

Participants/Inclusion and exclusion criteria

Entry requirements: Mother have infant without otitis media and she and her husband be satisfied to be in the educational intervention and mother have at least 5 calss literacy and mothers home be in arak city, No entry conditions: Reluctance to participate in the study, change of residence of the mother and lack of access to her

Intervention groups

Intervention group: Receiving an educational intervention in the field of strategies to prevent middle ear infection in infants, which is done once a week during 4 training sessions. An educational package containing educational videos, photos, booklets and pamphlets is also given to the intervention group members. Control group: The members of the control group receive only the routine trainings of the health center. In addition, they receive the training package including booklets and pamphlets and educational videos and photos.

Main outcome variables

Awareness Attitude Enabling factot Reinforcement factors Function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210202050228N1**

Registration date: **2021-05-21, 1400/02/31**

Registration timing: **prospective**

Last update: **2021-05-21, 1400/02/31**

Update count: **0**

Registration date

2021-05-21, 1400/02/31

Registrant information

Name

Atefe Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3862 4348

Email address

a.moradi98@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of educational intervention based on precede model on the performance of mothers with infants in preventive behaviors of middle ear infection

Public title

The effect of educational intervention based on precede model on the performance of mothers with infants in preventive behaviors of middle ear infection

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Mother have infant Resident of Arak city Literate (5 literacy classes) She and her husband's consent to participate in the study Her child does not currently have a middle ear infection (based on the mother's self-declaration)

Exclusion criteria:

Reluctance to participate in the study Change of mother's residence Lack of access to the mother

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization unit is a class. The tool used is SPSS. For this purpose, after entering the list of eligible people to participate in the study in SPSS software, use the random select option to randomly assign samples to the case and control groups. The randomization method is also simple.

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

Street address

Laleh Blvd., No. 209, Arghavan St

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2021-01-13, 1399/10/24

Ethics committee reference number

IR.ARAKMU.REC.1399.298

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

The effect of educational intervention based on precede model on the performance of mothers with infants in preventive behaviors of middle ear infection

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

Knowledge

Timepoint

At the beginning of the study and before the educational intervention. Then 3 months after the end of the educational intervention

Method of measurement

Through a researcher-made questionnaire

2**Description**

Attitude

Timepoint

At the beginning of the study and before the educational intervention. Then 3 months after the end of the educational intervention

Method of measurement

Through a researcher-made questionnaire

3**Description**

Behavior

Timepoint

At the beginning of the study and before the educational intervention. Then 3 months after the end of the educational intervention

Method of measurement

Through a researcher-made questionnaire

4**Description**

Enabling factor

Timepoint

At the beginning of the study and before the educational intervention. Then 3 months after the end of the educational intervention

Method of measurement

Through a researcher-made questionnaire

5**Description**

Reinforcement factors

Timepoint

At the beginning of the study and before the educational intervention. Then 3 months after the end of the educational intervention

Method of measurement

Through a researcher-made questionnaire

Secondary outcomes

empty

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

Intervention group: Receiving an educational intervention in the field of strategies to prevent middle ear infection in infants, which is done once a week during 4 training sessions. An educational package containing educational videos, photos, booklets and pamphlets is also given to the intervention group members.

Category

Behavior

2**Description**

Control group: The members of the control group receive only the routine trainings of the health center. In addition, they receive the training package including booklets and pamphlets and educational videos and photos.

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Comprehensive health centers of Arak city

Full name of responsible person

Atefe Moradi

Street address

Mostafa Khomeini St., Golestan St., Building No. 2 of Arak Medical Sciences

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Phone

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Email

a.moradi98@arakmu.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Dr Rahele Soltani

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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

Atefe Moradi

Position

University student

Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Atefe Mordai

Position

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Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Atefe Moradi

Position

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

After identifying people

When the data will become available and for how long

1 month

To whom data/document is available

researchers

Under which criteria data/document could be used

For information on future research

From where data/document is obtainable

Arak univercity of medical sciences

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

Sending email to atefe moradi

Comments