Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 housband 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 housband'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
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3366 2024
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
Street address
Mostafa Khomeini St., Golestan St., Building No. 2 of Arak Medical Sciences
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3366 2024
Email
a.moradi98@arakmu.ac.ir
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

Street address
Mostafa Khomeini St., Golestan St., Building No. 2 of Arak Medical Sciences
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3366 2024
Email
a.moradi98@arakmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Atefe Mordai
Position
University student
Latest degree
Bachelor
Other areas of specialty/work
Health Promotion
Street address
Mostafa Khomeini St., Golestan St., Building No. 2 of Arak Medical Sciences
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3366 2024
Email
a.moradi98@arakmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Atefe Moradi
Position
Univercity student
Latest degree
Bachelor
Other areas of specialty/work
Health Promotion
Street address
Mostafa Khomeini St., Golestan St., Building No. 2 of Arak Medical Sciences
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3366 2024
Email
a.mo4ad98@arakmu.ac.ir

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