

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of educational intervention based on the behavioral theory on the encouragement to oral health of mothers with children under the age of three years referring to Khaf health centers

Protocol summary

Study aim

This study will be done to determine the effect of educational intervention based on the theory of planned behavior to encourage mothers with children under the age of three to observe the oral health of their young children

Design

98 people will be selected from the Health centers under study. The assignment of the groups was non-random, the Health centers of Khaf are listed and 2 Health centers will be randomly selected as the intervention group. Then two Health centers will be selected as control group that are culturally and socially similar to the two intervention Health centers, but they are not geographically close. then 24 people are randomly selected from each village.

Settings and conduct

Educational intervention will be implemented with an emphasis on theory of planned behavior, for a maximum of 2 months on intervention group. Educational intervention will take place in 5 one-hour training sessions. The training sessions will be held in a group discussion. In this study, considering the characteristics of the target group and the objectives of the curriculum will be used various oral, written and combination methods such as lectures with questions and answers, providing and presenting suggestions, group discussion, practical presentation and role play.

Participants/Inclusion and exclusion criteria

Inclusion criteria: residence for at least 6 months in the research setting; having a child under three years of age. Exclusion criteria: employ in a profession related to dentistry.

Intervention groups

Intervention group: educational intervention is done with an emphasis on theory of planned behavior. Control Group: no intervention.

Main outcome variables

Oral care behavior

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180910040991N1**

Registration date: **2020-06-02, 1399/03/13**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-02, 1399/03/13**

Update count: **0**

Registration date

2020-06-02, 1399/03/13

Registrant information

Name

Mahdi Gholian-aval

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3189 2207

Email address

gholianam@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-06-09, 1399/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of educational intervention based on the behavioral theory on the encouragement to oral health of mothers with children under the age of three years referring to Khaf health centers

Public title
The effect of educational intervention based on the behavioral theory on the encouragement to oral health of mothers with children under the age of three years referring to Khaf health centers

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Residence for at least 6 months in the research setting
Having a child under three years of age
Exclusion criteria:
Employ in a profession related to dentistry

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
N/A

Randomization description

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 Mashhad University of Medical Sciences

Street address

Vice chancellor for research, Qoreishi Building, Daneshgah 18, Daneshgah Street

City

Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Approval date
2018-09-06, 1397/06/15

Ethics committee reference number
IR.MUMS.REC.1397.156

Health conditions studied

1

Description of health condition studied

Oral and dental diseases

ICD-10 code

K08.54

ICD-10 code description

Contour of existing restoration of tooth biologically incompatible with oral health

Primary outcomes

1

Description

Oral Health Behavior

Timepoint

Before the intervention, immediately and, tow months after the intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Educational intervention will be implemented with an emphasis on theory of planned behavior, for a maximum of 2 months on intervention group. Educational intervention will take place in 5 one-hour training sessions. The training sessions will be held in a group discussion. In this study, considering the characteristics of the target group and the objectives of the curriculum will be used various oral, written and combination methods such as lectures with questions and answers, providing and presenting suggestions, group discussion, practical presentation and role play

Category

Behavior

2

Description

Control group: No intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Khaf County Health Centers

Full name of responsible person

Mahin Osmani-roudi

Street address

School of Public Health, between 16th and 18th
Daneshgah, Daneshgah Street

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Email

Osmanim1@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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Vice President of Research, Qoreishi Building,
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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mahdi Gholian-aval

Position

Vice Chancellor for Health of Mashhad University of
Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Department of Health Education and Health
Promotion. School of Public Health, Mashhad
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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mahdi Gholian-aval

Position

Assistance Professor of Health Education and Health
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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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Assistance Professor of Health Education and Health Promotion

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

Not applicable

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

Title and more details about the data/document

Potential data is sharable after distinguishing people

When the data will become available and for how long

Start the access period one month after the publication of result

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Data is sent through an official request and by email

From where data/document is obtainable

Dr Mahdi Gholian-aval: gholianam@mums.ac.ir

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

Data is sent through an official request and by email

Comments