

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Design and Evaluation of family - based training programs on the prevention of tooth decay behaviors of 6 months to one - year - old based on intervention Mapping Approach

Protocol summary

Study aim

Determination of the effectiveness of a family-centered educational program

Design

Study Phase: Not true The blind group does not exist in the study. sample size: 60 people
Randomization: randomized allocation to Intervention and Control Groups Other design features of the study: First of all, Ilam city centers, city center number 6 was selected because of the high coverage of mothers. Samples were also randomly divided into intervention and control groups

Settings and conduct

The study site is Ilam Urban Comprehensive Health Center 6 Center 6 covers a population of 1,4856, with the highest population among urban centers. The population of the mothers covers 7605 people. Of these 98 mothers with children aged 6 months to 1 year, Samples were randomly divided into intervention and control groups

Participants/Inclusion and exclusion criteria

1- Having a child aged 6 months to 1 year 2. Having a healthy child 3. Having a health record 4. Have at least reading and writing skills Exclusion criteria 1- Being pregnant with mothers 2. The underlying disease of mothers and their children 3. Separation and Divorce of Parents

Intervention groups

Intervention group includes mothers who are eligible for study and receive education plan The control group consisted of mothers who were enrolled and did not receive training

Main outcome variables

The main implications of the application: intention of behavior Time sections of measurement: Prior to intervention and 6 months after intervention How to measure: The questionnaire

General information

Reason for update

Acronym

Tehran Tooth Study

IRCT registration information

IRCT registration number: **IRCT20190716044227N1**

Registration date: **2019-09-25, 1398/07/03**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-25, 1398/07/03**

Update count: **0**

Registration date

2019-09-25, 1398/07/03

Registrant information

Name

bahareh kabiry

Name of organization / entity

Tarbiat modares univercity

Country

Iran (Islamic Republic of)

Phone

+98 84 3333 6210

Email address

b.kabiri@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design and Evaluation of family - based training programs on the prevention of tooth decay behaviors of 6 months to one - year - old based on intervention Mapping Approach

Public title

Design and evaluation of dental caries prevention training program

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

1- Have a child aged 6 months to 1 year 2. Have a healthy child 3. Have a health record 4. Have at least reading and writing skills

Exclusion criteria:

1. Mothers are not pregnant. 2. Mothers do not have underlying illness. 3. Parents do not live apart.

Age

From **20 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with random number table

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Samples were randomly divided into intervention and control groups

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tarbiat Modares University

Street address

Jalal Street-under Paul Geisha-Tarbiat Modares University

City

Tehran

Province

Tehran

Postal code

1411713116

Approval date

2019-04-30, 1398/02/10

Ethics committee reference number

IR.ModARES.REC.1398.021

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

Oral Health

ICD-10 code

ko3.2

ICD-10 code description

بهداشت دهان و دندان

Primary outcomes**1****Description**

Awareness - attitude - perceived intensity - perceived benefits -perceived barriers- guidance for action - self - efficacy - intention of behavior - mental norms - social norms

Timepoint

Before educational intervention and 6 months after educational intervention

Method of measurement

Researcher-made questionnaire

Secondary outcomes

empty

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

Intervention group: Combined training including PowerPoint use, lectures, replica use and hands-on demonstration for 4 training sessions

Category

Behavior

2**Description**

Control group: The control group received no training

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

مرکز جامع سلامت شهری شماره شش شهرستان ایلام

Full name of responsible person

بهاره کبیری

Street address

میدان شهید کشوری- مرکز جامع سلامت شهری شماره شش

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Ilam

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6931943445

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kabirybahar@yahoo.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Assistance Research

Full name of responsible person

yacob fatolahi

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fatolahi@modares.ac.ir

Grant name

Is not used

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Assistance Research

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**

Tarbiat Modares University

Full name of responsible person

Alireza Heydarnia

Position

Professor, Department of Health Education, Faculty of Medicine, Tarbiat Modarres University, Tehran,

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tarbiat Modares University

Full name of responsible person

bahareh kabiry

Position

PhD student in health education and health promotion
Tarbiat Modarres

Latest degree

Master

Other areas of specialty/work

Health Promotion

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Person responsible for updating data

Contact**Name of organization / entity**

Tarbiat Modares University

Full name of responsible person

bahareh kabiry

Position

PhD student in health education and health promotion
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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

After the study is completed

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available