

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

A comparison of the effectiveness of the two interventions in the prevention of "Early childhood caries".

Protocol summary

Summary

Aim: a comparison of the effectiveness of the two interventions in the prevention of early childhood caries.
Methods and Materials: this study performed on 239 participants containing 2 to 3 year-old children and their mothers registered in public health centers in Tehran. Inclusion criteria were age of child which was 24-36 months and registration in public health center. Child excluded from the study if his/her mother refused to participate. Nine centers selected according to stratified random sampling and randomly allocated to two intervention groups and one control group. At baseline, mothers were interviewed for filling out two behavioral questionnaires; then, child's teeth were examined by two trained examiners using WHO and ICDAS methods. Plaque index was evaluated before dental exam and dental plaque was conducted to transfer medium. Group A and group B received oral and written(pictured) behavioral education and fluoridated varnish, respectively. Group C was control group and did not receive any intervention. Three months later, mothers were interviewed through phone call for behavioral changes. Six months later, mothers filled out the same two behavioral questionnaires and children were examined for dental caries and dental plaque. The reduction of dental caries, dental plaque and counts of mutant streptococcus and behavior change of mothers were primary outcomes of this study.

General information

Acronym

ECC- Early Childhood Caries, MS- Mutants Streptococcus, SDT- Self Determination Th

IRCT registration information

IRCT registration number: **IRCT2012120811693N1**
Registration date: **2013-03-16, 1391/12/26**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-03-16, 1391/12/26

Registrant information

Name

Hediyeh Toutouni

Name of organization / entity

Shahid Beheshti University of Medical Sciences-dental school

Country

Iran (Islamic Republic of)

Phone

+98 21 2242 1813

Email address

h.toutouni@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2012-04-10, 1391/01/22

Expected recruitment end date

2013-01-22, 1391/11/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the effectiveness of the two interventions in the prevention of "Early childhood caries".

Public title

A comparison of the two methods for prevention of tooth decay in young children.

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: age of children was more than 24 months and less than 36 months; mothers and their children enrolled in child health program at public health centers of Tehran. exclusion criteria: mother and children who do not want to participate in study.

Age

From **2 years** old to **3 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **239**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

central building, Daneshjoo blv, Evin

City

Tehran

Postal code

19834

Approval date

2011-01-30, 1389/11/10

Ethics committee reference number

614

Health conditions studied

1

Description of health condition studied

dental caries

ICD-10 code

K02.8

ICD-10 code description

other dental caries

Primary outcomes

1

Description

new dental caries lesion

Timepoint

6 months after intervention

Method of measurement

clinical examination

Secondary outcomes

1

Description

Mutants Streptococcus colony

Timepoint

6 months after baseline

Method of measurement

counting in lab

Intervention groups

1

Description

Behavioral intervention is performed using self determination theory/model through oral and written (pictured) statements at baseline and six months later. Three months after baseline, mothers interview through phone call and all the questions are answered by health provider during six month study, if any. Statements developed according to American Academy of Pediatric Dentistry's guideline for the prevention of early childhood caries considering self determination theory/ model structure to promote autonomy, competency and relatedness of mothers.

Category

Behavior

2

Description

Professional intervention using fluoridated varnish applied on surfaces of the teeth at baseline and six months later. Mothers interview through phone call three months after baseline examination to measure their behavior change.

Category

Prevention

3

Description

Control group received no intervention. Three months after baseline, mothers interview through phone call to measure their behavior change.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hediyeh Toutouni

Street address

dental school, shahid beheshti university, daneshjoo blv, evin

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Abdolhamid Zafarmand

Street address

dental school, shahid beheshti university, daneshjoo blv, evin

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid beheshti dental school

Full name of responsible person

Hediyeh Toutouni

Position

resident- Ph.D degree

Other areas of specialty/work

Street address

dental school, shahid beheshti university, daneshjoo blv, evin

City

Tehran

Postal code

19834

Phone

+98 21 2242 1813

Fax

+98 22421813

Email

h.toutouni@sbmu.ac.ir, h_toutouni@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

dental school, shahid beheshti university

Full name of responsible person

Hediyeh Toutouni

Position

resident- Ph.D degree

Other areas of specialty/work

Street address

shahid beheshti university, daneshjoo blv, evin

City

Tehran

Postal code

19834

Phone

+98 21 2242 1813

Fax

+98 22421813

Email

h.toutouni@sbmu.ac.ir h_toutouni@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

dental school- shahid beheshti university

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Fax

+98 22421813

Email

h.toutouni@sbmu.ac.ir h_toutouni@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty