Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 2026

Evaluation of effectiveness of two intervention packages for oral health promotion programs on oral self care of mothers and oral health status of toddlers

Protocol summary

Study aim

Determining the effectiveness of two intervention packages for oral health promotion on oral self-care of mothers and oral health status of toddlers in non-affluent areas of Tehran city

Design

A controlled trial with three parallel arms, double-blind, randomized, on 396 samples. The rand function of Excel software was used for randomization.

Settings and conduct

Comprehensive health centers in South Tehran. First, a written consent form for the mothers ,then the basic knowledge and attitude and self-care of the mothers are recorded through an interview with a questionnaire. After that, the condition of children's primary dental plaque according to the Silness & Loe index and the dental caries index (dmft) is registered.

Participants/Inclusion and exclusion criteria

Inclusion criteria for participants: mothers with minimal reading and writing literacy and consent to participate in the project, mothers with Iranian children aged 12-24 months who refer to comprehensive health centers in the south of Tehran for routine vaccination or child growth monitoring. Exclusion criteria for participants: mental or systemic problems of the child.

Intervention groups

The first group (mother and child level): educational booklet in the continuation of more educational materials in a virtual way The second group (community level, change in services): in addition to the first intervention, an additional service of toothbrush and fluoride toothpaste and this incentive is renewed in the second follow-up if the care continues. The third group (control group): Current situation and usual training in the centers.

Main outcome variables

dmft, index plaque, (knowledge, attitude, self-care of mothers for children)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131102015238N6**
Registration date: **2024-08-21, 1403/05/31**
Registration timing: **registered_while_recruiting**

Last update: **2024-08-21, 1403/05/31**
Update count: **0**

Registration date

2024-08-21, 1403/05/31

Registrant information

Name
Simin Z. Mohebbi
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
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smohebbi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-08-15, 1403/05/25

Expected recruitment end date

2024-09-15, 1403/06/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effectiveness of two intervention packages for oral health promotion programs on oral self care of mothers and oral health status of toddlers

Public title

Evaluation of effectiveness of two intervention packages on the self-care of mothers and its effect on the oral health of toddlers

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian children one to two years old who refer to comprehensive health centers in the south of Tehran for routine vaccination and growth monitoring. Mother's minimum literacy Mother's consent to participate in the plan.

Exclusion criteria:

Existence of systemic problems Mental disability of the child

Age

From **1 year** old to **2 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **396**

Randomization (investigator's opinion)

Randomized

Randomization description

The comprehensive health centers of southern areas of Tehran city are assigned to three groups by random sampling using random sequence generation software (Excel). Two intervention groups and one control group. In the Excel software page, the left column, the total number of comprehensive centers. It shows the health of southern areas of Tehran. The three groups of the first intervention, the second intervention, and the control group are randomized with the rand command, and in the next column it is determined that we will have 7 control groups, 5 first intervention groups, and 5 second intervention groups, and in the last column, comprehensive health centers are randomly selected in are placed in one of the intervention groups. Each comprehensive health center is assigned a code. Allocation of groups to intervention arms is done by the supervisor, and the examiner, researcher and the person who performs the statistical evaluation are unaware of this randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

The examiners and the researcher who conducts the statistical evaluation and analysis are blind to the allocation of the groups. Allocating groups to intervention arms is done by the supervisor. When entering information into the data file, groups are entered with numbers. Depending on which intervention group they are in, the participants in this study receive educational packages through health care providers. Before receiving the services and educational packages, a questionnaire and a blind intervention-type examination were conducted in another room, and then the participants went to the health care providers and received the services. The statistical analyzer also receives the information of the health centers in the form of codes or numbers and is unaware of the intervention groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

North Kargar Street

City

Tehran

Province

Tehran

Postal code

1439955943

Approval date

2023-11-29, 1402/09/08

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1402.089

Health conditions studied

1

Description of health condition studied

Oral health status of toddlers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Index (dmft)

Timepoint

First visit after 6 months and 12 months follow up

Method of measurement

Visual exam

2

Description

Plaque Index

Timepoint

First visit after 6 months and 12 months follow up

Method of measurement

Visual exam

Secondary outcomes

1

Description

Mother's knowledge about child's oral and dental health

Timepoint

Before the intervention and 6 and 12 months after the intervention

Method of measurement

Questionnaire with 22 questions

2

Description

Mother's attitude about child's oral and dental health

Timepoint

Before the intervention and 6 and 12 months after the intervention

Method of measurement

Questionnaire with 5 questions

3

Description

Mother's performance about child's oral and dental health

Timepoint

Before the intervention and 6 and 12 months after the intervention

Method of measurement

Questionnaire with 10 questions

4

Description

Mother's self-reported regarding the oral and dental health of the child and herself

Timepoint

Before the intervention and 6 and 12 months after the intervention

Method of measurement

Questionnaire with 6 questions

Intervention groups

1

Description

Intervention group: The first group (mother and child level): they will receive an educational booklet (self-care training to improve oral health and daily examination training for the child). For memorization, consolidation of information and motivation, and also the Back Teach method will be used to ensure the understanding of educational materials. The choice of the method of receiving more materials is the responsibility of the mother. (SMS/common social network/care site) children in this group are simplified by the lip the lift method after being taught by the mother herself.

Category

Lifestyle

2

Description

Intervention group: The second group (community level: change in services): In addition to the first intervention, they will have an additional service of toothbrush and fluoride toothpaste, and this incentive will be renewed if the care continues in the second follow-up

Category

Lifestyle

3

Description

Control group: The third group (control group): status quo. At the end of the intervention, this group will receive oral health education for children

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health centers in South Tehran

Full name of responsible person

Simin Zahra Mohebbi

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ali Akbari Sari
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
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Position
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Person responsible for updating data

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After deidentifying individuals and comprehensive health centers, all data can be shared in the programs of Tehran University of Medical Sciences, comprehensive health centers of the whole country and the Ministry of Health, Treatment and Medical Education.

When the data will become available and for how long

The data access period starts 6 months after the results are published.

To whom data/document is available

Considering that the result of the work will be published as an article, the above materials will be provided to the journal (most of the international journals currently request the above materials), to be available to the interested parties. All data can be shared in Tehran University of Medical Sciences for those interested.

Under which criteria data/document could be used

Considering that the result of the work will be published as an article, the above materials will be provided to the journal (most of the international journals currently request the above materials), to be available to the interested parties. All the data will be used for all comprehensive health centers in the country to improve the oral health status of toddlers.

From where data/document is obtainable

Responsible person: Simin Zahra Mohebi Email: smohebi@tums.ac.ir Phone: 02188015960

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

Correspondent: Simin Z Mohebbi Email: smohebbi@tums.ac.ir

Comments