

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Comparison of the effectiveness of two educational methods including lecturing and presenting pamphlets to parents about the observance of oral hygiene habits of pre-school children on oral health

Protocol summary

Study aim

Comparison of the effectiveness of two educational methods including lecturing and presenting pamphlets to parents about the observance of oral hygiene habits of pre-school children by measuring the Oral Hygiene Index Simplified (OHI-s).

Design

randomized, parallel, single-blind clinical trial with 40 patients. The simple randomization method has been used for randomization.

Settings and conduct

At the beginning, the simplified oral health index of all children in Shabestar preschool center is evaluated and registered by a dentist. The first group is given a lecture on oral hygiene habits in two one-hour sessions by a dentist. The teaching materials are prepared in the form of pamphlets and distributed among the second group. After 6 weeks, the simplified oral hygiene index of all children will be re-evaluated by the same dentist who is unaware of the classification. Finally, the information obtained in relation to the simplified oral health index of both groups at the beginning and end of the study will be compared and reviewed. Considering that The person examining the children's dental plaque index will not know in which study group the examined people are, Therefore, the study will be one-sided blind.

Participants/Inclusion and exclusion criteria

40 children whose plaque index is close to the average number and whose parents are literate will be included in the study and the rest will be excluded from the study.

Intervention groups

The first group (n = 20) will be assigned to the oral hygiene habits training group through lectures and the second group (n = 20) will be assigned to the pamphlet receiving group on the subject of oral hygiene habits training.

Main outcome variables

The main outcome of this project is a simplified oral health index of children, which will be measured by examining dental surfaces before and after the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210822052251N4**

Registration date: **2022-11-06, 1401/08/15**

Registration timing: **prospective**

Last update: **2022-11-06, 1401/08/15**

Update count: **0**

Registration date

2022-11-06, 1401/08/15

Registrant information

Name

Neda Yasamineh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-12, 1401/08/21

Expected recruitment end date

2022-11-12, 1401/08/21

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of two educational methods including lecturing and presenting pamphlets to parents about the observance of oral hygiene habits of pre-school children on oral health

Public title
"Comparison of the effectiveness of two educational methods including lecturing and presenting pamphlets to parents about the observance of oral hygiene habits of children"

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
40 preschool children whose parents are literate. 40 preschool children whose plaque index are almost the same.
Exclusion criteria:
Children who do not have the necessary cooperation for oral examination. Children whose parents are unable to participate in educational sessions.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals will be randomly assigned to one of two study groups with the help of a random number table and will receive the intervention of the allocated group. For allocation concealment, the method of sealed opaque envelopes which are numbered sequentially will be used. In this method, each random sequence is recorded on a card. Finally, the lids of the letter envelopes will be glued and placed inside a box. At the beginning of the study, according to the order of entry of eligible participants to study, one of the envelopes will be opened in order and the assigned group of the participant will be revealed.

Blinding (investigator's opinion)
Single blinded

Blinding description
The person examining the children's dental plaque index will not know in which study group the examined people are. Therefore, the study will be one-sided blind

Placebo
Not used

Assignment

Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz university of medical sciences

Street address
Central Building of Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran

City
tabriz

Province
East Azarbaijan

Postal code
5165665931

Approval date
2021-12-08, 1400/09/17

Ethics committee reference number
IR.TBZMED.REC.1400.892

Health conditions studied

1

Description of health condition studied
oral hygiene of children

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
simplified oral hygiene index

Timepoint
Before intervention and 6 weeks after training

Method of measurement
Examination of dental surfaces

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: presenting pamphlets to parents

Category
Prevention

2

Description

Control group: lecturing to parents

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shabestar preschool center

Full name of responsible person

Elnaz Mazaheri

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Shahid Jahanbakhsh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad samii

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Milad Emami

Position

student

Latest degree

A Level or less

Other areas of specialty/work

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

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