

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effects of an educational intervention on Plaque Index and Gingival Bleeding Index in mentally disabled school children

Protocol summary

Summary

The objective of this study is to evaluate the impact of an oral health education program on plaque and gingival bleeding indices among mentally disabled children. The study is a clinical trial, phase II. Target population: Female mentally disabled students of a special school in Tehran, aged 6 to 17 years old. Inclusion criteria: All the mentally disabled children aged 6 to 17 years old who can sit down on a chair to be examined and her parents had filled informed consent. Exclusion criteria: Those who are absent on the follow up examination. Minimum sample size was calculated 26 units, because of the total number of students of this school 51 students will enter the study. Intervention: Parents will attend an oral health educational session and a simpler educational recommendations will be said to disabled students. A colorful booklet which was written for students and parents will be sent to their home, motivational reminders and short message sending to parents are also planned, at least every 2 weeks. Oral examinations on Plaque Index and Gingival Bleeding Index will be done on baseline and 3-month follows up.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016091915806N7**

Registration date: **2016-12-22, 1395/10/02**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-12-22, 1395/10/02

Registrant information

Name

Ahmad Jafari

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-01-29, 1395/11/10

Expected recruitment end date

2017-03-05, 1395/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of an educational intervention on Plaque Index and Gingival Bleeding Index in mentally disabled school children

Public title

Effect of an oral health education on oral health condition of disabled children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Children aged 6 to 17 years old; Mentally disabled; Child can sit down on a chair to be examined; Her parents had filled an informed consent. Exclusion criteria: Absence on follow up examination.

Age

From **6 years** old to **17 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **51**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Committee of Ethics in Research, Medicine Faculty,
Poursina Ave., Keshavarz Blvd., Tehran, Iran

City

Tehran

Postal code

Approval date

2015-10-07, 1394/07/15

Ethics committee reference number

IR.TUMS.REC.1394.889

Health conditions studied

1

Description of health condition studied

Dental Examination

ICD-10 code

Z01.2

ICD-10 code description

Dental examination

2

Description of health condition studied

Gingivitis and Periodontal Diseases

ICD-10 code

K05

ICD-10 code description

Gingivitis and Periodontal Diseases

3

Description of health condition studied

Calculus and Plaque

ICD-10 code

K03.6

ICD-10 code description

Deposits [accretions] on teeth

Primary outcomes

1

Description

Plaque Index

Timepoint

Before intervention, 3 months after intervention

Method of measurement

Oral and dental examination

2

Description

Gingival bleeding Index

Timepoint

Before intervention, 3 months after intervention

Method of measurement

Oral and dental examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: Parents will attend an oral health educational session. A simpler educational recommendations will be said to disabled students. A colorful booklet which was written for students and parents will be gifted to them. Motivational reminders and short message sending to parents are also planned, at least every 2 weeks.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Special School of Milad

Full name of responsible person

Mrs. Arabi

Street address

Special School of Milad, After Madrese bus station,
Moallem Blvd., Yaft Abad Ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Office of Research Affairs

Street address

Office of Research Affairs, 2nd Floor, Dentistry
Faculty, AmirAbad Ave., Tehran, Iran

City

Tehran

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

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

Tehran University of Medical Sciences

Full name of responsible person

Dr Ahmad Jafari

Position

Associate Professor, Department of Pediatric
Dentistry, School of Dentistry, Alborz University of Me

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

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Position

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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