

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8801 5960

##### Email address

ajafari@tums.ac.ir

##### 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**

**Street address**

School of Dentistry, Sh. Katooeizadeh St., 45 M  
Golshahr Blvd., Karaj, Iran

**City**

Karaj

**Postal code**

**Phone**

+98 26 3353 1614

**Fax**

**Email**

ajafari@tums.ac.ir

**Web page address**

## Person responsible for scientific 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**

**Street address**

School of Dentistry, Sh. Katooeizadeh St., 45 M  
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**Phone**

+98 26 3353 1614

**Fax**

**Email**

ajafari@tums.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Atefeh Gohari

**Position**

Dental student

**Other areas of specialty/work**

**Street address**

East 4th Floor, Enterance 2, B32, Phase 3, Shahrak  
Apadana, Tehran, Iran

**City**

Tehran

**Postal code**

**Phone**

+98 21 4464 8321

**Fax**

**Email**

atp.gohari@gmail.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*