

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Designing and evaluation of an oral hygiene educational intervention to improve the oral health of elementary students (aged 6-15yrs) with autism spectrum disorders

#### Protocol summary

##### Study aim

Determining and comparing oral hygiene status of elementary students (6-15yrs) with Autism based on simplified oral hygiene index between two intervention and comparison groups in autistic schools before and after intervention.

##### Design

quasi-experimental clinical trial, with two parallel intervention groups, Non randomized ,on 90 students

##### Settings and conduct

Informed Consent will be obtained from parents of 90students from 4 Tehran autistic schools. they will complete a questionnaire and students will be examined and OHI-S will be recorded. In 2schools, the intervention packages will be provided, in 2 others comparison package will be given. After one-month intervention, parents will answer the post-intervention questionnaire and OHI-S will be recorded. After 3months OHI-S will be recorded.

##### Participants/Inclusion and exclusion criteria

inclusion criteria:1-consent of parents 2-The student should be in the first to sixth grade of elementary school. 3- Age of the student should be 6 to 15 years old. 4- Including only ASD Level1,2. 5-Family should have access to the WhatsApp. Exclusion criteria:1- Participants with other disabilities. 2-participants who are unable to cooperate.

##### Intervention groups

Intervention package:1-Teaching children how to brush their teeth with Fonnes technique through video modeling:2- Educational session for parents. 3- Installation of a poster of correct way of tooth brushing in bathroom at home. 4 - Educational session for teachers: to help peer working of students in class 5 - Reminder and motivation: twice a week Comparison Package: 1- Social story of oral hygiene along with a pamphlet containing similar information in the face-to-face

meeting held in the intervention group will be given to the parents. 2.A reminder message will be sent twice a week, similar to the intervention group. 3-Installation of a pictured poster

##### Main outcome variables

Oral hygiene status

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200208046413N1**

Registration date: **2020-07-05, 1399/04/15**

Registration timing: **retrospective**

Last update: **2020-07-05, 1399/04/15**

Update count: **0**

##### Registration date

2020-07-05, 1399/04/15

##### Registrant information

##### Name

Hediyeh Piraneh Haghighi Bonab

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4279 4175

##### Email address

h.piraneh@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-23, 1399/03/03

##### Expected recruitment end date

2020-06-02, 1399/03/13  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty  
**Scientific title**  
Designing and evaluation of an oral hygiene educational intervention to improve the oral health of elementary students (aged 6-15yrs) with autism spectrum disorders  
**Public title**  
Evaluation of an oral hygiene educational intervention to improve the oral health of elementary students with autism  
**Purpose**  
Education/Guidance  
**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Informed consent of parents The students should be at first to sixth grade of elementary school Age of the student should be 6 to 15 years old Including only ASD Level 1 and 2 Family should have access to the WhatsApp social network.  
**Exclusion criteria:**  
Participants with other disabilities. participants who are unable to cooperate. (Because of stress, panic attacks, fainting history, etc.)  
**Age**  
From **6 years** old to **15 years** old  
**Gender**  
Male  
**Phase**  
N/A  
**Groups that have been masked**  
*No information*  
**Sample size**  
Target sample size: **90**  
**Randomization (investigator's opinion)**  
Not randomized  
**Randomization description**  
**Blinding (investigator's opinion)**  
Not blinded  
**Blinding description**  
**Placebo**  
Not used  
**Assignment**  
Parallel  
**Other design features**

## Secondary Ids

empty

## Ethics committees

1

### Ethics committee

**Name of ethics committee**

Ethics committee of School of Dentistry- Tehran University of Medical Sciences

### Street address

School of Dentistry of Tehran University of Medical Sciences, Adjacent to the Atomic Energy Organization, End of North Kargar S.t, Tehran, Iran

### City

Tehran

### Province

Tehran

### Postal code

۱۳۳۹۹۵۵۹۹۱

### Approval date

2019-12-08, 1398/09/17

### Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1398.153

## Health conditions studied

1

### Description of health condition studied

Oral hygiene

### ICD-10 code

### ICD-10 code description

## Primary outcomes

1

### Description

Oral hygiene status

### Timepoint

before intervention, 30 days after the intervention and 3 Months later

### Method of measurement

Simplified-Oral-Hygiene-Index

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: 1- Teaching children how to brush their teeth with Fonnes technique through video: A CD containing a short film that teaches children with ASD, method of brushing with fonnes technique in a simple and understandable way, is designed and distributed. In it, a 10-year-old child is brushing his teeth and every part of his mouth that he brushes a Voice describes it behind the scenes with simple sentences and slow speed. The video file is provided to the parents of the intervention group through the WhatsApp social network and they are asked to play it to their children every day. 2- Educational session for the parents of the students: In each of the schools with Previous coordination with the school principal we ask students' parents to attend a group meeting. Speech with slides by a researcher for 15

minutes with the content of importance, prevalence, etiology and control of oral diseases including gum disease, caries and ways to deal with it, including nutritional recommendations and plaque control will take place. The brushing tutorial video is also shown to the audience, and the Fonnes brushing technique is taught to parents to monitor their child's brushing at home. A illustrated poster is then given to parents on how to brush properly to install on the wall of their bathroom at home to help the child brush properly. Parents are also asked to introduce conditions of the examination day to their children one week before the next clinical examination, through the social story given to them in the pre-intervention stage. 3- Teacher training session: Teachers also are taught how to brush with Fonnes Technic. And they are asked to show their students how to brush twice a week with a three-dimensional toothbrush and mouth model, and then accompany them to brush with their friends in the school environment. 4- Reminding and motivating Twice a week: a reminder is sent to parents of children through the WhatsApp social network.

**Category**

Prevention

**2**

**Description**

Control group: 1- A written guide in the form of a pamphlet containing information similar to the face-to-face meeting held in the intervention group is presented to the parents. 2- The social story on the subject of brushing with Fonnes technique is given to the parents of this group and they are asked to work on this social story at home with their child. 3. A reminder message will be sent to them twice a week, similar to the intervention group through whats App social network.

**Category**

Prevention

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Besharat special school

**Full name of responsible person**

Fatemeh Mashhadi

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No.6, Corner of 120 East St., 105 Tehranpars St. Khaghani CrossroadTehrane no St.

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**Web page address**

<http://www.besharat1374.blogfa.com/>

**2**

**Recruitment center**

**Name of recruitment center**

Imam Jafar Sadegh special school

**Full name of responsible person**

Zahra Mazloomi

**Street address**

No.10, Taheri St. ,Sajadieh Town, Ayatollah Boroujerdi Blvd. East Shousha St.

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**3**

**Recruitment center**

**Name of recruitment center**

Payambar-e- Azam special school

**Full name of responsible person**

Ali Ebrahimi

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**4**

**Recruitment center**

**Name of recruitment center**

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**Full name of responsible person**

Zeynab Chavoshzadeh

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Dr. Mohammadali Sahraian  
**Street address**  
6th floor, Central University Organization, corner of  
Quds Street, Keshavarz Boulevard  
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**Phone**  
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**Fax**  
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**Email**  
vcr@tums.ac.ir

**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**  
45  
**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

### 2

#### Sponsor

**Name of organization / entity**  
Dental caries prevention research center  
**Full name of responsible person**  
Dr. Amirreza Rokn  
**Street address**

Research Institute of Dental Sciences, School of  
Dentistry , Quds St., Enqelab St.

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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**  
Dental caries prevention research center  
**Proportion provided by this source**  
55  
**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**  
Hedieh Piraneh Haghghi Bonab  
**Position**  
PhD candidate  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
community oral health  
**Street address**  
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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Hedieh Piraneh Haghighi Bonab

**Position**

PhD candidate

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Hedieh Piraneh Haghighi Bonab

**Position**

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**Latest degree**

Medical doctor

**Other areas of specialty/work**

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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**

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**

Yes - There is 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

**Title and more details about the data/document**

All potential data can be shared after people have not been identified

**When the data will become available and for how long**

Start the access period 3 to 6 months after publishing the results

**To whom data/document is available**

Researchers and people working in the field of education or industry can apply for data.

**Under which criteria data/document could be used**

Any statistical use and analysis is permitted for the purpose of promoting oral health in people with autism.

**From where data/document is obtainable**

See Dr. Hedyeh Piraneh Haghighi Bonab Address: Department of Community Oral Health, Faculty of Dentistry of Tehran University of medical sciences, End of North kargar, Tehran, Iran. Postal Code: 1439955991 Email: h.piraneh@yahoo.com Mobile: 00989058873546

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

The applicant can send his / her details and the organization in which he / she works and the exact details and purpose of his / her request via e-mail. Finally, the response will be done within a week.

**Comments**