Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+98 21 4279 4175

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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

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Tehran

Postal code

۱۴۳۹۹۵۵۹۹۱

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

Street address

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2

Recruitment center

Name of recruitment center

Imam Jafar Sadegh special school

Full name of responsible person

Zahra Mazloomi

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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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No. 6, Koohsar Alley., Imam Hossein St.,Bahar St.,Kabiri St., Hemmat Highway,

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4

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Name of recruitment center

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Zeynab Chavoshzadeh

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Postal code
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Phone
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Fax
+98 21 8163 3686
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
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Research Institute of Dental Sciences, School of Dentistry , Quds St., Enqelab St.
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Tehran
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+98 21 8898 6688
Email
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Web page address
http://dri.tums.ac.ir
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 Haghighi Bonab
Position
PhD candidate
Latest degree
Medical doctor
Other areas of specialty/work
community oral health
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Web page 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

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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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