

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparing the effectiveness of oral and dental health education by video and face-to-face methods on the level of oral and dental health indicators and child cooperation in 6-12-year-old students with autism spectrum disorders

Protocol summary

Study aim

This study was aimed to compare the effectiveness of oral and dental health education by video and face-to-face methods on plaque index, gum index, child cooperation and habits related to oral and dental hygiene in 6-12-year-old students with autism spectrum disorders.

Design

Randomized, with a parallel group design of 65 patients

Settings and conduct

The current study is an interventional and semi-experimental study that will be conducted in Mashhad primary schools. Students of each group will be selected from a different school.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 6-12 years Patients in the mild to moderate stage of autism spectrum disorders
Signing the informed consent form
Exclusion criteria: -
Existence of other physical or developmental or mental disabilities and inability to cooperate with the patient -
The unwillingness of the child or his parents to participate or continue attending the study

Intervention groups

After matching the intervening variables randomly, patients (n=65) will be divided into two groups, including the video training group and the face-to-face training group.

Main outcome variables

Decay index; index plate; cooperation index; gingival index; The frequency of using a toothbrush

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231231060582N1**

Registration date: **2024-01-26, 1402/11/06**

Registration timing: **prospective**

Last update: **2024-01-26, 1402/11/06**

Update count: **0**

Registration date

2024-01-26, 1402/11/06

Registrant information

Name

Sahar Ebrahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-06-21, 1403/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of oral and dental health education by video and face-to-face methods on the

level of oral and dental health indicators and child cooperation in 6-12-year-old students with autism spectrum disorders	2023-10-09, 1402/07/17 Ethics committee reference number IR.BUMS.REC.1402.294
Public title Effects of health education on oral and dental health Purpose Education/Guidance Inclusion/Exclusion criteria Inclusion criteria: Age between 6-12 years old Patients on mild to moderate stage of autism spectrum disorders Signing consent form by parents Exclusion criteria: The existence of other physical or developmental or mental disabilities and inability to cooperate with the patient The unwillingness of the child or her/his parents to participate or continue the study Age From 6 years old to 12 years old Gender Both Phase N/A Groups that have been masked No information Sample size Target sample size: 65 Randomization (investigator's opinion) Not randomized Randomization description Blinding (investigator's opinion) Not blinded Blinding description Placebo Not used Assignment Parallel Other design features	Health conditions studied <u>1</u> Description of health condition studied autism spectrum disorder ICD-10 code F84.0 ICD-10 code description autism spectrum disorder, oral health, education Primary outcomes <u>1</u> Description Tooth decay Timepoint At the beginning of the study (before the start of the intervention) and after the intervention Method of measurement Based on dmft index <u>2</u> Description Children's cooperation index Timepoint At the beginning of the study (before the start of the intervention) and after the intervention Method of measurement Based on the Frankel Index <u>3</u> Description The frequency of using a toothbrush Timepoint At the beginning of the study (before the start of the intervention) and after the intervention Method of measurement Based on the number of times they brush their teeth
Secondary Ids empty	
Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics committee of Birjand University of Medical Sciences Street address Birjand University of Medical Sciences , Ghafari Street, Birjand, South Khorasan, Iran. City Birjand Province South Khorasan Postal code 9717853577 Approval date	Secondary outcomes empty Intervention groups <u>1</u> Description Intervention group: In order to carry out the intervention in the video intervention group, an educational video about self-care skills will be delivered to the patient. The content of educational videos will be designed under the supervision and guidance of a group of experts according to the objectives of the study and will be provided to the

instructors of this group. Educators will be asked to play video content for children three times a week according to the designed educational program and make sure that the child sees the video content. Also, the child will be asked to repeat the movements step by step along with the video. The families will be asked to install the reminder educational poster in front of the child during the implementation of oral and dental care techniques at home and to monitor the requirement every night while brushing teeth at home according to the principles stated in the pamphlet.

Category

Behavior

2

Description

Intervention group 2: In the face-to-face training group, before starting the study, the instructors will be taught the correct way of brushing teeth in certain children based on valid references by the researcher. children will receive oral and dental self-care educations three times a week according to the designed educational program. In this group, along with the teacher, children will learn brushing movements in front of the mirror and repeat it step by step. The same educational poster as the other group will be provided to this group as well. Also, like the video training group, parents should monitor and accompany the child during all stages of oral and dental self-care.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Birjand University of medical sciences

Full name of responsible person

Sahar Ebrahimi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

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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

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Mehrnaz Khademi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Comparing the effectiveness of oral and dental health education by video and face-to-face methods on the level of oral and dental health indicators and child cooperation in 6-12-year-old students with autism spectrum disorders

When the data will become available and for how long

Not decided yet

To whom data/document is available

People working in academic institutions and parents of children with autism

Under which criteria data/document could be used

Not decided yet

From where data/document is obtainable

Responsible persons: Sahar Ebrahimi
sahar_ebrahimi@yahoo.com Dr. Mehrnaz Khademi
mehr.kh6688@yahoo.com

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

The applicant must send his request for information or data to the email address of the respondents within 6 months after completing and analyzing the results. Requests will be processed after the results are published in scientific articles.

Comments