Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effectiveness of two methods of teaching tooth brushing, using flashcards and video in children with autism spectrum disorder.

Protocol summary

Study aim
Comparison of two educational methods for teaching tooth brushing to children with ASD

Design
A controlled, parallel-group, unblinded clinical trial will be conducted on 74 eligible autistic children. Randomization will be done by distributing coded papers among the sampled individuals at each center. Gender and disease level will be matched at the group level. In each group, 37 individuals will receive the intervention.

Settings and conduct
The sampling location is schools and centers for children with ASD in Bushehr and Shiraz. parents teach children at home every day and are taught how to practice tooth brushing with their children. Then the video and flashcards are provided to each group. Oral health status will be measured using the OHI_S index before the intervention and one and tree month later. Parents' views and knowledge will be measured through a valid and reliable questionnaire.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Parental cooperation and consent and access to smartphone and Child's cooperation for clinical oral and dental examination Exclusion criteria: Presence of motor impairment and potential inability to brush teeth and use of medications that have oral side effects such as dry mouth.

Intervention groups
In each group, 33 children with autism spectrum disorder will receive toothbrushing training .The technique taught in both groups is the Fones technique, and both groups receive training for same period of time. One group is trained with an educational video and the other group is trained with flashcards. The same child and the same environment were used in the production of the video and flashcards. The goal was to make the results generalizable to the type of education rather than contents.

Main outcome variables
The main variable is OHI_S. The result is to find a more effective way to teach tooth brushing to a child with ASD.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250324065150N1**
Registration date: **2025-04-10, 1404/01/21**
Registration timing: **prospective**

Last update: **2025-04-10, 1404/01/21**
Update count: **0**

Registration date
2025-04-10, 1404/01/21

Registrant information

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Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-04-19, 1404/01/30

Expected recruitment end date
2025-05-22, 1404/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effectiveness of two methods of teaching tooth brushing, using flashcards and video in children with autism spectrum disorder.

Public title
Comparing the effects of video and flashcard-based tooth brushing training in children with autism spectrum disorder.

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Parental consent and their access to smartphones Child's cooperation for clinical oral and dental examination
Exclusion criteria:
Use of medications that have oral side effects such as dry mouth Presence of motor disorders and potential inability to brush teeth

Age
From **6 years** old to **16 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
At each center, papers were prepared for the number of people eligible to participate in the study. Half of the papers were coded for the first intervention and the other half for the second intervention (video or flashcard training). The papers were folded so that it was not clear which one was related to which intervention. At each center, the papers were randomly distributed among the sample members. Gender and disease profile matching was performed at the group level.

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 Bushehr university of medical Sciences

Street address
Regional Secretariat of the Research Ethics Committee, Vice President for Research, First Floor, Medical Sciences Campus, Salman Farsi Street, Bahmani

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Approval date
2025-01-05, 1403/10/16

Ethics committee reference number
IR.BPUMS.REC.1403.320

Health conditions studied

1

Description of health condition studied
Teaching individuals with autism spectrum disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Assessing oral hygiene status through oral hygiene index simplified measurement

Timepoint
The oral hygiene index simplified will be measured before the intervention, one and tree month after the intervention.

Method of measurement
Clinical oral examination and completion of the oral hygiene index simplified chart

Secondary outcomes

1

Description
Children's oral health related behaviors

Timepoint
Before the intervention, one month and three months after the intervention

Method of measurement
A valid and reliable questionnaire that has previously been designed and used in a study by Dr. Piraneh and colleagues in the same field.

2

Description
Parents' knowledge and attitudes about oral health

Timepoint

Before the intervention, one month and three months after the intervention

Method of measurement

A valid and reliable questionnaire that has previously been designed and used in a study by Dr. Piraneh and colleagues in the same field.

3

Description

Child's cooperation during examination according to Frankl's classification

Timepoint

Before the intervention, one month and three months after the intervention

Method of measurement

Observing the child's behavior during the examination and recording the degree of cooperation according to Frankl's classification.

Intervention groups

1

Description

Intervention group: A group that learns how to brush their teeth with an educational video

Category

Rehabilitation

2

Description

Control group: A group that learns how to brush their teeth with flash cards

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Nasim School

Full name of responsible person

Neda Anjumrooz

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2

Recruitment center

Name of recruitment center

Autism Center of Andisheh, Bushehr

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Boushehr University of Medical Sciences
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Web page address
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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
Boushehr 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

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Name of organization / entity
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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
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
First, the data is made unidentifiable through coding, and then all data will be publishable.

When the data will become available and for how long
Access period begins three months after results are published.

To whom data/document is available
Researchers working in academic centers and educational and rehabilitation centers related to children with autism can apply for access to the data.

Under which criteria data/document could be used
No other conditions are considered, any statistical analysis is permitted, access and use of de-identified data from this study is permitted to help people with autism.

From where data/document is obtainable
De-identified data will be sent via email to the requesting researcher or journal. Author's name: Mahdiyeh Khiabani email: mahdiye.khiabany@gmail.com

What processes are involved for a request to access data/document
This article will be published as an original research article in a journal with a matching scope or topic, based on the standard checklist (CONSORT). After the publication of the article, other researchers or journals can request to receive the data by sending a request to the person responsible for the study, Mahdiye Khiabani, at the email address mahdiye.khiabany@gmail.com. After sending the request, the data will be made available to them within two weeks at the most.

Comments