

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparison between the influence of two methods of Visual Pedagogy, namely Poster and Educational Movie, on Tooth-brushing autonomy in 10-12-year-old Autistic Children

Protocol summary

Study aim

To evaluate the effectiveness of visual pedagogy via poster or educational movie on tooth-brushing abilities in autistic children

Design

Randomised controlled trial, single-blinded, parallel-group trial Randomisation was accomplished using random blocks of 64 participants

Settings and conduct

Fifty -six autistic eligible children aged 10-12 with mild autism, having the ability of speaking and simple conversations, will participate. The children are divided into two groups of poster and film by random blocking and should brush their teeth at least once daily. Children are being assessed in their own homes with the presence of their caregiver at the baseline (before education), and one and three months later. a blue toothbrush is used for the upper jaw and red for the lower jaw. The tooth-brushing process by the FONES method will be divided into 5 stages consisting of 24 steps. A Likert type scoring from 1 to 5 will be specified for each step. Finally, the average score of each of the 5 stages, and the autonomy score, that is derived from all stages will be calculated. The assessor is blind in follow-up times. Poster group: 16 pictures with white background, will demonstrate the steps by a human model. Posters are installed in the toothbrushing area. Film group: Silent film with a white background will demonstrate the tooth brushing and should be seen before brushing by tablet and then as many times as the child wants.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. Age between 10 to 12 2. Mild autism 3. Parental motivation to cooperate Exclusion Criteria: 1. Systemic diseases 2. Moderate and severe Autism 3. Mental retardation

Intervention groups

Intervention Group: The ones who are being trained with

movie Control Group: The ones who are being trained via Poster

Main outcome variables

Changes in tooth-brushing autonomy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090429001861N6**

Registration date: **2021-06-15, 1400/03/25**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-15, 1400/03/25**

Update count: **0**

Registration date

2021-06-15, 1400/03/25

Registrant information

Name

Katayoun Salem

Name of organization / entity

Tehran Azad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

nastaranegar@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-20, 1400/02/30

Expected recruitment end date

2021-09-21, 1400/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the influence of two methods of Visual Pedagogy, namely Poster and Educational Movie, on Tooth-brushing autonomy in 10-12-year-old Autistic Children

Public title

the influence of two methods of Visual Pedagogy on Tooth-brushing autonomy in Autistic Children

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Mild Autism Age between 10-12 years Parental motivation to cooperate

Exclusion criteria:

Other Systemic diseases other Mental disability

AgeFrom **10 years** old to **12 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Investigator

Sample sizeTarget sample size: **64****Randomization (investigator's opinion)**

Randomized

Randomization description

Children will be divided into two groups by permuted randomization block method. First, they will be specified to quadruple blocks, which randomly contain two a (poster) and two b(film). Randomization will take place by the methodologist who is not involved with the execution of the study. The examiner will not be informed about the randomization process. The whole process will occur with the aid of the rand option of the Excel software. With the rand option of this software 4 numbers are generated. the two firsts are assigned to a and the two seconds are assigned to b. then they are ranked from the highest to the lowest, forming a block. This process will be repeated 16 times until all of the blocks are formed. After the specification of the samples, information will be handed to the examiner in 64 closed envelopes. The examiner will open each envelope according to the sample codes, after the first evaluation.

Blinding (investigator's opinion)

Single blinded

Blinding description

The evaluator and data analyzer were Blinded

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Islamic Azad University of Medical science

Street address

No. 9, 9th Nezestan Alley, Pasdaran Ave

City

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Province

Tehran

Postal code

19585175

Approval date

2020-01-02, 1398/10/12

Ethics committee reference number

IR.IAU.DENTAL.REC.1399.002

Health conditions studied**1****Description of health condition studied**

Autistic disorder

ICD-10 code

F84.0

ICD-10 code description

Autistic disorder

Primary outcomes**1****Description**

autonomy score

Timepoint

Before the intervention, one month after the beginning of visual pedagogy, three months after the beginning of visual pedagogy

Method of measurement

Observation and filling the template for measuring the autonomy, designed based on the Lopez study. The template has no specific name.

<https://doi.org/10.1007/s40368-018-0396-y>

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Before any intervention, the toothbrushing performance will be observed and recorded. Then, a muted educational movie will be delivered to parents. The film should be viewed once before the brushing procedure. To avoid child distraction, unnecessary information is not given to children through this film. Since autistic children desire to repeat the tasks, they are allowed to watch the film as many times as they desire. To help the child to distinguish better, a blue toothbrush is used for the upper jaw and a red one for the lower jaw. Furthermore, the teacher's attire will be white; and the film will be muted for better concentration of the child. Tooth brushing is demonstrated by one of the teachers. The FONES brushing technique will be taught. Toothbrushing will be performed under the supervision of parents. Toothbrushes and toothpaste are given to study participants by a responsible investigator. The method of toothbrushing also is trained to parents for comprehensive supervision. The toothbrushing procedure will be divided into 5 stages including 24 steps as following: Stage one, preparation including, 1: taking the toothbrush, 2: opening the toothpaste, 3: pressing the toothpaste, 4: putting toothpaste on the toothbrush, 5: closing the toothpaste cap. Stage two, brushing the occlusal surfaces in 4 quadrants including, 6: upper left, 7: upper right, 8: lower left, 9: lower right. Stage three brushing the buccal surfaces including, 10: upper right, 11: upper anterior teeth, 12: upper right, 13: lower right, 14: lower anterior, 15: lower left. The fifth stage is the end of brushing, including; 22: rinsing the mouth, 23: cleaning the brush, 24: putting the brush in its place. The performance of toothbrushing will be evaluated after one and three months by a blinded investigator.

Category

Rehabilitation

2

Description

Control group: An educational poster will be placed where the kid brush his-her teeth. The poster included 24 steps of toothbrushing in 16 pictures. The FONES model of toothbrushing will be instructed. The pictures are provided according to a human model with white background. The child may see the pictures as many times as he/she wants.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Aein-e-Mehrvarzi Autism School

Full name of responsible person

Samane Fayyaz

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No. 32, Ghadiri Alley, SaadatAbad Ave

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Samanef.1361@gmail.com

Web page address

<https://autismschool.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Arash Azizi, DDS.MS.

Street address

No. 9, 9th Neyestan Alley., Pasdaran., Islamic Azad Dental School

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1946853314

Phone

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katayoun.salem@gmail.com

Grant name

none

Grant code / Reference number

none.....

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Katayoun Salem

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Hospital Dentistry

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

Film: The recorded videos' of toothbrushing steps can be shared as the outcome.

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

The documents will be shared only to the publisher, and does not available for public use.

Under which criteria data/document could be used

Any academic usage should be with the collaboration of main authors.

From where data/document is obtainable

1.Katayoun Salem Tehran Azad Dental school, Department of Pediatric Dentistry, 9th Neyestan, Pasdaran, Tehran cell: 0098 9122174076 email: katayoun.salem@gmail.com 2. Rojin Adabdokht Tehran Azad Dental school, Department of Pediatric Dentistry, 9th Neyestan, Pasdaran, Tehran cell: 0098912 2349907 rojinadabdokht@gmail.com

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

The documents will be available after publishing, and to receive the documents for reappraisal of results, the request should be sent to responsible author.

Comments