Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effectiveness of oral health education using Audio Tactile Performance (ATP) technique alone; ATP combined with oral health education for parents; ATP and art package, on oral health status of students with visual impairment

Protocol summary

Study aim

Comparison of the effectiveness of oral health education using Audio Tactile Performance (ATP) technique alone; ATP combined with oral health education for parents; ATP and art package, on oral health status of students with visual impairment

Design

Three arm parallel group randomized trial with blind examiner after intervention and blind analyst, 200 visually impaired students, between December 2018 and April 2019

Settings and conduct

This study will be done in three schools for blinds, in Tehran. After completing the questionnaire and oral examinations in the baseline study, the classes in each school, will be devided into three groups. One month and two months after beginning of the intervention, re-examination will be done for assessing treatment index, bleeding on probing index and oral hygiene simplified index by a second calibrated examiner who is not present during the interventions and groups' allocation. By coding for the clusters and groups, the analyst will be blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Students in preschool to 10th grade in schools for blinds; student and parent's consent for participation in the study. Exclusion criteria: Mentally disabled students; physically disabled students

Intervention groups

1. The control group: The students will receive education by Audio-Tactile-Performance (ATP) technique 2. The ATP and Parents group: The students will receive education by ATP and the parents will receive telephone education. 3. The ATP and art package group: In addition to ATP, education by moving fingers on educational dental cast, game-based education and music-based education will be performed. The intervention will be done 3 times with a one week interval, in each group. Students will be re-examined one and two months after the beginning of the intervention.

Main outcome variables

Treatment status; oral hygiene; gingival bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140624018214N2**
Registration date: **2018-11-29, 1397/09/08**
Registration timing: **prospective**

Last update: **2019-06-18, 1398/03/28**
Update count: **1**

Registration date

2018-11-29, 1397/09/08

Registrant information

Name

Katayoun Sargeran

Name of organization / entity

Tehran University of Medical Sciences, School of Dentistry

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2018-12-01, 1397/09/10
Expected recruitment end date
2019-04-20, 1398/01/31
Actual recruitment start date
2018-12-01, 1397/09/10
Actual recruitment end date
2019-04-17, 1398/01/28
Trial completion date
2019-04-17, 1398/01/28

Scientific title
Comparison of the effectiveness of oral health education using Audio Tactile Performance (ATP) technique alone; ATP combined with oral health education for parents; ATP and art package, on oral health status of students with visual impairment

Public title
Comparison of the effectiveness of different methods of oral health education for the visually impaired students
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Students in preschool to 10th grade in schools for blinds in Tehran The student and parent's consent for participation in the study
Exclusion criteria:
Mentally disabled students Physically disabled students
Age
From **6 years** old to **17 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **200**
Actual sample size reached: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization is done by Excel software. Each class is considered to be a cluster in each school. Stratification is then done in each school for clusters, and it creates 2 layers: fifth grade and lower; sixth grade and higher. Within the layers, for each cluster, as well as for each of the three study groups, a code is considered and recorded. For example, the first cluster will be coded as "QWZ" and control group as "GFD" . For each school, all codes will be entered into Excel software in two columns; a column for clusters; another column for study groups. A colleague who is not informed about the coding process, will be asked to run the randomization command in Excel for these two columns. Thus, each cluster will be randomly entered into one of the three study groups (control; the first intervention ; the second intervention).
Blinding (investigator's opinion)
Single blinded
Blinding description
The post-intervention examination will be done by the second calibrated examiner, who is not present in the oral health education (intervention) and the allocation of groups. 2. The data will be entered to the SPSS with special codes so that the analyst will be blind about the clusters and groups. Latin letters will be chosen by chance, for the first cluster, for example, "asd" , and for control group, "cbn". After finishing the data analysis, these codes will be renamed to the original names of the groups and clusters.
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, Tehran University of Medical Sciences, North Kargar Ave, Tehran
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Postal code
1439955991
Approval date
2018-10-14, 1397/07/22
Ethics committee reference number
IR.TUMS.DENTISTRY.REC.1397.104

Health conditions studied

1

Description of health condition studied
Gingivitis and periodontal diseases
ICD-10 code
K05
ICD-10 code description
Gingivitis and periodontal diseases

2

Description of health condition studied
Dental caries
ICD-10 code
K02

ICD-10 code description
Dental caries

Primary outcomes

1

Description
Treatment status
Timepoint
Baseline study, one month after the beginning of the intervention and two months after the beginning of the intervention
Method of measurement
Treatment index: First, the number of decayed, missing and filled teeth in primary (dmft) and permanent (DMFT) dentition, will be assessed.Treatment index will be calculated by these formulas:((M+F)/DMF)*100 and ((m+f)/dmf)*100 .Also, D, M, F, d, m, f indices will be reported separately.

2

Description
Gingival bleeding
Timepoint
Baseline study, one month after the beginning of the intervention and two months after the beginning of the intervention
Method of measurement
Bleeding on probing index (BOP): The presence or absence of gingival bleeding in all teeth will be evaluated using the WHO Periodontal Probe. The surrounding gingiva of each tooth is assessed for the presence or absence of bleeding.

3

Description
Oral hygiene
Timepoint
Baseline study, one month after the beginning of the intervention and two months after the beginning of the intervention
Method of measurement
Oral Hygiene Index-simplified (OHI-S): The Calculus Index (CI) and Debri Index (DI) for six teeth (16,11,26,36,31,46) will be evaluated and will be scored from 0 to 3 for each tooth and will be recorded in the examination form. The sum of calculus scores, divided by the number of examined teeth will represent the CI and and the sum of debri scores, divided by the number of examined teeth will represent the DI. Finally, the sum of CI and DI will be reported as OHI-S.

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group (ATP and parents): The parents' questionnaire will be completed by telephone. Then, training is provided to parents to raise their awareness of oral health.These educations include the importance of oral hygiene to prevent caries and gum disease, the role of fluoride in controlling caries, the necessity to control the consumption of sugar and the importance of regular dental visits. The parents will then be asked to brush twice daily for two minutes and encourage their child to do this, too. Oral health education by ATP (Audio Tactile Performance) technique will be delivered to the students in class. In this technique, a verbal oral health Education will be delivered on the importance of teeth, oral hygiene, proper brushing, dental floss, fluoride, and the importance of controlling the consumption of sugar, in accordance with the age of the students. Then, the proper brushing technique will be taught individually by intra-oral guidance of the student's hand with the students' own toothbrush, until it is ensured that the student can properly handle it. one week and two weeks after the beginning of the intervention, the intervention will be repeated.Post-intervention examination will be done one month and two months after the beginning of the intervention.
Category
Prevention

2

Description
The second intervention group (ATP and art package): In this group, in addition to ATP technique, educational dental cast, game-based education and music-based education will be used. Normal and common pathological conditions of the teeth and gingiva will be simulated on dental cast. The students will be asked to move their fingers over casts to distinguish the cavitated dental caries, calculus and gingival swelling. Using play dough to make hand craft about oral health, will be considered as a game-based education. Music-based education also will be used. A music is prepared which focuses on the direction of tooth brushing for each jaw, side and surface with equal time to give equal importance to all surfaces. The music will be played in the class and students will perform the tooth brushing; listening to the music until they get able to brush properly.This music will be given to them to use at home every day. One week and two weeks after the beginning of the intervention, the intervention will be repeated.The post intervention examination will be done one month and two months after the beginning of the intervention.To prevent the contamination between the second group (ATP and art package) with other groups, interventions for the second group (ATP and art package) will be performed after the intervention of the other two groups.
Category
Prevention

3

Description
The control group (ATP) :Oral health education by ATP (Audio Tactile Performance) technique will be delivered to the students. A verbal oral health education will be delivered on the importance of teeth, oral hygiene, proper brushing, dental floss, fluoride, and the importance of controlling the consumption of sugar, in accordance with the age of the students. Then, the proper brushing technique will be taught individually by intra-oral guidance of the student's hand with the students' own toothbrush, until it is ensured that the student can properly handle it. one week and two weeks after the beginning of the intervention, the intervention will be repeated.Post-intervention examination will be done one month and two months after the beginning of the intervention.

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Mohebbi Educational Complex for Blinds
Full name of responsible person
Nasrin Sharififard
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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3

Recruitment center
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Sponsors / Funding sources

1

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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
Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Nasrin Sharififard

Position

PhD student of Community Oral Health

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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