

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparison of oral health promotion program among visually impaired adolescents of special schools of Mashhad using braille pamphlet and Audio-tactile Performance Technique

Protocol summary

Study aim

Evaluation of oral health promotion program among visually impaired adolescents of special schools in Mashhad using braille pamphlet and Audio-tactile Performance Technique in comparison with control group

Design

A controlled, two-parallel, single-blind, simple-randomized clinical trial of 90 participants.

Settings and conduct

It will be done in Mashhad special schools. Oral health education is carried out in three phases (basic, three months later, six months later) to visually impaired adolescents, and its effects are investigated. The person collecting the data and those doing the statistical analysis are unaware of the groups.

Participants/Inclusion and exclusion criteria

Congenital, totally visually impaired adolescents Bring the parental consent form

Intervention groups

group1: receiving oral health education through braille pamphlet group2: receiving oral health education through Audio-tactile Performance Technique

Main outcome variables

After six months, the participants will be examined by a questionnaire. The data will be evaluated in three parts: knowledge, attitude, and how to deal with dental trauma.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231025059848N1**

Registration date: **2023-12-14, 1402/09/23**

Registration timing: **prospective**

Last update: **2023-12-14, 1402/09/23**

Update count: **0**

Registration date

2023-12-14, 1402/09/23

Registrant information

Name

Mahtab Mottaghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3766 5718

Email address

mottaghi961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-21, 1402/09/30

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of oral health promotion program among visually impaired adolescents of special schools of Mashhad using braille pamphlet and Audio-tactile Performance Technique

Public title

Comparison of the effect of braille pamphlet and Audio-tactile Performance Technique on the oral health of visually impaired adolescents

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Congenital, totally visually impaired adolescent bring the parental consent form Age 10 to 19 years

Exclusion criteria:

Unwillingness to participate in the study

Age

From **10 years** old to **19 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with a table of random numbers at the cluster level. A table of random numbers is prepared in the range [0, 1). According to the number of groups and participants in each group, a number is selected from the table of random numbers for each participant. The numbers are sorted from big to small; the first 30 numbers are in the first group, the second 30 numbers are in the second group, and the third 30 numbers are in the third group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Different individuals will do data collection and education of the participants. The person who collects data (either through a questionnaire or through oral examinations will be unaware of the groups. Also, the statistical consultant will not be aware of the groups when performing statistical evaluations.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

the Ethics Committee of the Faculty of Dentistry of Mashhad University of Medical Sciences

Street address

Mashhad, University Street, next to Hoizeh Cinema, Qorshi Building, Research and Technology Vice-

Chancellor

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2023-01-18, 1401/10/28

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1401.124

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

Evaluating the level of knowledge, attitude, and information about how to deal with dental trauma in visually impaired adolescents.

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The level of awareness of the participants in the form of knowledge score

Timepoint

before the intervention and six months after the intervention

Method of measurement

questionnaire

2**Description**

The level of awareness of the participants in the form of attitude score

Timepoint

before the intervention and six months after the intervention

Method of measurement

questionnaire

3**Description**

The level of awareness of the participants about how to deal with dental trauma.

Timepoint

before the intervention and six months after the intervention

Method of measurement

questionnaire

Secondary outcomes

1

Description

Determination of DMFT (Decayed, Missing, Filled Teeth) index.

Timepoint

before the intervention three, and six months after the intervention

Method of measurement

Clinical examination

2

Description

Determination of OHI (Oral Hygiene Index).

Timepoint

before the intervention three, and six months after the intervention

Method of measurement

Clinical examination

3

Description

Determination of DI (Debris Index).

Timepoint

before the intervention three, and six months after the intervention

Method of measurement

Clinical examination

4

Description

Determination of BOP (Bleeding on Probing) index.

Timepoint

before the intervention three, and six months after the intervention

Method of measurement

Clinical examination

Intervention groups

1

Description

Intervention group 1: Oral health education will be received using a braille pamphlet at the beginning of the study and three months after the survey. Participants read Braille pamphlets in the presence of an attendant.

Category

Behavior

2

Description

Intervention group 2: Oral health education will be received by 3D models with a lecture (Audio-tactile Performance technique) at the beginning of the study and three months after the survey.

Category

Behavior

3

Description

Control group: No oral health education will provide for this group.

Category

N/A

Recruitment centers

1

Recruitment center**Name of recruitment center**

Omid school

Full name of responsible person

Saeed Doolabi

Street address

Faramarz Abbasi 5, Omid Blind Education Center

City

Mashhad

Province

Razavi Khorasan

Postal code

9197973579

Phone

+98 51 3605 9533

Email

DoolabiSaeed1345@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

DR. Saber Babazadeh

Street address

Mashhad dentistry schoolm Vakilabad blvd, MASHhad

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Province

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Phone

+98 51 3882 9500

Email

mottaghim961@mums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Mahtab Mottaghi

Position

Consultant

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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No. 17, sixth Hejrat Ave., Sazemane ab Blvd.,
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mahtab Mottaghi

Position

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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

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Part of the data related to the main outcome can be shared after de-identification.

When the data will become available and for how long

The access period starts from 1402

To whom data/document is available

These data will be accessible to researchers working in academic institutions.

Under which criteria data/document could be used

If the data is used for cross-sectional studies.

From where data/document is obtainable

Mahtab Mottaghi mahmottaghi1999@gmail.com

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

When composing an email, clearly outline the reasons why the data is necessary.

Comments