

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

The evaluation of effect of different educational methods on oral health of blind children

Protocol summary

Study aim

the evaluation of effect of different educational methods on blind children 7-13 year old Tehran 1397

Design

clinical trial with control group, double blind , simple randomization-block ,sample number:100 persons

Settings and conduct

clinical trial,Tehran blind children's primary schools

Participants/Inclusion and exclusion criteria

children including both males and females aged 7-13 years totally visually impaired by birth(legally blind) , free from any other form of mental or physical handicapping condition and other systemic diseases ,haven't taken antibiotics and nonsteroidal anti-inflammatory drugs in the last month , do not using any orthodontic appliances or space maintainers ,have not gone under fluoride or fissure sealant therapy in the last month

Intervention groups

groups : braille text ,tactile with big model, braille-tactile , control

Main outcome variables

oral health educational methods

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161119030971N3**

Registration date: **2018-11-04, 1397/08/13**

Registration timing: **retrospective**

Last update: **2018-11-04, 1397/08/13**

Update count: **0**

Registration date

2018-11-04, 1397/08/13

Registrant information

Name

Nahid Askarizadeh

Name of organization / entity

Dental branch, Islamic Azad University

Country

Iran (Islamic Republic of)

Phone

+98 21225645713

Email address

n_asgarizadeh@dentaliau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-05, 1397/03/15

Expected recruitment end date

2018-10-07, 1397/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of effect of different educational methods on oral health of blind children

Public title

The evaluation of effect of different educational methods

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

children including both males and females aged 7-13 years totally visually impaired by birth(legally blind)

Exclusion criteria:

free from any other form of mental or physical handicapping condition other systemic diseases haven't

taken antibiotics and nonsteroidal anti-inflammatory drugs in the last month do not using any orthodontic appliances or space maintainers have not gone under fluoride or fissure sealant therapy in the last month

Age

From **7 years** old to **13 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization-block

Blinding (investigator's opinion)

Double blinded

Blinding description

double blind in which both the evaluator and the analyser are blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Dental College Medical Sciences of Islamic Azad University

Street address

Dental College ,Medical Sciences , Islamic Azad University No.9, 9th Neyestan Alley ,Pasdaran Ave.,

City

Tehran

Province

Tehran

Postal code

19585/175

Approval date

2018-04-22, 1397/02/02

Ethics committee reference number

IR.IAU.DENTAL.REC.1397,5

Health conditions studied

1

Description of health condition studied

oral health educational methods

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

oral health

Timepoint

after two months

Method of measurement

plaque and gingival index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: braille text

Category

Other

2

Description

Intervention group: tactile with big model

Category

Other

3

Description

Intervention group: braille-tactile

Category

Other

4

Description

Control group: no education

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Blind Primary Schools :Narjes , Mohebbi, Khazaeli

Full name of responsible person

Nahid Askarizadeh

Street address

no.81,West Jamali Alley,Vafamanesh Street,Heravi

Square
City
Tehran
Province
Tehran
Postal code
1668754518
Phone
+98 21 8870 2536
Email
n_asgarizadeh@dentaliau.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University
Full name of responsible person
Nahid Askarizadeh
Street address
no.81, West Jamali Alley, Vafamanesh Street, Heravi
Square
City
Tehran
Province
Tehran
Postal code
1668754518
Phone
+98 21 2298 7486
Email
n_asgarizadeh@dentaliau.ac.ir
Grant name
Grant code / Reference number
**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
Dental College of Medical Sciences , Islamic Azad
University
Full name of responsible person
Sheida Masoumi
Position

dental student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
No.9, 9th Neyestan Alley ,Pasdaran Ave.,Dental
College of Medical Sciences , Islamic Azad University
City
Tehran
Province
Tehran
Postal code
19585/175
Phone
+98 21 8870 2536
Email
sh_masoumi93@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Dental College of Medical Sciences , Islamic Azad
University
Full name of responsible person
Nahid Askarizadeh
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
No.9, 9th Neyestan Alley ,Pasdaran Ave.,Dental
College of Medical Sciences , Islamic Azad University
City
Tehran
Province
Tehran
Postal code
19585/175
Phone
+98 21 2256 4571
Email
n_asgarizadeh@dentaliau.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Dental College of Medical Sciences , Islamic Azad
University
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Sheida Masoumi
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19585/175

Phone

+98 21 8870 2536

Email

sh_masoumi93@yahoo.com

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

there is no more information

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