Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 MedicalSciences , 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
DentalCollege 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
Full name of responsible person
Sheida Masoumi
Position
dental student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry

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+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