

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of the effectiveness of parent management training on dental plaque index in children with attention deficit hyperactivity disorder

Protocol summary

Study aim

Determination and comparison of plaque index in ADHD children receiving methylphenidate before and after the routine oral health training 2. Determination and comparison of plaque index in ADHD children receiving methylphenidate before and after PMT with emphasis on health education 3. comparison of plaque index changes in case and control groups

Design

randomized, parallel, single-blind clinical trial with 36 patients. The simple randomization method has been used for randomization.

Settings and conduct

First, in both groups, the dental plaque index will be measured using a detector solution. Then, the control group will get routine health training and a month later their dental plaque index will be registered by the same dentist. Case group parents will participate in 8, 1-hour PMT sessions at Razi Hospital in Tabriz with an interval of 1 week. Children's dental plaque will be re-evaluated one month after the end of the sessions.

Participants/Inclusion and exclusion criteria

Entry requirements 1. Children in the age range of 6 to 12 years 2. IQ above 70 in children 3. Higher education of parents 4. Cooperation and participation of parents in PMT classes 5. Responsible of patient care 6. Written informed consent Not entry conditions 1. Existence of major psychiatric pathology in parents 2. Existence of major psychiatric pathology other than ADHD in children. 3. Taking other psychiatric medications by the child 4. Lack of cooperation of the child

Intervention groups

The children will be divided into two groups of case and control. The case group parents will participate in 8 PMT sessions focusing on children's oral health and the control group will get routine health training such as the correct method of rolling brushing technique.

Main outcome variables

The main consequence is the children's plaque index,

which will be measured by the detector solution before and after the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210822052251N1**

Registration date: **2021-10-18, 1400/07/26**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-18, 1400/07/26**

Update count: **0**

Registration date

2021-10-18, 1400/07/26

Registrant information

Name

Neda Yasamineh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-30, 1400/06/08

Expected recruitment end date

2021-12-28, 1400/10/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of parent management training on dental plaque index in children with attention deficit hyperactivity disorder

Public title

Evaluation of the effectiveness of parent management training on dental plaque index in children with attention deficit hyperactivity disorder

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Children in the age range of 6 to 12 years IQ above 70 children which will be determined by raven test intelligence screening Higher education level of parents Cooperation and participation of parents in PMT classes Being responsible of patient care Written informed consent

Exclusion criteria:

Existence of major psychopathology in the parent that will be measured through medical records and SCL-90 questionnaire Existence of major psychiatric pathology other than ADHD in children Taking other psychiatric medications by the child Lack of cooperation of the child

AgeFrom **6 years** old to **12 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **36****Randomization (investigator's opinion)**

Randomized

Randomization description

In this test, simple randomization will be used. in order to achieve two groups with equal sample size. 36 equal envelopes will be ready and 18 of them will be written group a and 18 of them will be written group b and the envelopes will be completely closed. Patients will be randomly assigned to one of these two groups by selecting an envelope. Group a will be the intervention group and group b will be the control.

Blinding (investigator's opinion)

Single blinded

Blinding description

The person examining the children's dental plaque index will not know in which study group the examined people are. Therefore, the study will be one-sided blind

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tabriz university of medical sciences

Street address

Central Building of Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2021-08-02, 1400/05/11

Ethics committee reference number

IR.TBZMED.REC.1400.448

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

attention deficit hyperactivity disorder

ICD-10 code

F90.0

ICD-10 code description

Attention-deficit hyperactivity disorder, predominantly inattentive type

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

dental plaque index

Timepoint

Before the intervention and one month after the end of the PMT sessions

Method of measurement

disclosing solution

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Parents of Case group, which is 18 people, in a group with a maximum of twelve people in a hall with sufficient space and appropriate spacing to comply with coronary prevention health protocols in Razi Hospital, Tabriz in 8 1-hour PMT sessions with emphasis on oral health education They will participate with an interval of 1 week. PMT sessions in the form of the first session explaining ADHD, the second session using rewards and points, the third session using induced praise, the fourth session neglecting, the fifth session high-risk behaviors, the sixth session eliminating Rewards and Points The seventh session will be the application of corporal punishment and the eighth session will be the use of surrender, which will be conducted under the supervision of a child and adolescent psychiatrist. 1 month after the end of the sessions, the people will be examined again by the same dentist and their dental plaque index will be evaluated and recorded.

Category

Lifestyle

2

Description

Control group: The control group, which consists of 18 people, will get the routine health training, such as the correct method of the rolling brushing technique, and one month after the end of the sessions, they will be examined by the same dentist and their dental plaque index will be evaluated and recorded.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital, Tabriz and specialized child and adolescent psychiatric clinics

Full name of responsible person

Gholamreza Nourazar

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Bakeri Blvd, Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Maryam Farsadbakhsh

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Latest degree

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Person responsible for updating data

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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