

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

The effect of Cognitive Behavioral Therapy on the dental plaque index of adolescents with bipolar mood disorder

Protocol summary

Study aim

The effect of Cognitive Behavioral Therapy on the dental plaque index of adolescents with bipolar mood disorder

Design

A clinical trial with parallel intervention group, single-blind, randomized, on 60 patients. The sampling method is random. Randomization is done using a table of random numbers.

Settings and conduct

Among the patients with youth bipolar mood disorder who are in the final stages of hospitalization and whose symptoms are in the phase of relative subsidence and who have the necessary cooperation, and from the child and adolescent department of Razi Hospital in Tabriz or from the child and adolescent psychiatry subspecialty clinics. With accessible sampling, they will be selected based on DSM-5 criteria, with the diagnosis of child and adolescent psychiatry subspecialist, and with the use of K-SADS semi-structured interview. At first, the participants in this study will be examined by a dentist, and their dental plaque index will be measured and recorded using a disclosing solution. Patients are randomly assigned to one of the groups. In the intervention group, they will participate in 8 face-to-face oral hygiene training sessions with cognitive-behavioral therapy techniques. One month after the sessions, they will be examined by a dentist who is unaware of the groupings, and their index plates will be recorded and evaluated. There is no intervention in the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: physically able to perform health measures, IQ above 70 (measured with the Raven test), having at least 20 teeth Exclusion criteria: Absence in any of the CBT sessions, presence of the orthodontic appliance

Intervention groups

Intervention: oral health education with cognitive-behavioral therapy technique Control: no intervention

Main outcome variables

Dental plaque index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230418057951N1**

Registration date: **2023-04-30, 1402/02/10**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-30, 1402/02/10**

Update count: **0**

Registration date

2023-04-30, 1402/02/10

Registrant information

Name

Amirreza Dehghani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-25, 1402/02/05

Expected recruitment end date

2023-05-25, 1402/03/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of Cognitive Behavioral Therapy on the dental plaque index of adolescents with bipolar mood disorder

Public title
The effect of oral hygiene education in adolescents with bipolar mood disorder

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Adolescents aged 12 to 18 with bipolar disorder Having written informed consent from the parent or legal guardian (consent) and oral consent from the participating adolescent (oral assent)
Exclusion criteria:
 Suffering from major psychiatric and other physical diseases Presence of congenital genetic disorder Use of anticholinergic drugs

Age
From **12 years** old to **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Random sampling will be done among the children and adolescents referred to Tabriz Razi Hospital or from the child and adolescent psychiatry clinics of Tabriz University of Medical Sciences who are eligible for the study. The randomization method is simple and its unit is individual. Our tool for randomizing a table of random numbers. Based on this, the type of treatment is marked with code A (oral health education with cognitive-behavioral therapy technique) and B (control) and placed inside the sealed envelopes. Then the envelopes are placed in a bag and mixed. Then it is randomly selected from the bag and treatment is given to the patient by observing the code. The researcher who has to enter the data into the checklist will not know the type of group the person is in.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is single blind. The researcher who has to enter the data into the checklist will not know about the type of group that the person is in.

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

Tabriz University of Medical Sciences, Golgasht St.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2023-03-06, 1401/12/15

Ethics committee reference number

IR.TBZMED.REC.1401.1088

Health conditions studied

1

Description of health condition studied

Dental plaque

ICD-10 code

K02

ICD-10 code description

Dental caries

Primary outcomes

1

Description

Dental Plaque

Timepoint

One month after the end of the sessions

Method of measurement

People will be examined by a dentist and training on dentistry will be shown in a practical way, and participants will practice the taught materials on dentistry. Then, the disclosing solution is contacted with all the dental surfaces for 30 seconds, and after washing the mouth, it is checked using a mirror and probe under the light of the unit, and the number of colored surfaces is calculated in relation to the total dental surfaces, and the index plate is obtained.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: People will be examined by a dentist and training on the dentic will be shown in a practical way, and participants will practice the taught materials on dentistry. Then, the disclosing solution is contacted with all the dental surfaces for 30 seconds, and after washing the mouth, it is checked using a mirror and probe under the light of the unit, and the number of colored surfaces is calculated in relation to the total dental surfaces, and the index plate is obtained. A week after the training session on the dentic, people will be called again and examined by a dentist, and their dental plaque index will be evaluated and recorded, and health education will be repeated if needed. Then the participants will be randomly divided into case and control groups. People in the intervention group will participate in 8 in-person oral hygiene training sessions with cognitive-behavioral therapy techniques. At the end of each session, assignments are given to these people and will be reviewed at the beginning of the next session. One month after the sessions, they will be examined by a dentist who is unaware of the groupings, and their index plates will be recorded and evaluated.

Category

Other

2

Description

Control group: People will be examined by a dentist and training on the dentic will be shown in a practical way, and participants will practice the taught materials on dentistry. Then, the disclosing solution is contacted with all the dental surfaces for 30 seconds, and after washing the mouth, it is checked using a mirror and probe under the light of the unit, and the number of colored surfaces is calculated in relation to the total dental surfaces, and the index plate is obtained. A week after the training session on the dentic, people will be called again and examined by a dentist, and their dental plaque index will be evaluated and recorded, and health education will be repeated if needed. Then the participants will be randomly divided into case and control groups. The people of the control group will be called one month later and their index plates will be evaluated and recorded.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Razi Hospital

Full name of responsible person

Amirreza Dehghani

Street address

Elgoli, Razi hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Soudabeh Kimiai

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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

Neda Yasmineh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable