

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

The effect of motivational interviewing on dental plaque index of adolescents with bipolar mood disorder

Protocol summary

Study aim

Comparison of plaque index in adolescents with bipolar disorder (BMD) by implementing motivational interviewing technique with traditional oral health education

Design

Randomized, parallel, double-blind clinical trial with 60 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 will participate in 2 PMT sessions at Razi Hospital in Tabriz with an interval of 1 month. Adolescent's dental plaque will be re-evaluated one month after the end of the sessions.

Participants/Inclusion and exclusion criteria

inclusion criteria: suffering bipolar mood disorder; adolescents between the ages of 12 and 18; IQ above 70 adolescents; cooperation and participation of adolescents in training classes; conscious written and oral consent. exclusion criteria: existence of major psychiatric pathology other than BMD in adolescents; taking other psychiatric medications by adolescents; lack of adolescent cooperation

Intervention groups

Adolescents with bipolar disorder will be divided into case and control groups. The members of the case group will participate in 2 CBT training sessions, and the members of the control group will be given the usual health training, such as the correct application of the brushing technique.

Main outcome variables

The main consequence is the Adolescent'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: **IRCT20210822052251N2**

Registration date: **2022-07-03, 1401/04/12**

Registration timing: **prospective**

Last update: **2022-07-03, 1401/04/12**

Update count: **0**

Registration date

2022-07-03, 1401/04/12

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

2022-07-11, 1401/04/20

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of motivational interviewing on dental plaque index of adolescents with bipolar mood disorder

Public title

The effect of motivational interviewing on dental plaque index of adolescents with bipolar mood disorder

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Suffering bipolar mood disorder Adolescents in the age range of 12 to 18 years IQ above 70 adolescents which will be determined by raven test intelligence screening written informed consent from the parent or legal guardian and oral assent from the adolescent Cooperation and participation of adolescent in CBT classes

Exclusion criteria:

Use of orthodontic applications Existence of major psychiatric pathology other than BMD in adolescent Taking other psychiatric medications by the adolescent Lack of cooperation of the adolescent

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, The person examining the adolescent's dental plaque index and the person who analyzes the data will not know in which study group the examined people are. Therefore, the study will be double-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

2021-12-18, 1400/09/27

Ethics committee reference number

IR.TBZMED.REC.1400.905

Health conditions studied

1

Description of health condition studied

Bipolar mood disorder

ICD-10 code

F31.0

ICD-10 code description

Bipolar affective disorder, current episode hypomanic

Primary outcomes

1

Description

Dental plaque index

Timepoint

Before the intervention and one month after the end of the CBTsessions

Method of measurement

Disclosing solution

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in addition to receiving traditional health education, the intervention group will participate in 2 sessions of oral health education through interviews with an interval of 1 month and will receive motivation with the guidance of the Lenthal model. Motivational interviews will take approximately 15-20 minutes. Oral health information and instructions will be given to the patient during the motivational interview (depending on the patient). The questionnaire prepared for the study will be used as a title to start the interview. Addressing the five dimensions of Lonthal interview theory, this letter follows the principles of motivation (physicians 'empathy, contradiction of patients' importance and values with their own opinion, and lack of direct

argument or confrontation). The questionnaire will consist of five questions: 1- What is dental health for you? 2. What are the factors that contribute to oral health? 3- What are the consequences of dental problems for you in daily life? 4. What kind of oral care do you do for your gums regularly, even daily, and what factors may increase your gum and tooth problems? 5- What treatment methods can you have to restore healthy teeth and gums? Explanations of conversion methods will naturally be considered during the next discussion that will be created (for example, in the brushing test method). After a month, the dentist will make an appointment for an oral examination, and in the second initial session, the dental plaque index will be evaluated and recorded by a physician from a unique grouping, and will be recorded as a new thing according to the amount of plaque reduction during these periods. شد. The motivational interview will address the problems encountered while brushing and creating a feeling of improvement in the patient's use of the disease. After a month, he will be examined again by a dentist who is unaware of the groupings and his dental plaque index will be evaluated and recorded.

Category

Lifestyle

2

Description

Control group: these people will receive routine hygiene training, which includes training to brush with the modified bass technique, flossing, and also showing the mouth using a mirror. After a week, the participants will be examined by a 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

Kamran Delavizbonab

Position

student

Latest degree

A Level or less

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

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