

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The efficacy of group therapy based on affect regulation training, drug therapy, and combination of affect regulation training with drug therapy in reducing adolescent conduct disorder symptoms

Protocol summary

Study aim

-Determining the effect of group therapy based on ART in reducing the number of conduct disorder symptoms. - Determining the effect of group therapy based on ART in reducing the severity of symptoms. - Determining the effect of drug treatment in reducing the number of symptoms. -Determining the effect of drug treatment in reducing the severity of symptoms. - Determining the effect of ART with drug treatment in reducing the number of symptoms. - Determining the effect of ART with drug treatment in reducing the severity of symptoms.

Design

A controlled, parallel-group, single-blind, non-randomized, phase 1-2 clinical trial on 36 patients.

Settings and conduct

The method of conducting the present research will be that first, the patients present in the clinic of Razi Medical Education Center in Tabriz will be clinically interviewed by a psychiatrist, and after receiving the diagnosis of behavioral disorder, they will undergo additional evaluations by a psychologist based on the Achenbach scale and ask questions related to The entry and exit criteria are checked. After the test, the evaluator checks the severity of symptoms and does not know the subject's group membership.

Participants/Inclusion and exclusion criteria

Referrals for treatment 16-18 years old Suffering from conduct disorder based on DSM-5 diagnostic criteria Not using any drugs for at least 3 weeks Not using any psychiatric medication two weeks before the treatment Male gender

Intervention groups

Experimental group with ART Drug test group
Experimental group with drug and ART combination the first experimental group received affect regulation training, the second experimental group received drug

therapy, and the third group received the combination of ART with drug therapy. The treatment course lasts for three weeks.

Main outcome variables

Number of conduct disorder symptoms Severity of conduct disorder symptoms

General information

Reason for update

Acronym

ART

IRCT registration information

IRCT registration number: **IRCT20091103002660N5**

Registration date: **2022-08-20, 1401/05/29**

Registration timing: **prospective**

Last update: **2022-08-20, 1401/05/29**

Update count: **0**

Registration date

2022-08-20, 1401/05/29

Registrant information

Name

Shahrokh Amiri Aziza Abad

Name of organization / entity

Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1380 4486

Email address

amirish@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01
Expected recruitment end date
 2023-03-20, 1401/12/29
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 The efficacy of group therapy based on affect regulation training, drug therapy, and combination of affect regulation training with drug therapy in reducing adolescent conduct disorder symptoms

Public title
 The efficacy of group therapy in reducing adolescent conduct disorder symptoms

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Referrals for treatment Being at least 16 years old and at most 18 years old Suffering from conduct disorder based on DSM-5(Diagnostic and Statistical Manual of Mental Disorders, 5th Edition) diagnostic criteria Not using any drugs for at least 3 weeks Not using any psychiatric medication during two weeks before the treatment male gender
Exclusion criteria:
 Suffering from severe psychiatric diseases other than Oppositional defiant Disorder and Attention deficit hyperactivity disorder Inability to read and write or having any problem that makes the person unable to respond to listening or writing assignments related to psychological treatments.

Age
 From **16 years** old to **18 years** old

Gender
 Male

Phase
 1-2

Groups that have been masked

- Outcome assessor

Sample size
 Target sample size: **36**

Randomization (investigator's opinion)
 Not randomized

Randomization description

Blinding (investigator's opinion)
 Single blinded

Blinding description
 In all stages, the evaluator, consisting of a psychologist and a psychiatrist, is unaware of the subjects' group membership and will not be aware of which subjects have been affected by which type of intervention.

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

El-Goli Road, Razi Medical Education Center, research center of Psychiatry and Behavioral Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5167846184

Approval date

2022-08-01, 1401/05/10

Ethics committee reference number

IR.TBZMED.REC.1401.377

Health conditions studied

1

Description of health condition studied

conduct disorder

ICD-10 code

F91

ICD-10 code description

اختلال سلوك

Primary outcomes

1

Description

number of symptoms

Timepoint

Immediately after receiving the intervention and two months later

Method of measurement

Achenbach questionnaire

2

Description

severity of symptoms

Timepoint

Immediately after receiving the intervention and two months later

Method of measurement

Achenbach questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: experimental group with affect regulation training

Category

Treatment - Drugs

2

Description

Intervention group: Experimental group with drugs

Category

Treatment - Drugs

3

Description

Intervention group: Experimental group with combination of affect regulation training and drugs

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital of Tabriz

Full name of responsible person

prof.shahrokh amiri

Street address

Elgoli road

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+98 41 3382 6512

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sh_amiri1348@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

prof.Ali fakhari

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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

Shahrokh Amiri Aziza Abad

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
zahra bakhtshokuhi
Position
Resident
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Specialist
Other areas of specialty/work
Psychiatrics
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

The printed article from the research will be available to the patients and their families.

When the data will become available and for how long

After the completion of the research and six months after the publication of the results

To whom data/document is available

The patient and the patient's family

Under which criteria data/document could be used

To raise awareness about the nature of the disorder and available treatments

From where data/document is obtainable

Research Center of Psychiatry and Behavioral Sciences, Tabriz University of Medical Sciences and project manager

What processes are involved for a request to access data/document

Visiting the project manager in person and calling or emailing to exchange information is defined.

Comments