

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The effectiveness of unified transdiagnostic group therapy on emotion self-regulation and irritability of children with DMDD

Protocol summary

Study aim

The research will be conducted with the aim of investigating the effectiveness of Unified Transdiagnostic treatment on the excitability and emotional regulation of children with DMDD

Design

Clinical trial with control group, random assignment on 30 patients. A simple random method was used for randomization.

Settings and conduct

The intervention was carried out at Ravan Yar Psychological Counseling and Services Center in Shiraz. First, the purpose, implementation method and lack of coercion to participate in the research were explained to the subjects and their mothers, and the agreements to participate in the research were confirmed through the consent form. The intervention plan of the research was an unified transdiagnostic course (Ehrenreich-May & Bilek, 2012) that was implemented in 15 two-hour sessions and over 15 weeks for children and their mothers.

Participants/Inclusion and exclusion criteria

Entry requirements: Not having other psychiatric and neurological disorders, cognitive disability, ascertaining the definite diagnosis of the disorder, age range of 9 to 12 years, not using medicine during the research period and a consent letter stating their agreement to participate in the research.

Intervention groups

30 children (15 in the experimental group and 15 in the control group) who received a definitive diagnosis of DMDD based on multidimensional structured diagnostic interview assessments based on DSM5 criteria by an independent psychiatrist and psychologist.

Main outcome variables

emotion self-regulation and irritability of children with DMDD

General information

Reason for update

Acronym

UTDMDD

IRCT registration information

IRCT registration number: **IRCT20180512039620N1**

Registration date: **2022-09-26, 1401/07/04**

Registration timing: **retrospective**

Last update: **2022-09-26, 1401/07/04**

Update count: **0**

Registration date

2022-09-26, 1401/07/04

Registrant information

Name

Mohamad Mehdi Hasanshahi

Name of organization / entity

The University of Arsanjan

Country

Iran (Islamic Republic of)

Phone

+98 71 3648 6971

Email address

hassanshahi_mehdi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2021-06-19, 1400/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of unified transdiagnostic group therapy on emotion self-regulation and irritability of children with DMDD

Public title

The effectiveness of unified transdiagnostic group therapy on DMDD

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

not having other psychiatric and neurological disorders
Not using medicine during the research period age range 9 to 12 years
Not using medicine during the research period
Consent letter stating their agreement to participate in the research

Exclusion criteria:

having other psychiatric and neurological disorders
Use of medicine during the research period
Lack of consent to participate in the research
cognitive disability,

Age

From **9 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The studied sample included 30 children (15 in the experimental group and 15 in the control group) of children who received a definitive diagnosis of disruptive mood disorder based on the multidimensional evaluations of the structured diagnostic interview based on DSM5 by an independent psychiatrist and psychologist. They were assigned to experimental and control groups in equal proportion by random assignment method. It is worth mentioning that the studied groups were matched in terms of education level and gender

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The studied sample included 30 children (15 in the experimental group and 15 in the control group) of children who received a definitive diagnosis of DMDD based on the multidimensional evaluations of the structured diagnostic interview based on DSM5 by an independent psychiatrist and psychologist. They were randomly assigned to experimental and control groups in equal proportions.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arsanjan Islamic Azad University

Street address

University Boulevard - Department of Psychology

City

Arsanjan

Province

Fars

Postal code

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Approval date

2021-11-29, 1400/09/08

Ethics committee reference number

IR.IAU.A.REC.1400.011

Health conditions studied

1

Description of health condition studied

Disruptive mood dysregulation disorder (DMDD)

ICD-10 code

F34.81

ICD-10 code description

Disruptive mood dysregulation disorder

Primary outcomes

1

Description

emotion self-regulation and irritability

Timepoint

Three rounds of pre-exam, post-exam and follow-up exam (3 months)

Method of measurement

Shields and Cicchetti's Emotional Regulation Checklist (1995)
The affective reactivity index (Stringaris et al., 2012)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention plan of the research is a unified transdiagnostic treatment course that is implemented in 15 two-hour sessions for 15 weeks for children and their mothers. In this research, the unified

transdiagnostic treatment protocol for children's emotional disorders, which was first implemented by Ehrenreich-May and Bilek (2012) on a group of 9-12-year-old children with emotional disorders and their parents, is used.

Category

Behavior

2

Description

Control group: The control group does not receive any treatment.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Farnam's Psychiatry Office RavanYar
Psychological and Counseling and Services Center

Full name of responsible person

Dr Rabert Farnam

Street address

No. 4, Shahid Faqih Ave., Zand Blvd., Shiraz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Saeed Mohtasham

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No. 1, Daneshgah Blvd., Arsanjan city

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Web page address

<https://arsanjan.iau.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

Islamic Azad University

Full name of responsible person

Mohamad Mehdi hasanshahi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Part of the data, such as the information related to the main outcome, can be shared.

When the data will become available and for how long

1 year after publication

To whom data/document is available

Researchers of academic and scientific institutions

Under which criteria data/document could be used

The data will be available only to researchers working in academic and scientific institutions

From where data/document is obtainable

-Vice President of Research, Arsanjan Islamic Azad University Fars Province, Arsanjan, University Blvd. Postal code: 7376153161 PO Box: 168-73761

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

Sending the application along with the confirmation of the university of the place of service - the purpose of using the data - the picture of scientific confirmations. Examining the application in the educational department of the university - providing an answer to the applicant

Comments