Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)
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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 Faqihi 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

Street address

No. 1, Daneshgah Blvd., Arsanjan city

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Email

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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 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