Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Developing a parental model based on attachment theory; and comparing the effectiveness of this model with the model of parent-child-interaction-based play-therapy in depression, self-control and emotion of regulation of children aged 6-12 years with disruptive mood dysregulation disorder in city of Isfahan.

Protocol summary

Study aim
Developing a parental model based on attachment theory; and comparing the effectiveness of model with the model of parent-child-interaction-based play-therapy in depression, self-control and emotion of regulation of children aged 6-12 years with disruptive mood dysregulation disorder in city of Isfahan.

Design
Clinical groups in simple randomized: control, parental model based on attachment theory, and therapeutic-game model based on parent-child-interaction

Settings and conduct
45 parents of children with disruptive mood dysregulation disorder who are referred to the children's psychiatric center of the Noor branch of Isfahan, Khorshid medical complex, are selected based on entry criteria and randomly categorized to 3 groups, as follow: Training of parental model based on attachment theory-Training of therapeutic-game model based on parent-child-interaction-Control group under one individual training session on the subject. Psychological evaluation in three stages as before, upon the completion of the intervention, and after 3 months follow-up

Participants/Inclusion and exclusion criteria
Diagnosis of disruptive mood dysregulation disorder of children aged 6- 12 years. Conscious consent to participate in the research.Physical and mental ability in order to attend the meetings.Education: finished elementary school, at least. Residency: city of Isfahan.Contact Number for invitation to participate in the intervention. Bipolar disorder.Opposition defiant disorder. Attention deficit hyperactivity disorder.Autism disorder. Participate in Psycho social or psychotherapy sessions over the past 6 months. Not being motivated to participate and continue in the intervention

Intervention groups
parental model based on attachment theory, therapeutic-game model based on parent-child-interaction, Participants in training waiting list

Main outcome variables
Self-control, depression, emotional of regulation

General information

Reason for update

Acronym
-

IRCT registration information
IRCT registration number: **IRCT20180623040196N1**
Registration date: **2018-09-08, 1397/06/17**
Registration timing: **registered_while_recruiting**

Last update: **2018-09-17, 1397/06/26**
Update count: **1**

Registration date
2018-09-08, 1397/06/17

Registrant information

Name
Azam Shahmohammadi Ghahsareh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3555 8997

Email address
a.shahmohammadi@khuisf.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-22, 1397/04/01
Expected recruitment end date
2018-09-22, 1397/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Developing a parental model based on attachment theory; and comparing the effectiveness of this model with the model of parent-child-interaction-based play-therapy in depression, self-control and emotion of regulation of children aged 6-12 years with disruptive mood dysregulation disorder in city of Isfahan.

Public title
Developing a parental model based on attachment theory and study its effectiveness on children with disordered disturbance disorder
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
disruptive mood dysregulation disorder of children aged 12- 10 years Conscious consent to participate in the research Physical and mental ability in order to attend the meetings Education: finished elementary school, at least. Residency: city of Isfahan Contact Number for invitation to participate in the intervention
Exclusion criteria:
Bipolar disorder Oppositional defiant disorder attention deficit hyperactivity disorder Autism disorder Participate in Psychosocial or psychotherapy sessions over the past 6 months Not being motivated to participate in the intervention Unwillingness to continue participating in the intervention
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple random sampling
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Examining the validity of the developed training package through qualitative method

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Islamic Azad University, Isfahan Branch (Khorasgan)
Street address
Islamic Azad University, Isfahan (Khorasgan)Branch, University BLVD, Arghavaniyeh, East Jey st.
City
Esfahan
Province
Isfehan
Postal code
8148617961
Approval date
2018-04-16, 1397/01/27
Ethics committee reference number
IR.IAU.KHUISF.REC.1397-013

Health conditions studied

1

Description of health condition studied
Disruptive mood dysregulation disorder
ICD-10 code
F34/8
ICD-10 code description

Primary outcomes

1

Description
Depression
Timepoint
Before the intervention, after the intervention, and three months after the end of the intervention
Method of measurement
Quakes Depression Inventory (1992)

2

Description
Self-control
Timepoint
Before the intervention, after the intervention, and three months after the end of the intervention
Method of measurement
Kendall Vickes Self Controller (1979)

3

Description
Emotion of regulation
Timepoint
Before the intervention, after the intervention, and three months after the end of the intervention
Method of measurement
ERQ short form questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Training of the package of parenting developed based on attachment theory
Category
Lifestyle

2

Description
Intervention group: Game therapy based on parenting and child relationships
Category
Treatment - Other

3

Description
Control group:One individual counseling session
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Psychiatry, Noor Branch of Isfahan, Khorshid Medical Complex
Full name of responsible person
Seyyed Ghafour Mousavi
Street address
Hasht-Behesht Ave., Ostandari St.
City
Esfahan
Province
Isfehan
Postal code
8145831451
Phone
+98 31 3222 2127
Fax
+98 31 3222 2255
Email
MOUSAVI@MED.MUI.AC.IR
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Researcher: Azam Shahmohammadi Ghahsareh
Street address
Islamic Azad University, Isfahan (Khorasgan)Branch, University BLVD, Arghavaniyeh, East Jey st.
City
Esfahan
Province
Isfehan
Postal code
81595158
Phone
+98 31 3555 8997
Email
a.shahmohammadi@khuisf.ac.ir
Web page address
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
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Azam Shahmohammadi Ghahsareh
Position
Psychologist
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
No. 106, 28th Alley,West Sheikh Toosi st.
City
Esfahan
Province

Isfehan

Postal code
8198863487

Phone
+98 31 3555 8997

Email
Azamshamohamadi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of Esfahan

Full name of responsible person
Dr. Ahmad Abedi

Position
Faculty member and deputy of research of the University of Isfahan

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
Isfahan University, Azadi Square, Isfahan.

City
Esfahan

Province
Isfehan

Postal code
8174673441

Phone
+98 31 3793 2509

Email
a.abedi@edu.ui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Azam Shahmohammadi Ghahsareh

Position
Psychologist

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
No.106, 28th Alley, West Sheikh Toosi st.

City
Esfahan

Province
Isfehan

Postal code
8198863487

Phone
+98 31 3555 8997

Email
Azamshamohamadi@gmail.com

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
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

Title and more details about the data/document
The results of the research

When the data will become available and for how long
6 months after printing results

To whom data/document is available
Researchers working in academia and academia

Under which criteria data/document could be used
To report the results in other research studies by maintaining its source

From where data/document is obtainable
Islamic Azad University (Khorasgan Branch)

What processes are involved for a request to access data/document
Islamic Azad University (Khorasga), Central Library, Thesis Department

Comments