Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A comparative study on the efficacy of Acceptance and Commitment Therapy(ACT) and Risperidone in treatment of children with Obsessive-Compulsive Disorder

Protocol summary

Study aim

To compare the effectiveness of Acceptance and Commitment Therapy (ACT) with Risperidone monotherapy in reducing symptom severity in children diagnosed with obsessive-compulsive disorder (OCD).

Design

A randomized, parallel-group clinical trial with a sample size of 25 children, designed to compare the effectiveness of ACT versus risperidone in treating pediatric OCD. Participants are randomized into two intervention arms with concealed allocation. This is a single-center study with outcome assessment conducted by evaluators over a 12-week period.

Settings and conduct

The trial is conducted at the Clinical Research Unit of Kargarnejad Psychiatric Hospital, Kashan University of Medical Sciences. Participants attend weekly sessions for therapy or medication monitoring. Asessors are aware of group allocation. Also participants and therapists are aware of the interventions.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Children aged 7 to 12 years. Diagnosed with obsessive-compulsive disorder (OCD) based on DSM-V criteria. Y-BOCS score of 16 or higher. Ability to participate in weekly sessions and assessments over a 12-week period. Exclusion Criteria: Presence of psychotic disorders or bipolar disorder. Severe physical illness Concurrent psychiatric therapy or medication for OCD. Diagnosis of intellectual disability, autism spectrum disorder, or ADHD.

Intervention groups

Group 1: Risperidone Monotherapy Group 2: Acceptance and Commitment Therapy (ACT)

Main outcome variables

Primary Outcome: Reduction in total Y-BOCS score to assess OCD symptom severity at weeks 0, 2, 4, 8, and 12. Secondary Outcomes: Change in Y-BOCS score based on illness duration, age, and gender. Reduction in compulsive behaviors and distress per Y-BOCS subscales.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241013063349N1**
Registration date: **2024-11-09, 1403/08/19**
Registration timing: **retrospective**

Last update: **2024-11-09, 1403/08/19**
Update count: **0**

Registration date

2024-11-09, 1403/08/19

Registrant information

Name

fada tolooee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4601 8290

Email address

fada.gp1373@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-15, 1402/03/25

Expected recruitment end date

2023-07-21, 1402/04/30

Actual recruitment start date

2023-06-18, 1402/03/28

Actual recruitment end date

2023-07-12, 1402/04/21

Trial completion date

2023-10-22, 1402/07/30

Scientific title

A comparative study on the efficacy of Acceptance and Commitment Therapy(ACT) and Risperidone in treatment of children with Obsessive-Compulsive Disorder

Public title

Acceptance and Commitment Therapy and Risperidone in Obsessive-Compulsive Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 7 to 12 years Yale-Brown Obsessive-compulsive Rating scale greater or equal to 16 A diagnosis of Obsessive-Compulsive Disorder according to DSM-5 criteria by a child and adolescent psychiatrist

Exclusion criteria:

Diagnosis of psychotic disorders Diagnosis of bipolar disorder Diagnosis of autism spectrum disorders Diagnosis of intellectual disabilities Any medical condition in which risperidone is contraindicated Any current psychotherapy

Age

From **7 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **19**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling method is randomly selected by permuted block randomized method with 4 blocks. Based on the table of random numbers, four samples of one of the blocks with the sequence AABB, BBAA, BAAB, BABA are selected. The letter A means assigning the individual to the ACT group and the letter B means assigning the individual to the risperidone group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committee of Kashan University of Medical Sciences

Street address

Qotb-e-Ravandi Blvd

City

Kashan

Province

Isfehan

Postal code

8715973474

Approval date

2023-06-11, 1402/03/21

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1402.054

Health conditions studied

1

Description of health condition studied

Obsessive-Compulsive Disorder

ICD-10 code

F42

ICD-10 code description

Obsessive-compulsive disorder

Primary outcomes

1

Description

Yale-Brown Obsessive-Compulsive Scale Score

Timepoint

At the beginning of the study (before the start of the intervention) and weeks 2, 4, 8 and 12 after the intervention

Method of measurement

Yale-Brown Obsessive- Compulsive Questionnaire

Secondary outcomes

1

Description

Change in Y-BOCS score based on the duration of illness in children.

Timepoint

Baseline (week 0), week 2, week 4, week 8, and week 12

Method of measurement

Y-BOCS score categorized by illness duration at each timepoint.

2

Description

Change in Y-BOCS score across different age groups of children.

Timepoint

Baseline (week 0), week 2, week 4, week 8, and week 12.

Method of measurement

Y-BOCS scores analyzed by age groups at each timepoint

3

Description

Gender-based comparison of Y-BOCS score changes in children

Timepoint

Baseline (week 0), week 2, week 4, week 8, and week 12.

Method of measurement

Y-BOCS scores assessed and compared by gender at each timepoint.

4

Description

Reduction in compulsive behavior score within the Y-BOCS, specifically addressing time spent on obsessive thoughts and the extent of distress caused.

Timepoint

Baseline (week 0), week 2, week 4, week 8, and week 12.

Method of measurement

Y-BOCS subscale specific to compulsive behavior dimensions, focusing on time, distress level, and interference with daily life.

Intervention groups

1

Description

Intervention group: Prescription of Risperidone manufactured by Poursina Pharmaceutical Company with an average dose of 1 mg per day for 12 weeks

Category

Treatment - Drugs

2

Description

Intervention group: Conducting Acceptance and Commitment Therapy(ACT) in 10 two-hour group sessions once a week. In the Acceptance and Commitment Therapy, Hayes Strosahl and Wilson's therapy manual was used, and a trained therapist was used to organize and conduct ACT group sessions.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Kargarnejad Educational and Medical Center

Full name of responsible person

Fatemeh Assarian

Street address

Kargarnejad Educational and Medical Center, End of Parastar Boulevard, Qotb Ravandi Highway, Kashan, Isfehan,Iran

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fa_assar@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr Gholamali Hamidi

Street address

Kashan University of Medical Sciences, Research Vice-Chancellor’s Office,5th kilometer, Qotb Ravandi Boulevard, Kashan, Iran

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8715988141

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research@kaums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person
Fada Tolouee

Position
Non-faculty Specialist Physician

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

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Kargarnejad Educational and Medical Center, End of Parastar Boulevard, Qotb Ravandi Highway, Kashan, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Fatemeh Assarian

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Psychiatrics

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Person responsible for updating data

Contact

Name of organization / entity
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Position
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Subspecialist

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not 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
Comparison of the Effectiveness of Acceptance and Commitment Therapy (ACT) and Risperidone in Children with Obsessive-Compulsive Disorder Referred from Psychiatric Clinics in Kashan Details on Data to be Shared: For individual participant data (IPD) sharing, the following deidentified data sets are available: Primary Outcome Data: Complete deidentified IPD related to the primary outcome, specifically Y-BOCS scores at each timepoint (weeks 0, 2, 4, 8, and 12). Secondary Outcome Data: Deidentified data on secondary outcomes, including Y-BOCS scores categorized by illness duration, age group, gender, and other specific obsessive-compulsive dimensions. Participant Demographics and Baseline Characteristics: Deidentified data including age, gender, illness duration, and baseline Y-BOCS scores. If additional details or data specifications are needed, please let me know.

When the data will become available and for how long
The deidentified IPD and supporting documents will become available 6 months after the publication of the summary results. Access to the data will remain open for a period of 5 years following the initial availability date. Start Date: 6 months post-publication of summary data. End Date: 5 years from the start date of availability. After this period, requests for data access will be considered

on a case-by-case basis, with priority given to research that significantly contributes to the field.

To whom data/document is available

Deidentified individual participant data (IPD) and additional supporting information/documents will be available to individuals affiliated with academic institutions, healthcare organizations, and research institutions**. Access to the data will be limited to those conducting research in related fields, with a preference for studies aimed at improving mental health treatment, particularly in pediatric populations with obsessive-compulsive disorder (OCD). Requests from individuals affiliated with for-profit businesses or commercial entities will be evaluated on a case-by-case basis, focusing on the research objectives and potential contributions to advancing OCD treatment methodologies.

Under which criteria data/document could be used

Deidentified IPD and supporting documents will be shared under the following access criteria: Types of Analysis: Access will be granted primarily for analyses focused on enhancing understanding or treatment of pediatric obsessive-compulsive disorder (OCD), particularly studies exploring therapy efficacy, treatment mechanisms, or longitudinal symptom tracking. Additional analyses contributing to related mental health fields may also be considered. Request Mechanism: Interested researchers should submit a formal request, detailing their research objectives, proposed analyses, and data handling practices to ensure compliance with data privacy standards. Review and Approval Process: All requests will be reviewed by an ethics and data access committee, composed of academic and clinical professionals in psychiatry and biostatistics. Approval criteria include relevance to OCD research, methodological rigor, data privacy adherence, and potential for advancing the field of pediatric mental health. Only requests meeting these standards will receive data access permissions.

From where data/document is obtainable

Applicants seeking access to the deidentified IPD and supporting documents should contact the Clinical Research Development Unit at Kashan University of Medical Sciences. The preferred communication method is email. Below are the contact details: Email: research.unit@kaums.ac.ir Postal Address: Kargarnejad Educational and Medical Center, End of Parastar Boulevard, Qotb Ravandi Highway, Kashan, Iran Telephone: +98 31 5558 9213Contact Person: Dr. Fatemeh Assarian

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

To obtain access to the requested deidentified IPD and supporting documents, the following steps must be completed: Submission of Request: The applicant submits a detailed request by email to the Clinical Research Development Unit, including a summary of the research proposal, data requirements, and intended analyses. Estimated Time: 1-2 business days for submission. Initial Review: Upon receipt, an initial review will be conducted by the data access coordinator to verify completeness and relevance to the study's criteria. Estimated Time: 3-5 business days. Ethics and Scientific Review: The request is forwarded to the ethics and scientific review committee, which evaluates the proposed research for ethical compliance, relevance to OCD research, and data privacy protection. Estimated Time: 2-3 weeks. Approval Notification: The applicant receives a notification regarding the approval or denial of the request. If approved, additional documentation, such as a data use agreement, may be required. Estimated Time: 2-3 business days after committee review. Data Access Setup: Following approval, data access is arranged through secure means, such as encrypted file sharing or on-site access as applicable. Estimated Time: 3-5 business days. Total Estimated Time: Approximately 4-6 weeks from initial request submission to data access setup, depending on the specifics of the review process and data handling requirements. Applicants are encouraged to account for this timeline when planning their research projects.

Comments