Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of Unified Protocol for Transdiagnostic Treatment in Children with Anxiety Disorders

Protocol summary

Study aim

The main objective: Effectiveness of Unified Protocol for Transdiagnostic Treatment (UP-C) in Children with Anxiety Disorders. Specific Objectives: Comparison of the effectiveness of UP-C and CBT on children's anxiety symptoms, children's emotion regulation, cognitive reassessment and emotional suppression in children with anxiety disorders.

Design

Randomized clinical trial (RCT) study.This research method is a pre-test, post-test, and follow-up with two experimental and control groups. Participants will be randomly assigned to two experimental and control groups.

Settings and conduct

The research site is the clinic of Iran University of Medical Sciences. After a diagnostic interview with the participants in the research and providing the necessary ethical explanations and obtaining informed consent from the child and parent of the participants enter the research. They will be randomly divided into two groups of 15 experimental and control. The experimental group receive individual sessions based on UP-C and the control group receive individual sessions of CBT. In the pre and post-test stage, participants answer the questionnaires. The questionnaires will be completed again after a three-month follow-up period.

Participants/Inclusion and exclusion criteria

Children between the ages of 8 and 12 who receive a diagnosis of anxiety disorder based on a KSADS-PL diagnostic interview and who do not take psychiatric medication to treat anxiety disorders can be included in the study.

Intervention groups

The experimental group receive Barlow unified protocol for transdiagnostic treatment (15 sessions)و and the control group receive usual treatment, that is children's cognitive behavioral therapy (16 sessions).

Main outcome variables

Symptoms and Signs of Anxiety Disorders in children, Cognitive Reassessment, Emotion Regulation, Emotional Suppression

General information

Reason for update

Acronym

UP-C

IRCT registration information

IRCT registration number: **IRCT20210723051963N1**
Registration date: **2021-11-06, 1400/08/15**
Registration timing: **prospective**

Last update: **2021-11-06, 1400/08/15**
Update count: **0**

Registration date

2021-11-06, 1400/08/15

Registrant information

Name

Pantea Ahadian Fard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 1616

Email address

pantea.ahadian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of Unified Protocol for Transdiagnostic Treatment in Children with Anxiety Disorders

Public title
Effectiveness of Unified Protocol for Transdiagnostic Treatment in Children with Anxiety Disorders
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 8 and 12 Receive a diagnosis of anxiety disorder based on a KSADS-PL diagnostic interview Do not take psychiatric medication to treat anxiety disorders
Exclusion criteria:
Co-occurrence of depressive disorder based on KSADS-PL diagnostic interview. Existence of developmental neurological disorders such as autism spectrum disorder and mental retardation based on parental report and KSADS-PL diagnostic interview. History of receiving psychotherapy for anxiety disorders in the last 2 years Existence of serious suicidal ideation in KSADS-PL5 diagnostic interview. Diagnosis or history of bipolar disorder or psychosis based on KSADS-PL diagnostic interview. Diagnosis of externalized disorders (coping disorders, conduct and attention deficit hyperactivity disorder) based on KSADS-PL diagnostic interview. Get a diagnosis or previous history of reading disorders
Age
From **8 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Among the children referred to the clinic of Tehran Psychiatric Institute, children 8 to 12 years old who will be interviewed with K-SADS-PL semi-structured interview with complaints of anxiety symptoms and those children who receive a diagnosis of anxiety disorders and considering the inclusion and exclusion criteria, enter into research after obtaining informed consent. These children based on restricted randomization are divided into experimental and control groups. Restricted randomization can be used when the researchers wish that all study groups have the same sample size. In this research, the random allocation rule of the restricted randomization method will be used. The random allocation rule is the simplest method of restricted randomization. In this method, a large block is used for the total sample size, so that at the end of the study, the balance in the number of people assigned to each group is observed. To do this, the researchers first determine the total sample size, then randomly assign a set of them to the experimental group and assign the remainder to the control group. For example, in this study, with a sample size of 30 people, 15 people for the intervention group and 15 people for the control group, a lottery bowl is placed and then the names are removed from the container randomly and replaced.
Blinding (investigator's opinion)
Single blinded
Blinding description
statistical analysis is blind to the research process so that data analysis can be done without bias.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
No 1, Mansouri Ave, Niayesh St, Sattarkhan
City
Tehran
Province
Tehran
Postal code
1445613111
Approval date
2021-03-16, 1399/12/26
Ethics committee reference number
IR.IUMS.REC.1399.1433

Health conditions studied

1

Description of health condition studied
Social phobias
ICD-10 code
F40.1
ICD-10 code description
Social phobias

2

Description of health condition studied
Generalized anxiety disorder
ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

3

Description of health condition studied

Specific (isolated) phobias

ICD-10 code

F40.2

ICD-10 code description

Specific (isolated) phobias

4

Description of health condition studied

Separation anxiety disorder of childhood

ICD-10 code

F93.0

ICD-10 code description

Separation anxiety disorder of childhood

5

Description of health condition studied

Panic disorder

ICD-10 code

F41.0

ICD-10 code description

Panic disorder [episodic paroxysmal anxiety] without agoraphobia

6

Description of health condition studied

Agoraphobia

ICD-10 code

F40.0

ICD-10 code description

Agoraphobia

Primary outcomes

1

Description

Anxiety Symptoms in Children

Timepoint

Beginning of study, end of study, follow-up after three months

Method of measurement

Screen for Child Anxiety Related Disorders & Kiddie Schedule for Affective Disorders and Schizophrenia and Adolescents & Children's Emotional Management Scales

2

Description

Emotion Regulation

Timepoint

Beginning of study, end of study, follow-up after three months

Method of measurement

Emotion Regulation Questionnaire for Children and Adolescents

3

Description

cognitive reappraisal

Timepoint

Beginning of study, end of study, follow-up after three months

Method of measurement

Emotion Regulation Questionnaire for Children and Adolescents

4

Description

expressive suppression

Timepoint

Beginning of study, end of study, follow-up after three months

Method of measurement

Emotion Regulation Questionnaire for Children and Adolescents

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Unified Protocol for Transdiagnostic Treatment in Children (UP-C)

Category

Treatment - Other

2

Description

Control group: Cognitive Behavior Therapy

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Institute of Psychiatry

Full name of responsible person

Pantea Ahadianfard

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Shahid Mansouri Street, Niyayesh Street, Satarkhan Avenue

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Sponsors / Funding sources

1

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Name of organization / entity
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research-m@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
1
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
Iran University of Medical Sciences
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Pantea Ahadianfard
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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