

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 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), 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

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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

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No 1, Mansouri Ave, Niayesh St, Sattarkhan

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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

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 & Children's Emotional Management Scales

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

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Sponsors / Funding sources

1

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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

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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