

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### Effectiveness of unified protocol for transdiagnostic treatment on improving psychopathological symptoms and quality of life in children with emotional disorders

#### Protocol summary

##### Study aim

Effectiveness of unified protocol for transdiagnostic treatment on improving psychopathological symptoms and quality of life in children with emotional disorders

##### Design

Clinical trial with control group, with parallel group, one-sided blind with randomized group

##### Settings and conduct

Treatment is individual or group and with the presence of one or both parents. Children are encouraged to learn the skills of this protocol, which are developed and organized around the identification of emotions and awareness of thoughts and emotions and the experience of emotions to solve the puzzle of their emotions. The place of study is the first and second elementary schools of Kermanshah city.

##### Participants/Inclusion and exclusion criteria

Include Criteria; Age group 8 to 13 years. Early diagnosis of anxiety disorders or depression. Consent of the child and the parent(s) Exclude Criteria:

##### Intervention groups

The intervention group receives 15 weekly sessions of individual 50-minute treatment, in schools and by a trained therapist. The presence of one or both parents in the treatment process is mandatory. Assessments will be performed before the intervention, after the intervention and 2 months after the intervention. The control group receives psychological training. Psychological training, relaxation techniques are provided to reduce the level of stress and stress. The control group will receive integrated meta-diagnostic therapy (UP\_C) after the end of the study.

##### Main outcome variables

Revised Child Anxiety and Depression Scale(RCADS)  
Pediatric Quality of Life Inventory Achenbach Behavior Inventory Score (CBCL)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180421039369N5**

Registration date: **2021-01-11, 1399/10/22**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-01-11, 1399/10/22**

Update count: **0**

##### Registration date

2021-01-11, 1399/10/22

##### Registrant information

##### Name

Nasrin Jaberghaderi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3427 4622

##### Email address

nasrin.jaberghaderi@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-11-10, 1399/08/20

##### Expected recruitment end date

2021-01-19, 1399/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Effectiveness of unified protocol for transdiagnostic treatment on improving psychopathological symptoms and quality of life in children with emotional disorders

## Public title

Effectiveness of unified protocol for transdiagnostic treatment on improving psychopathological symptoms and quality of life in children with emotional disorders

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Existence of primary diagnosis of anxiety disorders or depression  
Consent of the child and the parent(s) to participate in the treatment and research process  
Age 8 to 13 years  
Ability of parents and children to read, write and speak Persian

### Exclusion criteria:

Recurrence of psychological sign and symptoms before the start of the treatment process and after sampling  
Simultaneous infection with another disease  
Therapy with medicine or ECT

## Age

From **8 years** old to **13 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Outcome assessor
- Data analyser

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

Randomized

## Randomization description

After selecting the samples based on entry criteria, the random sample of the samples is sampled in a sealed envelope. Ultimately, people are assigned to the control and test group

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Blinding will only happen for the statistical analyst and data collector. In this way, after the assessment and disease, the sample is entered into the study and for each assessment or evaluation by another person who is not in the process of treatment and study. Information and data also will be coded and given to the statistical analyst for any necessary measurements without any personal details.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

##### Street address

In front of Taleghani Hospital, Naft square

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

56423-22222

##### Approval date

2020-11-04, 1399/08/14

##### Ethics committee reference number

IR.KUMS.REC.1399.814

## Health conditions studied

### 1

#### Description of health condition studied

Emotional disorders in children

#### ICD-10 code

F93

#### ICD-10 code description

Emotional disorders with onset specific to childhood

## Primary outcomes

### 1

#### Description

Children's Anxiety and Depression score

#### Timepoint

pre-test, post-test, follow-up

#### Method of measurement

Revised Children's Anxiety and Depression Scale

### 2

#### Description

children's quality of life score

#### Timepoint

pre-test, post-test, follow-up

#### Method of measurement

Children's Quality of Life Questionnaire

### 3

#### Description

Child Behavior Checklist - Akhenbakh

#### Timepoint

pre-test, post-test, follow-up

#### Method of measurement

Child Behavior Checklist of scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Experimental or intervention group, treatment plan will be done in 15 sessions of individual therapy (50 minutes per session) by the researcher and psychotherapist who has received the necessary training in the implementation of this treatment. The presence of one or both parents in the treatment process is mandatory.

#### Category

Rehabilitation

### 2

#### Description

Control group: The number of members of the control group is 15 people. Participants are trained during the treatment sessions of the experimental group. These trainings make children and their parents aware of the nature of the problems they are involved in, if necessary and in case of aggravation of symptoms, along with psychological trainings, relaxation techniques to reduce the level of stress and psychological stress. Members of the control group will receive integrated meta-diagnostic therapy (UP\_C) after the end of the study.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Department of Education of Kermanshah Province

##### Full name of responsible person

Nasrin JaberGhaderi

##### Street address

Department of Education of Kermanshah province, Farhangian1 Blv, Shahid Mostafa Emami Avenu, Kermanshah, Iran

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

49564-39936

##### Phone

+98 83 3822 6451

##### Email

Pardis.jm7374@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Reza Khodarahmi

##### Street address

Kermanshah University of Medical Science, Sepah Square, Shahid Beheshti Blv, Kermanshah, Iran.

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

4562388887

##### Phone

+98 83 3838 4180

##### Email

pardis.jm7374@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

##### Full name of responsible person

Pardis Jamshid Mofid

##### Position

Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Psychology

##### Street address

Faculty of Medical, Sorkhe lize Ave, Parastar Blvd

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

8614733481

##### Phone

0918723036

##### Email

pardis.jm7374@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Nasrin JaberGhaderi

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

**Street address**

Medical School, Kermanshah University of Medical Sciences, Parastar Blvd

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

671451568

**Phone**

+98 83 3887 4371

**Email**

n\_jg2004@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Nasrin JaberGhaderi

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

**Street address**

Medical School, Kermanshah University of Medical Sciences, Parastar Blvd

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

671451568

**Phone**

+98 83 3887 4371

**Email**

n\_jg2004@yahoo.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

Not applicable

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available