

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### Comparison of the Effectiveness of unified protocol adolescents (UP\_A) with music therapy and mindfulness as an adjunct treatment of UP\_A in Improving Psychological Symptoms in adolescents with emotional disorders.

#### Protocol summary

##### Study aim

Comparison of the Effectiveness of unified protocol for adolescents (UP\_A) with Music Therapy and mindfulness as an adjunct treatment of UP\_A in Improving Psychological Symptoms in adolescents with emotional disorders.

##### Design

Randomized, with a sample size of 90, a clinical trial with a control group.

##### Settings and conduct

This treatment consists of three groups (two intervention groups and one control group). One group receives UP-A treatment with mindfulness, Another group receives UP-A with music therapy, and the control group that receives only UP-A treatment. This treatment is grouped and each group consists of 30 people. Mindfulness therapy is based on the self-help book "Sitting Like a Frog". The music content is basically a child's music that is selected after consultation with a number of musicians and psychologist. This study is without blindness.

Treatment is done at Farabi Hospital.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: adolescents with emotional disorders; In the age range of eleven to sixteen years; Exclusion criteria: Lack of medication during intervention; Not attending all treatment sessions

##### Intervention groups

Patients are randomly divided into two experimental groups and one control group, and the treatment program will be provided to experimental groups for 15 sessions, and the control group will receive only UP\_A treatment. one of the experimental groups UP\_A plus mindfulness and another group UP\_A plus music therapy received.

##### Main outcome variables

Anxiety, depression, stress.

#### General information

##### Reason for update

Because the control group did not receive treatment, to follow the moral principles, it was decided that this group would also receive treatment

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180205038630N2**

Registration date: **2018-07-24, 1397/05/02**

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

Last update: **2020-04-28, 1399/02/09**

Update count: **1**

##### Registration date

2018-07-24, 1397/05/02

##### Registrant information

##### Name

Ali Akbar Foroughi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3837 4371

##### Email address

aliakbar.foroughi@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-07-23, 1397/05/01

##### Expected recruitment end date

2018-09-23, 1397/07/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the Effectiveness of unified protocol adolescents (UP\_A) with music therapy and mindfulness as an adjunct treatment of UP\_A in Improving Psychological Symptoms in adolescents with emotional disorders.

**Public title**

Comparison of the Effectiveness of UP\_A with music therapy and mindfulness as an adjunct treatment of UP\_A

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Students with emotional disorders The age range is 11-16 years

**Exclusion criteria:**

Receiving the medication during the intervention Lack of participation in all treatment sessions

**Age**

From **11 years** old to **16 days** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

By simple random method individuals are assigned to the control and test groups using sealed envelope

**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**

Ethics committee of kermanshah University of Medical Sciences

**Street address**

No 6715847141, Shahid Beheshty Ave, In Front Of Imam Ali Hospital, Building No. 2 of Medical University, Kermanshah

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**Postal code**

6715847141

**Approval date**

2018-06-20, 1397/03/30

**Ethics committee reference number**

IR.KUMS.REC.1397.178

**Health conditions studied****1****Description of health condition studied**

Attention deficit-hyperactivity disorder

**ICD-10 code**

F90

**ICD-10 code description**

Attention-deficit hyperactivity disorders

**2****Description of health condition studied**

Social anxiety disorder of childhood

**ICD-10 code**

F93.2

**ICD-10 code description**

Social anxiety disorder of childhood

**3****Description of health condition studied**

Phobic anxiety disorder of childhood

**ICD-10 code**

F93.1

**ICD-10 code description**

Phobic anxiety disorder of childhood

**4****Description of health condition studied**

Unsocialized conduct disorder

**ICD-10 code**

F91.1

**ICD-10 code description**

Unsocialized conduct disorder

**Primary outcomes****1****Description**

Score in the Aggression Questionnaire

**Timepoint**

At the beginning of the study, after the end of the intervention and two months after the study

**Method of measurement**

Bass & Perry the aggression Questionnaire

(SCARED)

## 2

### **Description**

Score in the teenage inventory of social skills

### **Timepoint**

At the beginning of the study, after the end of the intervention and two months after the study

### **Method of measurement**

Inderbitzen & Foster The teenage inventory of social skills

## 3

### **Description**

Depression score in depression, anxiety, stress scale

### **Timepoint**

At the beginning of the study, after the end of the intervention and two months after the study

### **Method of measurement**

Depression, anxiety, stress scale (DASS)

## 4

### **Description**

Anxiety score in depression, anxiety, stress scale

### **Timepoint**

At the beginning of the study, after the end of the intervention and two months after the study

### **Method of measurement**

Depression, anxiety, stress scale (DASS)

## 5

### **Description**

Stress score in depression, anxiety, stress scale

### **Timepoint**

At the beginning of the study, after the end of the intervention and two months after the study

### **Method of measurement**

Depression, anxiety, stress scale (DASS)

## 6

### **Description**

Score in Clinician global impression-severity scale

### **Timepoint**

At the beginning of the study, after the end of the intervention and two months after the study

### **Method of measurement**

Clinician global impression-severity scale (CGI-S)

## 7

### **Description**

Score in the screen for child anxiety related emotional Disorders (SCARED)

### **Timepoint**

At the beginning of the study, after the end of the intervention and two months after the study

### **Method of measurement**

screen for child anxiety related emotional Disorders

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

First intervention group: For fifteen weeks receives unified protocol adolescents (UP-A) plus mindfulness.

#### **Category**

Behavior

### 2

#### **Description**

Second intervention group: For fifteen weeks receives unified protocol adolescents (UP-A) plus music therapy

#### **Category**

Behavior

### 3

#### **Description**

Control group: it only receives UP\_A treatment

#### **Category**

N/A

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Kermanshah university of medical sciences

##### **Full name of responsible person**

Dr. Aliakbar Foroughi

##### **Street address**

Shahid Shiroudi Blvd - University Street - Nursing Blvd  
- School of Medicine

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Kermanshah University of Medical Sciences

##### **Full name of responsible person**

Farid Najafi

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Building No. 2 of Medical University, Shahid Beheshti  
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**Grant name**

**Grant code / Reference number**

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

No

**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**

Shahram Amiri

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

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school, Parastar Blvd

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## Person responsible for scientific inquiries

**Contact**

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**Position**

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## 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**

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