

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)

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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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Kermanshah

Province

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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-5)

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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

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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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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