

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Effectiveness of transdiagnostic unified protocol on anxiety symptoms, emotion dysregulation and intolerance of uncertainty in youth with anxiety disorders

#### Protocol summary

##### Study aim

The aim of this study was to evaluate the effectiveness of an integrated transdiagnostic treatment protocol on the symptoms of anxiety, emotion dysregulation and intolerance in adolescents with mental disorders.

##### Design

This research has a control group and an experimental group; no blinding. This treatment was performed on 60 samples. People were placed randomly into two groups by throwing the coin method.

##### Settings and conduct

The statistical population in this study consists of all adolescents aged 15 to 17 years with anxiety disorders in Sanandaj. To select the sample using the target sampling method, 60 adolescents aged 15 to 17 years to patients with mental disorders studying in the academic year 1401-1400 in high schools in Sanandaj who have referred to school counseling centers and are willing to Collaborate. The characteristics of participating in the research will be selected and randomly assigned to the experimental and control groups.

##### Participants/Inclusion and exclusion criteria

Age 15 to 17 years; willingness to cooperation

##### Intervention groups

The integrated metadiagnostic treatment protocol includes 8 modules. This protocol is a type of cognitive-behavioral therapy focused on emotion, which is designed for people with emotional disorders, especially people with anxiety disorders. In order to comply with the ethical principles of the research, after the completion of the treatment period, the control group will also receive the mentioned intervention.

##### Main outcome variables

Anxiety symptoms, emotion dysregulation, and intolerance of ambiguity.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220303054173N1**

Registration date: **2022-08-09, 1401/05/18**

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

Last update: **2022-08-09, 1401/05/18**

Update count: **0**

##### Registration date

2022-08-09, 1401/05/18

##### Registrant information

##### Name

Saman Ezati

##### Name of organization / entity

The University of Kurdistan

##### Country

Iran (Islamic Republic of)

##### Phone

+98 87 3562 3220

##### Email address

samanezatii1372@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-07-31, 1401/05/09

##### Expected recruitment end date

2022-08-31, 1401/06/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Effectiveness of transdiagnostic unified protocol on anxiety symptoms, emotion dysregulation and intolerance of uncertainty in youth with anxiety disorders

### Public title

Effectiveness of transdiagnostic unified protocol on anxiety symptoms, emotion dysregulation and intolerance of uncertainty in youth with anxiety disorders

### Purpose

Prevention

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Age 15 to 17 Evidence of diagnosis of comorbid anxiety disorders according to DSM-5 criteria based on psychiatrist or clinical psychologist diagnosis according to structured interview SCID-5 Do not take sedatives Failure to receive other therapeutic interventions at the same time as the present study

#### Exclusion criteria:

A diagnosis other than anxiety disorders Lack of parental consent The teenager's lack of consent Not being a student this year

### Age

From **15 years** old to **17 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

Randomized

### Randomization description

In this research, in order to randomize the coin toss method, which is usually used to create a random sequence in two-group trials, in such a way that one of the Rashir study groups and the other group are considered as lines and based on the desired sample size. We threw the same number of coins and randomly assigned people to two groups.

### 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

Research Ethics Committees of university of kurdistan

#### Street address

Resalat St., Ahmad Fani Blvd., Nehzat Apartment, Block 7, No. 4

#### City

Sanandaj

#### Province

Kurdistan

#### Postal code

6617775864

### Approval date

2022-01-07, 1400/10/17

### Ethics committee reference number

IR.UOK.REC.1400.033

## Health conditions studied

1

### Description of health condition studied

Anxiety symptoms

### ICD-10 code

### ICD-10 code description

## Primary outcomes

1

### Description

anxiety symptoms

### Timepoint

Pre-test-post-test -6 months follow-up

### Method of measurement

(YAM)DSM-5,(ERQ-C),(IUSC-12),(PSWQ-C)

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: This group underwent integrated meta-diagnostic treatment for 12 sessions. This treatment consists of 8 modules, each session is one hour long.

### Category

Diagnosis

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Zanyaran School-Pooyesh School

**Full name of responsible person**

Saman Ezzati

**Street address**

Qaradian Street

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

6617775864

**Phone**

+98 87 3562 3220

**Email**

samanezatii1372@gmail.com

**Position**

Senior students

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

**Street address**

Qaradian Street

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

6617775864

**Phone**

+98 87 3562 3220

**Email**

samanezatii1372@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

The University of Kordestan

**Full name of responsible person**

Jamal Mohamadi

**Street address**

Qaradian Street

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

6617775864

**Phone**

+98 87 3562 3220

**Email**

samanezatii1372@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

The University of Kordestan

**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**

The University of Kordestan

**Full name of responsible person**

Saman Ezzati

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

The University of Kordestan

**Full name of responsible person**

Saman Ezzati

**Position**

Senior students

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

**Street address**

Qaradian Street

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

6617775864

**Phone**

+98 87 3562 3220

**Email**

samanezatii1372@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

The University of kurdestan

**Full name of responsible person**

Saman Ezzati

**Position**

Senior students

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

**Street address**

Qaradian Street

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

6617775864

**Phone**

+98 87 3562 3220

**Email**

samanezatii1372@gmail.com

## Sharing plan

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is 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**

Yes - There is 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

**Title and more details about the data/document**

Information about the main message and the like will be shared.

**When the data will become available and for how long**

Start of access period from 1401م

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

Acquire scientific information in the framework laws

**From where data/document is obtainable**

SAMAN EZATI samanezatii1372@gmail.com

**What processes are involved for a request to access data/document**

Legal cases and within its framework

**Comments**