

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

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Qaradian Street

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Postal code

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Email

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Position

Senior students

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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

The University of Kordestan

Full name of responsible person

Jamal Mohamadi

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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

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

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Other areas of specialty/work

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

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Full name of responsible person

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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