

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### The efficacy of Unified Protocol and transdiagnostic mediator factors in reducing students anxiety and depression

#### Protocol summary

##### Summary

Objectives: determine the efficacy of Unified Protocol and transdiagnostic mediator factors in reducing students' anxiety and depression. Study design: Intervention, Random assignment to intervention group and control group, not blinded, without placebo. Method of the study: A) Study population: 350 Zanzan University of Medical Sciences students. Inclusion criteria: Residence in Zanzan while doing research; tending to participate in research and having the cut point in Beck Depression and Anxiety Tests. Exclusion criteria: having previous psychiatry problems; previous history of psychological interventions, especially cognitive-behavioral therapy, over 5 sessions of psychotherapy; missing more than two consecutive sessions in the unified protocol and not attending in one of the three evaluation stages. At first, a sample of 350 students was selected by Convenience Sampling and after initial screening based on the cut point of Beck Depression and Anxiety Tests 32 qualified students was selected and randomly and based on their homogeneity will be divided into two groups of 16 intervention and control. B) Intervention or interventions: In this study, Barlow unified protocol for transdiagnostic treatment will be used. C) Duration of intervention: It will take 6 months. 18 one-hour sessions. D) Initial outcomes and implications of the study: the efficacy of Unified Protocol and transdiagnostic mediator factors in reducing Zanzan University of Medical Sciences students' anxiety and depression.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017072335245N1**

Registration date: **2017-09-02, 1396/06/11**

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

Last update:

Update count: **0**

##### Registration date

2017-09-02, 1396/06/11

##### Registrant information

###### Name

Sahel Khakpoor

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2218 0083

###### Email address

sahelkhakpoor@zums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Zanzan University of Medical Sciences.

##### Expected recruitment start date

2017-08-23, 1396/06/01

##### Expected recruitment end date

2017-09-23, 1396/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The efficacy of Unified Protocol and transdiagnostic mediator factors in reducing students anxiety and depression

##### Public title

The efficacy of Unified Protocol in reducing students anxiety and depression

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: Residence in Zanjan while doing research; tending to participate in research and having the cut point in Beck Depression and Anxiety Tests.

Exclusion criteria: having previous psychiatry problems; previous history of psychological interventions, especially cognitive-behavioral therapy, over 5 sessions of psychotherapy; missing more than two consecutive sessions in the unified protocol and not attending in one of the three evaluation stages.

### **Age**

From **18 years** old to **35 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **32**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **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**

Zanjan University of Medical Sciences Ethics Committee

##### **Street address**

Zanjan University Of Medical Science, Azadi Blvd

##### **City**

Zanjan

##### **Postal code**

#### **Approval date**

2017-08-11, 1396/05/20

#### **Ethics committee reference number**

ZUMS.REC.1396.143

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Anxiety

### **ICD-10 code**

F41.1

### **ICD-10 code description**

Generalized anxiety disorder

### 2

#### **Description of health condition studied**

Depression

### **ICD-10 code**

F32

### **ICD-10 code description**

Depressive episode

## **Primary outcomes**

### 1

#### **Description**

Anxiety

#### **Timepoint**

Pretest, Posttest and Follow up after 2 month

#### **Method of measurement**

Beck Anxiety Inventory

### 2

#### **Description**

Depression

#### **Timepoint**

Pretest, Posttest and Follow up after 2 month

#### **Method of measurement**

Beck Depression Inventory

## **Secondary outcomes**

### 1

#### **Description**

Emotion regulation

#### **Timepoint**

Pretest, Posttest and Follow up after 2 month

#### **Method of measurement**

Difficulties in Emotion Regulation Scale (DERS)

### 2

#### **Description**

Imbalance of uncertainty

#### **Timepoint**

Pretest, Posttest and Follow up after 2 month

#### **Method of measurement**

Imbalance of uncertainty Scale (IUS-12)

### 3

#### **Description**

Avoid Experiences

#### **Timepoint**

Pretest, Posttest and Follow up after 2 month

#### **Method of measurement**

Acceptance and action questionnaire - Second Edition

(AAQ-2)

#### 4

##### **Description**

Negative affection

##### **Timepoint**

Pretest, Posttest and Follow up after 2 month

##### **Method of measurement**

Positive and Negative Affect Scale-Negative Affect (PANAS-NA)

#### 5

##### **Description**

Perceived control

##### **Timepoint**

Pretest, Posttest and Follow up after 2 month

##### **Method of measurement**

Perceived Control Questionnaire

#### 6

##### **Description**

Occupational and social performance

##### **Timepoint**

Pretest, Posttest and Follow up after 2 month

##### **Method of measurement**

Social-Job Adaptation Scale (WSAS)

## **Intervention groups**

#### 1

##### **Description**

Barlow unified protocol for transdiagnostic treatment will be used- 18 one-hour sessions on experimental group.

##### **Category**

Other

#### 2

##### **Description**

No action was not subjected to the control group and intervention.

##### **Category**

N/A

## **Recruitment centers**

#### 1

##### **Recruitment center**

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

Zanjan University of Medical Sciences

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

Omid Saed (PhD)

###### **Street address**

Zanjan University of Medical Sciences, Azadi Blvd

###### **City**

Zanjan

## **Sponsors / Funding sources**

#### 1

##### **Sponsor**

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

Vice chancellor for research, Zanjan University of Medical Sciences

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

Soghrat Faghizade

###### **Street address**

Zanjan University of Medical Sciences, Azadi Blvd

###### **City**

Zanjan

##### **Grant name**

##### **Grant code / Reference number**

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

Yes

##### **Title of funding source**

Vice chancellor for research, Zanjan University of Medical Sciences

##### **Proportion provided by this source**

100

##### **Public or private sector**

*empty*

##### **Domestic or foreign origin**

*empty*

##### **Category of foreign source of funding**

*empty*

##### **Country of origin**

##### **Type of organization providing the funding**

*empty*

## **Person responsible for general inquiries**

##### **Contact**

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

Zanjan University of Medical Sciences

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

Omid Saed

###### **Position**

PhD

###### **Other areas of specialty/work**

###### **Street address**

Beheshti Hospital, Gate the Ark, Sadi Crossroad

###### **City**

Zanjan

###### **Postal code**

###### **Phone**

+98 242433424766

###### **Fax**

###### **Email**

o.saed@zums.ac.ir

###### **Web page address**

## **Person responsible for scientific inquiries**

##### **Contact**

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

Zanjan University of Medical Sciences

**Full name of responsible person**

Sahel Khakpoor Borazjani

**Position**

M.Sc.candidate in clinical psychology

**Other areas of specialty/work****Street address**

Beheshti Hospital, Gate the Ark, Sadi Crossroad.

**City**

Zanjan

**Postal code****Phone**

+98 242433424766

**Fax****Email**

sahelkhakpoor@zums.ac.ir;

khakpoorsahel@gmail.com

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

Zanjan University of Medical Sciences

**Full name of responsible person**

Sahel Khakpoor Borazjani

**Position**

M.Sc.candidate in clinical psychology

**Other areas of specialty/work****Street address**

Beheshti Hospital, Gate the Ark, Sadi Crossroad

**City**

Zanjan

**Postal code****Phone**

+98 242433424766

**Fax****Email**

sahelkhakpoor@zums.ac.ir;

khakpoorsahel@gmail.com

**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*