# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## The Efficacy of Unified Trans diagnostic Therapy in Reducing Worry, Anxiety, Depressive Sympotom and Emotion Regulation in Patients With Generalized Anxiety Disorder

### Protocol summary

**Study aim**
The Efficacy of Unified Trans diagnostic Therapy in Reducing Worry, Anxiety, Depressive Sympotom and Emotion Regulation in Patients With Generalized Anxiety Disorder

**Design**
Semi-experimental research design, pre-test and post-test, two-tiered, twenty patients, randomly divided into two experimental and control groups, each with 10 patients

**Settings and conduct**
The diagnosis was made by a psychiatrist. Psychotherapy was performed by a clinical psychologist. Patients entered the treatment groups with satisfaction and using random numbers table. Anxiety, depression, worry and emotional regulation questionnaires were administered to the two groups. Pre-test and post-test were performed on both groups. The control group received no intervention. Experimental approach was used in the experimental group. The approach was individual.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Being resident in Sanandaj; Having generalized anxiety disorder criterion; Having motivation and satisfaction for attending in sessions; level of education: at least high school diploma; Exclusion criteria: Diagnosis of any comorbid disorders (except for anxiety and depression); having major depressive disorder; having psychotic symptoms and drug abuse and suicidal thoughts: having all symptoms of personality disorders.

**Intervention groups**
Experimental approach was used in the intervention group individually. The control group received no intervention. both groups received medication therapy.

**Main outcome variables**
Anxiety and depression and worry

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20100614004178N3**
Registration date: **2020-01-26, 1398/11/06**
Registration timing: **retrospective**

Last update: **2020-01-26, 1398/11/06**
Update count: **0**

**Registration date**
2020-01-26, 1398/11/06

**Registrant information**

**Name**
Abolfazl Mohammadi
**Name of organization / entity**
Tehran University of Medical Sciences
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2018-03-26, 1397/01/06

**Expected recruitment end date**
2018-09-21, 1397/06/30

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**

empty

**Scientific title**
The Efficacy of Unified Trans diagnostic Therapy in Reducing Worry, Anxiety, Depressive Sympotom and Emotion Regulation in Patients With Generalized Anxiety Disorder

**Public title**
The Efficacy of Unified Transdiagnostic Therapy in Reducing Worry, Anxiety, Depressive Sympotom and Emotion Regulation in Patients With Generalized Anxiety Disorder

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Being resident in sanandaj) Having generalized anxiety disorder symptoms based on psychiatric or clinical psychologists diagnosis according to SCID-1 Having motivation and satisfaction for attending in treatment sessions level of education :Having at least high school diploma

**Exclusion criteria:**
diagnosis of any comorbid disorders except for anxiety and depression which has been mentioned in the research having major depressive disorder (MDD) having psychotic symptoms and drug abuse and suicidal thoughts having all symptoms of personality disorders according to DSM-5

**Age**
From **18 years** old to **50 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **20**

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

**Randomization description**
Samples will be divided into two experimental and control groups using simple random sampling using sealed envelopes. This will provide 20 envelopes with 10 letters on the letter A (the intervention group) and 10 letters on the cards B (control group) and put in the envelope. The envelopes will be mixed together and randomly one of the envelopes will be selected by the patient and assigned to one of the groups accordingly.

**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 Kurdestan University of Medical Sciences

**Street address**
Ave.,Nahid4.,Street Sharifabad

**City**
Sanandaj

**Province**
Kurdistan

**Postal code**
۶۶۱۷۹۳۴۵۸۴

**Approval date**
2017-07-01, 1396/04/10

**Ethics committee reference number**
IR.MUK.REC.1396.5008

## Health conditions studied

### 1

**Description of health condition studied**
Generalized Anxiety Disorder

**ICD-10 code**
F41.1

**ICD-10 code description**
Generalized anxiety disorder

## Primary outcomes

### 1

**Description**
anxiety score in beck anxiety inventory

**Timepoint**
pre and post treatment and after 1month follow up

**Method of measurement**
beck depression inventory 2, beck anxiety inventory,

## Secondary outcomes

### 1

**Description**
Anxiety

**Timepoint**
pre and post treatment and after 3 month fallow up

**Method of measurement**
Beck anxiety inventory

### 2

**Description**
depression

**Timepoint**
pre and post treatment and after 3 month fallow up
**Method of measurement**
beck depression inventory

**3**

**Description**
woryy
**Timepoint**
pre and post treatment and after 3 month fallow up
**Method of measurement**
Pennsylvania worry questionnaire

**4**

**Description**
emotion regulation
**Timepoint**
pre and post treatment and after 3 month fallow up
**Method of measurement**
difficulties in emotion regulation questionnaire

## Intervention groups

**1**

**Description**
Intervention group: En Experimental was participated in transdiagnostic therapy at 8-12 weeks for 1 hours. Therapeutic components of transdiagnostic therapy were including: home work, Positive and Negative Feedback, Summary, Three-System Thriller Model, Emotional Components, Cognitive Distortions, Automatic Thoughts, Ingection PracticeThinking, Downward Arrow, Dysfunctional Attitude Classification, LogicalAnalysis, Analysis of the Utility of Beliefs./ Pre-test and finally post-test were performed on the experimental group
**Category**
Treatment - Other

**2**

**Description**
Control group: In the control group, there was no intervention,Pre-test and post-test were performed on control group.
**Category**
Treatment - Other

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Sanandaj Welfare Psychological Center
**Full name of responsible person**
Shelir Kolahzari
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Safari St.
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## Sponsors / Funding sources

**1**

**Sponsor**
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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**
Shelir Kolahzari
**Proportion provided by this source**
100
**Public or private sector**
Private
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Persons

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Shelir Kolahzari
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Shelir Kolahzari
**Position**
Mental Health
**Latest degree**
Master
**Other areas of specialty/work**

Psychology
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available
**Justification/reason for indecision/not sharing IPD**
dissemination of patient information is not necessary
**Study Protocol**
No - There is not a plan to make this available
**Statistical Analysis Plan**
Yes - There is a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
No - There is not a plan to make this available
**Data Dictionary**
No - There is not a plan to make this available
**Title and more details about the data/document**
original article in journal
**When the data will become available and for how long**
after 6month post treatment
**To whom data/document is available**
report is accessible for researchers
**Under which criteria data/document could be used**
researcher in this field
**From where data/document is obtainable**
corresponding author
**What processes are involved for a request to access data/document**
via email request
**Comments**