

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Efficacy of transdiagnostic group intervention versus anxiety-based cognitive behavioral group therapy in subclinical paranoia: a comparison study

#### Protocol summary

##### Study aim

Determine the efficacy of transdiagnostic intervention compared to anxiety-based cognitive behavioral therapy on reducing paranoid thinking

##### Design

A randomized clinical trial with a control group based on the student community, with parallel groups, one blinded

##### Settings and conduct

In psychotherapy private clinic, blinding was performed for participants, they do not know in which treatment group assigned.

##### Participants/Inclusion and exclusion criteria

The inclusion criteria: age between 18 to 35 years old; subclinical paranoia scoring >1 based on the SCL-90 questionnaire and scoring >40 in the paranoia scale; and being based in Mashhad at the time of group therapy. The main selection criteria, however, was suffering from subclinical paranoia and its consequent dysfunction. Exclusion criteria : substance dependence; a case note DSM-V diagnosis of schizophrenia and any psychotic disorder; already being in receipt of psychological therapy and organic impairments.

##### Intervention groups

The content of transdiagnostic intervention sessions were prepared based on the protocol of Barlow et al. (2011) included emotional awareness, prevention of emotional avoidance and focus to emotional exposure. based on freeman et al. cognitive model, emphasize on anxiety role in formation and maintenance paranoia, and anxiety-based CBT modeled by key and crask(2003) include psychoeducation, relaxation and cognitive restructuring

##### Main outcome variables

Paranoid ideation; general performance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150315021482N4**

Registration date: **2018-06-30, 1397/04/09**

Registration timing: **retrospective**

Last update: **2018-06-30, 1397/04/09**

Update count: **0**

##### Registration date

2018-06-30, 1397/04/09

##### Registrant information

##### Name

Nahid Mojaver

##### Name of organization / entity

Mashhad University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3852 3300

##### Email address

mojavern1@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-08, 1397/01/19

##### Expected recruitment end date

2018-06-19, 1397/03/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Efficacy of transdiagnostic group intervention versus anxiety-based cognitive behavioral group therapy in subclinical paranoia: a comparison study

### Public title

Efficacy of transdiagnostic approach versus cognitive behavioral in paranoid

### Purpose

Education/Guidance

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Subclinical paranoia scoring >1 based on the SCL-90 questionnaire and scoring >40 in the paranoia scale  
Living in Mashhad city at the time of group therapy

#### Exclusion criteria:

Substance dependence A case note DSM-V diagnosis of schizophrenia and any psychotic disorder Already being in receipt of psychological therapy Organic impairments

### Age

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

### Gender

Female

### Phase

2-3

### Groups that have been masked

- Participant

### Sample size

Target sample size: **30**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The randomization sequence was generated in block and the randomization code was written onto sealed numbered envelopes, ensuring that the random assignment of the groups was observed.

### Blinding (investigator's opinion)

Single blinded

### Blinding description

Because of both control and examination group, received the treatment, so the participants did not know in which group they were.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Iran University of Medical

Sciences

### Street address

Iran University of Medical Sciences, Corner of Milad tower, Hemat highway, Tehran City

### City

Tehran

### Province

Tehran

### Postal code

1449614535

### Approval date

2015-12-11, 1394/09/20

### Ethics committee reference number

IR.IUMS.FMD.REC.1394,9211521201

## Health conditions studied

### 1

#### Description of health condition studied

Subclinical paranoia

#### ICD-10 code

F22

#### ICD-10 code description

Delusional disorders

## Primary outcomes

### 1

#### Description

Paranoid ideation

#### Timepoint

pre-intervention, post intervention, 3 months after intervention

#### Method of measurement

In screening Based on score >1 in PAR; sub-scale in SCL90-R and score >40 in Paranoia scale. Totally, in pre-intervention, post- intervention and follow-up, Paranoia scale is used for measure paranoia.

### 2

#### Description

General performance

#### Timepoint

pre-intervention, post intervention, 3 months after intervention

#### Method of measurement

Work and Social Adjustment Scale

## Secondary outcomes

### 1

#### Description

Depression

#### Timepoint

Pre and post intervention and 3 months follow up

#### Method of measurement

Beck depression inventory

## 2

### **Description**

Anxiety

### **Timepoint**

Pre and post intervention and 3 months follow up

### **Method of measurement**

Beck anxiety inventory

## **Intervention groups**

### 1

### **Description**

Intervention group: In the first group, group Transdiagnostic Cognitive Behavioral Therapy (10 sessions) will hold.

### **Category**

Treatment - Other

### 2

### **Description**

Control group: In the second group, group Anxiety Based Cognitive Behavioral Therapy (10 sessions) will hold.

### **Category**

Treatment - Other

## **Recruitment centers**

### 1

### **Recruitment center**

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

Ferdowsi University; Mashhad Payame Nour University

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

Leila Amirpour

#### **Street address**

No. 38, Nastaran 1 St, Malek Abad Blvd, Mashhad

#### **City**

Mashhad

#### **Province**

Razavi Khorasan

#### **Postal code**

9185757696

#### **Phone**

+98 51 3761 2510

#### **Email**

leila.amirpour@gmail.com

## **Sponsors / Funding sources**

### 1

### **Sponsor**

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

Iran University of Medical Sciences

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

Reza Arezumandan

#### **Street address**

School of Behavioral Sciences and Mental Health,

Shahid Mansouri St, Niyayesh St, Satarkhan Ave, Tehran

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1445613111

#### **Phone**

+98 21 6655 1655

#### **Email**

Ertebat.tip@iums.ac.ir

### **Grant name**

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

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

Yes

### **Title of funding source**

Iran 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**

Mashhad University of Medical Sciences

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

Nahid Mojaver

#### **Position**

Bachelor of Science

#### **Latest degree**

Bachelor

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

Medical Informatics

#### **Street address**

Ghaem Hospital, Orthopedic Research Center, Shariati Square, Ahmadabad St, Mashhad

#### **City**

Mashhad

#### **Province**

Razavi Khorasan

#### **Postal code**

91766-99199

#### **Phone**

+98 51 3801 2638

#### **Email**

nahid.mojaver@gmail.com

## **Person responsible for scientific inquiries**

### **Contact**

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Leila Amirpour  
**Position**  
PhD Student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Psychology  
**Street address**  
School of Behavioral Sciences and Mental Health  
Shahid Mansouri St, Niyayesh St, Satarkhan Ave,  
Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1445613111  
**Phone**  
+98 21 6655 1655  
**Email**  
nahid.mojaver@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Nahid.Mojaver@gmail.com  
**Position**  
Bachelor of Science  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Medical Informatics  
**Street address**  
Ghaem Hospital, Orthopedic Research Center,  
Shariati Square, Ahmadabad St, Mashhad  
**City**  
Mashhad  
**Province**

Razavi Khorasan  
**Postal code**  
9176699199  
**Phone**  
+98 51 3801 2638  
**Email**  
nahid.mojaver@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

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Yes - There is 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

Not applicable

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

It is possible to share completed questionnaires file (SPSS version) by the participants in the study.

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

1 year after publish the paper

### To whom data/document is available

All psychologists and psychiatrists (Clinicians) working in the paranoid field

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

For meta-analysis and review articles

### From where data/document is obtainable

linked via leila.amirpour@gmail.com

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

After sending the official application along with the letter of approval of the research project and the applicant's authentication, the file will be sent within one month.

### Comments