# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

06 Nov 2026

## Effectiveness of group therapy based on acceptance and commitment with psychodrama components on social anxiety, shyness and fear of negative evaluations in people with social anxiety disorder

## Protocol summary

**Study aim**

Determination the effectiveness of group therapy based on acceptance and commitment with psychodrama components on social anxiety, shyness and fear of negative evaluations in students with social anxiety symptoms

**Design**

The clinical trial has an intervention group and three control group, randomized and not blind

**Settings and conduct**

The aim of this study was to determination the effectiveness of group therapy based on ACT with psychodrama components on social anxiety, shyness and fear of negative evaluations in students with social anxiety symptoms in Torbat Heydarieh University of Medical Sciences. At first, 48 patients were selected through simple random sampling and then assigned to an intervention group and three control groups using the Random block split method .The intervention group received therapeutic course based on the protocol that fit into social anxiety disorder, by the researcher is designed and used experimentally.The first control group at this stage will receive only ACT treatment.The second control group at this stage will only receive the psychodrama treatment.The third control group will not receive any treatment at this stage.

**Participants/Inclusion and exclusion criteria**

Age of 18 to 60 years Earn the minimum score in a Shyness Questionnaire Earn the minimum cut score in Social Anxiety Inventory Earn the minimum score in a questionnaire for fear of negative evaluations

**Intervention groups**

The intervention group received therapeutic course based on the protocol that fit into social anxiety disorder, by the researcher is designed and used experimentally.The first control group at this stage will receive only ACT treatment.The second control group at this stage will only receive the psychodrama treatment.The third control group will not receive any treatment at this stage.

**Main outcome variables**

social anxiety, shyness and fear of negative evaluation in students

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20181009041282N3**
Registration date: **2018-12-01, 1397/09/10**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-01, 1397/09/10**
Update count: **0**

**Registration date**

2018-12-01, 1397/09/10

**Registrant information**

**Name**

Maliheh Eshaghzadeh

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 51 5222 6011

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2018-11-21, 1397/08/30

**Expected recruitment end date**

2019-02-19, 1397/11/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effectiveness of group therapy based on acceptance and commitment with psychodrama components on social anxiety, shyness and fear of negative evaluations in people with social anxiety disorder

**Public title**

Effectiveness of group therapy based on acceptance and commitment with psychodrama components in people with social anxiety disorder

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Earn the minimum score in a Shyness Questionnaire Earn the minimum cut score in Social Anxiety Inventory Earn the minimum score in a questionnaire for fear of negative evaluations

**Exclusion criteria:**

Unwillingness to cooperate in the study Use of other psychological treatment Having mental or nervous disorders

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **48**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

At first, 48 patients were selected through simple random sampling and then assigned to an intervention group and three control groups using the Random block split method and Randomization.com site.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Factorial

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Torbat Heydarieh University of Medical Sciences

**Street address**

Razi street

**City**

Torbat Heydarieh

**Province**

Razavi Khorasan

**Postal code**

9516915169

**Approval date**

2018-06-24, 1397/04/03

**Ethics committee reference number**

IR.THUMS.REC.1397.008

## Health conditions studied

### 1

**Description of health condition studied**

Social anxiety

**ICD-10 code**

F41

**ICD-10 code description**

Other anxiety disorders

### 2

**Description of health condition studied**

Shyness

**ICD-10 code**

**ICD-10 code description**

### 3

**Description of health condition studied**

Fear of negative evaluations

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

Social Phobia: Refers to the obvious and continuous fear of social and functional situations that results in a negative evaluation of the participation in communication situations and can lead to the remoteness and separation of the individual from the community.

**Timepoint**

The beginning of the study and after the intervention

**Method of measurement**

Social Phobia Inventory

**2**

**Description**
Shyness : The tendency to avoid social interactions and feelings of failure are called proper participation in shyness social situations.
**Timepoint**
The beginning of the study and after the intervention
**Method of measurement**
Stanford Shyness Questionnaire

**3**

**Description**
Fear of negative evaluation: The feeling of apprehension and concern about others' assessments is the concern raised by these negative assessments, expectations and expectations that a person is about others and that others will only judge him negatively, Gets
**Timepoint**
The beginning of the study and after the intervention
**Method of measurement**
Fear of Negative Evaluation Scale

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: The intervention group (combined psychotherapy group) received 12 sessions of 90 minutes and a weekly 2 sessions based on the protocol (based on the protocol for ACT treatment of Hayes and Strosahl and the psychodrama-Dayton protocol) that fit into social anxiety disorder, by the researcher is designed and used experimentally. Acceptance and commitment therapy (ACT) encourages a person to accept what is beyond his control and commitment to social goals. In fact, ACT uses acceptance processes, mindfulness, and change in behavior and commitment to create psychological flexibility.The psychodrama treatment protocol is a group therapy approach that highlights personality traits, interpersonal communication, psychological conflicts, and disorders of individuals through special methods of presentation.
**Category**
Behavior

**2**

**Description**
Control group: The first control group at this stage will receive only ACT treatment for in 10 sessions of two hours for 10 weeks. Acceptance and commitment therapy (ACT) encourages a person to accept what is beyond his control and commitment to social goals. In fact, ACT uses acceptance processes, mindfulness, and change in behavior and commitment to create psychological flexibility.
**Category**
Behavior

**3**

**Description**
Control group: The second control group at this stage will only receive the psychodrama treatment in 10 sessions of two hours for 10 weeks. The psychodrama treatment protocol is a group therapy approach that highlights personality traits, interpersonal communication, psychological conflicts, and disorders of individuals through special methods of presentation.
**Category**
Behavior

**4**

**Description**
Control group: The third control group will not receive any treatment at this stage.
**Category**
N/A

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Torbat Heydarieh University of Medical Sciences
**Full name of responsible person**
Samaneh Eshaghzadeh
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
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**Full name of responsible person**
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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**
Torbate-Heidaria 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**
Torbate-Heidaria University of Medical Sciences

**Full name of responsible person**
Seddigheh Abbaspour

**Position**
Instructor

**Latest degree**
Master

**Other areas of specialty/work**
Nursery

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

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

**Clinical Study Report**
Undecided - It is not yet known if there will be 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