

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 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 Heydariyeh 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)

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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

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Torbate-Heidaria University of Medical Sciences

Full name of responsible person

Hasan Azhdari Zarmehri

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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

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Position

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Latest degree

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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