Comparison of the Effectiveness of Compassion Focused Therapy (CFT) and Acceptance and Commitment Therapy (ACT) in Patients with Generalized Social Anxiety Disorder

Protocol summary

Study aim
The purpose of this study is comparison the effectiveness of Compassion Focused Therapy (CFT) and Acceptance and Commitment Therapy (ACT) in patients with Generalized Social Anxiety Disorder (SAD). The present research is randomized controlled trial study with pre-test, post-test and follow-up along with a control group. 48 patients with SAD was randomly allocated to one of the 3 groups: CFT, ACT and control group. 12 weekly sessions individual intervention based on CFT for one group and 12 weekly sessions individual intervention based on ACT for another group will run. the control group did not receive any treatment. At the beginning of the research, after 12 weeks and after a follow-up period of 8 weeks, research variables will be evaluated.

Design
Clinical controlled trial, pragmatic, parallel group, randomised

Settings and conduct
After the necessary coordination with Tehran Psychiatric Institute's authorities and considering the individuality of the treatments, each member of the sample was randomly assigned to a group through flipping a coin.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Suffering social anxiety disorder; Age range 20-40; Consent to participate in the research; The minimum Diploma education. Exclusion Criteria: Suffering other psychiatric disorders; Suffering severe levels of personality disorders; Severe physical illnesses; The initiation of treatment with psychiatric drugs within the last 3 months or change of drug dose during that time.

Intervention groups
The CFT group received 12 individual treatment sessions based on the Boersma et al protocol (2014). The ACT group received 12 individual treatment sessions based on the Eifert and Forsyth protocol (2005). The control group did not receive any treatment.

Main outcome variables
social anxiety symptoms; self-criticism; psychological flexibility; quality of life; mindfulness; self-compassion

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: IRCT2018060740000N1
Registration date: 2018-06-18, 1397/03/28
Registration timing: retrospective

Last update: 2018-06-18, 1397/03/28
Update count: 0
Registration date
2018-06-18, 1397/03/28

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-12-11, 1396/09/20
Expected recruitment end date
2018-01-20, 1396/10/30
Actual recruitment start date

Comparison of the Effectiveness of Compassion Focused Therapy (CFT) and Acceptance and Commitment Therapy (ACT) in Patients with Generalized Social Anxiety Disorder

Effect of Compassion Focused Therapy (CFT) and Acceptance and Commitment Therapy (ACT) on Social Anxiety Disorder

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
- Suffering social anxiety disorder based on DSM5 diagnostic criteria (in case of other psychiatric diagnoses, SAD diagnosis should have been clearly identified as the primary diagnosis)
- Age between 20-40 years
- Consent to participate in the research and completing the treatment sessions
- The minimum Diploma education

Exclusion criteria:
- Suffering other psychiatric disorders of the first axis that are an obstacle to the treatment of Social Anxiety Disorder (e.g. Psychotic disorders, Bipolar disorder with psychotic features)
- Suffering severe levels of personality disorders with serious communication problems including Schizotypal, Schizoid, Paranoid, Borderline, Antisocial, and Avoidant personality disorders
- Suffering severe physical illnesses such as Cancer and AIDS, whose physical illness should be prioritized for treatment
- The initiation of treatment with psychiatric drugs within the last 3 months or change of drug dose during that time.

Age
- From 20 years old to 60 years old

Gender
- Both

Phase
- N/A

Groups that have been masked
- No information

Sample size
- Target sample size: 52
- Actual sample size reached: 48

Randomization (investigator's opinion)
- Randomized

Randomization description
- Considering the individuality of the treatments, each member of the sample assigned to a group with simple randomization and through flipping a coin.

Blinding (investigator's opinion)
- Not blinded

Blinding description
- Placebo
- Not used

Assignment
- Parallel

Secondary Ids
- empty

Ethics committees

1

Ethics committee
- Name of ethics committee
  - Ethics committee of Iran University of Medical Sciences
- Street address
  - Shahid Hemmat Highway, Tehran
- City
  - Tehran
- Province
  - Tehran
- Postal code
  - 1333813444

Approval date
- 2017-12-08, 1396/09/17

Ethics committee reference number
- IR.IUMS.REC 1396.9211521214

Health conditions studied

1

Description of health condition studied
- Social Anxiety Disorder

ICD-10 code
- F40.11

ICD-10 code description
- Social phobia, generalized

Primary outcomes

1

Description
- Social Anxiety Symptom

Timepoint
- Before intervention, After intervention, After a follow-up period of 8 weeks

Method of measurement
- Liebowitz Social Anxiety Scale (LSAS)

2

Description
- Quality of Life

Timepoint
- Before intervention, After intervention, After a follow-up period of 8 weeks

Method of measurement
- World Health Organization Questionnaire of the Quality of Life (WHOQOL-BREF)
3
Description
Psychological Flexibility

Timepoint
Before intervention, After intervention, After a follow-up period of 8 weeks

Method of measurement
Acceptance and Action Questionnaire-second version (AAQ-II)

4
Description
Self Compassion

Timepoint
Before intervention, After intervention, After a follow-up period of 8 weeks

Method of measurement
Self-Compassion Scale (SCS)

5
Description
Self-Criticism

Timepoint
Before intervention, After intervention, After a follow-up period of 8 weeks

Method of measurement
Level of Self-Criticism Scale (LOSC)

6
Description
Mindfulness

Timepoint
Before intervention, After intervention, After a follow-up period of 8 weeks

Method of measurement
Ryan and Brown’s Mindful Attention Awareness Scale (MAAS)

Secondary outcomes
empty

Intervention groups

1
Description
Intervention group (1st): Compassion Focused Therapy (CFT) group that received 12 individual treatment sessions of one hour based on the Boersma et al. (2014).
Category
Behavior

2
Description
Intervention group (2nd): Acceptance and Commitment Therapy (ACT) group that received 12 individual treatment sessions of one hour based on the Eifert and Forsyth protocol (2005).
Category
Behavior

3
Description
Control group: did not receive any treatment interventions and were merely put on the waiting list.
Category
N/A

Recruitment centers

1
Recruitment center
Name of recruitment center
School of Behavioral Sciences and Mental Health Clinic

Full name of responsible person
Komeil Zahedi Tajrishi

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Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Iran University of Medical Sciences

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
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
Iran University of Medical Sciences
Full name of responsible person
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Ph.D student in clinical psychology
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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
No - There is not 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
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable