Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Feasibility, adaptability and efficacy of the emotional schema model in people with generalized anxiety disorder

Protocol summary

Study aim
Determining the effectiveness of emotional schema therapy on generalized anxiety disorder

Design
The clinical trial of single-subject designs, the second phase will be conducted on 3 patients, one person will be considered as a control, one head will be blinded, and the rand function of Excel software will be used for randomization.

Settings and conduct
At first, the emotional schemas of patients with generalized anxiety disorder will be identified through a questionnaire, then three people will be randomly selected and one person will be considered as a control. First, the patients' baseline is determined through the pre-test, then they will be placed in the treatment process, and the post-test and visual charts will show the changes compared to the baseline. And finally, the effectiveness of the treatment is checked through the examination of visual charts and the comparison of the pre-test and post-test scales of pervasive anxiety and emotional schemas.

Participants/Inclusion and exclusion criteria
Being at least 20 years old and having at least a diploma. Having a diagnosis of generalized anxiety disorder and Having no other psychological disorder Not having a physical disorder and Not under drug treatment

Intervention groups
This research will be a single-subject study and three people will be selected based on the entry criteria and will undergo therapeutic intervention based on the emotional schema therapy protocol, and the effectiveness of the protocol on the symptoms of generalized anxiety disorder will be investigated

Main outcome variables
Determine the effectiveness of emotional schema therapy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180306038973N1**
Registration date: **2023-01-15, 1401/10/25**
Registration timing: **prospective**

Last update: **2023-01-15, 1401/10/25**
Update count: **0**

Registration date
2023-01-15, 1401/10/25

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-12, 1401/12/21

Expected recruitment end date
2023-04-10, 1402/01/21

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Feasibility, adaptability and efficacy of the emotional schema model in people with generalized anxiety disorder

Public title
Efficacy of emotional schema therapy on generalized anxiety disorder
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are diagnosed with generalized anxiety disorder
Exclusion criteria:
having physical illness Having another psychological disorder Being treated with medication
Age
From **20 years** old to **35 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **3**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics committee of Shahed University
Street address
Khalig Fars Highway, Shahed University,Tehran
City
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Province
Tehran
Postal code
3319118651
Approval date
2023-01-02, 1401/10/12
Ethics committee reference number
IR.SHAHED.REC.1401.125

Health conditions studied

1

Description of health condition studied
General Anxiety Disorder
ICD-10 code
F41.1
ICD-10 code description
Generalized anxiety disorder

Primary outcomes

1

Description
The generalized anxiety score in the generalized anxiety scale
Timepoint
Measuring generalized anxiety at the beginning of the study and after ten treatment sessions
Method of measurement
Questionnaire to measure generalized anxiety

Secondary outcomes

empty

Intervention groups

1

Description
The emotional schema therapy protocol was published by Leahy in 2015, which focuses on 14 emotional schemas and uses therapy techniques, including emotion regulation, mindfulness, meta cognitive, and acceptance techniques, to change each emotional schema.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Warsh Psychological Clinic
Full name of responsible person
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Sponsors / Funding sources

1

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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
Shahed University
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
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Professor
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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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Access will be available to researchers working in universities and scientific centers

Under which criteria data/document could be used

People requesting data should be experts in the field of psychological issues Adhere to the principles of confidentiality

From where data/document is obtainable

mm.morvaridi88@gmail.com rasolroshan@yahoo.com

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

Emailing and introducing themselves Explanation of the reason for requesting information The waiting time for reviewing the application and providing a response is one month

Comments