Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A Combined Protocol of Emotional Schema Therapy and Integrated Transdiagnostic Therapy on Brain Executive Functions and Emotional Regulation in People with Generalized Anxiety Disorder

Protocol summary

Study aim

"Evaluating the effectiveness of a combined emotional schema therapy protocol and an integrated transdiagnostic protocol on brain executive functions and emotional regulation in individuals diagnosed with generalized anxiety disorder."

Design

"A single, non-blinded clinical trial on 5 patients."

Settings and conduct

"First, we make an announcement at the Imam Hossein psychiatric clinic. Then, using convenience sampling, we select the sample participants based on the inclusion criteria. Next, for these individuals, both orally and in writing, the research plan and type of treatment are explained, and they will sign a consent form related to the ethics committee. After the individuals' agreement and completion of the relevant questionnaires, we will hold the therapy sessions at Imam Hossein Hospital."

Participants/Inclusion and exclusion criteria

"Individuals diagnosed with generalized anxiety disorder are included in the study, while those with a comorbid psychiatric disorder or any other psychiatric disorder are not included."

Intervention groups

"After evaluating the patients, we proceed to modify their emotional schemas, undertake cognitive restructuring, and provide psychological training on mindfulness, emotional regulation, and cognitive flexibility. After each session, an assignment will be given to the patient to reinforce the teachings and generalize them to everyday life."

Main outcome variables

emotional regulation ; Brain Executive Functions ; Generalized Anxiety Disorder

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230901059319N1**
Registration date: **2023-10-05, 1402/07/13**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-05, 1402/07/13**
Update count: **0**

Registration date

2023-10-05, 1402/07/13

Registrant information

Name
Mahsa Khajooei
Name of organization / entity
Khatam University
Country
Iran (Islamic Republic of)
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Email address
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-13, 1402/06/22

Expected recruitment end date

2023-10-14, 1402/07/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A Combined Protocol of Emotional Schema Therapy and Integrated Transdiagnostic Therapy on Brain Executive Functions and Emotional Regulation in People with Generalized Anxiety Disorder

Public title
Investigating the effectiveness of integrated psychotherapy on generalized anxiety disorder

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Clients to the Imam Hossein psychiatric clinic in Tehran Diagnosed with generalized anxiety disorder (based on a psychiatric specialist's diagnosis) At least 4 weeks should have passed since the medications were stabilized Age range of 20 to 45 years Middle socio-economic level Intermediate level of education (from diploma to bachelor's degree)

Exclusion criteria:
Diagnosed Social anxiety disorder (based on a psychiatric specialist's diagnosis) Patients with delusions and hallucinations (psychosis) Patients with verbal disabilities (due to the impossibility of obtaining information from them) Patients with generalized anxiety disorder who are currently going to psychotherapy sessions. Patients with thyroid problems Patients using drugs Diagnosed with a mental disorder comorbid

Age
From **20 years** old to **45 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **5**

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
Ethics Committee of Shahid Beheshti University

Street address
Shahid Shahriari square., Evin., Tehran

City
Tehran

Province
Tehran

Postal code
1983969411

Approval date
2023-08-29, 1402/06/07

Ethics committee reference number
IR.SBU.REC.1402.087

Health conditions studied

1

Description of health condition studied
Generalized anxiety disorder

ICD-10 code
F41.1

ICD-10 code description
Generalized anxiety disorder

Primary outcomes

1

Description
The score of Executive Functions the short Persian form (Parhun et al., 2023) of the Adult Self-Report of Executive Functions Scale (Roth et al.) is obtained

Timepoint
"Before the start of the study, three times at intervals of one week, then at 3, 6, 9 weeks after the start of psychotherapy sessions, once at the end of the treatment, and once 1 month after the end of therapy sessions."

Method of measurement
Persian version of Adult Executive Functions Scale (normized version of Behavioral Rating of Executive Functions) Roth et al.

2

Description
the score of the Cognitive Emotion Regulation Questionnaire (Garnefski and Kraaij, 2006)

Timepoint
"Before the start of the study, three times at intervals of one week, then at 3, 6, 9 weeks after the start of psychotherapy sessions, once at the end of the treatment, and once 1 month after the end of therapy sessions."

Method of measurement
Cognitive Regulation of Emotion Questionnaire (Garnefski and Kraaij, 2006)

3

Description
the score of the Generalized Anxiety Disorder questionnaire (GAD-7)

Timepoint
"Before the start of the study, three times at intervals of one week, then at 3, 6, 9 weeks after the start of psychotherapy sessions, once at the end of the treatment, and once 1 month after the end of therapy sessions."

Method of measurement
Generalized Anxiety Disorder Scale Questionnaire (GAD-7)

Secondary outcomes

empty

Intervention groups

1

Description
"Intervention group: 5 participants in the research study, diagnosed with generalized anxiety disorder, participate in 10 individual psychotherapy sessions.The duration of each session is one hour. During the sessions Using the integrated protocol of Leahy's emotional schema therapy and Barlow's integrative transdiagnostic therapy , the evaluation and modification of emotional schemas, cognitive reconstruction, training and application of mindfulness, emotional regulation, and cognitive flexibility are addressed. Description of the intervention : Pre- Assessment The first stage involves a comprehensive assessment to evaluate the patient's level of anxiety, emotional regulation abilities, and executive function performance. Standardized assessment tools like the Generalized Anxiety Disorder 7-item (GAD-7) scale, Cognitive Regulation of Emotion Questionnaire (Garnefski and Kraaij, 2006), and Persian version of Adult Executive Functions Scale (Parhun et al., 2023) will be used. Schema Identification : We begin by identifying the patient's schemas that relate to their anxiety, focusing on the cognitive, emotional, and behavioral responses that contribute to their Generalized anxiety disorder. Schema Modification : Through a process of cognitive restructuring, patients are guided to challenge their schemas, change their maladaptive thought patterns, and develop healthier ways of interpreting their experiences.Emotional Regulation Training : We utilize the techniques from Dialectical Behavior Therapy (DBT) and Acceptance and Commitment Therapy (ACT) to teach patients skills to understand and manage their emotions better. Cognitive Flexibility Training : Using a combination of cognitive-behavioral techniques and mindfulness practices, we aim to enhance the patient's ability to shift their attention and adapt their thinking in response to changing circumstances. Schema- Focused Emotional Regulation : After separately working on Emotional Schema Therapy and Integrated Transdiagnostic Therapy , we integrate the two by focusing on schema-focused emotional regulation. This helps patients recognize and alter schemas while simultaneously regulating their emotions. Cognitive Flexibility and Schema Modification: As patients gain better control over their emotional responses, we further integrate cognitive flexibility training within schema modification, which aids them to challenge and change their schemas more effectively.Post- Assessment : The same standardized tools used in the pre-assessment will be employed to evaluate the progress and efficacy of the therapy. Finally, patients are provided with strategies and plans to maintain their gains and cope with potential future stressors. Regular follow-ups are conducted to reinforce the therapy's effectiveness and manage any recurring symptoms

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Hossein Hospital Psychiatry Clinic

Full name of responsible person
Marzieh Hashemi

Street address
No.30, Hakim Azam St., Shiraz North St., Mollasadrah St., Khatam University

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Khatam University

Full name of responsible person
Dr. Bahauddin Shariat

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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

Khatam University

Proportion provided by this source

100

Public or private sector

Private

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

Khatam University

Full name of responsible person

Mahsa Khajooei

Position

Student and intern of psychological and counseling clinic of Khatam University

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Marzie Hashemi

Position

"Assistant Professor of the Department of Psychology and Educational Sciences, Faculty of Humanities

Latest degree

Ph.D.

Other areas of specialty/work

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

"Since the research plan is related to a thesis, only the study protocol, clinical study report, and study results will be published. The participant data file contains information about the participants, and due to the preservation of individuals' privacy, it cannot be published."

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

"The steps of the clinical study, such as the number of participants, the inclusion and exclusion criteria for the research plan, the sampling method, the therapeutic protocol, and the study results, will be detailed in the thesis and article."

When the data will become available and for how long

"Access period starts 6 months after the publication of the results."

To whom data/document is available

"Article reviewers and research and academic individuals."

Under which criteria data/document could be used

"For the purpose of study or research with proper citation."

From where data/document is obtainable

Send an email to the thesis supervisor at hashemi.hs@gmail.com

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

"First, the individual requesting the data sends their request to the provided email address, and the request will be responded to as soon as possible."

Comments