Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing Unified Transdiagnostic Intervention with Acceptance and Commitment Therapy on Sensory Processing Sensitivity, Interpretive Bias, and Experiential Avoidance among Individuals with Functional Seizures

Protocol summary

Study aim
The aim of this study is to compare the effectiveness of Unified Transdiagnostic Intervention and Acceptance and Commitment Therapy on sensory processing sensitivity, interpretive bias, and experiential avoidance in individuals with functional seizures.

Design
This study is a randomized quasi experimental trial with parallel groups and a control group involving 45 participants. Participants will be allocated to three groups using block randomization with a 1:1:1 allocation ratio. Outcome assessors will remain blinded to group allocation. The study phase is not applicable.

Settings and conduct
The study will be conducted at Razi Psychiatric and Neuropsychological Center in Tabriz, Iran. After screening and obtaining informed consent, participants will be randomly assigned to study groups. Assessments will be conducted at pretest, posttest, and three month follow up by outcome assessors blinded to group allocation.

Participants/Inclusion and exclusion criteria
Individuals with functional seizures aged 18 to 55 years, diagnosed by a psychiatrist or neurologist, with stable medication during the previous three months, ability to read and write Persian, and informed consent will be included. Individuals with severe psychotic disorders, severe neurological comorbidities, inability to participate regularly in treatment sessions, or changes in psychiatric medications during the study will be excluded.

Intervention groups
The first group will receive Unified Transdiagnostic Intervention in 12 weekly group sessions. The second group will receive Acceptance and Commitment Therapy in 8 weekly group sessions. The control group will remain on a waitlist and will not receive structured psychological intervention during the study period.

Main outcome variables
Sensory processing sensitivity; interpretive bias; experiential avoidance

General information

Reason for update

Acronym
UTFS-ACT

IRCT registration information
IRCT registration number: **IRCT20251124068098N1**
Registration date: **2026-05-19, 1405/02/29**
Registration timing: **prospective**

Last update: **2026-05-19, 1405/02/29**
Update count: **0**

Registration date
2026-05-19, 1405/02/29

Registrant information

Name
Somayeh Tajfar

Name of organization / entity
دانشگاه آزاد اسلامی

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Recruitment status
recruiting

Funding source

Expected recruitment start date

2026-06-22, 1405/04/01

Expected recruitment end date

2026-12-22, 1405/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing Unified Transdiagnostic Intervention with Acceptance and Commitment Therapy on Sensory Processing Sensitivity, Interpretive Bias, and Experiential Avoidance among Individuals with Functional Seizures

Public title

Comparison of Unified Transdiagnostic Treatment and Acceptance and Commitment Therapy in Patients with Functional Seizures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of functional seizure disorder by a psychiatrist or neurologist Age between 18 and 55 years Stable medication regimen during the past three months Ability to read and write Persian Providing informed consent for participation

Exclusion criteria:

Severe psychotic disorders Presence of severe neurological disorders Inability to participate regularly in treatment sessions Changes in psychiatric medications during the study

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization with a 1:1:1 allocation ratio will be used. The unit of randomization is the individual participant. After confirming eligibility criteria and obtaining informed consent, participants will be randomly assigned to one of three groups: Unified Transdiagnostic Intervention, Acceptance and Commitment Therapy, or waitlist control group. The random allocation sequence will be generated using statistical software and equal-sized blocks to ensure balanced group sizes. Randomization will be performed by an independent research assistant who is not involved in outcome assessment or intervention delivery. Allocation concealment will be maintained using sequentially numbered, opaque, sealed envelopes. Group assignment will only be revealed after the participant is formally enrolled in the study. Outcome assessors will remain blinded to group allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, outcome assessors and data collectors will be blinded to participants' group allocation. Random assignment will be conducted by an independent researcher, and allocation information will be kept in sealed opaque envelopes. During the pretest, posttest, and follow-up assessments, evaluators will only have access to participants' research codes and will remain unaware of the intervention group assignment. Data analysis will also be conducted using anonymized coded data. Due to the nature of the psychological interventions, blinding of participants and therapists is not feasible, as participants are aware of the type of treatment they receive and therapists directly administer the interventions. However, standardized instructions, structured treatment protocols, and blinded outcome assessment will be used to minimize potential bias.

Placebo

Not used

Assignment

Parallel

Other design features

This study is a quasi-experimental trial with a pretest-posttest design and a three-month follow-up. Participants will be randomly assigned to three groups: Unified Transdiagnostic Treatment, Acceptance and Commitment Therapy, and a waitlist control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University, Urmia Branch

Street address

Islamic Azad University, Urmia Branch, Urmia

City

Urmia

Province

West Azarbaijan

Postal code

۶۳۸۹۶۵۷۱۶۹

Approval date

2026-04-21, 1405/02/01

Ethics committee reference number

IR.IAU.URMIA.REC.1405.010

Health conditions studied

1

Description of health condition studied
Functional Seizure Disorder
ICD-10 code
F44.5
ICD-10 code description
Conversion disorder with seizures or convulsions

Primary outcomes

1

Description
Sensory processing sensitivity score in individuals with functional seizures
Timepoint
Before the intervention, immediately after completion of the intervention, and three months after the intervention
Method of measurement
Aron and Aron Sensory Processing Sensitivity Questionnaire

2

Description
Interpretive bias score in individuals with functional seizures
Timepoint
Before the intervention, immediately after completion of the intervention, and three months after the intervention
Method of measurement
Ambiguous Scenarios Test for Depression

3

Description
Experiential avoidance score in individuals with functional seizures
Timepoint
Before the intervention, immediately after completion of the intervention, and three months after the intervention
Method of measurement
Multidimensional Experiential Avoidance Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants in this group will receive Unified Transdiagnostic Intervention in 12 weekly 60 minute group sessions. The intervention includes psychoeducation about emotions, emotional awareness, mindfulness training, cognitive reappraisal, reduction of emotional avoidance, modification of emotion driven behaviors, interoceptive and situational exposure, and relapse prevention.
Category
Behavior

2

Description
Intervention group: Participants in this group will receive Acceptance and Commitment Therapy in 8 weekly 90 minute group sessions. The intervention includes acceptance of internal experiences, mindfulness training, cognitive defusion, contact with the present moment, clarification of personal values, commitment to value based actions, and modification of maladaptive behavioral patterns.
Category
Behavior

3

Description
Control group: Participants in this group will be placed on a waitlist and will not receive any structured psychological intervention from the research team during the study period. They will continue receiving routine medical care only. After completion of data collection, they will be offered one of the therapeutic interventions.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Educational, Therapeutic and Psychiatric Center
Full name of responsible person
Ali Khademi
Street address
Razi Educational, Therapeutic and Psychiatric Center, Near Shohada Educational and Therapeutic Center, El Goli Road, Tabriz, East Azerbaijan, Iran
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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
Islamic Azad 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
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Somayeh Tajfar

Position
دانشجو

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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

Deidentified participant data, study protocol, statistical analysis plan, informed consent form, data dictionary, and analysis codes will be available for sharing after completion of the study and removal of identifiable participant information.

When the data will become available and for how long

The data and documents will be available from six months after publication of the study results for a period of five years.

To whom data/document is available

Researchers, faculty members, graduate students, and investigators affiliated with academic and scientific institutions may request access to the data and study documents.

Under which criteria data/document could be used

The data and documents may only be used for scientific, research, and educational purposes. Applicants must submit a formal request and agree to use the data solely for approved research objectives while maintaining participant confidentiality.

From where data/document is obtainable

Applicants may contact the principal investigator, Ali Khademi, through the academic email address below to request access to the data and documents. Email: Ali.khademi@iau.ac.ir

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

After receiving a formal request, the application will be reviewed by the principal investigator. If the research purpose is approved and confidentiality requirements are met, the requested data and documents will be provided within four weeks.

Comments