Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effectiveness of Schema Therapy and Metacognitive Therapy Based on the Health Anxiety Model on Quality of Life, Reduction of Anxiety Sensitivity, and Intolerance of Uncertainty in Individuals with Health Anxiety

Protocol summary

Study aim

Inclusion Criteria: High scores on the Health Anxiety Questionnaire; age between 18 and 55 years; and absence of physical health conditions or comorbid psychiatric disorders ڇExclusion Criteria: The presence of physical illnesses or comorbid psychiatric disorders; age below 18 or above 55 years; and low scores on the Health Anxiety Questionnaire.

Design

A single-subject design was implemented with three participants diagnosed with health anxiety, encompassing baseline, intervention, and follow-up stages for each individual. Participants were selected through purposive sampling based on predefined inclusion and exclusion criteria. Given the nature of the single-subject design, control groups and randomization were not employed.

Settings and conduct

This study was conducted at the Sehat Psychological Clinic in Pakdasht using an ABA single-subject reversal design. The research procedure comprised baseline, intervention, and follow-up phases. During the intervention phase, an integrated protocol of Schema Therapy and Metacognitive Therapy was implemented across twelve 75-minute sessions. Health anxiety, quality of life, anxiety sensitivity, and intolerance of uncertainty were assessed using their respective standardized questionnaires. Given the single-subject nature of the study and the absence of a control group, no blinding procedures were utilized.»

Participants/Inclusion and exclusion criteria

Investigating the Effectiveness of an Integrated Schema and Metacognitive Therapy Protocol on Reducing Anxiety Sensitivity, Intolerance of Ambiguity, and Improving Quality of Life in Individuals with Health Anxiety”

Intervention groups

An integrated Schema and Metacognitive Therapy protocol based on the Health Anxiety Model (Single-Subject Design)

Main outcome variables

Health Anxiety; Anxiety Sensitivity; Intolerance of Uncertainty; Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260105068560N1**
Registration date: **2026-09-27, 1405/07/05**
Registration timing: **prospective**

Last update: **2026-09-27, 1405/07/05**
Update count: **0**

Registration date

2026-09-27, 1405/07/05

Registrant information

Name
Samane Ghadampour
Name of organization / entity
Lorestan University
Country
Iran (Islamic Republic of)
Phone
+98 21 3601 1744
Email address
samaneh.ghadampour@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date
2026-10-02, 1405/07/10
Expected recruitment end date
2026-11-20, 1405/08/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effectiveness of Schema Therapy and Metacognitive Therapy Based on the Health Anxiety Model on Quality of Life, Reduction of Anxiety Sensitivity, and Intolerance of Uncertainty in Individuals with Health Anxiety

Public title
Efficacy of Schema Therapy and Metacognitive Therapy Based on the Health Anxiety Model on Quality of Life and Health Anxiety–Related Symptoms in Patients with Health Anxiety
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
High scores on the Health Anxiety Questionnaire; age between 18 and 55 years; and absence of physical health conditions or comorbid psychiatric disorders
Exclusion criteria:
The presence of physical illnesses or comorbid psychiatric disorders; age below 18 or above 55 years; and low scores on the Health Anxiety Questionnaire.
Age
From **18 years** old to **55 years** old
Gender
Female

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
Ethics Committee of Lorestan University of Medical Sciences
Street address
No. 38, Saviz Lane, Oghaf Street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
3391434847
Approval date
2025-12-01, 1404/09/10
Ethics committee reference number
1404.189REC.LUMS.IR

Health conditions studied

1

Description of health condition studied
Health anxiety
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Anxiety Sensitivity, Intolerance of Uncertainty
Timepoint
Measurement of the dependent variables was conducted over 12 weekly sessions, followed by two follow-up sessions scheduled one month apart.
Method of measurement
Salkovskis et al.’s Health Anxiety Inventory (HAI)؛ Taylor and Cox Anxiety Sensitivity Questionnaire؛ Freeston et al.’s Intolerance of Uncertainty Questionnaire

Secondary outcomes

1

Description
Quality of Life
Timepoint
The intervention consisted of 12 weekly sessions, followed by two follow-up sessions at one-month intervals
Method of measurement
World Health Organization Quality of Life Questionnaire (WHOQOL)

Intervention groups

1

Description
Intervention group: A single-subject design was employed; therefore, neither an intervention group nor a control group was used
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati and Imam Khomeini Hospitals in Tehran
Full name of responsible person
Samaneh Ghadampour
Street address
No. 38, Saviz Alley, Oqaf St., Tehran
City
Tehran
Province
Tehran
Postal code
3391434847
Phone
+98 21 3601 1744
Email
samaneh.ghadampour@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The University of Lorestan
Full name of responsible person
Samaneh Ghadampour
Street address
No. 38, Saviz Alley, Oqaf St., Tehran
City
Tehran
Province
Tehran
Postal code
3391434847
Phone
+98 21 3601 1744
Email
samaneh.ghadampour@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Lorestan 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
Lorestan University
Full name of responsible person
Samaneh Ghadampour
Position
Phd
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
No. 38, Saviz Alley, Oqaf St., Tehran
City
Tehran
Province
Tehran
Postal code
3391434847
Phone
+98 21 3601 1744
Email
samaneh.ghadampour@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Lorestan University
Full name of responsible person
Samaneh Ghadampour
Position
Phd
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
No. 38, Saviz Alley, Oqaf St., Tehran
City
Tehran
Province
Tehran
Postal code
3391434847
Phone
+98 21 3601 1744
Email
samaneh.ghadampour@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Lorestan University

Full name of responsible person
Samaneh Ghadampour

Position
Phd

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
No. 38, Saviz Alley, Oqaf St., Tehran

City
Tehran

Province
Tehran

Postal code
3391434847

Phone
+98 21 3601 1744

Email
samaneh.ghadampour@gmail.com

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
Not applicable

Title and more details about the data/document
The data include de-identified individual participant data and scores for anxiety sensitivity, intolerance of uncertainty, and quality of life collected during the baseline, intervention, and follow-up phases. Identifying information will not be shared.

When the data will become available and for how long
The data will be available six months after publication of the primary study results or after final approval of the dissertation, whichever is later.

To whom data/document is available
Researchers, faculty members, and graduate students affiliated with reputable academic or research institutions may request access.

Under which criteria data/document could be used
The data may be used only for scientific and research purposes, such as reanalysis and verification of reproducibility. Re-identification of participants, commercial use, and transfer to third parties are prohibited. Data use is subject to request approval and confidentiality requirements.

From where data/document is obtainable
Applicants should submit a request describing the research purpose, requested data, proposed analysis, and institutional affiliation to the principal investigator. Principal investigator: [Full name] Email: [Email address] Institutional affiliation: [University/Institution]

What processes are involved for a request to access data/document
Requests will be reviewed for completeness, scientific relevance, and ethical compliance. Approved applicants must agree to maintain confidentiality. An initial decision will generally be provided within 30 business days, after which the data will be transferred through a secure channel.

Comments