

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Oct 2026

Neurophenomenological Transformation in Adolescents with Social Anxiety Disorder: Comparing the Effectiveness of a Neural-Embodied Regulation Intervention versus Another Therapeutic Intervention in Improving Interoceptive Markers

Protocol summary

Interoceptive awareness and embodied lived experience.

Study aim

The aim of this study is to evaluate neurophenomenological transformation in adolescents with social anxiety following a neuro-somatic regulation intervention. Changes in HRV, EDA, lived experience, and interoceptive awareness are examined throughout the 8-session protocol and integrated using a mixed quantitative-qualitative approach.

Design

This study is a single-arm interventional clinical trial with a pre-post design and a 6-month follow-up. Thirty-eight adolescents with social anxiety receive an 8-session neuro-somatic regulation protocol. No control group, randomization, or blinding is applied, and the trial phase is not applicable.

Settings and conduct

This study is conducted in the psychology clinics of the "Rah-e Zendegi" organization. Participants receive a neuro-somatic regulation intervention after providing informed consent. No blinding is applied.

Participants/Inclusion and exclusion criteria

Inclusion criteria: DSM-5 SAD diagnosis (MINI-KID); SCARED social anxiety ≥ 25 ; PDS ≥ 3 ; completion of the 8-session protocol; no psychotropic medication in the past 6 months. Exclusion criteria: psychotic disorders, moderate-severe neurodevelopmental disorders, or substance use.

Intervention groups

This study includes a single intervention group. Participants receive an 8-session neuro-somatic regulation protocol based on Polyvagal Theory and Somatic Experiencing.

Main outcome variables

Heart rate variability (HRV; RMSSD): Electrodermal activity (EDA, SCL): Severity of social anxiety symptoms and social avoidance: Somatic anxiety symptoms:

General information

Reason for update

Acronym

NATB

IRCT registration information

IRCT registration number: **IRCT20260107068587N1**

Registration date: **2026-01-27, 1404/11/07**

Registration timing: **prospective**

Last update: **2026-01-27, 1404/11/07**

Update count: **0**

Registration date

2026-01-27, 1404/11/07

Registrant information

Name

Parvaneh رحمتی

Name of organization / entity

Imam Khomeini Relief Committee

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-01-29, 1404/11/09

Expected recruitment end date

2026-02-12, 1404/11/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Neurophenomenological Transformation in Adolescents with Social Anxiety Disorder: Comparing the Effectiveness of a Neural-Embodied Regulation Intervention versus Another Therapeutic Intervention in Improving Interoceptive Markers

Public title

Effect of a Neurophenomenological Intervention on Social Anxiety in Adolescents

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Formal diagnosis of Social Anxiety Disorder based on DSM-5 criteria using the MINI-KID interview Score of 25 or higher on the Social Anxiety subscale of the SCARED questionnaire Score of 3 or higher on the Pubertal Development Scale as an indicator of entry into the target developmental stage Willingness to participate in the treatment program and adherence until completion of the 8-session protocol No use of psychotropic medications during the past 6 months

Exclusion criteria:

History of psychotic disorders Moderate to severe neurodevelopmental disorders Confirmed substance use or substance use disorder

AgeFrom **13 years** old to **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **38****Randomization (investigator's opinion)**

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features

This study is a single-arm interventional clinical trial with a pretest-posttest design in which all eligible participants will receive the neurophenomenological neural-embodied regulation intervention delivered in an 8-session protocol. Primary outcomes, including interoceptive markers and social anxiety severity, will be assessed at baseline and after completion of the

intervention. In addition, a qualitative component will be conducted to explore participants' lived experiences of bodily and emotional changes throughout the treatment process.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Islamic Azad University of Medical Sciences, Qom Branch

Street address

15 Khordad Blvd., Islamic Azad University of Medical Sciences, Qom Branch, Qom, Iran

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Approval date

2025-11-05, 1404/08/14

Ethics committee reference number

IR.IAU.QOM.REC.1404.125

Health conditions studied**1****Description of health condition studied**

Adolescent Social Anxiety Disorder

ICD-10 code

F40.1

ICD-10 code description

Social phobias

Primary outcomes**1****Description**

Heart rate variability (HRV) as an index of autonomic nervous system regulation, measured by resting RMSSD

Timepoint

Baseline (pre-test; week 0) Post-intervention (post-test; week 3) 6-month follow-up after completion of the intervention (approximately week 26)

Method of measurement

Heart rate variability is recorded using the BioPac MP150 physiological recording system with a finger photoplethysmography sensor, and the root mean square of successive differences of beat-to-beat intervals is extracted from resting recordings.

2

Description

Skin conductance level (electrodermal activity) as an index of sympathetic autonomic arousal

Timepoint

Baseline (pre-test; week 0); end of intervention (post-test; week 3); 6-month follow-up after the intervention (approximately week 26)

Method of measurement

Skin conductance level will be measured using the BioPac MP150 physiological recording system with silver/silver chloride surface electrodes

Secondary outcomes

1

Description

Severity of social anxiety symptoms based on the social anxiety subscale score of the Screen for Child and Adolescent Anxiety Related Emotional Disorders questionnaire (SCARED; Birmaher et al., 1999)

Timepoint

Baseline (pre-test; week 0); end of intervention (post-test; week 3); six-month follow-up after the intervention (approximately week 26)

Method of measurement

Screen for Child and Adolescent Anxiety Related Emotional Disorders questionnaire (SCARED; Birmaher et al., 1999), social anxiety subscale

2

Description

Severity of social avoidance based on the social avoidance subscale score of the Screen for Child and Adolescent Anxiety Related Emotional Disorders questionnaire (SCARED; Birmaher et al., 1999)

Timepoint

Baseline (pre-test; week 0); end of intervention (post-test; week 3); six-month follow-up after the intervention (approximately week 26)

Method of measurement

Screen for Child and Adolescent Anxiety Related Emotional Disorders questionnaire (SCARED; Birmaher et al., 1999), social avoidance subscale

Intervention groups

1

Description

Intervention group: An individual, face-to-face autonomic regulation psychotherapy based on Polyvagal Theory and Somatic Experiencing for adolescents with Social Anxiety Disorder. This intervention is delivered at the “Rah-e Zendegi” psychology clinics and consists of eight structured therapeutic sessions. Each session lasts 60 minutes and is provided over a 3-week period (three sessions per week). A 6-month follow-up assessment will also be conducted after completion of the

intervention. Session content includes: (1) establishing safety and therapeutic alliance with initial psychoeducation about threat and safety responses; (2) enhancing interoceptive awareness and identifying bodily anxiety signals; (3) grounding exercises and body-based attentional regulation; (4) autonomic arousal regulation with gradual exposure to age-appropriate social situations; (5) working with threat responses through controlled oscillation between tension and calm states (pendulation); (6) therapist-client co-regulation and relational repair; (7) integrating felt safety into social interactions through body-based interpersonal exercises; and (8) review, consolidation, and relapse-prevention planning. In selected sessions, brief video-assisted recall is used to facilitate embodied reflection on lived experience and bodily changes. The intervention is delivered by trained psychotherapists under supervision. Treatment fidelity is monitored using a standardized checklist, and a randomly selected subset of sessions is reviewed by an independent supervisor. This study includes no pharmacological intervention or consumable substance.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rah-e Zendegi Psychology Clinics, Affiliated with Imam Khomeini Relief Foundation

Full name of responsible person

Parvaneh Rahmati Sangkar

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No. 78, Doroudian Alley, South Sajjad Street, Baharan Square, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rah-e Zendegi Psychological Clinics, affiliated with the Imam Khomeini Relief Foundation (IRF)

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
Rah-e Zendegi Psychological Clinics, affiliated with the Imam Khomeini Relief Foundation (IRF)

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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Imam Khomeini Relief Foundation

Full name of responsible person
Parvaneh Rahmati Sangkar

Position
Senior Officer for Counseling and Prevention

Latest degree
Master

Other areas of specialty/work
Clinical Psychologist and Therapist in Clinical and Personality Disorders

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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

Due to the sensitive psychological and physiological data collected from adolescents and the need to protect participant confidentiality, there is no plan to publicly share individual participant data.

Study Protocol

Yes - There is 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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Eight-session neuro-somatic regulation intervention protocol for adolescents with social anxiety disorder (session structure and implementation guide)

When the data will become available and for how long

Available from study completion or publication of results (whichever occurs first)

To whom data/document is available

Researchers, clinicians, and postgraduate students

Under which criteria data/document could be used

For scientific/educational purposes or planning similar studies only; with proper citation, and without commercial use or redistribution without permission

From where data/document is obtainable

Requests should be sent via email to the principal investigator

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

Applicants submit a formal request and intended use; after a brief review, the protocol will be provided within 1 to 2 weeks

Comments