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

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 us

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؛ Interoceptive awareness and embodied lived experience.

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
Age
From **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
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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
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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
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
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Person responsible for updating data

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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