Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of Contextual Schema Therapy on Emotion Regulation, Interpersonal Problems, Painful Physical Symptoms, Fear of Negative and Positive Evaluation in Individuals with Social Anxiety Disorder: Single Subject Design

Protocol summary

Study aim
The aim of this research is to investigate the effectiveness of Contextual Schema Therapy on Emotion Regulation, Interpersonal Problems, Painful Physical Symptoms and Fear of Negative and Positive Evaluation of Social Anxiety Disorder.

Design
The Single Subject design included 12 individuals with Social Anxiety Disorder

Settings and conduct
This research will be done in Mashhad city. Variables are measured one week before the start of treatment and at the baseline stage. Subjects will then undergo the Contextual Schema Therapy for 16 one-hour weekly sessions. During treatment, the variables will be measured four times. Finally, the measurement of variables will be repeated at the end of treatment and then with a 3-month follow-up.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis of Social Anxiety Disorder based on Structured Clinical Interview for DSM-5, Age range 20 to 30 years, Level of education: minimum Diploma and Consent of participants to attend treatment sessions. Exclusion criteria: psychiatric disorders and comorbid disorders, addictive behaviors, medical disorders, concurrent psychological interventions.

Intervention groups
Contextual Schema Therapy: psychological education about the Contextual Schema Therapy model. Addressing the coping modes. Using the chair technique to access the child modes and critical modes, strengthen the healthy adult mode using Acceptance and Commitment Therapy (ACT) and Mindfulness techniques, the Imagery exercises, and reparenting techniques, learning to use the Schema-Mode flashcard, developing the behavioral experiments to solve behavioral problems.

Main outcome variables
Emotion Regulation; Interpersonal Problems; Painful Physical Symptoms and Fear of Negative and Positive evaluation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211006052690N1**
Registration date: **2021-10-26, 1400/08/04**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-26, 1400/08/04**
Update count: **0**

Registration date
2021-10-26, 1400/08/04

Registrant information

Name
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The University of Semnan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2021-10-19, 1400/07/27

Expected recruitment end date

2021-11-18, 1400/08/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Contextual Schema Therapy on Emotion Regulation, Interpersonal Problems, Painful Physical Symptoms, Fear of Negative and Positive Evaluation in Individuals with Social Anxiety Disorder: Single Subject Design

Public title

Effectiveness of Contextual Schema Therapy on Emotion Regulation, Interpersonal Problems, Painful Physical Symptoms, Fear of Negative and Positive Evaluation in Individuals with Social Anxiety Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of Social Anxiety Disorder based on Structured Clinical Interview for DSM-5 (SCID-5) Age range 20 to 30 Years Level of education, minimum diploma Consent of the participants to attend the treatment sessions

Exclusion criteria:

Psychiatric disorders such as psychotic disorders and personality disorders and comorbid disorders such as other anxiety disorders, mood disorders, body dysmorphic disorder and substance use disorders Addictive behaviors such as Internet Addiction (measured in the context of the interview) Medical disorders (assessment by reviewing the file and medical history) Receiving simultaneous psychological interventions

Age

From **20 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **12**

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 Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences and Health Services., Basij Blvd., Semnan., Semnan province.

City

Semnan

Province

Semnan

Postal code

35147-99442

Approval date

2021-08-24, 1400/06/02

Ethics committee reference number

IR.SEMUMS.REC.1400.128

Health conditions studied

1

Description of health condition studied

Social Anxiety Disorder

ICD-10 code

F40.1

ICD-10 code description

Social phobias

Primary outcomes

1

Description

Emotion regulation score in the Emotion Regulation Questionnaire (ERQ)

Timepoint

The variable will be assessed one week before the start of treatment and at the baseline stage. It will then be assessed four times during treatment. At the end of treatment and then with a 3 months follow-up, the assessment will be repeated.

Method of measurement

Emotion Regulation Questionnaire (ERQ)

2

Description

Interpersonal Problems score in the Inventory of Interpersonal Problems (IIP-32)

Timepoint

The variable will be assessed one week before the start of treatment and at the baseline stage. It will then be assessed four times during treatment. At the end of

treatment and then with a 3 months follow-up, the assessment will be repeated.

Method of measurement

Inventory of Interpersonal Problems (IIP-32)

3

Description

Score of Painful Physical Symptoms in the Visual Analogue Scale (VAS)

Timepoint

The variable will be assessed one week before the start of treatment and at the baseline stage. It will then be assessed four times during treatment. At the end of treatment and then with a 3 months follow-up, the assessment will be repeated.

Method of measurement

Visual Analogue Scale (VAS)

4

Description

Fear of Negative Evaluation score in the Brief Fear of Negative Evaluation-II (BFNE-II)

Timepoint

The variable will be assessed one week before the start of treatment and at the baseline stage. It will then be assessed four times during treatment. At the end of treatment and then with a 3 months follow-up, the assessment will be repeated.

Method of measurement

Brief Fear of Negative Evaluation-II (BFNE-II)

5

Description

Fear of Positive Evaluation score on the Fear of Positive Evaluation Scale (FPES)

Timepoint

The variable will be assessed one week before the start of treatment and at the baseline stage. It will then be assessed four times during treatment. At the end of treatment and then with a 3 months follow-up, the assessment will be repeated.

Method of measurement

Fear of Positive Evaluation Scale (FPES)

Secondary outcomes

empty

Intervention groups

1

Description

Contextual Schema Therapy will be performed on the subjects in the form of the Single Subject Design for 16 sessions of 1 hour per week. Contextual Schema Therapy will be performed on the subjects in the form of the Single Subject Design for 16 sessions of 1 hour per week. Pharmacological intervention will not be used in this research. The treatment protocol is based on the book "Contextual Schema Therapy; An Integrative Approach to Personality Disorders, Emotional Dysregulation, and Interpersonal Functioning." The authors of this book are Eckhard Roediger, Bruce A. Stevens and Robert Brockman. Contextual Schema Therapy interweaves conceptual underpinnings of Schema Therapy with cuttingedge theoretical advances, contextualizing it within the framework of Second and Third Wave psychotherapy approaches.This model integrates the important concepts of Third Wave approaches such as Mentalization, Mindfulness, Acceptance, Metacognition, and human values into the basic Schema Therapy model. Contextual Schema Therapy uses the Third Wave therapeutic approaches to break through detachment; to confront harmful internal messengers; and to access and protect Vulnerable Modes, while strengthening the Healthy Adult Mode in order to thwart self-defeating patterns in favor of healthier responses. Therefore, the reason for naming this model as Contextual Schema Therapy is that it has been revised in light of contemporary contributions and understandings from Third Wave therapies. Sessions 1 to 3: Establishing the therapeutic relationship- Assessment- Preparing the problem list- Conceptualizing according to the Schema Therapy approach- Providing psychological education about the Contextual Schema Therapy model (Early Maladaptive Schemas, how they are formed and their continuation, explanation about the Modes and the Mode Model)- Providing an explanation of the descriptive diagram of the subject's modes and the Dimensional Mode Map. Sessions 4 to 6: Dealing with the Coping Modes, including identifying and labeling them, examining their advantages and disadvantages in the past and present (for Avoidant Coping Modes: reviewing the history and functional analysis of these Modes- for Submissive Coping Mode: using empathetic confrontation to access constructive anger- for Overcompensatory Coping Modes: highlighting the need for attachment). Using the Chair technique to bypass the Coping Modes and thus access to the Child Modes and Critical Modes- Identifying and meet the needs of the Child Modes- Identifying the Inner Critical Mode beliefs and addressing them through the Acceptance and Commitment approach: identifying and translating them into Second person and creating inconsistency, putting them on a chair, examining the negative effects of these beliefs on the person, using metaphors to defuse these beliefs and increasing the focus on the present- Strengthening the Healthy Adult Mode: using ACT and Mindfulness Techniques (such as Mindfulness of Breath Meditation, the 5–4–3 exercise, the Emotion Surfing, Self-Compassion exercise and The Eightieth Birthday imagery exercise to identify values)- Planning to do these exercises in the interval between sessions. Teaching how to complete the Mode Monitoring Form. Sessions 7 to 10: Presenting the logic of the Experiential techniques and Imagery Exercises– Imaging the important life events- Re-parenting and re-framing the events- if necessary, use the Chair technique to bypass the Coping Modes, Identifying and meet Needs of the Child Modes- Developing behavioral solutions for the interval between sessions- Preparing an audio file of Imagery exercises to

listen to them 1-2 times in the interval between sessions. Sessions 11-13: Increasing the performance of the Healthy Adult Mode through the Two-Chair technique and creating a dialogue between the Healthy Adult Mode and Inner Critic Mode- Teaching the use of Schema-Mode flash cards and preparing a daily conversation notebook to write down the negative beliefs of the Inner Critic Mode and Adult Healthy Mode responses to them. Sessions 14 to 16: Preparing a list of behavioral problems- Developing the Behavioral Experiment and practice in the session in two ways: the Future-directed Imagery to plan behavior and fill out the form of behavioral activation or role-playing- Summarizing tips- helping to consolidate what has been learned through talking about obstacles and setbacks- Talking about ending treatment and expressing feelings about it.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Ferdowsi University of Mashhad

Full name of responsible person
Dr. Mohammad Kafi

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Sponsors / Funding sources

1

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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
The Ferdowsi University of Mashhad

Proportion provided by this source
50

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

2

Sponsor

Name of organization / entity
The Semnan University

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
The Semnan University

Proportion provided by this source
50

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

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Position
Associate Professor

Latest degree
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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
This data may be misused by individuals and reported as data from other research.

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

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
Only the part of the original outcome data can be shared.

When the data will become available and for how long
Access starts after printing the results.

To whom data/document is available
Students, Specialists and Professors of Psychology

Under which criteria data/document could be used
For Study Only

From where data/document is obtainable
Email: zahra_emamzamani@yahoo.com

What processes are involved for a request to access data/document
Give an email and state the reason for their request.

Comments