

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The Effectiveness of Parent-Focused Group Schema Therapy in Reducing Clinical Symptoms and Improving Parent-Child Relationship Among Adolescents with Anorexia Nervosa

Protocol summary

Study aim

The current study aims to investigate the effectiveness of the group schema therapy in reducing the clinical symptoms of adolescents with Anorexia Nervosa, improving parents emotion regulation skills, parent-child interaction and family quality of life.

Design

The multiple baseline design across three groups of 6 people, with control groups, currently in the recruitment phase, with blinded participants, random assignment to each group, using the table of random numbers.

Settings and conduct

This online intervention will be held on Google Meet platform, once a week, for 90 minutes. The parents as participants are blind and they do not know in which group they will enter.

Participants/Inclusion and exclusion criteria

Adolescents must be between the ages of 12 and 18. Having a caregiver in the home willing to participate in treatment. (BMI) between 14 and 18, Meeting DSM-5 criteria for Anorexia Nervosa Being sufficiently stable for outpatient treatment, Being on a stable medication dose for a period of at least 8 weeks before the intervention. Exclusion Criteria: Adolescents with current severe substance abuse, current acute psychosis, or at acute risk for suicide and intellectual disability. Participants who have had schema therapy sessions over the past 12 months before the study begins Current or a history of recent or past physical or sexual abuse by a family member.

Intervention groups

Intervention group: 18 parents of adolescents with Anorexia Nervosa after being assessed will be randomly allocated to this group. Participants will undergo the online parent-focused group schema therapy once a week for 90 minutes, in total 12 weeks. Control group: 18 parents of adolescents with Anorexia Nervosa that

measurements will be made simultaneously and in accordance with the intervention group.

Main outcome variables

Anorexia symptoms, Parent-child interaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220714055467N1**

Registration date: **2022-09-28, 1401/07/06**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-28, 1401/07/06**

Update count: **0**

Registration date

2022-09-28, 1401/07/06

Registrant information

Name

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Name of organization / entity

Shiraz University

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2023-01-20, 1401/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Parent-Focused Group Schema Therapy in Reducing Clinical Symptoms and Improving Parent-Child Relationship Among Adolescents with Anorexia Nervosa

Public title

Effect of Parent-Focused Group Schema Therapy for Adolescents with Anorexia Nervosa:

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Parents of adolescents between the ages of 12 and 18
Having at least a caregiver in the home willing to participate in treatment
Adolescents must meet DSM-5 criteria for Anorexia Nervosa based on the clinical interview
Having body mass index (BMI) between 14 and 18
Being sufficiently medically stable for outpatient treatment
Parents must read and speak Persian to at least a sixth-grade level
Adolescents on psychotropic medication must be on a stable dose for a period of at least 8 weeks

Exclusion criteria:

Adolescents with severe substance abuse, acute psychosis, or at acute risk for suicide
Adolescents or caregivers with intellectual disability
Experience of participating in Schema Therapy sessions with a trained clinician over the past 12 months before the study begins
Report of a current or history of recent or past physical or sexual abuse by a family member

AgeFrom **11 years** old to **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant

Sample sizeTarget sample size: **18****Randomization (investigator's opinion)**

Randomized

Randomization description

In this non-concurrent multiple baseline design, the researchers introduce the intervention to three groups on a staggered schedule and in a random order. The randomization assignment will be simple and individual, also will be done by means of table of random numbers. Before any intervention occurs, the outcome is measured in each group(the baseline phase). Then the intervention is initiated in 1 group while the others continue in the control and baseline condition. After sufficient time has passed for the intervention to affect the outcome in the

first group, outcome measurements are conducted in all groups and the intervention is introduced in second and third groups. This proceeds until all groups receive the intervention. Once a group starts the intervention, it remains in that condition until the end of the study. If every group shows a similar change after crossing to the intervention condition and does not change at other times, the experiment provides compelling evidence that the changes resulted from the intervention.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the parents as participants are blind. Meaning that they do not know in which group they will enter. In this non-concurrent multiple baseline design, the researchers introduce the intervention to three groups on in a random order and the parents do not have an idea of in which group they will enter.

Placebo

Not used

Assignment

Other

Other design features

For the quantitative part of this pilot study, the single-case design has been chosen because it is an approach often advocated for early phase behavioral studies. SCD is suggested as an economical and flexible approach used in the experimental analysis of behavior and applied behavior analysis and it experimentally demonstrate that a change in targeted behavior results from a novel intervention, and that the behavior change, in turn, is associated with clinically meaningful improvements in health outcomes. Three essential characteristics of a SCD which will be performed in this study are the followings: data will be gathered, analyzed and interpreted for 3 groups of participants) (2) the participants will be observed repeatedly during baseline and treatment phases, and (3) outcomes during and after the treatment will be compared with outcomes before treatment. These groups provide their own controls for purpose of comparison. Additional advantages of SCD include the ability to study highly fragmented populations that have a low prevalence rate or have rare diseases (The same as patients with eating disorders in this study) , the reduction in the gap between research and practice by allowing the therapists to implement SCD in natural setting, the provision of detailed information about variations in the treatment effect related to participant's individual differences, and assessment of treatment effectiveness trends over time.

Secondary Ids

empty

Ethics committees1**Ethics committee****Name of ethics committee**

Research Ethics Committees of Shiraz University of

Medical Sciences

Street address

Department of clinical psychology, Shiraz University,
Jomhoori Eslami Blvd, Shiraz, Fars, Iran

City

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Province

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Postal code

7194684759

Approval date

2022-06-20, 1401/03/30

Ethics committee reference number

IR.SUMS.REC.1401.212

Health conditions studied

1

Description of health condition studied

Anorexia Nervosa

ICD-10 code

F50.0

ICD-10 code description

Anorexia nervosa

Primary outcomes

1

Description

The score of the Eating Disorder Examination
questionnaire (EDEQ)

Timepoint

Measuring the eating disorder in Baseline, Mid-
treatment, post-treatment and 3- month follow-up.

Method of measurement

Eating Disorder Examination questionnaire (EDEQ)

2

Description

The score of Parent-Child Interaction Questionnaire-
Revised (PACIQ-R)

Timepoint

Measuring the parent-child interaction in Baseline, Mid-
treatment, post-treatment and 3- month follow-up.

Method of measurement

Parent-Child Interaction Questionnaire-Revised (PACIQ-
R)

Secondary outcomes

1

Description

The score of Difficulties in Emotion Regulation Scale
(DERS-16)

Timepoint

Measuring the parents' emotion regulation in Baseline,
Mid-treatment, Post-treatment and 3-months follow-up.

Method of measurement

The Difficulties in Emotion Regulation Scale (DERS-16)

2

Description

The score of Family Quality of Life Scale (FQOL)

Timepoint

Measuring the family's quality of life in Baseline, Mid-
treatment, Post-treatment and 3-months follow-up.

Method of measurement

Family Quality of Life Scale (FQOL)

3

Description

The score of Visual Analogue Scale (VAS)

Timepoint

The VAS scales will be collected twice per week during
baseline period, once a week after each group session,
twice per week during the follow-up and once during the
follow-up measure.

Method of measurement

Visual Analogue Scale (VAS)

Intervention groups

1

Description

Intervention group: 18 parents of adolescents with
Anorexia Nervosa after being clinically assessed and
diagnosed, will be randomly allocated to this group.
Participants will undergo the online parent-focused group
schema therapy once a week for 90 minutes, in total 12
weeks. The adolescents' symptoms measurements and
measures related to parents as participants will be made
at baseline, mid, post treatment and 3 months follow-up.

Category

Treatment - Other

2

Description

Control group: 18 parents of adolescents with Anorexia
Nervosa after being clinically assessed and diagnosed,
will be randomly allocated to this group. Measurements
will be made at baseline, mid, post treatment and 3
months follow-up simultaneously and in accordance with
the intervention group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Clinical Psychology

Full name of responsible person

Javad Molazadeh

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Sponsors / Funding sources

1

Sponsor

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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

Shiraz 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
Shiraz University
Full name of responsible person
Javad Molazadeh
Position
Associate professor
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)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Considering ethical codes

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

No - There is not 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

Sharing the protocol and the treatment outcomes

When the data will become available and for how long

Accessing the data from 2023

To whom data/document is available

Researchers working in academic and scientific institutes.

Under which criteria data/document could be used

After official publishing in valid scientific journals will be accessible.

From where data/document is obtainable

fatemeh.seifi@shirazu.ac.ir

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

After 2 years, the person who requests, can access the protocol and treatment outcomes, after the article being published officially.

Comments