

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The effectiveness of Schema Therapy on Eating Habits, Body Mass Index, weight-related LifeStyle Self-Efficacy, Cognitive Emotion Regulation, Self-management Behaviors, eating Addiction, Coping styles, and Schematic mentality in patients undergoing bariatric surgery

Protocol summary

Study aim

The effectiveness of schema therapy on body mass index, weight-related lifestyle self-efficacy, emotion regulation and schema mentality in people undergoing bariatric surgery

Design

Clinical trials with a control group and blind and randomized intervention group

Settings and conduct

The Ghadir Mother and child hospital in Shiraz, in the experimental group, in addition to receiving the primary care nutritional program after the bariatric surgery, an independent schemata variable will be applied. - In the control group, no independent variables were applied, and they will receive only the nutrition program and primary care after bariatric surgery. - In the independent variable, the schema will be presented in 10 sessions (one session of 1.5 hours per week). - The dependent variables are BMI, lifestyle self-efficacy related to weight, emotional regulation, and schematical mentality. - In the test and control group, two evaluations will be carried out in the pre-test and post-test

Participants/Inclusion and exclusion criteria

Inclusion criteria: Performing bariatric surgery in 1397, the age range of 55-20 years, living in Shiraz, having minimum cycle education, the ability to communicate verbally, patient agreement with written consent to participate in the study. Exclusion criteria: suffering from severe psychiatric disorders and their related problems

Intervention groups

There were 15 people in the experimental group and 15 in the control group

Main outcome variables

Schema Therapy; BMI; Self-efficacy of lifestyle; Weight; Scale Thrice Adjustment and Scheme Mind

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180523039802N2**

Registration date: **2020-08-05, 1399/05/15**

Registration timing: **prospective**

Last update: **2020-08-05, 1399/05/15**

Update count: **0**

Registration date

2020-08-05, 1399/05/15

Registrant information

Name

Zahra Sobhani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3227 9711

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-09, 1399/05/19

Expected recruitment end date

2020-09-09, 1399/06/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of Schema Therapy on Eating Habits, Body Mass Index, weight-related LifeStyle Self-Efficacy, Cognitive Emotion Regulation, Self-management Behaviors, eating Addiction, Coping styles, and Schematic mentality in patients undergoing bariatric surgery

Public title

The effectiveness of Schema Therapy on Eating Habits, Body Mass Index, Weight-related LifeStyle Self-Efficacy, Cognitive Emotion Regulation, Self-management Behaviors and Schema mentality in patients undergoing bariatric surgery

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Performing bariatric surgery in 1397, the age range of 55-20 years, living in Shiraz, having minimum cycle education, ability to communicate verbally, patient agreement with written consent to participate in the study

Exclusion criteria:

Severe mental disorders and their related problems

Age

From **20 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization: 30 people who have the inclusion criteria: 15 people will be selected for the schema therapy in the experimental group and 15 people for the control group were randomly selected by the sealed envelope site. Block sizes were 4, 6, and 8, and the patients selected according to the patient list.

Blinding (investigator's opinion)

Double blinded

Blinding description

The objectives of the research will be explained to the participants. The objectives of the research will be explained to the participants. Neither the participants in the experimental group know that there is a control group nor the participants in the control group know that there is an experimental group. Also, the groups are not related to each other. The health care staff of the obesity clinic who are responsible for caring for patients, data collectors, and those evaluating the outcome are also

blind and will not be informed of the objectives of the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz university of medical sciences

Street address

Khalili Street, Research Tower of Mohammad Rasool Allah, Colorectal Research Center

City

shiraz

Province

Fars

Postal code

7193635899

Approval date

2019-03-12, 1397/12/21

Ethics committee reference number

IR.SUMS.REC.1398.237

Health conditions studied

1

Description of health condition studied

obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

1-Weight Loss Life Style Self-Efficacy: This questionnaire, designed and developed by Clark, contains 20 questions about self-efficacy of eating behavior, in which subjects rate their confidence and control in controlling and preventing eating behaviors in different situations. The temptation is based on a five-point Likert scale (from 0 to 4, very reliable, 4). 2. Cognitive Emotion Regulation (DERS): A 36-point scale developed by Graz and Roemer And has a general score and six special scores in the sub-scales that relate to different dimensions of difficulty in tuning the emotion, including Emotional responsiveness, difficulty in targeting behavior, difficulty in controlling impulse, lack of emotional acuity, lack of

emotional transparency, and limited access to emotion regulation strategies. 3-Schematic mentality: This questionnaire is a self-report tool with 124 sentences, and the subject must specify, on a 6-point Likert scale, the amount of his consent or opposition to each of the phrases. The higher the individual's score in these mindsets implies the inflexibility of that mentality.

Timepoint

Before the start of the intervention, a pretest is taken and the schema therapy intervention will be performed in 10 sessions and a weekly 1.5 hour session, and then one month after the intervention, post-test will be taken.

Method of measurement

Demographic information questionnaire, Linear scale, Weight Loss Life Style Self-Efficacy, Cognitive Emotion Regulation (DERS), BSSQ, Schematic mentality

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Schema received 10 sessions per week and 1.5 hours per week received

Category

N/A

2

Description

Control group: The control group will not receive any interventions and will be considered as a comparison group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mother and Child Emergency Hospital in Ghadir, Shiraz

Full name of responsible person

masoud amini

Street address

laparoscopy Research Center, Mother and Child Hospital Ghadir, above gate Quran, First Town Gulshan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

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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 of Medical Sciences

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 of Medical Sciences

Full name of responsible person

Zahra Sobhani

Position

Post Doc

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Not applicable