

# 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)

##### Phone

+98 71 3227 9711

##### Email address

zahrasobhani120@yahoo.com

##### 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

###### **City**

Shiraz

###### **Province**

Fars

###### **Postal code**

71449-9537

###### **Phone**

+98 71 3631 9937

###### **Fax**

+98 71 3227 9711

###### **Email**

aminima@sums.ac.ir

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Shiraz University of Medical Sciences

###### **Full name of responsible person**

Seyed Vahid Hosseini

###### **Street address**

Khalili street, mohammad rasoul allah tower, Colorectal research center

###### **City**

Shiraz

###### **Province**

Fars

###### **Postal code**

7193635899

###### **Phone**

+98 71 3628 1453

###### **Email**

colorectal@sums.ac.ir

##### **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

###### **Street address**

NO. 5 Moallem street, Moallem square

###### **City**

Shiraz  
**Province**  
Fars  
**Postal code**  
7186837152  
**Phone**  
+98 71 3631 9937  
**Email**  
zahrasobhani120@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
ZAHRA SOBHANI  
**Position**  
Postdoctoral student  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Psychology  
**Street address**  
No. 5, Moalem Ave, Moralem Square  
**City**  
SHIRAZ  
**Province**  
Fars  
**Postal code**  
7186837152  
**Phone**  
0087136319937  
**Email**  
zahrasobhani120@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**

Zahra Zabangirfard  
**Position**  
Research Expert, Administrative Relationship Expert  
Translations of Expert  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Library and Medical Information  
**Street address**  
Khalili Street, Research Tower of Mohammad Rasool  
Allah, Colorectal Research Center  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**  
7193635899  
**Phone**  
+98 71 3628 1453  
**Email**  
colorectal2@sums.ac.ir

## 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