

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparing the effect of two educational methods; Family-centered and traditional empowerment model on adherence to treatment and perceived social support in patients undergoing Bariatric surgery

Protocol summary

Study aim

Determining the effect of two educational methods; family-centered and traditional empowerment model on adherence to treatment and perceived social support in patients undergoing bariatric surgery

Design

A randomized controlled clinical trial

Settings and conduct

The study will be conducted in 3 sessions. The first session will be held at the time of the patient's visit to the hospital for surgery case compilation; the second session will be held three weeks before the surgery; the third session will be held 15 days before surgery. The meetings will be actively attended by the patient and family members or the primary caregiver. In these sessions, under the management of the researcher, discussions and questions and answers about adherence to treatment and its importance will be discussed. These sessions will be held in the Obesity Clinic of Madar va Koodak Ghadir Hospital in Shiraz.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having full consent to enter the study; being a candidate of Bariatric surgery; the family member (caregiver and main companion) have at least diploma Exclusion criteria: having disorders related to treatable endocrine glands; having alcohol or drug addiction; being afflicted with a severe and well-known mental illness

Intervention groups

In the intervention group, the anticipated steps of the family-centered empowerment model will be implemented, which include the perceived threat step, the problem-solving step, and the educational participation step in three 1-hour sessions. During the research, the researcher will be in contact with the patient through social networks and telephone to resolve ambiguities and possible questions. The control group

follows the normal routine of the hospital.

Main outcome variables

Adherence to treatment, perceived social support

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180523039802N3**

Registration date: **2020-12-13, 1399/09/23**

Registration timing: **prospective**

Last update: **2020-12-13, 1399/09/23**

Update count: **0**

Registration date

2020-12-13, 1399/09/23

Registrant information

Name

Zahra Sobhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3227 9711

Email address

zahasobhani120@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-03-05, 1399/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of two educational methods;
Family-centered and traditional empowerment model on adherence to treatment and perceived social support in patients undergoing Bariatric surgery

Public title

The effect of implementing family-centered empowerment model on adherence to treatment and perceived social support

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Complete consent to study candidate for Bariatric surgery family member (primary caregiver) with minimum diploma literacy

Exclusion criteria:

Having treatable endocrine disorders Alcohol or drug addiction With severe and well-known mental illness

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization: Based on the formula of sample size comparison of two means with an error of 5%, with a power of 90% and using the results of a similar study, the sample size in each group was calculated at least 18 people. Which was taken to increase the accuracy of 20 patients in each group. Accordingly, 80 patients who meet the inclusion criteria are randomly divided into two groups of 20 with block randomization (with the size of each block equal to 4). The randomization list is generated and used using random allocation software.

Blinding (investigator's opinion)

Double blinded

Blinding description

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**

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

۷۳۳۶ - ۷۱۳۴۸

Approval date

2019-06-09, 1398/03/19

Ethics committee reference number

IR.SUMS.REC.1398.515

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**

Adherence

Timepoint

At baseline and 3 months and 6 months after surgery

Method of measurement

Treatment Compliance Questionnaire

2**Description**

perceived social support

Timepoint

At baseline and 3 months and 6 months after surgery

Method of measurement

Perceived Social Support Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Session 1: Perceived threat step. In this session, issues about surgery and its process, complications, risk factors and effects of defects and failures in the treatment plan, methods of prevention and control of complications, self-care behaviors (adherence to diet, medication, exercise regime) and its importance is explained in simple language to patients and their caregivers. Patients' questions will then be discussed and answered. Session 2: Problem-solving step. This meeting will be held aimed at problem-solving. The problem-solving steps include diagnosing the problem, explaining the goals, providing solutions, and selecting the best solution. Discussion on how to choose and implement the best solution to achieve the desired goals according to the ability of the patient and the family, will be the focus of this meeting. At this stage, the skills needed to achieve the goal will be taught (physical exercise, fixing the meal time to prevent reflux and dumping syndrome). Booklets and pamphlets will also be provided to the patient and family. A patient who has undergone surgery and achieved the best postoperative results will also be invited to help provide solutions. Session 3: Educational Participation step. In this session, the patient himself/herself assists the researcher in educating other patients and families. This participation will be done to increase the patient's self-confidence and gain family support. During the research, the researcher will be in contact with patients through social networks and telephone to resolve ambiguities and possible questions. Each session will last for one hour and the last session will be held at least 15 days before surgery.

Category

Lifestyle

2

Description

Control group: The 40-person group will go through the routine procedures of the hospital and will receive routine training.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghadir Shiraz Mother and Child Hospital

Full name of responsible person

Zinat Mohebi

Street address

Mother and Child Hospital, Beginning of Golshan Town, Shiraz Above the Quran Gate

City

Shiraz

Province

Fars

Postal code

7144995377

Phone

+98 71 3227 9721

Email

motherhosp@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Younes Qasemi

Street address

Zand Street, Shiraz University of Medical Sciences

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

Consultant

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

No. 5, Moalem Street

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

Consultant

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

No. 5, Moalem Street

City

Shiraz

Province

Fars

Postal code

7186837152

Phone

+98 71 3631 9937

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 Sobhani

Position

Consultant

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

No. 5, Moalem Street

City

Shiraz

Province

Fars

Postal code

7186837152

Phone

+98 71 3631 9937

Email

zahrasobhani120@yahoo.com

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

Not applicable

Data Dictionary

Not applicable