Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Impact of Education Based on Orem’s Theory on Self-Care Behaviors and Quality of Life in Patients Following Bariatric Surgery

Protocol summary

Study aim

This study aims to investigate the effect of self-care education based on Orem's theory on self-care behaviors and quality of life of patients after bariatric surgery.

Design

This study is a randomized, double-blind, single-center, phase II clinical trial with two parallel groups. Randomization will be performed using a block method and concealed allocation by an independent investigator using a random number table. On 50 patients

Settings and conduct

The study will take place at Aram Hospital, Karaj, bariatric surgery department. Participants will be recruited, consented, and randomly assigned to intervention or control groups. Blinding is not possible due to the educational intervention, but outcome assessments will be done by a blinded independent assessor.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients aged 30 to 50 years, who underwent bariatric surgery (e.g., sleeve gastrectomy), with BMI ≥ 35 kg/m², and willing and able to participate in the intervention. Exclusion criteria: cognitive or learning difficulties, non-participation in at least two sessions, and diagnosed chronic psychiatric disorders (e.g., severe depression or uncontrolled anxiety) that may interfere with study outcomes.

Intervention groups

The intervention group will receive a culturally adapted, structured self-care educational program based on Orem’s theory, tailored to the needs of Iranian patients post-bariatric surgery. The control group will receive routine post-operative care, including standard medical and nursing advice on nutrition, medication adherence, wound care, and follow-up plans.

Main outcome variables

Self-care behaviors and quality of life after surgery.

General information

Reason for update

Acronym

QLPB

IRCT registration information

IRCT registration number: **IRCT20250327065166N1**

Registration date: **2025-05-18, 1404/02/28**

Registration timing: **prospective**

Last update: **2025-05-18, 1404/02/28**

Update count: **0**

Registration date

2025-05-18, 1404/02/28

Registrant information

Name

Alireza ANDARVAZH

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 26 3428 7018

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-22, 1404/03/01

Expected recruitment end date

2025-06-20, 1404/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Impact of Education Based on Orem’s Theory on Self-Care Behaviors and Quality of Life in Patients Following Bariatric Surgery

Public title
The effect of self-care training on the quality of life of patients after bariatric surgery.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients must undergo bariatric surgery (such as sleeve gastrectomy) Body mass index (BMI) ≥ 35 kg/m2. age:%20Patients%20should%20be%20between%2030-50%20years%20old. Patients must be willing and able to participate in nursing education and implement self-care interventions. Informed consent to participate in the study. High school diploma level of literacy Effective communication ability: Patients must be able to understand and speak Persian and understand and respond to Persian questionnaires. Physically healthy individuals who are able to perform self-care training. Ability to use educational technologies: Patients should have the ability to access a smartphone, computer, or tablet and use educational podcasts.

Exclusion criteria:
Cognitive and learning problems Failure to cooperate during the study period. (Failure to attend at least two sessions will result in exclusion of the individual) Patients with chronic mental health problems or diagnosed psychiatric disorders that may affect the study results (such as severe depression or uncontrollable anxiety) The presence of chronic diseases that affect self-care behavior and quality of life after bariatric surgery (e.g., cardiovascular disease or type 1 diabetes). Unsuccessful surgery or serious side effects from surgery that require longer hospitalization and medical follow-up. Inability to follow up or failure to complete data at different stages of the study. Lack of access to technology: Patients who are unable to use educational podcasts for any reason (such as lack of access to the internet, smartphone, or other devices).

Age
From **30 years** old to **50 years** old

Gender
Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, block randomization was employed to ensure a balanced allocation of participants into the intervention and control groups. Participants were stratified into eight blocks based on key variables, including educational level (high school diploma, bachelor’s degree or higher), gender (male, female), and body mass index (BMI 35–40, BMI >40). This stratification aimed to control for potential confounding effects of these variables and enhance the homogeneity between groups. Within each block, participants were randomly assigned to one of the two study groups in a 1:1 ratio using a computer-generated randomization sequence. The randomization process was conducted by an independent staff member who was not involved in the study procedures, ensuring allocation concealment and minimizing the risk of selection bias.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Karaj Azad University

Street address
Islamic Azad University, Karaj Branch, Research Ethics Committee, Amir Al-Mo'menin Academic Complex, at the intersection of Moazen and Esteghlal Boulevards, end of Rajaee Shahr, Karaj, Iran.

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Karaj

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Alborz

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3155845475

Approval date
2025-04-22, 1404/02/02

Ethics committee reference number
IR.IAU.K.REC.1404.020

Health conditions studied

1

Description of health condition studied
The Impact of Education Based on Orem’s Theory on Self-Care Behaviors and Quality of Life in Patients Following Bariatric Surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Education Based on Orem’s Theory

Timepoint

Before the start of the intervention, two weeks after the intervention, and 30 days and 45 days after the start of the intervention

Method of measurement

Quality of life questionnaire and self-care behaviors questionnaire after bariatric surgery

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention in this study is a structured self-care educational program based on Orem’s Self-Care Deficit Nursing Theory, specifically designed for patients undergoing bariatric surgery. The program is culturally tailored for Iranian patients and aims to enhance their ability to perform essential self-care behaviors following surgery. The educational content focuses on various aspects of post-surgical care, including nutritional management, physical activity, wound care, medication adherence, complication prevention, and psychological support. Emphasis is placed on enabling patients to recognize early signs of complications, maintain dietary discipline, manage stress, and adhere to follow-up recommendations.The intervention is delivered through face-to-face group sessions led by a trained nurse educator, supplemented by educational podcasts provided to participants for continued learning at home. The program consists of four interactive sessions held over two weeks, with each session lasting approximately 60 to 90 minutes. Sessions incorporate visual aids, discussions, and experience-sharing among participants to encourage engagement and facilitate learning. Participants also receive printed educational materials to support self-directed learning after the sessions.

Category

Other

2

Description

Control group: The control group will receive routine post-operative care, which includes standard medical and nursing advice typically provided after bariatric surgery, such as general recommendations on diet, medication use, wound care, and routine follow-up appointments. They will not receive any structured or theory-based educational intervention.All intervention sessions will be conducted at the bariatric surgery department of Aram Hospital in Karaj. Participants in the intervention group are required to attend at least three of the four sessions to be considered fully exposed to the program. Attendance will be closely monitored, and make-up sessions will be offered if necessary. To ensure fidelity, the intervention will follow a standardized protocol, and the nurse educator will undergo specific training before the study begins.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Aram hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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?

No

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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
Islamic Azad University
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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not 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
Yes - There is 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
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 research team has access to the information.
When the data will become available and for how long
Up to 5 years after results are published
To whom data/document is available
The research team is allowed
Under which criteria data/document could be used
Big data can be used upon request of the journal, reviewer, and researchers.
From where data/document is obtainable
Andarvazh07@gmail.com /alireza andarvazh/09123605519
What processes are involved for a request to access data/document

Information is sent upon request from journals and researchers.

Comments