

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Investigating the effect of telephone intervention on the level of self-care and complications in patients undergoing pelvic organ

Protocol summary

Study aim

The effect of telephone intervention on self-care and complications in patients undergoing pelvic organ surgery referred to the gynecological surgery department

Design

A randomized, single-blind clinical trial will be conducted. Eligible patients will be selected based on the objectives, inclusion criteria and reviewing the medical records. Then they will be assigned to the control and intervention groups in a simple randomization (table of random numbers).

Settings and conduct

Patients undergoing pelvic organ surgery (hysterectomy, caesarean section, ovarian cyst removal, ectopic pregnancy laparotomy and removal of uterine myoma) referring to the women's surgery department of Imam Khomeini Hospital in Ahvaz, Iran.

Participants/Inclusion and exclusion criteria

Willingness to participate in the study Without a history of participating in similar training programs Having an active medical record in the gynecological surgery department and visiting regularly to receive services Access to mobile phone Without any behavioral or mental disorders, and hearing or speech problems

Intervention groups

In the intervention group, 4 phone calls (at least 10 minutes) will be made with the patient during one month. In each conversation, after the greeting and checking the patient's knowledge status, the educational content is presented in the form of questions and answers. It includes diet, rest, exercises, walking, drug and treatment recommendations, and the operation site care. In case of non-adherence, the reason is investigated. Then solutions are suggested. A phone number is provided by the researcher to this group to probable questions.

Main outcome variables

Diet, Physical activity, and Drug adherence

Complications after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231103059936N1**

Registration date: **2023-12-18, 1402/09/27**

Registration timing: **prospective**

Last update: **2023-12-18, 1402/09/27**

Update count: **0**

Registration date

2023-12-18, 1402/09/27

Registrant information

Name

Marziyeh Asadizaker

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3311 5633

Email address

marziyehasadizaker@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-05, 1402/10/15

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Investigating the effect of telephone intervention on the level of self-care and complications in patients undergoing pelvic organ
Public title	Effect of telephone intervention on self-care
Purpose	Supportive
Inclusion/Exclusion criteria	
Inclusion criteria:	Willingness to participate in study and training via telephone Without a history of participating in similar educational programs Having an active medical record in the gynecological surgery department and visiting regularly to receive services Having a mobile phone personally or in the family Not having behavioral and mental disorders, hearing and speech problems
Exclusion criteria:	Failure to participate in more than 2 telephone intervention sessions
Age	No age limit
Gender	Female
Phase	N/A
Groups that have been masked	Participant
Sample size	Target sample size: 90
Randomization (investigator's opinion)	Randomized
Randomization description	The names of the patients were randomly selected using random numbers and in order to avoid interaction between the two intervention and control groups, on two separate days, even days (control group) and odd days (intervention group) until the sampling was completed and Examples of each group are assigned.
Blinding (investigator's opinion)	Single blinded
Blinding description	The names of the patients were randomly selected using random numbers and in order to avoid interaction between the two intervention and control groups, on two separate days, even days (control group) and odd days (intervention group) until the sampling was completed and Examples of each group are assigned.
Placebo	Not used
Assignment	Single
Other design features	N/A

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran.

Street address

Golestan highway, Ahvaz Jandishapur University of Medical Sciences, Ahvaz, Iran.

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2023-11-04, 1402/08/13

Ethics committee reference number

IR.AJUMS.REC.1402.332

Health conditions studied

1

Description of health condition studied

Gynecology and productive diseases

ICD-10 code

ICD-10 code description

Maternal care for known or suspected abnormality of pelvic organs

Primary outcomes

1

Description

Self-care

Timepoint

one month after intervention

Method of measurement

researcher-made self- care questionnaire

Secondary outcomes

1

Description

Complications

Timepoint

one month after intervention

Method of measurement

Researcher-made complications checklist

Intervention groups

1

Description

Intervention group:

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Women's Department of Imam Khomeini Hospital
(RA) Ahvaz

Full name of responsible person

Marzyieh Asadizaker

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Azadegan Street - Imam Khomeini Educational and
Medical Center, Ahvaz, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerkish

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Marzyieh Asadizaker

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mohabbat Rahmati

Position

Master of Science Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Master of Science student

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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

No - There is not a plan to make this available

Title and more details about the data/document

Publish the results of statistical analysis on the collected data in the form of an article

When the data will become available and for how long

Access as soon as the article is published

To whom data/document is available

The general public

Under which criteria data/document could be used

It is not possible to use the data in other studies.

From where data/document is obtainable

Vice President of Research, Ahvaz Jundishapur University of Medical Sciences

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

It is not possible to use the data in other studies.

Comments