Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
Street address
Azadegan Street - Imam Khomeini Educational and Medical Center, Ahvaz, Iran.
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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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https://vchresearch.ajums.ac.ir/
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
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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