Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effect of Lymphedema Self-Management Education in Two Methods of Group-Based and Social-Network-Based on Quality of Life and Fear of Disease Recurrence in Women With Breast Cancer.

Protocol summary

Study aim

Comparison of the Effect of Lymphedema Self-Management Education in Two Methods of Group-Based and Social-Network-Based on Quality of Life and Fear of Disease Recurrence in Women With Breast Cancer.

Design

Three-group clinical trial with control group, randomized by assigning 105 women with lymphedema to group-based education (n = 35), social network- based education (n = 35) and control group (n = 35) using a random block method.

Settings and conduct

The study was conducted on women with lymphedema referring in Seyyed-e-Khandan physiotherapy institute in Tehran as a randomized clinical trial.

Participants/Inclusion and exclusion criteria

History of breast cancer stages 0 to IV, lymphedema approved by physician during the last year, age 18-65, treatments completion, ability to read and write, and work with Telegram, access to the Internet and a cellphone, no use of psychiatric treatments and psychological counseling after catching cancer, negative tumor margin, being Iranian.

Intervention groups

Group-based education was conducted in 7 groups of 5 subjects in 5 sessions 60 to 90 minutes 2 times a week for 3 weeks. At the end of the sessions, CD containing educational materials was given to the participants. Social network-based education was presented 5 times and 2 times a week for 3 weeks on a channel in application of Telegram™. All participants received usual treatment (20 sessions complete decongestive therapy). The control group were completed the questionnaires at the beginning of the study, immediately after the usual treatment and three months later. At the end of the intervention, CD containing educational materials was given to the participants in control group.Before the intervention, immediately and three months after the intervention questionnaires were completed by participants in intervention groups.

Main outcome variables

Quality of life; fear of cancer recurrence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052834176N1**
Registration date: **2017-08-21, 1396/05/30**
Registration timing: **prospective**

Last update: **2019-05-11, 1398/02/21**
Update count: **1**

Registration date

2017-08-21, 1396/05/30

Registrant information

Name

zahra omidi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date
2018-03-19, 1396/12/28
Actual recruitment start date
2017-09-23, 1396/07/01
Actual recruitment end date
2018-03-17, 1396/12/26
Trial completion date
2018-06-20, 1397/03/30

Scientific title
Comparison of the Effect of Lymphedema Self-Management Education in Two Methods of Group-Based and Social-Network-Based on Quality of Life and Fear of Disease Recurrence in Women With Breast Cancer.

Public title
teaching lymphedema self management in breast cancer patients
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Approved breast cancer stages 0 to IV Lymphedema of upper limb approved by physician during the last year Age between 18-65 Treatment completion Having literacy reading and writing The ability to work with Telegram™ via a laptop or mobile phone Having access to the Internet and a cellphone No use of psychiatric treatments and psychological counseling after catching cancer Negative tumor margin Being Iranian
Exclusion criteria:
Metastasis A history of cancer recurrence
Age
From **18 years** old to **65 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **105**
Actual sample size reached: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling was done continuously. Before the intervention 35 sets from ABC, BAC, ... with numbers 1-35 by software was randomly produced.Every three women who entered the study assigned in one of the sets. Given that group education should be provided in groups of 5 people, every five people who entered the group-based education were received the intervention.The phone numbers of women who entered the social network-based education group were recorded to enter the Telegram channel after completing the sample size. Women who assigned to the control group were asked to complete questionnaire in the beginning, immediately after the usual treatment and three months after.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran,Iran
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2017-03-11, 1395/12/21
Ethics committee reference number
ir.iums.rec1395.9411373002

Health conditions studied

1

Description of health condition studied
Breast cancer
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

2

Description of health condition studied
lymphedema
ICD-10 code
I97.2
ICD-10 code description
Postmastectomy lymphoedema syndrome

Primary outcomes

1

Description
quality of life
Timepoint
before,Immediately, 3 months after intervention
Method of measurement
questionnaires of QLQ-BR23,QLQC30 and LLIS

2

Description
fear of recurrence cancer
Timepoint
before,Immediately, 3 months after intervention
Method of measurement
short form of fear of progression questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
In the in-person interference group which consists of 35 people, after filling out the written consent form, the questionnaires of the fear of cancer progression, the effect of lymphedema on life, and the Iranian version of the European Organization for Research and Treatment of Cancer (EORTC) Quality of life questionnaire (QLQ-C30) and it's supplementary Breast Cancer-Specific Quality of life questionnaire (QLQ_BR23) are filled out by people. In seven groups of five people, patients receive self-management training in five sessions in the form of speech, group discussion and question and answer which last as long as 60 minutes, and based on the patients' need for question and answer, as long as 90 minutes. At the end of the interference sessions, the CDs containing the educational materials are given to be reviewed at home. The educational content is as follows:First session: preventing stress, fear and the anxiety caused by breast cancer with a focus on lymphedema Second session: general skills for self-management Third session: problem-solving skill with an explanation on lymphedema and its side effects, ways to control lymphedema and the phases of the self-management of lymphedema (the second phase of the standard treatment of lymphedema) Fourth session: decision making and the use of resources with an explanation on which phase of self-management ought to be utilized according to their own condition Fifth session: cooperation with the treatment team and the implementation of the learned skills at home. Participants are required to fill out the questionnaires immediately after the intervention and after three months.All people will also receive the usual treatment.
Category
Behavior

2

Description
In the interference group based on the social network which consists of 35 people, after filling out the written consent form, the questionnaires of the fear of cancer progression, lymphedema life impact scale, and Iranian version of the European Organization for Research and Treatment of Cancer (EORTC) Quality of life questionnaire (QLQ-C30) and it's supplementary Breast Cancer-Specific Quality of life questionnaire (QLQ_BR23) are filled out by people. To preserve the patients' privacy and their numbers, on a Telegram™-based channel the same educational content are taught five times on different days in the afternoon hours. Channel members can pose their questions and answers with the administrator of the channel (i.e. the researcher). Also, after posing the content, to make sure of receiving messages from all the members, they are each required to inform the administrator of the channel or give their opinion(s) after receiving the content. Members are reminded to use Telegram™ software through SMS twice a week. The educational content is as follows:First session: preventing stress, fear and the anxiety caused by breast cancer with a focus on lymphedemaSecond session: general skills for self-managementThird session: problem-solving skill with an explanation on lymphedema and its side effects, ways to control lymphedema and the phases of the self-management of lymphedema (the second phase of the standard treatment of lymphedema)Fourth session: decision making and the use of resources with an explanation on which phase of self-management ought to be utilized according to their own conditionFifth session: cooperation with the treatment team and the implementation of the learned skills at home. Participants are required to fill out the questionnairesr immediately after the intervention and after three months.All people will also receive the usual treatment.
Category
Behavior

3

Description
In the control group which consists of 35 patients, after filling out the written consent form, the questionnaires of the fear of cancer progression, lymphedema life impact scale and Iranian version of the European Organization for Research and Treatment of Cancer (EORTC) Quality of life questionnaire (QLQ-C30) and it's supplementary Breast Cancer-Specific Quality of life questionnaire (QLQ_BR23) will be filled out by people. All the members of the control group will receive the routine trainings of the center including the care and prevention of lymphedema brochure and the CDs of rehabilitative sports for lymphedema which are routinely given to the clients and 20 sessions of complete decongestive therapy . Participants required to fill out the questionnaires immediately after the usual treatment and three months later. After collecting the data, the materials and educational CD will also be at the disposal of the control group members.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center

Seyyed-e-Khandan physiotherapy institute

Full name of responsible person
Shahpar Haghighat

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Building No. 17. South Abouzar St, Khajeh Abdollah Ansari St, Seyed Khandan Bridge, Tehran, 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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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Masoomeh Kheirkhah

Position
assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Education

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Person responsible for updating data

Contact

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Zahra Omidi
Position
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Latest degree
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Other areas of specialty/work
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available