Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

The effect of an online occupation-based intervention program on arm lymphedema, spirituality, occupational performance, sexuality function and adaptive response in women with breast cancer

Protocol summary

Study aim

The effect of an online and occupation-based intervention program on arm lymphedema, spirituality, occupational function, sexual function and adaptive response in women with breast cancer

Design

A single-blind randomized controlled clinical trial study

Settings and conduct

Lymphatic rehabilitation centers in Tehran and Ahvaz and 40 participants will be divided into two groups of intervention and control by Stratified Balanced Block Randomization with equal block method. Out of a maximum of 20 modes for the six blocks, three will be in the intervention group or A and three in the control group will be created using the RANDBETWEEN (1,20) command in Excel software. Participants will be divided equally into two groups according to the random sequence created.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ability to verbally communicate and speak in Persian, read and write, Being over 18 years of age, having access to a telephone,, Get a score above 22 on the MMSE cognitive test, Histologically confirmed malignancy based on the physician's diagnosis. Exclusion criteria: people with brain metastases, mental disabilities, psychosis and dementia.

Intervention groups

Intervention group: Combined program including lymphatic therapy (CDT) and an individual, remote (telephone and available applications) and occupation-based treatment during 10 weeks based on the Occupational Adaptation Practice Guideline (OAPG) during a 5-week intervention program and during 10 sessions. Control group: Complete decongestive therapy (CDT) for ten sessions one hour sessions within 5 weeks in lymph therapy clinics.

Main outcome variables

Canadian Occupational Performance Measurement Relative Mastery Scale the 12-item Spiritual Well-being scale The Persian version of the Lymphedema Life Impact Scale (LLIS) The Female Sexual Function Index (FSFI)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211220053459N2**
Registration date: **2023-03-07, 1401/12/16**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-07, 1401/12/16**
Update count: **0**

Registration date

2023-03-07, 1401/12/16

Registrant information

Name

Fatemeh Motaharinezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3365 4180

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fatemeh.motahari64@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-01, 1401/12/10

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of an online occupation-based intervention program on arm lymphedema, spirituality, occupational performance, sexuality function and adaptive response in women with breast cancer

Public title
The effect of occupational therapy in women with breast cancer
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Ability to verbally communicate and speak in Persian Read and write Being over 18 years of age Having access to a telephone Get a score above 22 on the MMSE cognitive test Histologically confirmed malignancy based on the physician's diagnosis
Exclusion criteria:
People with brain metastases Mental disabilities Psychosis Dementia
Age
From **18 years** old
Gender
Female

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
50 participants will be divided into two groups of intervention and control by Stratified Balanced Block Randomization with equal block method. Out of a maximum of 20 modes for the six blocks, three will be in the intervention group or A and three in the control group will be created using the RANDBETWEEN (1,20) command in Excel software. Participants will be divided equally into two groups according to the random sequence created.
Blinding (investigator's opinion)
Single blinded
Blinding description
Outcome evaluator: The person or people who evaluate the outcome or non-outcome of the outcome in the participants or collect data on the outcome variables.
Placebo
Not used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Semnan University of Medical Sciences
Street address
سمنان بلوار بسیج ستاد دانشگاه علوم پزشکی و خدمات بهداشتی درمانی استان سمنان
City
Semnan
Province
Semnan
Postal code
3514799442
Approval date
2023-02-06, 1401/11/17
Ethics committee reference number
IR.SEMUMS.REC.1401.260

Health conditions studied

1

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

Primary outcomes

1

Description
level of occupational performance and satisfaction of occupational performance
Timepoint
Before the intervention, after the intervention and one month after the intervention
Method of measurement
Canadian Occupational Performance Measurement

2

Description
Adaptation
Timepoint
Before the intervention, after the intervention and one month after the intervention
Method of measurement
Relative Mastery Scale

Secondary outcomes

1

Description
Spirituality
Timepoint
En Before the intervention, after the intervention and one month after the intervention
Method of measurement
the 12-item Spiritual Well-being scale

2

Description
Lymphedema
Timepoint
Before the intervention, after the intervention and one month after the intervention
Method of measurement
The Persian version of the Lymphedema Life Impact Scale (LLIS)

3

Description
Sexual Function
Timepoint
Before the intervention, after the intervention and one month after the intervention
Method of measurement
The Female Sexual Function Index (FSFI)

Intervention groups

1

Description
Intervention group: Participants in the intervention group will receive a combined program including lymphatic therapy (CDT) and an individual, remote (telephone and available applications) and occupation-based treatment during 10 weeks. Occupation-based treatment will be based on Occupational Adaptation Practice Guideline (OAPG) during a 5-week intervention program and during 10 sessions (two sessions of 40 minutes each week). Based on this guideline, the interaction between personal characteristics (physical, motor, cognitive, psychological skills, etc.) with environmental subsystems (characteristics of the physical, social environment, etc.) of the participant will examine and provide specific occupational therapy interventions for each participant to facilitate this interaction and to help for better adaptation with the existing conditions.
Category
Rehabilitation

2

Description
Control group: Complete decongestive therapy (CDT) for ten sessions one hour sessions within 5 weeks in lymph therapy clinics. Complete decongestive therapy (CDT) is a noninvasive treatment for lymphedema. The key components of a CDT program are: Manual lymphatic drainage (MLD), Compression, Regular Exercises and Skin care.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Lymphatic rehabilitation centers
Full name of responsible person
Fatemeh Motaharinezhad
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Famili Rehabilitation Clinic, Ayatollah Madani Blvd, Famili St., Semnan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Dr Majid Mirmohammadkhani
Street address
Headquarter of Semnan University of Medical Sciences and Health Services, Bassij Blvd, Semnan, Iran.
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3514799442
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Email
info@semums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan 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
Semnan University of Medical Sciences

Full name of responsible person
Fatemeh Motaharinezhad

Position
Faculty member

Latest degree
Ph.D.

Other areas of specialty/work
Occupational Therapy

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Person responsible for scientific inquiries

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Position
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Other areas of specialty/work
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Person responsible for updating data

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Faculty Member

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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
.

When the data will become available and for how long
.

To whom data/document is available
.

Under which criteria data/document could be used
.

From where data/document is obtainable

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