Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation the effectiveness of a group psychoeducational intervention in reducing the level of cancer-related fatigue in women receiving chemotherapy for breast cancer: A randomized controlled Trial

Protocol summary

Study aim
Evaluate the effectiveness of a group psychoeducational intervention in reducing the level of cancer related fatigue in women receiving chemotherapy for breast cancer

Design
a randomized, parallel, single blinded, controlled clinical trial on 42 patient

Settings and conduct
the study had been performed in Isfahan Seyedoshohada hospital and patient didn' t know about which educational group had been enrolled

Participants/Inclusion and exclusion criteria
Inclusion criteria: Definite diagnosis of breast cancer for at least 2 month ago, Under outpatient chemotherapy, Age between 18 to 60, Having a hemoglobin of 11 or more, Have reading and writing skills, Lack of metastasis, Lack of any chronic cardiac and respiratory disease and diabetes and absence of severe bone pain and balance problem Exclusion criteria: Acute respiratory, cardiac or infectious disease, reduce hemoglobin below 11، patient death

Intervention groups
In intervention group we used a self designed educational package consist of sleep health, energy management and concentration body movement therapy in three, forty minutes weekly sessions; in control group some general information about feeding, how to deal with hair loss and lymph edema, stress management and ... had been educated.

Main outcome variables
decreased fatigue in interventin group

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180623040193N2**
Registration date: **2018-08-12, 1397/05/21**
Registration timing: **retrospective**

Last update: **2018-08-12, 1397/05/21**
Update count: **0**

Registration date
2018-08-12, 1397/05/21

Registrant information

Name
Elham Zarean

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 38 3222 0016

Email address
e.zarean@skums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-01-21, 1396/11/01

Expected recruitment end date
2018-05-10, 1397/02/20

Actual recruitment start date
2018-01-21, 1396/11/01

Actual recruitment end date
2018-05-10, 1397/02/20

Trial completion date
empty

Scientific title
Evaluation the effectiveness of a group psychoeducational intervention in reducing the level of

cancer-related fatigue in women receiving chemotherapy for breast cancer: A randomized controlled Trial

Public title
effectiveness of a group psychoeducational intervention in reducing the level of cancer-related fatigue
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Definite diagnosis of breast cancer for at least 2 month ago Under outpatient chemotherapy Age 18-60 years old Having a hemoglobin of 11 or more Have reading and writing skills Lack of metastasis Lack of any chronic cardiac and respiratory disease and diabetes and absence of severe bone pain and balance problem Informed consent
Exclusion criteria:
acute respiratory, cardiac or infectious disease reduce hemoglobin below 11 any mental or physical state that interfere participating in group intervention patient death
Age
From **18 years** old to **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **42**
Actual sample size reached: **43**
Randomization (investigator's opinion)
Randomized
Randomization description
Patient were randomly allocated to either intervention or controlled group using random number generator software
Blinding (investigator's opinion)
Single blinded
Blinding description
Participant are blinded
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
. Ethics committee of SHahrekord University of Medical Sciences
Street address
Kashani Ave,SHahrekord university of medical science
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
۸۸۱۵۷۱۳۴۷۱
Approval date
2018-01-21, 1396/11/01
Ethics committee reference number
IR.SKUMS.REC.1396.247

Health conditions studied

1

Description of health condition studied
breast cancer, fatigue
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
fatigue
Timepoint
before intervention, immediately after end of intervention, 2 and 4 weeks later
Method of measurement
Fatigue Visual Analogue Scale, cancer fatigue scale, Piper Fatigue scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: We used a self designed educational package consist of sleep health, energy management and concentration body movement therapy in three, forty minutes weekly sessions.
Category
Treatment - Other

2

Description
Control group: three, 45 minutes weekly session about feeding, how to deal with lymph edema and hair loss, stress management and how to deal with children, spouse and family, how to access self help groups and supportive centers and external prosthesis
Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Seyedalshohada hospital

Full name of responsible person
Zahra Ahmadzadeh

Street address
Nahrefarshadi Alley, Khayam Ave, seyedalshohada Hosp

City
Isfahan

Province
Isfehan

Postal code
-

Phone
+98 31 3236 8005

Email
e.zarean@skums.ac.ir

2

Recruitment center

Name of recruitment center
Ala medical center

Full name of responsible person
Zahra Ahmadzadeh

Street address
Aminodoleh Deadend, no 35 alley, after Shiri Bridge, Motahari Ave, Isfahan

City
Isfahan

Province
Isfehan

Postal code
-

Phone
+98 31 3233 3029

Email
e.zarean@skums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Kamal Solati

Street address
Deputy of research and technology, Kashani Ave, Shahrekord

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815713471

Phone
+98 38 3333 0061

Email
kamal_solati@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences

Full name of responsible person
Elham Zarean

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

Street address
Department of Psychiatry, Hajar Hosp, parastar Ave, SHahre-kord

City
SHahre-kord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8816758915

Phone
+98 38 3222 0016

Fax

Email
ezarean@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Elham Zarean

Position
Assistant professor

Latest degree

Specialist

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Province

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Postal code

8816758915

Phone

+98 38 3222 0016

Fax

Email

ezarean@gmail.com

Person responsible for updating data

Contact

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Shahre-kord University of Medical Sciences

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Elham Zarean

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Postal code

8816758915

Phone

+98 38 3222 0016

Fax

Email

ezarean@gmail.com

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

data collected using questioners, statistical analysis and outcomes

When the data will become available and for how long

starting 6 months after publication for 3 months

To whom data/document is available

only available for people working in academic institutions

Under which criteria data/document could be used

Doing similar research

From where data/document is obtainable

email

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

after receiving request via email, evaluation will be done

Comments