

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 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**

Isfahan

**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

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**Postal code**

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## 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

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8815713471

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+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

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Shahre-kord University of Medical Sciences  
**Full name of responsible person**  
Elham Zarean  
**Position**  
Assistant professor  
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**Other areas of specialty/work**  
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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