

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of energy saving strategies education on fatigue and selfcare efficacy of women with breast cancer receiving chemotherapy in hospitals of the Zahedan University medical sciences in 2019

#### Protocol summary

##### Study aim

Determine of effect of Energy Storage Strategies on Fatigue and Career Self-efficacy in Women with Breast Cancer Under Chemotherapy

##### Design

Type of study is controlled randomized clinical trial, and after explaining the objective of the project and taking the written consent from the qualified patients, the people are selected in accessible manner. The sample volume of this study is 40 people per group. By referring and gradually selecting individuals, a card will assign to them, which will determine the individual group.

##### Settings and conduct

The target population includes all patient diagnosed with Breast Cancer, who referred to Khatam-al-anbia and Ali-ebn Abi taleb Hospitals of Zahedan in 2019 for chemotherapy, having the entry conditions.

##### Participants/Inclusion and exclusion criteria

The conditions to enter: The Age between 20-60 At cancer stage 1 or 2 or 3 Receiving at least a chemotherapy session Being able to establish relationship or Cooperation Lack of cardio-pulmonary disease Lock of known neuropsychiatric disorder and consuming relevant medicines. Being able to read and write. The conditions not to enter: An absent during the training sessions Lock of executing the training plan for one ongoing week patient metastasis Death of patient

##### Intervention groups

Intervention Group: the strategies of energy saving, which will be conducted in the experimental group within 3 individual session, one per week. After Full filling the 3 training session, they will be followed for 6 weeks. The above-mentioned interval, the questions are distributed to control and intervention group, while the post- test will be taken. The control group receives no special cars, except rut in cares.

##### Main outcome variables

Training Energy saving strategies is a methods needs no cost and executable doting daily activities to reduce fatigue and increasing core efficiency of patient.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171009036675N4**

Registration date: **2019-01-27, 1397/11/07**

Registration timing: **prospective**

Last update: **2019-01-27, 1397/11/07**

Update count: **0**

##### Registration date

2019-01-27, 1397/11/07

##### Registrant information

##### Name

Fatemeh Kiani

##### Name of organization / entity

Faculty member, Zahedan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 3329 5715

##### Email address

f.kiani@zaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-02-19, 1397/11/30

##### Expected recruitment end date

2019-04-08, 1398/01/19

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of energy saving strategies education on fatigue and selfcare efficacy of women with breast cancer receiving chemotherapy in hospitals of the Zahedan University medical sciences in 2019

**Public title**

Effect of energy saving strategies education on fatigue and selfcare efficacy of women with breast cancer

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

The Age between 20-60 being at 1 or 2 or 3 cancer stage Receiving at least one session chemotherapy Being able to establish relationship or cooperation. Lack of cardiovascular disease. Lack of known neuropsychiatric disorder and consuming relevant medicines. Being able to read and write

**Exclusion criteria:**

An absent during the training sessions Lock of executing the training plan for one ongoing week patient metastasis Death of patient

**Age**

From **20 years** old to **60 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The researcher will refer to the chemotherapy wards of Ali ibn Abi Talib (PBUH) and Khatam al-Anbia (PBUH) hospitals after approving the proposal and obtaining university permissions and performing the necessary coordination. Then, intervention and control groups will be gradually selected. After explaining the purpose of the project and obtaining written consent from eligible patients, individuals are selected in a non-random and accessible manner. To allocate randomness, first, the total number of envelopes containing the groups arranged and randomly sorted. By referring and gradually selecting individuals, one of these cards will be assigned, which will determine the individual group.

**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 Zahedan University of Medical Sciences

**Street address**

Zahedan University of Medical Sciences, Dr Hesabi Sq.

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743463

**Approval date**

2019-01-15, 1397/10/25

**Ethics committee reference number**

IR.ZAUMS.REC.1397.392

**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**

Fatigue of breast cancer patient

**Timepoint**

Before intervention and 6 weeks after intervention

**Method of measurement**

Multidimensional Fatigue Inventory

**2****Description**

Self-efficacy of breast cancer patient

**Timepoint**

Before intervention and 6 weeks after intervention

**Method of measurement**

Strategies Used By People to Promote Health Inventory

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention Group: the strategies of energy saving, which will be conducted in the experimental group within 3 individual sessions, one per week. After Full filling the sessions, they will be followed for 6 weeks.

#### Category

Behavior

### 2

#### Description

Control group: The control group, except for routine care, does not receive special care.

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Khatam al anbia hospital

##### Full name of responsible person

Fatemeh Kiani

##### Street address

Zahedan, Jam-e-jam Ave.

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9815733169

##### Phone

+98 54 3322 6269

##### Fax

##### Email

khatamhospital-zah@yahoo.com

##### Web page address

<http://zaums.ac.ir>

### 2

#### Recruitment center

##### Name of recruitment center

Ali ibn abi taleb hospital

##### Full name of responsible person

Fatemeh Kiani

##### Street address

Persian gulf highway, Salamat Ave.

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816743111

##### Phone

+98 54 3329 5570

##### Email

[drkazemmomeni@gmail.com](mailto:drkazemmomeni@gmail.com)

##### Web page address

<http://zaums.ac.ir>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Zahedan University of Medical Sciences

##### Full name of responsible person

Mohsen Taheri

##### Street address

Deputy of Research and Technology, Medical Sciences Campus, Dr.Hesabi Sq.

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816743463

##### Phone

+98 54 3329 5796

##### Email

[taheri@zaums.ac.ir](mailto:taheri@zaums.ac.ir)

##### Web page address

<http://zaums.ac.ir>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

##### Full name of responsible person

Fatemeh Kiani

##### Position

Instructor, faculty member

##### Latest degree

Master

**Other areas of specialty/work**

Nursery

**Street address**

Faculty of nursing and midwifery, Mashahir sq.

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743463

**Phone**

+98 54 3344 2481

**Email**

f.kiani@zaums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Fatemeh Kiani

**Position**

Instructor, faculty member

**Latest degree**

Master

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**Person responsible for updating data****Contact****Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Fatemeh Kiani

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**Phone**

+98 54 3344 2481

**Email**

f.kiani@zaums.ac.ir

**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**

Undecided - It is not yet known if there will be 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**

only the main outcome data will be available

**When the data will become available and for how long**

After publishing the article in 2019

**To whom data/document is available**

all people

**Under which criteria data/document could be used**

Improve treatment conditions

**From where data/document is obtainable**

Zahedan University of Medical Sciences

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

Applying from the university research deputy

**Comments**