# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## The effect of the combined intervention of low intensity exercise and slow stroke back massage(SSBM) on physical activity and severity of fatigue in the patients undergoing chemotherapy

## Protocol summary

**Study aim**
Determination The effect of the combined intervention of low intensity exercise and slow stroke back massage(SSBM) on physical activity and severity of fatigue in the patients undergoing chemotherapy

**Design**
A randomized controlled clinical trial study in the oncology ward of Ahvaz Baghaee Hospital

**Settings and conduct**
Oncology Department of Baqaee Hospital 2 Ahvaz

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Age between 18 and 65 The lack of musculoskeletal problems and abnormalities which prevent massage or exercise of patient The lack of cardiovascular disease history for doing exercise Receiving at least one period of chemotherapy before study Exclusion criteria: The lack of ability to do daily activities Conducting chemotherapy and radiotherapy at the same time Cerebral or skeletal metastasis

**Intervention groups**
In the case group, three days a week for 4 weeks and 10 minutes each session, back massage will be performed on a superficial shock method. Back massaging will be done by superficial technique in the form of surface blows on the back of the patient. Exercise is carried out daily 15 minutes of active, isometric, stretching and walking, which will be done according to the agreed moves, respectively. Each limb movement of 10 seconds and repetitive movements will take 10 of each. The movements in total 10 minutes and walk will take 5 minutes. The control group will be monitored under a routine routine care program for patients undergoing chemotherapy that will be administered in the hospital.

**Main outcome variables**
Physical activity and patient fatigue

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20171203037737N4**
Registration date: **2019-05-05, 1398/02/15**
Registration timing: **retrospective**

Last update: **2019-05-05, 1398/02/15**
Update count: **0**

**Registration date**
2019-05-05, 1398/02/15

**Registrant information**

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sedighe ghobadian

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-02-20, 1397/12/01

**Expected recruitment end date**
2019-03-06, 1397/12/15

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The effect of the combined intervention of low intensity exercise and slow stroke back massage(SSBM) on physical activity and severity of fatigue in the patients undergoing chemotherapy

**Public title**
The effect of the combined intervention on physical activity and severity of fatigue in the patients undergoing chemotherapy

**Purpose**
Health service research

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Men and women with different types of cancer and undergoing chemotherapy in oncology departments of women and men in Baqaee Hospital 2 in Ahwaz The Lack of musculoskeletal problems and abnormalities which prevent massage or exercise of patient The lack of cardiovascular disease history for doing exercise Not doing any other exercise during study Have at least one chemotherapy course before the study In the base CBC examination (WBC) above 3000, the patient's platelet is above 50,000 and hemoglobin is above 8 In each period, vital signs are within the normal range. Patients living in the city of Ahvaz and the suburbs

**Exclusion criteria:**
The lack of ability to do daily activities Conducting chemotherapy and radiotherapy at the same time Cerebral or skeletal metastasis

**Age**
From **18 years** old to **65 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **46**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
- Subjects participating in research will be placed randomly in control and intervention groups. Assigning intervention to participants was done randomly by randomized permutated blocks with 4 blocks (using randomized permutation table). - Randomization list is prepared by statistics expert. Intervention used in this research is assigned according to randomized list by a person out of study who is not aware of research objectives and will be put in a signed pocket and is given to each participant with regard to corresponding codes. - Determining effect of mixed intervention of low intensity exercise and back massage (in form of surface smashing) on physical activity and exhaustion of patients receiving chemotherapy

**Blinding (investigator's opinion)**
Not blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Factorial

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
The Ethics Committee of the Jundishapur University of Medical Sciences, Ahwaz

**Street address**
Golestan

**City**
Ahvaz

**Province**
Khouzestan

**Postal code**
15794-61357

**Approval date**
2018-11-17, 1397/08/26

**Ethics committee reference number**
IR.AJUMS.REC.1397.619

## Health conditions studied

### 1

**Description of health condition studied**
Fatigue in patients undergoing chemotherapy

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Fatigue severity

**Timepoint**
The intensity of fatigue of patients will be measured by a questionnaire for 4 weeks and at regular intervals (control group at the same time as the intervention group).

**Method of measurement**
Using the Piper Fatigue Scale and the Standard Physical Activity Scale (IPAQ)

### 2

**Description**
Physical activity status

**Timepoint**
physical activity of patients will be measured by a questionnaire for 4 weeks and at regular intervals (control group at the same time as the intervention group).

**Method of measurement**
Using the Piper Fatigue Scale and the Standard Physical Activity Scale (IPAQ)

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
In the intervention group, back massage is performed three days a week for 4 weeks and each session for 10 minutes. Dorsal massage will be performed in the form of a superficial shock on the back of the patient. Exercise 15 minutes a day as active and isometric movements, stretching and feeding, which will select patients to arrange the movements. The front moves in each member will be 10 seconds and repetitive movements will be 10 times. The mentioned moves will take 10 minutes and the walk will be 5 minutes. The beginning of the week intervention will be zero. At the beginning of the intervention (week zero), at the end of each week, the intensity of fatigue and physical activity will be measured by the tools mentioned.
**Category**
Rehabilitation

### 2

**Description**
Control group: Control group received routine program for patients treating with chemotherapy. In control group, amount of exhaustion and physical activity was assessed for 4 weeks in regular intervals (at the same time with intervention group) by mentioned tools
**Category**
Rehabilitation

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Baghaii 2 Hospital
**Full name of responsible person**
Marzieh Asadizaker
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## Sponsors / Funding sources

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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**
Ahvaz University of Medical Sciences
**Proportion provided by this source**
50
**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**
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## Person responsible for scientific inquiries

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## 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**
The patient information file will be confidential for ethical reasons
**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**
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**
Not applicable
**Data Dictionary**
Not applicable
**Title and more details about the data/document**
The protocol and clinical study report will be presented as an article.
**When the data will become available and for how long**
After the publication of the article, access to information will be possible.
**To whom data/document is available**
Health managers in the rehabilitation area, researchers and enthusiasts
**Under which criteria data/document could be used**
For scientific studies with the permission of the magazine that published the article.
**From where data/document is obtainable**
The file that the magazine gives readers.
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