

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Aug 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

Name

sedighe ghobadian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3320 9717

Email address

ghobadian.s@ajums.ac.ir

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 permuted 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**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Marzieh Asadizaker

Position

Educational faculty of Ahwaz University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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.

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

Log in to the magazine site and download the article file

Comments