Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Sep 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 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
Street address
Golestan
City
Ahvaz
Province
Khouzestan
Postal code
15794-61357
Phone
+98 61 3373 8331
Fax
+98 61 3373 8333
Email
asadizaker_m@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Marzieh Asadizaker
Street address
Golestan
City
Ahvaz
Province
Khouzestan
Postal code
15794-61357
Phone
+98 61 3373 8331
Fax
+98 61 3373 8333
Email
asadizaker_m@ajums.ac.ir
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
Street address
Golestan
City

Ahvaz
Province
Khouzestan
Postal code
15794-61357
Phone
+98 61 3373 8331
Fax
+98 61 3373 8333
Email
asadizaker_m@ajums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Tina Vosoughi
Position
Educational faculty of Ahwaz University of Medical Sciences
Latest degree
Subspecialist
Other areas of specialty/work
Hematology
Street address
golestan
City
Ahvaz
Province
Khouzestan
Postal code
15794-61357
Phone
+98 61 3333 0074
Fax
+98 61 3333 2036
Email
Vosoughi.hto@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Maryam Fazeli
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Golestan
City
Ahvaz
Province
Khouzestan
Postal code
15794-61357
Phone
+98 61 3373 8331
Fax
+98 61 3373 8333
Email
M.fazelee@yahoo.com

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
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