

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Effect of the Planned Walking Exercise Program on Cancer-related Fatigue among Patients with Acute Myeloid Leukemia Undergoing Chemotherapy

Protocol summary

Study aim

Determining the effect of planned walking on cancer-related fatigue in patients with acute leukemia under chemotherapy

Design

In this pretest-post test study, 50 eligible patients with acute myelogenous leukemia who were referred to Shafa hospital were selected.

Settings and conduct

This study was carried out in a referral teaching hospital as the only specialized cancer and chemotherapy hospital in the south west of Iran

Participants/Inclusion and exclusion criteria

Inclusion criteria: being at the age of 18 years and older; being diagnosed with acute AML or the recurrence of AML; taking part in at least two chemotherapy sessions at the time of this study. Exclusion criteria: History of underlying diseases such as cardiovascular disease, diabetes and hypertension, other cancers, inability to attend two walking sessions, hemodynamic instability, discharge from the hospital or death, life expectancy less than one month, and intractable and uncontrolled pain

Intervention groups

The intervention group consisted of only one group (pre test-post test) and there was no control group. The patients were assigned to two groups of males and females to facilitate the implementation of the walking exercise program in each gender group. The patients walked slowly in the warm-up phase and took deep breathing and then entered the main walking program including a 10-minute quick-paced walking.

Subsequently, the patients were asked to walk in a slow pace to feel their heartbeat and do cool down exercises for 5 minutes. After the walking exercise program, the patient laid on the bed and breathed deeply for ten minutes, and their vital signs were measured again by the researcher. In the fifth day and tenth day of the

intervention, the BFI was completed again.

Main outcome variables

cancer-related fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091017002599N2**

Registration date: **2018-01-27, 1396/11/07**

Registration timing: **retrospective**

Last update: **2018-01-27, 1396/11/07**

Update count: **0**

Registration date

2018-01-27, 1396/11/07

Registrant information

Name

shahram baraz

Name of organization / entity

ahwaz joundishapour university medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1373 8333

Email address

shahrambaraz@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-06-21, 1396/03/31

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty
Scientific title
Effect of the Planned Walking Exercise Program on Cancer-related Fatigue among Patients with Acute Myeloid Leukemia Undergoing Chemotherapy
Public title
The effect of planned walking on fatigue of patients with acute leukemia
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
being 18 years old and over being diagnosed with acute AML or the recurrence of AML taking part in at least two chemotherapy sessions
Exclusion criteria:
history of underlying diseases including cardiovascular diseases, diabetes mellitus and hypertension and any other cancers Inability to attend walking tours Unstable hemodynamic status Hospital discharge or death Life expectancy less than a month Uncontrollable pain
Age
From **18 years** old to **60 years** old
Gender
Both
Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Jundishapur University of Medical Sciences

Street address

School of nursing and midwifery, Ahvaz Jundishapur University of Medical sciences, Golestan Blvd, Daneshgah square,Ahvaz, Iran

City

Ahvaz

Province

Khuzestan

Postal code

61357-15794

Approval date

2016-12-03, 1395/09/13

Ethics committee reference number

IR.AJUMS.REC.1395.663

Health conditions studied

1

Description of health condition studied

Acute Myeloid Leukemia

ICD-10 code

C92.0

ICD-10 code description

Acute myeloblastic leukemia

Primary outcomes

1

Description

The score obtained from The Brief Fatigue Questionnaire (BFI)

Timepoint

Fatigue measurement at the beginning of the study, 5 and 10 days after the planned walking

Method of measurement

The Brief Fatigue Questionnaire (BFI)

Secondary outcomes

1

Description

Fatigue interference with everyday life activities

Timepoint

Before the intervention, 5 and 10 days after the intervention

Method of measurement

The Brief Fatigue Questionnaire (BFI)

Intervention groups

1

Description

Intervention group: The researcher provided a quiet and private place in the hospital's courtyard to perform the walking exercise program . Before each session, the patients' vital signs including blood pressure, pulse and respiratory rate were measured by the researcher. The patients were assigned to the group of males and

females to facilitate the implementation of the walking exercise program in each gender group. Similar to the intervention by Wenzel et al. (2013), the patients were asked to perform a 30-minute walk program in two 5-day non-stop periods and within a specified time each day in the following phases: warm-up and preparing the body (5 minutes), a fast-paced walking on the basis of their tolerance (10 minutes), slow-paced walking and body cooling (5 minutes) followed by 10 minutes of rest and relaxation. The patients walked slowly in the warm-up phase and took deep breathing and then entered the main walking program including a 10-minute quick-paced walking. Subsequently, the patients were asked to walk in a slow pace to feel their heartbeat and do cool down exercises for 5 minutes. After the walking exercise program, the patient laid on the bed and breathed deeply for ten minutes, and their vital signs were measured again by the researcher. In the fifth day and tenth day of the intervention, the BFI was completed again.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Hospital

Full name of responsible person

Shahram Baraz

Street address

school of nursing and midwifery, Ahvaz Jundishapur University of Medical sciences, Golestan Blvd, Daneshgah square,Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

13570088611

Phone

+98 61 3373 8331

Fax

+98 61 3373 8333

Email

shahrambaraz@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Shahram Baraz

Street address

school of nursing and midwifery, Ahvaz Jundishapur University of Medical sciences, Golestan Blvd, Daneshgah square,Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

88611135700

Phone

+98 61 3373 8331

Fax

+98 61 3373 8333

Email

shahrambaraz@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

80

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

shahram baraz

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

school of nursing and midwifery, Ahvaz Jundishapur University of Medical sciences, Golestan Blvd, University square,Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

88611135700

Phone

+98 61 3373 8331

Fax

+98 61 3373 8333

Email

shahrambaraz@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Shahram Baraz

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

school of nursing and midwifery, Ahvaz Jundishapur
University of Medical sciences, Golestan Blvd,
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Phone

+98 61 3373 8333

Fax

+98 61 3373 8331

Email

shahrambaraz@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Shahram Baraz

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Province

Khouzestan

Postal code

88611135700

Phone

+98 61 3373 8331

Fax

+98 61 3373 8333

Email

shahrambaraz@ajums.ac.ir

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

Yes - There is a plan to make this available

Title and more details about the data/document

A portion of the original outcome data is shared

When the data will become available and for how long

Starting the access period from 2020

To whom data/document is available

The data will only be available to academic researchers

Under which criteria data/document could be used

Requests for doing a systematic review and meta-
analysis of data are available

From where data/document is obtainable

Contact the email of the author

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

It takes about one month

Comments