

# 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

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### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Ahvaz University of Medical Sciences

###### **Full name of responsible person**

Shahram Baraz

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

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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**

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

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## Person responsible for scientific inquiries

### Contact

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## 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**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

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Shahram Baraz

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Assistant professor

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