

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the Effectiveness of Massage Therapy with Music Therapy on the Pain and fatigue Intensities in the Adult Patients with Acute Leukemia

Protocol summary

Study aim

The aim of this study is to compare the effectiveness of massage therapy with music therapy on the pain and fatigue intensities in the adult patients with acute leukemia.

Design

Three parallel group randomized trial with concealment for nurses who will be collected data.

Settings and conduct

This study will be performed at the Shahid Baghai 2 hospital, Ahvaz, southwest of Iran. Participants will be allocated to massage therapy group, music therapy group and usual care group. Participants will be received 15 minutes intervention sessions, thrice weekly for 4 weeks. Pain and fatigue intensities will be measured using the numeric rating scale at the end of each week of study. Also, in this study concealment will be done for nurses who will be collected data.

Participants/Inclusion and exclusion criteria

Inclusion criteria to the study: Eighteen years or older, undergoing chemotherapy, at least 3 months after diagnosis of acute leukemia. Exclusion criteria to the study: Known disorders of pain in their medical history underlying co-morbidities such as diabetes or other types of cancer.

Intervention groups

Participants will be allocated to massage therapy group, music therapy group and usual care group. participants of massage and music therapy groups will be received 15 minutes intervention sessions, thrice weekly for 4 weeks. Also, participants of usual care group will be received 15 minutes bed rest in the privacy room at similar sessions with massage and music groups.

Main outcome variables

Pain intensity more than 3 according to the 0 to 10 numeric rating scale

General information

Reason for update

At the time of recording the trial, the fatigue intensity variable was not inadvertently recorded. In the proposal approved by the university and Behsan system, the variable of fatigue severity was recorded. The fatigue intensity measuring instrument is the same as the pain intensity measuring instrument.

Acronym

IRCT registration information

IRCT registration number: **IRCT20150302021307N3**
Registration date: **2018-08-13, 1397/05/22**
Registration timing: **prospective**

Last update: **2021-02-05, 1399/11/17**

Update count: **1**

Registration date

2018-08-13, 1397/05/22

Registrant information

Name

Mojtaba Miladinia

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 613333333

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-11, 1397/05/20

Expected recruitment end date

2018-10-12, 1397/07/20
Actual recruitment start date
 2018-12-01, 1397/09/10
Actual recruitment end date
 2019-03-18, 1397/12/27
Trial completion date
 2019-03-21, 1398/01/01

Scientific title
 Comparison of the Effectiveness of Massage Therapy with Music Therapy on the Pain and fatigue Intensities in the Adult Patients with Acute Leukemia

Public title
 Effectiveness of Complementary Medicine in Improving pain and fatigue in Leukemia Patients

Purpose
 Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Eighteen years or older Undergoing chemotherapy At least 3 months after diagnosis of acute leukemia
Exclusion criteria:
 Known disorders of pain in their medical history
 Underlying co-morbidities such as diabetes or other types of cancer

Age
 From **18 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
 Target sample size: **107**
 Actual sample size reached: **104**

Randomization (investigator's opinion)
 Randomized

Randomization description
 The randomization was performed by a research assistant and with use of the computer-generated random numbers. We gave to the each participant an identification number from 001 to 107, and then was used the randomizer form to generate 1 set of 107 non-unique, unsorted numbers with a range from 1 to 3. Finally, 107 participants were randomly allocated to the three study groups (35 participants in the massage therapy group, 33 participants in the music therapy group and 39 participants in the usual care group). Also, in this study concealment will be done for nurses who will be collected data.

Blinding (investigator's opinion)
 Single blinded

Blinding description
 The outcome assessor nurse and data analyzer have no knowledge of patient grouping.

Placebo
 Not used

Assignment

Parallel

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
 Ahvaz University of Medical Sciences, Esfand Ave., Golestan Blvd
City
 Ahvaz
Province
 Khuzestan
Postal code
 61357-15794
Approval date
 2017-10-28, 1396/08/06
Ethics committee reference number
 IR.AJUMS.REC.1396.726

Health conditions studied

1

Description of health condition studied
 Leukemia
ICD-10 code
 C91.0
ICD-10 code description
 Acute lymphoblastic leukemia [ALL]

Primary outcomes

1

Description
 Pain and fatigue intensities more than 3 according to the 0 to 10 numeric rating scale

Timepoint
 Pain and fatigue intensities will be measured before intervention. During the four weeks of interventions, pain and fatigue intensities will be measured at the end of each week of study. Also, one week and two weeks after end of the interventions (week 5 and week 6), the pain and fatigue intensities will be measured again. Totally, pain and fatigue intensities will be measured for 7 times.

Method of measurement
 0-10 Numeric Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: Participants of massage therapy group will be received 15 minutes slow-stroke back massage (SSBM) sessions, thrice weekly (every other day) for 4 weeks in addition to the usual cares. Totally, 12 sessions will be performed for each participant (225 minutes massage therapy).

Category

Rehabilitation

2

Description

Second intervention group: Participants of music therapy group will be received 15 minutes music sessions, thrice weekly (every other day) for 4 weeks in addition to the usual cares. Totally, 12 sessions will be performed for each participant (225 minutes music therapy). Participant will be listened to self-selected instrumental music, using a headphone connected to the CD player.

Category

Rehabilitation

3

Description

Usual care group: Participants of usual care group will be received 15 minutes bed rest in the privacy separate room without environmental stimulation, thrice weekly (every other day) for 4 weeks in addition to the usual cares. Moreover, during bed rest period, a oncology nurse who had communication skills will be stayed with the participant and to speak about their condition, treatment process. Totally, 12 sessions will be performed for each participant.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Baghai 2 Hospital

Full name of responsible person

Shahram Baraz

Street address

Shahid Baghai 2 Hospital., Golestan Ave.,
Khoramshahr Blvd

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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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

100

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

Mojtaba Miladinia

Position

Instructor of faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

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Nursing faculty, Ahvaz University of Medical Science,
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
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Person responsible for updating data

Contact

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Web page address

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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The data file will be subscribed to by the SPSS software format. Only the original outcome can be shared.

When the data will become available and for how long

The start of the access period is 10 months after the publication of the results and for 2 months.

To whom data/document is available

Data will only be available to researchers working in academia.

Under which criteria data/document could be used

Data will only be available for use in review studies and meta-analyzes articles.

From where data/document is obtainable

Mojtaba Miladinia Academic email:
miladinia.m@ajums.ac.ir

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

First, send an e-mail to the author and mention the purpose of obtaining the information. In the absence of a problem, you will receive information one to three weeks later.

Comments