Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

A comparative study of the effect of music therapy with Jacobson's relaxation technique on the severity of fatigue and quality of life of lymphoma patients undergoing chemotherapy

Protocol summary

Study aim
Comparison the effect of music therapy with Jacobson's relaxation technique on the severity of fatigue and quality level of lymphoma patients

Design
It is a randomized cross-over clinical trial in which without blinding and randomly using a block method of four, the people referred to the above treatment center are equally divided into two test groups A (30 people) and B (30 people).

Settings and conduct
The mentioned plan is carried out in Shariati Hospital located in Tehran. Also, based on the nature of the intervention and its effect on other patients, all interventions will be performed individually and in a single room for each person

Participants/Inclusion and exclusion criteria
Inclusion criteria: age range of 18 to 60 years, definitive diagnosis of lymph node cancer, willingness to use both music therapy and progressive muscle relaxation methods, and exclusion criteria: unwillingness to participate in the study.

Intervention groups
Eligible patients will be divided into two groups using random blocks. For group A, listening to one of the soothing songs of wordless music using hands-free and for group B, the Jacobson relaxation technique is performed, and the patient is asked to do the taught things for 4 weeks at home daily for 20 minutes. execute Questionnaires will be completed at the beginning and one week and four weeks after the start of the intervention. A wash-out month will be included and then the interventions will be implemented crosswise on the groups.

Main outcome variables
Fatigue,quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200926048842N5**
Registration date: **2023-07-10, 1402/04/19**
Registration timing: **prospective**

Last update: **2023-07-10, 1402/04/19**
Update count: **0**

Registration date
2023-07-10, 1402/04/19

Registrant information

Name
Sajad Salehipour

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-11, 1402/04/20

Expected recruitment end date
2024-03-10, 1402/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study of the effect of music therapy with Jacobson's relaxation technique on the severity of fatigue and quality of life of lymphoma patients undergoing chemotherapy

Public title
Comparison of the effect of music therapy with Jacobson's relaxation technique on the severity of fatigue and quality of life of lymphoma patients undergoing chemotherapy

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Being aged between 18 to 60 years A definitive diagnosis of lymph node cancer and its type (Hodgkin's and non-Hodgkin's) has been made by a hematologist and oncologist. Receiving ABVD drug regimen in Hodgkin's lymphoma patients Receiving drug regimen R-CHOP or R-EPOCH in non-Hodgkin's lymphoma patients Being alert and trainable No mental disorders Not using muscle relaxants, sleeping pills and psychoactive drugs Interested in both music therapy and progressive muscle relaxation Absence of physical disorders such as (hearing and movement problems) and acute mental disorders At least 3 months have passed since the person was diagnosed with cancer Having a normal body mass index Having hemoglobin of at least 8gr/dl

Exclusion criteria:
Refusal to continue participating in the study Decreased level of alertness while studying The occurrence of severe physical complications caused by the disease Metastasis to other parts of the body Implementation of less than four days a week and its non-compliance with the training given death of the patient suffering from diseases characterized by fatigue (multiple sclerosis, fibromyalgia, AIDS, joint rheumatism)

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: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling will be done by the available method. All patients with lymph node cancer referred to Shariati Hospital affiliated to Tehran University of Medical Sciences who meet the inclusion criteria will be included in the study. Then the selected patients are divided into two groups (A and B) in a crosswise manner. In this way, first of all, an envelope containing the name of the group will be prepared for the total number of people studied and randomly arranged, and with the gradual selection of people, one of the cards will be assigned to them, which will determine the individual's group. According to random sampling, the research samples will have an equal chance to be selected in two groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Semnan University of Medical Sciences

Street address
headquarters of Semnan University of Medical Sciences and Health Services, Basij Blvd

City
Semnan

Province
Semnan

Postal code
3514799442

Approval date
2023-06-26, 1402/04/05

Ethics committee reference number
IR.SEMUMS.REC.1402.071

Health conditions studied

1

Description of health condition studied
lymphoma

ICD-10 code
C83.00

ICD-10 code description
Small cell B-cell lymphoma, unspecified site

Primary outcomes

1

Description
Level of quality of life

Timepoint
Before the start of the intervention, it will be completed at the end of the first and fourth week after the start of the intervention.

Method of measurement
The score given by the patient from the questionnaire (EORTC QLQ-C30) which is specific for cancer patients and measures 5 functional domains, 9 symptom domains

and one general domain of quality of life. This questionnaire is based on a four-point Likert scale. Not at all (score 1), a little (score 2), a bit (score 3), very much (score 4). To calculate the score of each subscale, the score of each item related to that subscale is added together. To calculate the total score of the questionnaire, the scores of all questionnaire items are added together. The minimum and maximum score of this questionnaire is 30 and 126. The higher the score obtained from this questionnaire, the higher the quality of life and vice versa.

2

Description

Fatigue intensity

Timepoint

Before the start of the intervention, it will be completed at the end of the first and fourth week after the start of the intervention.

Method of measurement

The questionnaire (MFI) consists of 20 items and 5 subscales of general fatigue (4 questions), physical fatigue (4 questions), decreased activity (4 questions), decreased motivation (4 questions) and mental fatigue (4 questions), which It is used to measure fatigue. The scoring of the questionnaire is on a 5-option Likert scale from 1 = yes, completely true to 5 = no, completely false. Questions number 2, 5, 9, 10, 13, 14, 16, 17, 18, 19 are graded in reverse order and are graded as 5 completely correct to 1 completely incorrect. To get the overall score of the questionnaire, the scores of all items are added together. The total score of each field is 4-20 and the total score of fatigue determined by the sum of the scores of the fields can be between 20-100. A higher score indicates greater fatigue.

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: At first, in the first session of his intervention, the researcher appeared in the department one hour before the start of chemotherapy, then after obtaining informed consent from the patients of group A and their families, the demographic information checklist, the quality of life questionnaire (EORTC QLQ) -C30) and the fatigue measurement questionnaire (MFI) will be completed for them. Also, in order to follow up the intervention process, a contact number is obtained from all patients. In order not to affect the intervention on other patients, this treatment program is carried out individually in the ward's training room. At first, a music therapy program is performed for patients in group A. The process of performing the test (listening to music) will be explained to the patients. Patients will also be taught how to listen to music using hands-free and personal cell phones. If you do not have a hands-free device, it will be provided by the researcher for free. In this study, music therapy is performed in such a way that the patient leans on the chair, puts his hands comfortably on the thighs or the chair, and then closes his eyes slowly. In this case, the body is leaned on the chair in the most comfortable position and the patient is asked to take four deep breaths. According to his interest, the patient listens to one of the relaxing songs of wordless music that has a uniform and gentle rhythm and is far from any melodic and rhythmic emotions, for a period of 20 minutes using hands-free. The first session of music therapy will be done one hour before the patient's chemotherapy in the ward's training room and individually. Also, music audio files are provided to patients in the form of CDs, flash drives, or through a virtual network. Then the patients were asked to listen to one of the selected music according to their interest for 20 minutes every day for four weeks. In order to ensure the performance of music therapy on the scheduled days, a checklist is provided to the samples to record the day, time and duration of the process and, if not, the reason. In order to solve possible problems in the implementation of the music therapy process, during the research period, the researcher made phone calls with the research samples two days a week (with an interval of three days), to ensure the process of its implementation and the completion of the checklist. On the other hand, if the patient placed in group A does not perform the test less than four days a week and according to the determined method, he will be removed from the research. After four weeks of music therapy, the person will be asked not to do any Do not intervene. After this one month without intervention, first of all, the desired questionnaires are completed again, and Jacobson's relaxation technique is explained to the patient, and he is asked to, like music therapy, for four weeks, daily for 20 minutes, Do the Jacobson relaxation technique. Again, the desired questionnaires will be completed at the end of the first week and the fourth week after the start of the second intervention.

Category

Rehabilitation

2

Description

The second intervention group: In the first session of his intervention, the researcher appeared in the department one hour before the start of chemotherapy, then after obtaining oral and written informed consent from the patients and their families, the demographic information checklist, the quality of life questionnaire (EORTC QLQ-C30) and fatigue measurement questionnaire (MFI) will be completed for this group of patients under research. Also, in order to follow up the intervention process, a contact number will be obtained from all patients. For patients in group B, Jacobson's relaxation technique program will be performed at first. In this way, the implementation process (Jacobson's relaxation technique) will be explained one hour before the start of the patient's chemotherapy in the teaching room and individually. The first session of this technique is taught by the researcher in the presence of the patient and a

member of the family for a period of 30 to 45 minutes in the mentioned medical centers. At the end of the first session, the patient is asked to perform the training and this stage will end by asking the patient and answering the questions about how to perform the technique. Then the patients were asked to do 20 minutes every day for four weeks; Do relaxation exercises according to the program at home. Before the intervention, the researcher will complete the theoretical and practical training of the relaxation technique in several stages under the supervision of a clinical psychologist. Performing the technique is as follows: at first, before performing the relaxation technique; The patient should take out all the extra items such as watches, bracelets, rings and all the items that can be separated and put them next to him, and then Jacobson's relaxation steps are taught to the patients as follows: At first, the patient closes his eyes. And as much as possible, he is in a calm state and should focus all his attention on his breathing. He is asked to take 5 deep breaths through his nose. And every time, empty your lungs completely of air and empty them slowly through your mouth. And at the same time, he repeats a relaxing word like (God, love, rain, rainbow and the like) in his mind. Then the patients should perform muscle contraction and expansion respectively for 14 muscle groups, including facial muscles (forehead, eyelids, jaws and lips), neck muscles, fingers, palms, forearms, arms, shoulders, back, waist, chest, abdomen, seat, It does thighs, calves, soles of the feet. The contraction of each muscle takes 5 seconds and its expansion takes 10 seconds, and also during muscle contraction; They should not be too tight and put pressure on themselves. Rather, it is sufficient to cause contraction in the usual level. After 15-20 minutes, ask the patient to take 5 deep breaths, slowly open your eyes and do not get up for a few minutes. The patient should not worry whether he has reached a deep level of relaxation or not; Let the relaxation happen to its own tune and when disturbing thoughts come, try to ignore them. Then the patients were asked to practice Jacobson's relaxation technique at home for 20 minutes every day for four weeks. Perform as they were taught. In order to ensure the implementation of the relaxation technique on the prescribed days, a checklist is provided to the samples to record the day, time and duration of the technique and, if not, the reason. In addition, a technique training CD is also provided to the patient. Also, in order to solve possible problems in the implementation of the technique, during the research period, the researcher made phone calls with the research samples two days a week (with an interval of three days), to ensure the process of the technique implementation and the completion of the checklist. Also, the families of these patients are requested to monitor the process of implementation of the technique by the patient at home and inform the researcher if any problem occurs. On the other hand, if the patient placed in group B does not perform the test less than four days a week and according to the determined method, he will be removed from the research. After four weeks of Jacobson relaxation technique, the person is asked not to do any intervention during the next month. After this one month without intervention, first of all, the desired questionnaires are completed again, and then the music therapy method is explained to the patient, and he is asked to use the relaxation technique of Jacobson, for four weeks, daily for 20 minutes. , perform music therapy. Again, the desired questionnaires will be completed at the end of the first week and the fourth week after the start of the second intervention.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University of Medical Sciences, Shariati Hospital

Full name of responsible person

Sajad Salehipour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?
No
Title of funding source
Semnan 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
Semnan University of Medical Sciences
Full name of responsible person
Sajad Salehipour
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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