Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the Effectiveness of Aromatherapy-Massage with Classic Massage in Chemotherapy-Induced Neuropathic Pain and Fatigue in Cancer Patients

Protocol summary

Study aim
Comparison of the Effectiveness of Aromatherapy-Massage with Classic Massage in Chemotherapy-Induced Neuropathic Pain and Fatigue in Cancer Patients

Design
Three arm parallel group clinical randomized trial with control group, double blinded and controlled

Settings and conduct
The intervention of aromatherapy massage with the main combined oil and base oil will be for 4 weeks. Sampling will be done in Khorramabad and oncology ward of Shahid Rahimi Hospital. The study will be double-blinded.

Participants/Inclusion and exclusion criteria
The patient should be between 18 and 80 years old Have at least one paraesthesia point (based on Numeric Pain Rating Scale) Has received at least one session of chemotherapy Existence of fatigue resistant to common treatments The patient must be in stage II or III cancer No spread of metastasis to distant and vital organs such as brain and lymph nodes

Intervention groups
There will be three groups in this study. The first group will be Aromatherapy-Massage with the main combination oil, the second group will be the classic massage with base coconut oil and the third group will be control and without intervention.

Main outcome variables
Neuropathic pain intensity score based on Douleur Neuropathique 4 questionnaire and fatigue score based on Cancer Fatigue Scale questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150919024080N19**
Registration date: **2021-06-24, 1400/04/03**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-24, 1400/04/03**
Update count: **0**

Registration date
2021-06-24, 1400/04/03

Registrant information

Name
Mohammad Gholami

Name of organization / entity
Lorestan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-21, 1400/02/01

Expected recruitment end date
2021-09-23, 1400/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Aromatherapy-Massage with Classic Massage in Chemotherapy-Induced

Neuropathic Pain and Fatigue in Cancer Patients

Public title

Effect of Aromatherapy in CIPN and Fatigue

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The patient should be between 18 and 80 years old Have at least one paraesthesia point (based on NRS) More than 10,000 platelets per cubic millimeter of blood No severe inflammatory lesions, itching or sores on the hands or feet The patient must be in stage II or III cancer Has received at least one session of chemotherapy and is scheduled to receive at least three more sessions within the next month Existence of fatigue resistant to common treatments If a specific cause for fatigue, such as anemia, insomnia, depression, or hypercalcemia, is identified, it should be treated first. No history of peripheral neuropathy for any cause including diabetes mellitus, autoimmune disease, AIDS or previous chemotherapy Patients with the infection are first treated with oral or intravenous antibiotics No known mental illness Ability to communicate and make telephone calls in Persian After standardizing the fatigue score in the range of 0-100 people with a fatigue score above 30 and a pain score of 3 enter the study Patient consent to participate in the study No spread of metastasis to distant and vital organs such as brain and lymph nodes Inclusion criteria for family caregiver: having a spouse or child relationship with the patient, experience of caring and following the patient for at least one month and willingness to participate in the study

Exclusion criteria:

Deep vein thrombosis Perform Aromatherapy-Massage for the past month Dose reduction or discontinuation of medications Allergy to lavender, chamomile and mint oils Acute infections require oral or intravenous antibiotics or antiviral and antifungal drugs. Drug therapy during the study to prevent or treat neuropathy Existence of coagulation problems or taking anticoagulants haemorrhage Pregnancy Soft tissue infection Oncological emergencies (such as Tumor Lysis Syndrome) Participate in other rehabilitation programs, meditation and hydrotherapy, etc. while studying Exclusion criteria for family caregiver: change the role of family caregiver and transfer his/her role to other family members during the study

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

First, patients are entered into the study consecutively, then patients who meet the inclusion criteria, by a person outside the research team, due to the observance of allocation concealment, based on a list of computer random numbers using stratified random block method in equal numbers in three groups of Aromatherapy-massage with main oil combination, classic massage with coconut oil or control with routine care. The strata in this study in order to match the groups is in terms of gender and the presence of neuropathic pain less than or equal to 3 and more than or equal to 4. Randomization stratas include: man with less than or equal to 3 pain score, man with more than or equal to 4 pain score, woman with less than or equal to 3 pain score, and woman with more than or equal to 4 pain score.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants are informed about the three main groups and which group they are in, but their caregivers do not know which study group the patients are in. They are unaware of the composition and nature of the oils.; The primary caregiver who performs the intervention does not know what oil he is using and the intervention is performed using nasal clips; The research assistant who completes the questionnaires is independent of the intervention / massage procedure and does not know their group by coding the samples. Also, the statistician is not aware of the random assignment of groups when analyzing the data.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Lorestan University of Medical Sciences

Street address

In Front of Kahrizak Town, 5Km past Boroujerd Exit

City

Khorammabad

Province

Lorestan

Postal code

381351698

Approval date

2021-05-04, 1400/02/14

Ethics committee reference number

IR.LUMS.REC.1399.266

Health conditions studied

1

Description of health condition studied
Drug-induced polyneuropathy
ICD-10 code
G62.0
ICD-10 code description

2

Description of health condition studied
Neoplastic (malignant) related fatigue
ICD-10 code
R53.0
ICD-10 code description
Neoplastic (malignant) related fatigue

Primary outcomes

1

Description
Neropathic Pain
Timepoint
Before, 14 and 28 days after the start of the intervention
Method of measurement
DN4 questionnaire

2

Description
Fatigue
Timepoint
Before, 14 and 28 days after the start of the intervention
Method of measurement
CFS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
First Intervention group: In this group, Aromatherapy-Massage is performed using the main combination oil (lavender, chamomile, mint, coconut) prepared by Adonis Goldaroo Company. The main researcher teaches the family caregiver and the patient in a practical demonstration and video clip the steps of performing the procedure in a private and quiet space located in the oncology department in 30 minutes. The patient and the family caregiver practice Aromatherapy-Massage techniques several times in this practical session and after the researcher is sure of their understanding, the training ends; Then the researcher delivers a bottle containing 50 cc of 3% combined essential oil (for the Aromatherapy-Massage group) along with an pamphlet containing image (to explain and show the steps of the massage technique) and a schedule for the weekly massage to each participant. The family caregiver and the patient are asked to give aromatherapy massage three times a week for 30 minutes (with a break of 1 or 2 days between sessions) for 4 weeks in a room with a suitable temperature and privacy and during the hours when the patient is more comfortable and has the least severity of the side effects of chemotherapy (such as pain, nausea, fatigue), in the following order: 1.The participants firstly lay on a bench, supine position, at the start of massage session. The PI (Primary Investigator) sit on a chair facing the patients' feet, which is at the PI's chest level during foot massage. The foot massage session begins by holding the right foot gently but firmly in both of the PI's hands. Effleurage is applied from toes to the ankle of foot, continued for all the fingers, and plantar muscles. 2.The PI uses her thumb to make superficial friction over the entire sole and all fingers of the foot. The sole is spread by the PI's fingers. 3.Then superficial friction is utilized for all fingers. Following the dorsum and all fingers massage, effleurage, and superficial friction is performed for the sole. 4.Finally, the foot massage is finished with petrissage for the plantar muscles (10 min). 5.Immediately after that, all massage techniques is utilized in a same manner for the left foot (10 min). 6.After completion of foot massage, the patients are asked to sit on the bench. The PI hold the patient's hand gently in one of her hands.The hand massage begins with the right hand, and moving on to the left hand. 7.Effleurage is administered for the dorsum of the hand, and then moving on to all the fingers, and continued from the palm to the wrist. 8.And then, the PI uses thumb and fingers to make superficial friction over the patient's entire palm, all fingers, and the outer surface of the hand, and finally petrissage for the thenar and hypothenar muscle groups. The palm is spread by the investigator's fingers.(5 min). 9.All massage techniques are used for the left hand (5 min). 2 and 1 cc of oil will be used on each foot and hand, respectively.
Category
Treatment - Other

2

Description
Second Intervention group: For the second group or the classic massage group, instead of the combined oil, the classic massage is done only with coconut base oil prepared by Adonis Goldaroo company, in exactly the same way as described for the first group or Aromatherapy-Massage. In the second group, the amount of coconut oil and the time of the classic massage are similar to the first group.
Category
Treatment - Other

3

Description
Control group: For the third group or control group, no

intervention will be performed except standard and routine care.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Rahimi Hospital in Khorramabad

Full name of responsible person
Amirhosein Hasanvand

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Khoram-Abad University of Medical Sciences

Full name of responsible person
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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
Khoram-Abad 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
Khoram-Abad University of Medical Sciences

Full name of responsible person
Amirhosein Hasanvand

Position
Nursing Student

Latest degree
A Level or less

Other areas of specialty/work
Nursery

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Other areas of specialty/work
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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