Dose-response Evaluation of Massage Therapy for Controlling Pain, Fatigue and Sleep Disorder in the Adult Patients with Cancer

Protocol summary

Study aim
- Determining the effect of each massage dose on the intensity of symptom cluster of pain, fatigue and sleep disturbance
- Determining the effect durability of each massage dose
- Determining the Optimal Dose of Massage Therapy for Controlling Pain, Fatigue and Sleep Disorder in the Patients with Cancer

Design
Randomized clinical trial on 273 patients, with parallel-group. Eligible Patients are randomly assigned to one of the study groups using permuted block randomization method. The study statistician generate the random allocation sequence using free statistical software R.

Settings and conduct
This study will be performed at Shahid Baghaei 2 oncology Hospital, department of clinical oncology and Shafa oncology clinic in Ahvaz, southwestern Iran. Patients will receive different doses of gentle massage therapy for 4 weeks. Pain intensity, fatigue, and sleep disturbance will be measured at the end of each week of the study. In this study, patients are not aware of the amount of massage dose received by other groups. The statisticians will be blind by labeling study groups during the data analysis. Also, the main researchers will be blind from the time of randomization to the end of patient follow-up.

Participants/Inclusion and exclusion criteria
Inclusion criterion: Adult 18 to 64 years of age. Exclusion criterion: Platelet count less than 15,000 per cubic millimeter.

Intervention groups
In this study, 6 intervention groups will receive different doses of light massage therapy for 4 weeks. Patients in the control group also receive routine care plus a short visit by a nurse for 4 weeks. The frequency of massage therapy sessions is 2 or 3 times a week and the duration of the massage in each session is from 15 to 60 minutes (short-term, medium-term and long-term).

Main outcome variables
- Intensity of symptom cluster of pain
- Fatigue and sleep disorder
- Analgesic received

General information

Reason for update
Added actual recruitment dates

Acronym
IRCT registration information
IRCT registration number: IRCT20150302021307N5
Registration date: 2021-08-11, 1400/05/20
Registration timing: prospective

Last update: 2022-04-20, 1401/01/31
Update count: 3

Registration date
2021-08-11, 1400/05/20

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
Email address
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-08-11, 1400/05/20
Expected recruitment end date
2021-10-12, 1400/07/20
Actual recruitment start date
2021-08-13, 1400/05/22
**Actual recruitment end date**  
2021-11-11, 1400/08/20

**Trial completion date**  
2022-01-12, 1400/08/22

**Scientific title**  
Dose-response Evaluation of Massage Therapy for Controlling Pain, Fatigue and Sleep Disorder in the Adult Patients with Cancer

**Public title**  
Dose-response Evaluation of Massage Therapy Intervention in the Patients with Cancer

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Adults 18 to 64 years of age Reporting all three symptoms of pain, fatigue, and sleep disorder with at least two of the three rated ≥ 4 in the last 24-hour Being currently on a chemotherapy regimen or have recently been on chemotherapy. Being at cancer stage I to IV

**Exclusion criteria:**  
Platelet count less than 15,000 per cubic millimeter Existence of underlying diseases such as diabetes, peripheral neuropathy disease, etc. Skin disorders in massage area Known pain, fatigue and sleep disorders that are not caused by cancer and or its treatments Receiving any type of complementary medicine methods during the trial or within the last three months

**Age**  
From **18 years** old to **64 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **273**  
Actual sample size reached: **248**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
273 patients are randomly assigned to 1 of the 7 study group using a permuted block randomization method and equal allocation ratio (39 patient in each group). The study statistician generate the random allocation sequence using free statistical software R. Intervention allocation is only known by the statistician and the study assistants that assign patients to study groups.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**

1- Patients are not aware of the amount of massage dose received by other groups. 2- The statisticians will be blind by labeling study groups during the data analysis. 3- The principal researchers, the oncologist and the pain management specialist will be blind to group assignment from the time of randomization until the end of patient follow-up (eighth week). 4- Those responsible for data collection contact patients only to remind them to record information in the booklets and are blind to the allocation of patients to study groups.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**  
Also in this study, subgroups analysis based on the linear mixed-effect tree algorithm will be performed.

**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**  
2021-08-02, 1400/05/11

**Ethics committee reference number**  
IR.AJUMS.REC.1400.287

**Health conditions studied**

1

**Description of health condition studied**  
Pain

- **ICD-10 code**  
  G89.29

- **ICD-10 code description**  
  Other chronic pain

2

**Description of health condition studied**  
Sleep disorder

- **ICD-10 code**  
  F51

- **ICD-10 code description**  
  Sleep disorders not due to a substance or known physiological condition
Description of health condition studied
Fatigue

ICD-10 code
R53.82

ICD-10 code description
Chronic fatigue, unspecified

Primary outcomes

1
Description
Pain intensity

Timepoint
Pain intensity will be measured before interventions. During the four weeks of interventions, the pain intensity will be measured at the end of each week of study. Also, during the four weeks of follow-up, the pain intensity will be measured at the end of each week. Totally, pain intensity will be measured for 9 times.

Method of measurement
0–10 Numeric Rating Scale

2
Description
Fatigue intensity

Timepoint
Fatigue intensity will be measured before interventions. During the four weeks of interventions, the fatigue intensity will be measured at the end of each week of study. Also, during the four weeks of follow-up, the fatigue intensity will be measured at the end of each week. Totally, fatigue intensity will be measured for 9 times.

Method of measurement
0–10 Numeric Rating Scale

3
Description
Sleep disorder intensity

Timepoint
Sleep disorder intensity will be measured before interventions. During the four weeks of interventions, the sleep disorder intensity will be measured at the end of each week of study. Also, during the four weeks of follow-up, the sleep disorder intensity will be measured at the end of each week. Totally, sleep disorder intensity will be measured for 9 times.

Method of measurement
0–10 Numeric Rating Scale

4
Description
Intensity of symptom cluster of pain, fatigue and sleep disorder

Timepoint
Nine times from baseline to endpoint of follow-up.

Method of measurement
Symptom cluster intensity will be measured using pain, fatigue, and sleep disturbance items. The mean scores of the three symptoms will be calculated as the symptom cluster intensity.

Secondary outcomes

1
Description
Analgesic received

Timepoint
Analgesic received will be measured before interventions. During the four weeks of interventions will be measured at the end of each week of study. Also, during the four weeks of follow-up will be measured at the end of each week. Totally, analgesic received will be measured for 9 times.

Method of measurement
The analgesic received in the last 24 hours will be documented by the patient in the booklet.

Intervention groups

1
Description
Control group: will receive routine care in addition to a short visit by a nurse (2 sessions per week for four weeks) to ask about the course of their illness.

Category
Rehabilitation

2
Description
First intervention group: will receive 15-minute massage sessions twice a week for four weeks.

Category
Rehabilitation

3
Description
Second intervention group: will receive 30-minute massage sessions twice a week for four weeks.

Category
Rehabilitation

4
Description
Third intervention group: will receive 60-minute massage sessions twice a week for four weeks.

Category
Rehabilitation

5
Description
Fourth intervention group: will receive 15-minute massage sessions 3 times a week for four weeks.
**Category**
Rehabilitation

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**6**

**Description**
Fifth intervention group: will receive 30-minute massage sessions 3 times a week for four weeks.

**Category**
Rehabilitation

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**7**

**Description**
Sixth intervention group: will receive 60-minute massage sessions 3 times a week for four weeks.

**Category**
Rehabilitation

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**Recruitment centers**

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**1**

**Recruitment center**

**Name of recruitment center**
Shahid Baghai 2 Hospital

**Full name of responsible person**
Mojtaba Miladinia

**Street address**
Shahid Baghai 2 Hospital., Khoramshahr Blvd

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**2**

**Recruitment center**

**Name of recruitment center**
Shafa Clinic

**Full name of responsible person**
Mojtaba Miladinia

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**Sponsors / Funding sources**

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**1**

**Sponsor**

**Name of organization / entity**
Ahvaz University of Medical Sciences

**Full name of responsible person**
Mehdi Ahmadi Moghaddam

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Research center, University of Medical Science, Golestan Blvd., 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**
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
Faculty member
Latest degree
Master
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Not applicable
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 6 months after the publication of the results.
To whom data/document is available
Data will be available to researchers working in the academic institutions.
Under which criteria data/document could be used
Data will only be available for use in the review and meta-analyze studies.
From where data/document is obtainable
Mojtaba Miladinia via 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
This study will use both a per-protocol approach and an
intention-to-treat approach for data analysis.