

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of massage therapy on the comfort and ease of cancer patients under chemotherapy

Protocol summary

Study aim

Determination of the effect of massage therapy on the comfort and ease of chemotherapy cancer patients

Design

Preset investigation is designed as clinical trial with pretest and posttest with separated groups as well as computer randomized selection of 50 persons so that in the list, ones having odd numbers were selected as controls and those with even number were selected as the members of intervention group.

Settings and conduct

As research aimed to check impact of massage on cancer patients, thus the intervention group received massage therapy in ten sessions of forty-five minutes, and the questionnaire was filled once before starting the session and once at the end of last massage session. It was conducted in Bu-Ali hospital in Tehran and no blinding was done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: aged 18 and over, not being placed in the final stage of the disease, receiving at least 3 sessions of chemotherapy Exclusion criteria: Placing in the final stage, more than one absentee session in the massage session

Intervention groups

Group One includes eligible cancer patients receiving massage therapy Group two includes eligible cancer patients not receiving massage therapy

Main outcome variables

One of the variables is the symptoms that include the related signs and symptoms and the other one is comfort

Registration timing: **retrospective**

Last update: **2020-03-15, 1398/12/25**

Update count: **0**

Registration date

2020-03-15, 1398/12/25

Registrant information

Name

narges mardaneh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3360 3970

Email address

seo.sami1990@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-15, 1396/10/25

Expected recruitment end date

2018-07-03, 1397/04/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of massage therapy on the comfort and ease of cancer patients under chemotherapy

Public title

The effect of massage on cancer symptoms reduction

Purpose

Health service research

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180803040680N1**

Registration date: **2020-03-15, 1398/12/25**

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 and above Reception of at least 3 chemotherapy sessions

Exclusion criteria:

The onset of severe metastatic complications or physical and mental health problems affecting the intervention
Unwillingness of the selected patient to collaborate after sampling

Age

From **27 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Permuted block randomization
Randomization unit: Blocks (5 persons) Lack of using stratified randomization Randomization tools: In this study, the block randomization approach was used. The 5-person blocks were used and the samples were divided into 5-person groups (blocks) based on the inclusion criteria. Selected blocks were consecutively considered as an intervention and control group. It did so that the first block was considered as the intervention and the second block as control and continued until the sampling was completed. Random sequence generation: The sequence generation method in this study was restricted randomization. Permuted block randomization was used among the restricted randomization methods. Allocation concealment: The blocks assigned to the intervention and control groups were made without the participants' knowledge and they were not aware of how the groups were assigned. Sequentially numbered, sealed, opaque envelopes were used to record information about the random sequence created, with the number assigned to the members of each block and the envelopes arranged according to the exact sequence to be used at the start of the study.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Islamic Azad University Ethical Committee

Street address

No. 4- Dead End 5 -Ravanbakhsh St - Toos Street-Kian
Shahr - Tehran

City

Tehran

Province

Tehran

Postal code

1853794939

Approval date

2018-03-11, 1396/12/20

Ethics committee reference number

IR.IAU.TMU.REC.1396.132

Health conditions studied

1

Description of health condition studied

Cancer

ICD-10 code

D70.1

ICD-10 code description

Agranulocytosis secondary to cancer chemotherapy

Primary outcomes

1

Description

The effect of massage therapy on the feeling of comfort

Timepoint

Once at the beginning and once the end of the intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

This study examines the impact of massage therapy on cancer patients. The intervention group included patients with cancer who received massage therapy in 10 sessions for 45 minutes in addition to receiving routine treatments.

Category

Other

2

Description

In this study, the control group included cancer patients who received only their routine medicines (routine care, no massage, and no extra work).

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu-Ali Hospital in Tehran

Full name of responsible person

Narges Mardaneh

Street address

Damavand Khiaban-Imam Hossein Square-Bu'ali Hospital

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Tehran

Postal code

17117

Phone

+98 21 3334 8037

Fax

Email

booali.hospital96@gmail.com

Web page address

http://bouali-hospital.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Eftekhar Ardebili

Street address

Islamic Azad University, Tehran Medical Branch-Khaghani St-Shariati St

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Tehran

Province

Tehran

Postal code

1916893813

Phone

+98 21 2200 6660

Email

iautmu@iautmu.ac.ir

Web page address

http://www.iautmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

20

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

Islamic Azad University

Full name of responsible person

Narges Mardaneh

Position

University Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

Study protocol and statistical information on how to do clinical work and outcomes

When the data will become available and for how long

Get started four months after printing

To whom data/document is available

For researchers and students

Under which criteria data/document could be used

For use in scientific work and documentation

From where data/document is obtainable

Men's Narcissus .+989394048285

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

Applying for and explaining which information is used in the right direction

Comments