

# 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

**City**

Tehran

**Province**

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

**City**

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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**Contact**

**Name of organization / entity**

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University Student

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Islamic Azad University

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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**