

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### The effects of laughter therapy program on fatigue and depression of cancer patients undergoing chemotherapy in cancer patients undergoing chemotherapy intervention group compared with the control group

#### Protocol summary

##### Summary

The purpose behind this study is to determine the effects of Laughter Therapy on fatigue and depression in cancer patients undergoing chemotherapy. The study is a random clinical trial by throwing a coin in two groups of Intervention and Control. Laughter therapy program includes comedy and funny movies, and lively programs. Intervention group is 8 sessions for each session to be between 25 to 30 minutes in 8 weeks. And Control group enjoys only the usual cares. The main criteria for inclusion in the study include having the age of 18 to 55, being on the list of chemotherapy patients, and lack of known depression disorder. The main criteria for exclusion from the study are Lack of desire for continuing, and having depression score over 28 using Beck Questionnaire. Therefore, the total sample size in this study is 90 samples from which 45 patients are in Intervention group and 45 patients in Control group. Before the beginning of intervention, the questionnaire will be given to the samples. Then, at end of the second, fourth, sixth and eighth week in the Intervention group, a quiz is taken from the samples and they are asked to complete Beck Depression Questionnaire and CFS Questionnaire; after that, again, Fatigue Questionnaire and Beck Depression Questionnaire will be given to them. Finally, a month passed the last session Laughter Therapy will begin.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015012620819N1**  
Registration date: **2015-06-13, 1394/03/23**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-06-13, 1394/03/23

##### Registrant information

###### Name

Roya Hashemi

###### Name of organization / entity

Tehran University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8163 3302

###### Email address

gh.a526@yahoo.com

##### Recruitment status

###### Recruitment complete

##### Funding source

A research project at the University of Tehran in the form of a thesis presented to the faculty Tehran

##### Expected recruitment start date

2015-02-04, 1393/11/15

##### Expected recruitment end date

2015-05-05, 1394/02/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of laughter therapy program on fatigue and depression of cancer patients undergoing chemotherapy in cancer patients undergoing chemotherapy intervention group compared with the control group

##### Public title

Effect of laughter therapy on cancer patients

**Purpose**

Health service research

**Inclusion/Exclusion criteria**

Inclusion criteria: Informed consent for collaboration  
Having the age of 18 to 55  
Being on the list of chemotherapy patients  
Having a minimum degree of literacy – Having acceptable listening and speaking abilities  
Lack of known depression disorder  
Exclusion criteria: Lack of desire for continuing  
Provided during the research for a new effective drug, new drugs be added to patients' medications. Depression score over 28, using Beck Questionnaire  
Presence of acute complications arising from chemotherapy during the research  
Death of the patient

**Age**

From **18 years** old to **55 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

How random is that the researcher with a coin toss after sampling, samples were placed in pairs and then toss on tap and the other one in the intervention group and the control group were placed.

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

**Street address**

Sixth Floor, Central Organization of University, Qods St., Keshavarz Blvd., Tehran

**City**

Tehran

**Postal code**

66927171

**Approval date**

2015-01-07, 1393/10/17

**Ethics committee reference number**

9111196054-125130

**Health conditions studied**

1

**Description of health condition studied**

Cancer

**ICD-10 code**

C00-C97

**ICD-10 code description**

Malignant Neoplasms

**Primary outcomes**

1

**Description**

Depression

**Timepoint**

Before the intervention, the second week, fourth, sixth, eighth and one month after intervention

**Method of measurement**

Beck Depression Inventory

**Secondary outcomes**

1

**Description**

Fatigue

**Timepoint**

Before intervention of the second week, fourth, sixth, eighth and one month after intervention

**Method of measurement**

Cancer Fatigue Scale

**Intervention groups**

1

**Description**

The control group received only routine care check vital signs, the physician's instructions and monitoring chemotherapy drugs, blood factors and the routine tests will enjoy not done any intervention by the researcher

**Category**

Other

2

**Description**

Laughter Therapy package includes short funny comedy clips on a DVD from a site authorized and approved by the Department of Cultural and Educational School of Nursing and Midwifery Tehran that every two weeks to see samples They will be given a period of 25-30 minutes

**Category**

Other

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Namazie Hospital

**Full name of responsible person**

Hashemi Roya

**Street address**

71937-11351 ,Namazie Hospital, Namazie Square,  
Shiraz, Fars.

**City**

Shiraz

### 2

#### Recruitment center

**Name of recruitment center**

Oncology Hospital Amir

**Full name of responsible person**

Hashemi Roya

**Street address**

36323731-33 ,opposite the pool Kosar, the culture of  
the city, Shiraz

**City**

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

School of Nursing and Midwifery Tehran University of  
Medical Sciences

**Full name of responsible person**

Doctor M. Yvnsyyan

**Street address**

71937-11351 ,School of Nursing and Midwifery  
Tehran University of Medical Sciences, Eastern Nosrat  
St, Tohid Sq Tehran

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor  
organization/entity?**

Yes

**Title of funding source**

School of Nursing and Midwifery Tehran University of  
Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Hashemi Roya

**Position**

Nursing Graduate Student

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## Person responsible for scientific inquiries

#### Contact

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Doctor Z. Parsa Yekta

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PhD in Nursing

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## Person responsible for updating data

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*