

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)

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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

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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

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

Other areas of specialty/work**Street address**

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

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Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty