

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### The effect of laughter yoga on emesis and mental wellbeing in patients under chemotherapy with non-metastatic cancer

#### Protocol summary

##### Study aim

Determining the effect of laughing yoga on nausea, vomiting and mental well-being in chemotherapy patients

##### Design

This research has two groups of control and intervention. Randomization is done by spss software. The sample size is 30 patients for the intervention group and 30 patients for the control group. In this study, the study design is parallel. Type of trial is equivalence. Blindness in this study is blind.

##### Settings and conduct

This study was conducted on patients undergoing chemotherapy in Reza Medical Center located at Client's Blvd. Laugh yoga program is conducted in the hall near the chemotherapy department.

##### Participants/Inclusion and exclusion criteria

1. Refer to Imam Reza Medical Center for chemotherapy.
- 2- Age between 18 and 60 years.
3. Be alert.
4. Have non-metastatic cancer.
5. Satisfaction to participate in the research.
6. Do not have audible and visual problems.
7. Phone number to track.
8. A moderate or severe chemotherapy regimen.
9. Between two to four sessions of chemotherapy in one week.
10. No symptoms of osteomyelitis.
11. Do not have upper gastrointestinal cancer.
12. Do not use radiotherapy.
13. Physically and mentally healthy.

##### Intervention groups

In the intervention group: people will laugh yoga for 20-30 minutes before the first to the fourth session of chemotherapy. Laugh yogic exercises include the four main clapping steps, deep breathing, baby play and laugh exercises. After each laugh yoga session, chemotherapy is performed according to the protocol in the center. Yoga exercises are grouped together. And the number of groups is from 2 to 15 people. In the control group, other than the usual self-care education to control the nausea by the researcher (about 5 minutes), no further action will be taken.

##### Main outcome variables

nausea, severity of nausea, duration of nausea, vomiting, vomiting duration, vomiting and well-being score

#### General information

##### Reason for update

Due to the availability of a large number of research samples in this age range and the limitations of the study on the effect of laughter yoga on the mentioned problems in this age group, researchers are interested in continuing the study in this age range and adding this age group to the study.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180429039463N1**  
Registration date: **2018-08-21, 1397/05/30**  
Registration timing: **prospective**

Last update: **2023-02-22, 1401/12/03**

Update count: **2**

##### Registration date

2018-08-21, 1397/05/30

##### Registrant information

###### Name

mohammad namazinia

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 5222 5280

###### Email address

namazinm951@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-23, 1397/06/01  
**Expected recruitment end date**  
2018-10-07, 1397/07/15  
**Actual recruitment start date**  
2018-10-07, 1397/07/15  
**Actual recruitment end date**  
2019-06-05, 1398/03/15  
**Trial completion date**  
2019-06-05, 1398/03/15

#### **Scientific title**

The effect of laughter yoga on emesis and mental wellbeing in patients under chemotherapy with non-metastatic cancer

#### **Public title**

The effect of laughter yoga on emesis and mental wellbeing in patients under chemotherapy with non-metastatic cancer

#### **Purpose**

Supportive

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

To chemotherapy, they have visited Imam Reza's center of Mashhad. Age between 18 and 60 years old. Be alert. Have non-metastatic cancer (based on diagnostic tests, signs and clinical examinations and an approved oncology doctor). Complete consent to participate in the research. Auditory problems (full hearing despite the use of auxiliary equipment) and visual (the ability to read a newspaper at a distance of 30 centimeters with glasses). The phone number should be available to the researcher for follow up. A chemotherapy regimen with moderate or severe nausea. The number of chemotherapy sessions between two to four sessions per week is prescribed to him. There are no symptoms of osteomyelitis (such as redness, burning and mouth ulcers, the presence of false membranes, and sputum in the mouth). Do not have upper gastrointestinal cancer. Do not use radiotherapy at the same time. Mentally and physically, you can do yoga exercises.

##### **Exclusion criteria:**

Do not want to continue to participate in research. At the time of the research, there was a major stress (close relatives' death, financial failure, etc.). Worried and needs special care. The chemotherapy program is postponed by thrombocytopenia or any other factor. Diagnosis of metastasis is based on diagnostic tests by an oncology specialist. Symptoms of osteomyelitis (such as redness, burning and mouth ulcers, false membranes, and sputum in the mouth). For whatever reason, you will not be able to attend laugh yoga sessions. Changes to the chemotherapy regimen.

#### **Age**

From **18 years** old to **75 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **30**

Actual sample size reached: **69**

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

Randomized

#### **Randomization description**

Random Type: Simple In this method, computer randomization methods are used, and the division of people into two groups is done randomly by the sequence generated by SPSS software. The unit is the individual accident. Allocation Concealment Hiding is done by the statistic consultant.

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

##### **Placebo**

Not used

##### **Assignment**

Parallel

#### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of school of nursing & midwifery-mashhad university of medical sciences

##### **Street address**

Mashhad, Ibn Sina St.-doctora four war

##### **City**

mashhad

##### **Province**

Razavi Khorasan

##### **Postal code**

9137913199

#### **Approval date**

2018-07-31, 1397/05/09

#### **Ethics committee reference number**

IR.MUMS.NURSE.REC.1397.021

## **Health conditions studied**

### 1

#### **Description of health condition studied**

cancer

##### **ICD-10 code**

C80

##### **ICD-10 code description**

Malignant neoplasm without specification of site

## **Primary outcomes**

### 1

#### **Description**

Frequency of nausea

## **Timepoint**

Nausea before the onset of the intervention and at each chemotherapy session for up to four sessions

## **Method of measurement**

MORROW ASSESSMENT OF NAUSEA AND EMESIS

## **2**

### **Description**

Severe of nausea

### **Timepoint**

Severe of Nausea before the onset of the intervention and at each chemotherapy session for up to four sessions

### **Method of measurement**

MORROW ASSESSMENT OF NAUSEA AND EMESIS

## **3**

### **Description**

Duration of nausea

### **Timepoint**

Duration Nausea before the onset of the intervention and at each chemotherapy session for up to four sessions

### **Method of measurement**

MORROW ASSESSMENT OF NAUSEA AND EMESIS

## **4**

### **Description**

Frequency of vomiting

### **Timepoint**

vomiting before the onset of the intervention and at each chemotherapy session for up to four sessions

### **Method of measurement**

MORROW ASSESSMENT OF NAUSEA AND EMESIS

## **5**

### **Description**

Duration of vomiting

### **Timepoint**

Duration of vomiting before the onset of the intervention and at each chemotherapy session for up to four sessions

### **Method of measurement**

MORROW ASSESSMENT OF NAUSEA AND EMESIS

## **6**

### **Description**

Severe of nausea

### **Timepoint**

severe of vomiting before the onset of the intervention and at each chemotherapy session for up to four sessions

### **Method of measurement**

MORROW ASSESSMENT OF NAUSEA AND EMESIS

## **7**

### **Description**

well-being score

## **Timepoint**

En well-being is measured once before the start of the first chemotherapy session and once after the fourth session of chemotherapy.

## **Method of measurement**

En To measure the score of well-being, we will use the Warwick-Edinburgh Subjective Well-Being Scale

## **Secondary outcomes**

### **1**

#### **Description**

sleep quality

#### **Timepoint**

sleep quality is measured once before the start of the first chemotherapy session and once after the fourth session of chemotherapy

#### **Method of measurement**

Petersburg Sleep Quality Tool

### **2**

#### **Description**

Depression

#### **Timepoint**

Depression is measured once before the start of the first chemotherapy session and once after the fourth session of chemotherapy

#### **Method of measurement**

Beck Depression Tools

### **3**

#### **Description**

Quality of Life

#### **Timepoint**

Quality of Life is measured once before the start of the first chemotherapy session and once after the fourth session of chemotherapy

#### **Method of measurement**

European Organization for Research and Treatment of Cancer tools

## **Intervention groups**

### **1**

#### **Description**

"In the intervention group": people will laugh yoga for 20-30 minutes before the first to fourth chemotherapy sessions. Laugh yogic exercises include four main clapping steps, deep breathing, child play and laughter exercises. This program will be performed by the researcher (after receiving the necessary training) and under the supervision of a yoga laughter coach at the hall next to the chemo therapy section. The yoga program is laughing at talking about some cheerful issues such as national and religious ceremonies, having a positive sense of everyday life, and so on. Then touching with tracks 1, 2, and 3 begins to touch open hands so that the fingers and palms of each other are in

contact. We continue to move up and down and form a pendulum with movement in other parts of the body. Then the voice is simple and simple as Ho Ho. In addition, coordinated movements have been added for fertility enhancer. Broken words and words, such as words used by children in the game, are said to help in reducing individual impediments and talent. Later, the exercises begin to start laughing, which helps the person to experience mental and physical relaxation. Laughter is looking for laughter. Later, yoga exercises begin, so that each exercise lasts about 30 to 45 seconds with the touch of ho ho horns and deep deep deeps, including laughing yoga practice techniques (laughter, laughter with closed mouths, gradual laughter) Laughter laugh, laughter, laughter, laughter, telephone conversation, laughter) and laughter techniques (laughter and laughter laugh, laughter, laughter, laughter, laughter ...). This program takes about 5 minutes. At the end of the contest, the words are said loudly: "I am the happiest man on earth". They repeat themselves and look at each other and laugh. It takes about 5 minutes. After each yoga session, chemotherapy is performed according to the protocol in the center

**Category**

Rehabilitation

**2****Description**

Control group: Except for the usual self-care education to control the nausea by the researcher (about 5 minutes), no further action will be taken.

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Radiotherapy and Oncology Center of Reza (AS)

**Full name of responsible person**

Dr Varshoie Tabrizi

**Street address**

Mashhad - Exhibition Boulevard - Misagh Highway - Seventh Azar Square (Cemetery) - Cemetery 19

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mashhad

**Province**

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9138813944

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**Email**

Info@rroc.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghody

**Street address**

University Blvd

**City**

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**Province**

Razavi Khorasan

**Postal code**

9138813944

**Phone**

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**Email**

vpresearch@mums.ac.ir

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

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohammad Namazi Nia

**Position**

Master Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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namazinm951@mums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohammad Namazi Nia

**Position**

Master Student

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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**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is 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**

Presenting findings from research in seminars, conferences and publication of articles extracted from research in domestic and abroad journals for the use of non-metastatic cancer patients as well as researchers who intend to conduct research related to the subject matter.

**When the data will become available and for how long**

Start the access period 6 months after printing the results

**To whom data/document is available**

Delivering research results to other researchers for further research.

**Under which criteria data/document could be used**

The results obtained in this study can be found in the oncology (cancer) sections of all hospitals and even in other sections, especially in chronic patients who require special medications due to their long-term complications and special care. Have to be used.

**From where data/document is obtainable**

Referring to Mashhad Nursing and Midwifery Faculty

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

After sending the email to the person responsible for the response process begins.

**Comments**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohammad Namazi Nia

**Position**

Master Student

**Latest degree**

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