

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

City

mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3522 4472

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

Mashhhsd

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 2081

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

Street address

Bahonar Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948988

Phone

+98 51 5222 5280

Email

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

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Bahonar Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948988

Phone

+98 51 5222 5280

Email

namazinm951@mums.ac.ir

Phone

+98 51 5222 5280

Email

namazinm951@mums.ac.ir

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

Master

Other areas of specialty/work

Nurse

Street address

Modares Street

City

Torbat-e Heydariyeh

Province

Razavi Khorasan

Postal code

9519883561