Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of laughter therapy on nausea and vomiting in patients undergoing chemotherapy for cancer

Protocol summary

Study aim

Determining the effect of laughter therapy on chemotherapy-induced nausea and vomiting in cancer patients

Design

The clinical trial has a blind and randomized two-way control group using random number table method. The sample size is 80 people who are in two groups of 40 people (intervention and control). Both groups receive routine care to control nausea and vomiting, but in the intervention group, in addition to routine care, they also participate in laughter therapy sessions.

Settings and conduct

This is a clinical trial study that will be performed in the oncology ward of Shahid Rahimi Hospital in Khorramabad. Prior to the study, informed consent will be obtained from all patients participating in the study and then they will be divided into two groups of 40 intervention and control. The data collection tool is a demographic characteristics questionnaire and Moro nausea and vomiting scale. In this study, the researcher and the patients participating in the study are kept blind

Participants/Inclusion and exclusion criteria

nclusion criteria: Complete satisfaction to participate in the study, having a type of cancer, performing at least one session of chemotherapy, no auditory and visual problems. Exclusion criteria: Patients with known psychological problems, critically ill patients in need of intensive care

Intervention groups

Intervention group: Cancer patients undergoing chemotherapy and attend laughter therapy sessions for 30 minutes 3 times a week for 3 weeks. Control group: Cancer patients who are undergoing chemotherapy and do not attend laughter therapy sessions.

Main outcome variables

Incidence, severity and duration of nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180714040458N2**
Registration date: **2020-09-22, 1399/07/01**
Registration timing: **retrospective**

Last update: **2020-09-22, 1399/07/01**
Update count: **0**

Registration date

2020-09-22, 1399/07/01

Registrant information

Name
mehran naghibeiranvand
Name of organization / entity
Islamic Azad university khorramabad
Country
Iran (Islamic Republic of)
Phone
+98 66 3312 0351
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-07-06, 1398/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of laughter therapy on nausea and vomiting in patients undergoing chemotherapy for cancer

Public title
The effect of laughter therapy on chemotherapy-induced nausea and vomiting
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
The research units have full satisfaction to participate in the study The study units have a type of cancer Perform at least one chemotherapy session Absence of vision and hearing problems Having nausea or vomiting after chemotherapy Treated with chemotherapy drugs with gastrointestinal side effects
Exclusion criteria:
Need to be admitted to the intensive care unit Patients with known psychological problems
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
In the present study, participating patients, clinical caregivers (nurses), and data analysts were kept blind in the study. None of the participants know which intervention or control group they belong to and only know that they are participating in the research. Also, the nurses who are responsible for caring for the patients under study do not know the type of intervention or patient control group. Finally, the data analyzer will not know the type of patient group and the data will be provided as a code.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Islamic Azad University, Borujerd Branch
Street address
Vice Chancellor for Medical Sciences.Islamic Azad University Borujerd Branch.Modares Square,Modares st,Boroujerd
City
Borujerd
Province
Lorestan
Postal code
6915136111
Approval date
2020-07-22, 1399/05/01
Ethics committee reference number
IR.IAU.B.REC.1399.011

Health conditions studied

1

Description of health condition studied
nausea and vomiting
ICD-10 code
R11
ICD-10 code description
Nausea and vomiting

Primary outcomes

1

Description
Information on the incidence of nausea and vomiting by the Moro scale
Timepoint
Measurement of incidence of nausea and vomiting after laughter therapy intervention
Method of measurement
Moro Nausea and Vomiting Scale

2

Description
Information on the severity of nausea and vomiting by the Moro scale
Timepoint
Measurement of the severity of nausea and vomiting after laughter therapy intervention
Method of measurement
Moro Nausea and Vomiting Scale

3

Description
Information on the duration of nausea and vomiting by the Moro scale
Timepoint
Measuring the duration of nausea and vomiting after

laughter therapy intervention

Method of measurement

Moro Nausea and Vomiting Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group undergoes laughter therapy for 30 minutes 3 times a week for 3 weeks. Laughter therapy includes 10 minutes of funny short films, 5 minutes of jokes and finally 15 minutes of live funny programs by a small group of theaters approved by the Ministry of Culture and Guidance.

Category

Treatment - Other

2

Description

Control group: Control group: This group will not receive any intervention other than routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rahimi hospital

Full name of responsible person

Mehran Naghi Beiranvand

Street address

Shahid Rahimi hospital, Mojahedin Islam St, Azadi Square, Khorramabad

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mehranbeiranvandmsc@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Reza Mirdeikvand

Street address

Ayatollah Kamalvand University Complex, 5km of Khorramabad-Tehran road

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Mehran Naghi Beiranvand

Position

faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific

inquiries

Contact

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Position
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
The data is kept confidential by the researcher and provided to the study participants if desired. Data analysis is presented in the form of tables and charts..

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable