Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of laughter therapy on anxiety in patients with gastrointestinal cancers undergoing chemotherapy

Protocol summary

Study aim
Determining the effect of laughter therapy on anxiety in patients with gastrointestinal cancers undergoing chemotherapy

Design
The present study is an experimental study of pre-test-post-test with a control group and in a single-blind manner. In this clinical trial study, 60 patients undergoing chemotherapy and inclusion criteria were selected and divided into two groups of intervention and control by minimization technique.

Settings and conduct
The study units included 60 patients undergoing chemotherapy in the Imam Khomeini Hospital of Ardabil. 30 minutes before the intervention, the intensity of the patient's anxiety was assessed in both groups, and the intervention group was treated with a funny clip or movie for 30 minutes once a day as a group and in one of the ward rooms, and 30 minutes later, the severity of anxiety assessed again. In the control group, the severity of anxiety is also assessed, only the patient will receive routine intervention instead of intervention.

Participants/Inclusion and exclusion criteria
Be 18-70 years old; have gastrointestinal cancer and undergo at least one chemotherapy course and be hospitalized for at least three days; have no hearing or visual impairment, mental disorder, recent surgery, glaucoma, transmissible respiratory disease, and heart disease. Be a native of the province. Exclusion criteria: unwillingness to participate in the study; patient transfer to home; patient's death; Absence of the patient in meetings even once; change of medication type or increase or decrease of anxiolytic drug dose during the intervention.

Intervention groups
Patients in the intervention group participate in laughter therapy sessions once a day for half an hour and three consecutive days. Meetings will be held with comedy videos and comic clips. Patients in the control group receive routine care.

Main outcome variables
anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200819048458N1**
Registration date: **2020-10-07, 1399/07/16**
Registration timing: **retrospective**

Last update: **2020-10-07, 1399/07/16**
Update count: **0**

Registration date
2020-10-07, 1399/07/16

Registrant information

Name
Mehdi Ajri-khameslou

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 45 3372 6085

Email address
ajri@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-23, 1398/06/01

Expected recruitment end date
2019-12-22, 1398/10/01

Actual recruitment start date
2019-09-23, 1398/07/01

Actual recruitment end date

2020-01-21, 1398/11/01

Trial completion date

2020-01-21, 1398/11/01

Scientific title

The effect of laughter therapy on anxiety in patients with gastrointestinal cancers undergoing chemotherapy

Public title

The effect of laughter therapy in patients with gastrointestinal cancers

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study Having a gastrointestinal cancers Existence of anxiety based on visual analog scale Do not have audible and visual problems Do not use radiotherapy along with chemotherapy

Exclusion criteria:

Discharge from the hospital Death of the patient Absence of the patient in laughter therapy sessions even once increase or decrease the dose of anxiety medication during the intervention

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The study units were divided into intervention and control groups with Minimazation technique on 3 variables: age (in the range of 18-35, 36-32 and 53-70), sex (female or male) and disease severity (stageII, stageIII and stageIV) and with Using the Minimization Taves formula.

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 Ardabil University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Ardebil University of Medical Sciences, North side, University square, University street

City

Ardabil

Province

Ardabil

Postal code

5618985991

Approval date

2019-08-23, 1398/06/01

Ethics committee reference number

IR.ARUMS.REC.1398.318

Health conditions studied

1

Description of health condition studied

Malignant neoplasms of digestive organs

ICD-10 code

C15-C26

ICD-10 code description

Malignant neoplasms of digestive organs

Primary outcomes

1

Description

Anxiety in patients undergoing chemotherapy

Timepoint

30 min before and 30 min after laughter therapy in both groups and daily for three days.

Method of measurement

spilberger anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, laughter therapy performed with comedy videos and humorous clips for 30 minutes once a day for 3 consecutive days

Category

Behavior

2

Description

Control group: patients received routine care.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Ardabil

Full name of responsible person

Dr farzaneh

Street address

Imam Khomeini Hospital Ardabil, saheli street, ardabil, iran

City

Ardabil

Province

Ardabil

Postal code

5618953141

Phone

+98 45 3325 1401

Email

Emamhe@arums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr.shahab bohlooli

Street address

Ardabil University of Medical Sciences Administrative Complex, End of University Street

City

Ardabil

Province

Ardabil

Postal code

۵۶۱۸۹-۸۵۹۹۱

Phone

+98 45 3353 4715

Email

ravabet@arums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ardabil 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

Ardabil University of Medical Sciences

Full name of responsible person

Mehdi Ajri-khameslou

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Ardabil School of Nursing and Midwifery, Between Hafez and Saadi crossroads, Martyrs Highway

City

Ardabil

Province

Ardabil

Postal code

5615754136

Phone

+98 45 3372 6085

Fax

+98 45 3372 8004

Email

ajri.mehdi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Mehdi Ajri-khameslou

Position

Assistant Professor

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+98 45 3372 6085

Email

ajri.mehdi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Ardabil University of Medical Sciences

Full name of responsible person
Mehdi Ajri-khameslou

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

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

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

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