

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 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 (stagell, stagelll and stagelV) 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, sahehi 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**

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**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

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Mehdi Ajri-khameslou

**Position**

Assistant Professor

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## Person responsible for updating data

ajri.mehdi@gmail.com

### Contact

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**Email**

## 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