Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Investigating of the effect of psychotherapy intervention on anxiety of gastrointestinal cancer patients and in Valiasr hospital oncology ward Zanjan in 2022

Protocol summary

Study aim
Determining the effect of group psychotherapy and support on the level of anxiety in patients with gastrointestinal cancer

Design
The present study is a randomized clinical trial study of parallel design, double-blind and with a control group, which will be performed on 50 patients with gastrointestinal cancers with anxiety referring to the oncology department of Waliasr Hospital. Then the patients will be randomly divided into two groups of intervention (N=25) and control (N=25) using the table of random numbers. For the intervention group, 6 sessions of psychotherapy will be held for 30 minutes (2 sessions per week), and for the control group, a series of trainings and routine care will take place. It should be noted that for better education and class management, intervention group patients will be divided into groups of 10 if necessary.

Settings and conduct
This study is a clinical trial study. The target group is patients over 18 years old with one of the gastrointestinal cancers who have symptoms of anxiety and depression. The location of this research is the oncology department of Waliasr Hospital, Zanjan-1401. Data collection tool based on demographic and clinical characteristics. The second version of Beck's anxiety questionnaire is BDI-II, which is through interviews with patients; For the intervention group, six psychotherapy sessions will be held for 30 minutes and 2 sessions per week, and there will be no intervention for the control group. Finally, the data is entered into SPSS26 software after collection.

Participants/Inclusion and exclusion criteria
Patients over 18 years of age with one of the gastrointestinal cancers referred to the oncology department

Intervention groups
Intervention group: 6 psychotherapy sessions for 30 minutes (2 sessions per week). Control group: education and routine care.

Main outcome variables
Anxiety; Depression

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221118056532N1**
Registration date: **2022-12-18, 1401/09/27**
Registration timing: **prospective**

Last update: **2022-12-18, 1401/09/27**
Update count: **0**

Registration date
2022-12-18, 1401/09/27

Registrant information

Name
Kazem Ashrafi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 24 3354 4001

Email address
beheshti@zums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-22, 1401/10/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating of the effect of psychotherapy intervention on anxiety of gastrointestinal cancer patients and in Valiasr hospital oncology ward Zanjan in 2022

Public title

Investigating of the effect of psychotherapy intervention on anxiety of gastrointestinal cancer patients and in Valiasr hospital oncology ward Zanjan in 2022

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

volunteering to enter the study, Age above 18 years Having one of the gasterointestinal cancer

Exclusion criteria:

Having diagnosed psychological illness including anxiety and depression Participation in psychotherapy classes death of a loved one; Divorced in the last 6 months

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

To use the table of random numbers, we first determine the direction of reading the numbers in the table (for example, up, down, left or right), then even numbers are considered for the intervention group and odd numbers for the control group. In the next step, the researcher puts his hand on one of the numbers and moves in one of the predetermined directions and records the numbers and assigns them to different groups, and this should continue until the samples are assigned to two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be double-blind, so that the patients and the researcher responsible for data analysis will not have any intervention or control information regarding the allocation of people to groups. To blind the patients, we will provide a series of trainings and routine care to the control group. For the purpose of blinding the statistician who is responsible for data analysis, the intervention and control groups will be coded and provided to him for analysis without mentioning the intervention and control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Committee of ethics in biomedical research

Street address

Ark square, Hospitalof Shahid Beheshti Educational & Treatment Center of Shahid Beheshti

City

Zanjan

Province

Zanjan

Postal code

4513615788

Approval date

2022-10-25, 1401/08/03

Ethics committee reference number

IR.ZUMS.REC.A-12-1523-6

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

2

Description of health condition studied

cancer

ICD-10 code

D70.1

ICD-10 code description

Agranulocytosis secondary to cancer chemotherapy

Primary outcomes

1

Description

depression

Timepoint

Before starting the study - 6 sessions

Method of measurement

BDI-II

Secondary outcomes

1

Description
Anxiety and depression score
Timepoint
Before the intervention - six sessions
Method of measurement
BDI-II,Depression questionnaire

Intervention groups

1

Description
Intervention group: will participate in 6 psychotherapy sessions for 30 to 60 minutes and 2 sessions per week. The first session: supportive psychotherapy and its importance, getting to know the principles of the group, getting to know more about the members and getting to know the disease. The second session: discussion and exchange of opinions of members about cancer and its impact on life. Session 6-3: Focus on members' concerns and problems.
Category
Behavior

2

Description
Control group: The control group will receive regular training and care during the study period.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Oncology Department of Valiasr Hospital, Zanjan
Full name of responsible person
Kazem Ashrafi
Street address
Valiasr Hospital, Valiasr square, Zanjan
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45157-77978
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr. Samad Nedri
Street address
Arg Square, Dr. Shahid Beheshti Hospital
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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
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Kazem Ashrafi
Position
Associate
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
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Position

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Latest degree

Medical doctor

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

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Information about the main message can be shared

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

People working in medical and academic institutions

Under which criteria data/document could be used

It is allowed for therapeutic and research use.

From where data/document is obtainable

People can refer to Dr. Kazem Ashrafi working at Shahid Beheshti Hospital in Zanjan for receipts.

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

After applying to the University of Medical Sciences and obtaining permission.

Comments