

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The efficacy of group logotherapy based on Frankl school on depression and life expectancy in patients with gastrointestinal cancer

Protocol summary

Study aim

The efficacy of group logotherapy based on Frankl school on depression and life expectancy in patients with gastrointestinal cancer referred to Omid Hospital in Urmia, 2022

Design

A clinical trial with a control group, without blinding, randomized on fifty patients, cards with numbers 1 or 2 were used for randomization.

Settings and conduct

In this study, 50 patients with gastrointestinal cancer referred to Omid Urmia Hospital were selected based on the inclusion and exclusion criteria of the study and were randomly assigned to intervention and control groups using cards. will get For people in the intervention group, 10 group logotherapy sessions will be held daily except Thursday and Friday for 60-90 minutes. Beck's depression and Schneider's life expectancy questionnaires will be completed in this study.

Participants/Inclusion and exclusion criteria

Entry requirements: Being 20-60 years old Have a minimum literacy Having Information on the type of disease Having the ability to perform activities independently Having a proper physical condition Lack of experience in critical situations in the last six months Not being on stage 4 disease Having a cell phone Having basic information about cyberspace Consent to participate in the study A score of 5 or higher on the Beck Depression Inventory A score of 36 or lower on the Schneider Life expectancy questionnaire No entry conditions: Withdrawal from attending meetings Deterioration of physical condition Occurrence of a critical accident during the study Absence from more than one meeting See a psychiatrist or psychologist while studying

Intervention groups

There will be no intervention for the control group, but the intervention group will participate in ten group logotherapy sessions. Both of the groups will receive the

routine interventions of the hospital.

Main outcome variables

Depression , life expectancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220507054762N1**

Registration date: **2022-08-09, 1401/05/18**

Registration timing: **prospective**

Last update: **2022-08-09, 1401/05/18**

Update count: **0**

Registration date

2022-08-09, 1401/05/18

Registrant information

Name

Laia Rezapour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3347 0678

Email address

rezapourlaia331@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The efficacy of group logotherapy based on Frankl school on depression and life expectancy in patients with gastrointestinal cancer

Public title
The efficacy of group logotherapy on depression and life expectancy in patients with gastrointestinal cancer

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Age 20-60 years Having a minimum literacy Knowledge of the type of disease Having the ability to perform personal and simple activities independently Having a physical condition so that he can participate in meetings Having no experience of accidents and critical situations in the last six months Not being on stage 4 of the disease Having a mobile phone Having basic information about cyberspace Patient consent to participate in the study Getting a score of 5 or higher in the Beck Depression Inventory Getting a score of 36 and below in Schneider Life expectancy questionnaire
Exclusion criteria:
 Withdrawal from attending logotherapy sessions Deterioration of physical condition Occurrence of a critical accident while studying for the patient Absence from more than one session See a psychiatrist or psychologist while studying and undergoing psychotherapy or medication

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Using the available sampling method and taking into account the drop in samples, 50 people who meet the criteria for entering the study will be selected and randomly (by choosing one of the two cards that contain the content of number 1 or 2) will be placed in two control and intervention groups. In this way, 25 people will be assigned to each of the control and intervention groups. The control group will not receive group logotherapy. The groups will fit together.

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 Urmia University of Medical Sciences

Street address

Unit Fourteen, Fifth Floor, Nine Apartments, Opposite Aftab Apartments, Baqer Sonboli Alley, Kashani St., Urmia

City

Urmia

Province

West Azarbaijan

Postal code

5715774173

Approval date

2022-06-29, 1401/04/08

Ethics committee reference number

IR.UMSU.REC.1401.138

Health conditions studied

1

Description of health condition studied

Gastrointestinal cancer

ICD-10 code

C15-C26

ICD-10 code description

Malignant neoplasms of digestive organs

Primary outcomes

1

Description

depression

Timepoint

Before the intervention, four days and thirty days after the intervention

Method of measurement

Beck Depression Inventory

2

Description

Life expectancy

Timepoint

Before the intervention, four days and thirty days after the intervention

Method of measurement

Schneider Life expectancy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will be randomly divided into two groups of 12 and 13 people. 10 group logotherapy sessions will be held for the intervention group. Meetings will be held daily except Thursday and Friday, and each meeting will be 60-90 minutes. Holding logotherapy sessions will be based on the Frankel school. The intervention group will also receive the hospital's routine interventions in addition to logotherapy.

Category

N/A

2

Description

Control group: Will receive routine hospital interventions.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid Hospital

Full name of responsible person

Laia Rezapour

Street address

Unit Fourteen, Fifth Floor, Nine Apartments, Opposite Aftab Apartments, Baqer Sonboli Alley, Kashani St., Urmia

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Saber Gholizadeh

Street address

Research and Technology Vice-Chancellor Building, University Headquarters, End of Emergency Coy, Resalat Blvd, Urmia.

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Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Laia Rezapour

Position

Master's student in psychiatric nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Moloud Radfar

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

The documents will be published as articles. All demographic information such as age, education level, job position, etc. can be published. Also, the level of life expectancy and depression of people can be published.

When the data will become available and for how long

Access starts 3 months after results are published

To whom data/document is available

Accessible to all researchers in the field of psychiatry

Under which criteria data/document could be used

Comparison of demographic characteristics with life expectancy and depression or two groups with each other

From where data/document is obtainable

Moulad Radfar: Associate Professor of Urmia University of Medical Sciences Mradfar1343@gmail.com
Laia Rezapour: Master's degree in Urmia University of Medical Sciences rezapourlaia331@gmail.com

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

Sending an email, and if there is no response after one day, calling on the phone and coordinating with the research members, and if they agree, provide information in about a week.

Comments