

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The Effect of Dialectical Behavioral Therapy on Loneliness of Oncology Patients

Protocol summary

Study aim

Determining the Effect of Dialectical Behavior Therapy on the Feeling of Loneliness in Oncology patients

Design

Randomized, Controlled, Single blinded clinical trial on 30 Patients. The block method will be used for random allocation.

Settings and conduct

In this study, UCLA Loneliness Questionnaire will be completed by all the patients who meet the inclusion criteria in the first half of 1402 at the Radiotherapy and Oncology Center of Birjand, and among them 30 people who will get the cut score of UCLA Loneliness Questionnaire will be selected. Before random allocation, the participants are told that dialectical therapy skills will be provided in PDF form or face-to-face training. Dialectical behavioral therapy skills will be taught for the intervention group during 8 sessions at Iran Mehr Radiotherapy and Oncology Center in Birjand. At the end of the study, the summary of the skills taught in the dialectic behavior therapy sessions will be provided to the control group in PDF format.

Participants/Inclusion and exclusion criteria

The Ability to Communicate Diagnosis of Cancer by an Oncologist Completing at least One Course of Radiotherapy or Chemotherapy The Ability to Read and Write Living in Birjand 20 to 65 years old Non-participation in the present research project intervention Not participating in a research program at the same time Not suffering from a specific physical or mental illness except cancer Not taking special medical and psychiatric drugs (except cancer treatment drugs)

Intervention groups

In this study, after random sampling and allocation, dialectical behavior therapy skills will be taught to the intervention group under the supervision of a psychologist in 8 sessions. At the end of the study, the summary of the skills taught in the dialectical behavior therapy sessions will be available for the control group in

PDF format.

Main outcome variables

Feeling of Loneliness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240121060762N1**

Registration date: **2024-02-11, 1402/11/22**

Registration timing: **prospective**

Last update: **2024-02-11, 1402/11/22**

Update count: **0**

Registration date

2024-02-11, 1402/11/22

Registrant information

Name

Mahdi Mirhoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4422 5510

Email address

mahdi.mirhoseini99@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-03-15, 1402/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
The Effect of Dialectical Behavioral Therapy on Loneliness of Oncology Patients

Public title
The Effect of Dialectical Behavioral Therapy on Loneliness of Oncology Patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
The Ability to Communicate Diagnosis of Cancer by an Oncologist Completing at least One Course of Radiotherapy or Chemotherapy The Ability to Read and Write Living in Birjand 20 to 65 years old

Exclusion criteria:
The History of Participating in the Intervention of the Present Research Project Concurrent Participation in the same Research Program Suffering from Specific Physical and Mental Illness except Cancer Not taking special Medical and Psychiatric Drugs (except Drugs for Cancer Treatment)

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
The random block method will be as follows: 1)The size of each block will be 6. 2)All possible balanced combinations will be written with 3 control cases and 3 intervention cases. (20 combinations) 3)Blocks are randomly selected to allocate each 30 participants.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, after sampling and before random allocation, participants are told that dialectical behavior therapy skills will be provided in PDF form or face-to-face training.

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Birjand University of Medical Sciences
Street address
Ghafari Blvd., Birjand University of Medical Sciences
City
Birjand
Province
South Khorasan
Postal code
9717853076
Approval date
2024-01-21, 1402/11/01
Ethics committee reference number
IR.BUMS.REC.1402.463

Health conditions studied

1

Description of health condition studied
Cancer
ICD-10 code
C16
ICD-10 code description
Malignant neoplasm of stomach

2

Description of health condition studied
Cancer
ICD-10 code
C18
ICD-10 code description
Malignant neoplasm of colon

3

Description of health condition studied
Cancer
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast

4

Description of health condition studied
Cancer
ICD-10 code
C94
ICD-10 code description
Other leukemias of specified cell type

5

Description of health condition studied
Cancer

ICD-10 code

C53

ICD-10 code description

Malignant neoplasm of cervix uteri

Primary outcomes**1****Description**

Feeling of Loneliness

Timepoint

Before Starting the Intervention,After Completing the Intervention and one Month After Completing the Intervention

Method of measurement

UCLA Loneliness Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In this study, dialectical behavior therapy skills will be taught face-to-face in 8 sessions for intervention group.

Category

Rehabilitation

2**Description**

Control group: After the end of the study, the summary of the skills taught to the intervention group will be provided to the control group in PDF format.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Iranmehr Radiotherapy and Oncology Center

Full name of responsible person

Dr. Hasan Mortazi

Street address

30 th Ghafari Ave.,Ghafari Blvd.,

City

Birjand

Province

South Khorasan

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9717853076

Phone

+98 56 3162 6800

Email

Iranmehr@bums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

Dr. Masoud Yousefi

Street address

Ghafari Blvd., Birjand University of Medical Sciences

City

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South Khorasan

Postal code

9717853076

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+98 56 3239 5000

Email

webda@bums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Birjand 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**

Birjand University of Medical Sciences

Full name of responsible person

Mahdi Mirhoseini

Position

Psychiatric Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 251, 30 th West Ebneyamin Ave., Taleghani Blvd.,

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr Ahmad Nasiri

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Position

Psychiatric Nursing Student

Latest degree

Bachelor

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

Baerd on Ethical Issues

Study Protocol

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

Statistical Analysis Plan

No - There is not 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

No - There is not 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