Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 IranMehr 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
Postal code
9717853076
Phone
+98 56 3162 6800
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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
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Postal code
9717853076
Phone
+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
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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
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Person responsible for updating data

Contact
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Psychiatric Nursing Student
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Mahdi.mirhoseini99@bums.ac.ir

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
Baesd 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