

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effectiveness of cognitive behavioral therapy and emotional focused therapy on grief, psychological distress, symptoms related to sleep disturbances, coping strategies and quality of life in caregivers of cancer patients

Protocol summary

Study aim

Comparing the effectiveness of cognitive behavioral therapy and emotional therapy on bereavement, psychological disturbances, symptoms related to sleep disturbances, coping strategies and quality of life in caregivers of cancer patients

Design

First, through the Maxa Cancer Control Charitable Foundation located in The city of Mashhad will obtain the necessary permission for cooperation and then help for referral and introduction Participants (families of cancer patients), this foundation will make the necessary arrangements

Settings and conduct

The implementation method in this research will be as follows, first through the Maxa Cancer Control Charitable Foundation located in The city of Mashhad will obtain the necessary permission for cooperation and then help for referral and introduction Participants (families of cancer patients), this foundation will make the necessary arrangements

Participants/Inclusion and exclusion criteria

Age above 18 years - Having a minimum education degree - Having a caring role for a person with cancer - Caring for patients who have been diagnosed with cancer for at least a year - Suffering from severe cognitive and personality disorders and taking psychiatric drugs - Drug abuse - Simultaneous participation in other psychological interventions

Intervention groups

45 samples and sampling methods will be available. There are 15 people in each experimental group and 15 people in the control group

Main outcome variables

Although in the treatment of disorders psychological and behavioral problems, both cognitive behavioral

approaches and emotion-based therapy are used, repetition And the comparison of these two approaches in terms of examining the effectiveness of cognitive techniques against emotional as one of The reasons raised in the necessity of conducting this research will be considered

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230910059391N1**

Registration date: **2024-03-01, 1402/12/11**

Registration timing: **prospective**

Last update: **2024-03-01, 1402/12/11**

Update count: **0**

Registration date

2024-03-01, 1402/12/11

Registrant information

Name

Iran Habibi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3882 9543

Email address

arezoo.habibi051@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-08, 1403/01/20
Expected recruitment end date
2024-06-19, 1403/03/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effectiveness of cognitive behavioral therapy and emotional focused therapy on grief, psychological distress, symptoms related to sleep disturbances, coping strategies and quality of life in caregivers of cancer patients

Public title
Comparing the effectiveness of cognitive behavioral therapy and emotional focused therapy on grief, psychological distress, symptoms related to sleep disturbances, coping strategies and quality of life in caregivers of cancer patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Having at least a diploma Having a caregiver role for a person with cancer (usually as a family member or close friend) Caring for patients who have been diagnosed with cancer for at least one year The cancer must be of an advanced type as diagnosed by the doctor Informed consent to receive medical services Regular participation in therapy sessions (cognitive behavioral therapy and emotion-oriented therapy) according to protocol therapy
Exclusion criteria:
Having severe cognitive and personality disorders and taking psychiatric drugs Drug abuse Simultaneous participation in other psychological interventions

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of implementation in this research will be as follows: First, permission will be obtained through the Maxa Cancer Control Charitable Foundation located in Mashhad, and then in order to help refer and introduce the participants (families of cancer patients), from This foundation will make the necessary arrangements. In the following, 45 people will be selected from the mentioned statistical population using the available sampling method and will be assigned to three groups of 15

people in the test and the control group using random replacement. Next, necessary information will be given on how to implement the protocol and efforts will be made to establish a good relationship with mutual cooperation. After the pre-test, separate test groups will participate in cognitive-behavioral therapy and emotion-oriented therapy sessions, and then the post-test and 2-month follow-up will be performed

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

National system of ethics in biomedical research

Street address

Khorasan Razavi Province, Neishabur, Research Blvd., Islamic Azad University Complex, Neishabur branch

City

neyshabour

Province

Razavi Khorasan

Postal code

93199V5A53

Approval date

2024-02-14, 1402/11/25

Ethics committee reference number

IR.IAU.NEYSHABUR.REC.1402.032

Health conditions studied

1

Description of health condition studied

grief

ICD-10 code

F43.8

ICD-10 code description

Other reactions to severe stress

2

Description of health condition studied

psychological distress

ICD-10 code

F68.0

ICD-10 code description

Elaboration of physical symptoms for psychological reasons

3

Description of health condition studied

symptoms related to sleep disturbances

ICD-10 code

G47.2

ICD-10 code description

Disorders of the sleep-wake schedule / Delayed sleep phase syndrome / Irregular sleep-wake pattern

4

Description of health condition studied

coping strategies

ICD-10 code

F43.9

ICD-10 code description

Reaction to severe stress, unspecified

5

Description of health condition studied

quality of life

ICD-10 code

Z62.8

ICD-10 code description

Other specified problems related to upbringing

Primary outcomes

1

Description

Bereavement score in the Caregiver Anticipatory Assessment Scale

Timepoint

Bereavement measurement is done at the beginning of the study and before the start of therapeutic interventions and then at the end of the treatment sessions, which are 8 sessions in one treatment and 10 sessions in the other treatment, and the measurement is done in the follow-up sessions with an interval of two months after the end of the treatment. will be

Method of measurement

Caregiver Anticipatory Grief Assessment Scale

2

Description

The score of coping strategies in the Jalovis coping scale questionnaire

Timepoint

Coping strategies are carried out at the beginning of the study and before the start of therapeutic interventions and then at the end of the treatment sessions, which are 8 sessions in one treatment and 10 sessions in the other treatment, and the measurement is done in the follow-up sessions with an interval of two months after the end of the treatment. will be

Method of measurement

Jallowis coping questionnaire

3

Description

Quality of life score in the quality of life questionnaire

Timepoint

The quality of life is measured at the beginning of the study and before the start of treatment interventions and then at the end of the treatment sessions, which are 8 sessions in one treatment and 10 sessions in the other treatment, and the measurement is done in the follow-up sessions with an interval of two months after the end of the treatment. to be

Method of measurement

Quality of life questionnaire

4

Description

The score of psychological disturbances in Wechsler's standard psychological distress questionnaire form 10 questions

Timepoint

Psychological disturbances

Method of measurement

Wechsler psychological distress scale

5

Description

The score of symptoms related to sleep disturbances in the Pittsburgh Sleep Questionnaire

Timepoint

Symptoms related to sleep disturbances are measured at the beginning of the study and before the start of therapeutic interventions, and then at the end of the treatment sessions, which are 8 sessions in one treatment and 10 sessions in the other treatment, and measurements are taken in follow-up sessions with an interval of two months after The treatment is completed

Method of measurement

Petersburg Sleep Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group 1 on which cognitive behavioral therapy is implemented

Category

Treatment - Other

2

Description

Intervention group: Intervention group 2, on which emotion-oriented therapy is implemented

Category

Treatment - Other

3

Description

Control group: The number of people in the control group is 15 who do not receive any treatment

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian Cancer Control Charitable Institute

Full name of responsible person

Mohammadreza Khodabakhsh

Street address

No. 4 between Qayim 2 and Ahmed Abad Margin
Ahmad Abad Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Neyshabour University of Medical Sciences

Full name of responsible person

Mohamaderza Khodabakhsh

Street address

headquarter of Neishabur medical sciences
faculty Moalem square Farhangian town

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mr_khodabakhsh@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Neyshabour University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Arezo Habibi

Position

Student

Latest degree

Master

Other areas of specialty/work

Psychology

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Contact

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Person responsible for updating data

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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

Comparing the effectiveness of cognitive behavioral therapy and emotional focused therapy on grief, psychological distress, symptoms related to sleep disturbances, coping strategies and quality of life in caregivers of cancer patients

When the data will become available and for how long

Starting from February 1402 and with a period of 6 months

To whom data/document is available

Academic sciences

Under which criteria data/document could be used

The general public

From where data/document is obtainable

09151079787

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

Message or email

Comments