

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The Effectiveness of Compassion-Focused Therapy (CFT) on psychological Symptoms and Quality of Life on Patients with Cancer

Protocol summary

Study aim

Evaluating the effectiveness of compassion-Focused therapy on some psychological symptoms and improving the quality of life of cancer patients

Design

The present study will include the Men and women over 18 years of age who are referred to the Department of Chemotherapy emamkhomeini hospital and have received diagnosis any type of cancer diagnosis. The final sample will consist of 30 participants who will be randomly assigned to both control and intervention groups.

Settings and conduct

The experimental group will participate in eight sessions of 2 hours of Compassion Therapy (CFT) therapy group that will be held at Imam Khomeini Hospital in Tehran. Before and after the treatment, the members of the group were asked to give a questionnaire of compassion Self, depression, anxiety and stress, quality of life will respond, and then the compassion-based therapy will be performed for the group; The experimental group is in the intervention of this program. And the control group remain in waiting list. The total time of this study will be about one year.

Participants/Inclusion and exclusion criteria

Inclusion criteria: under chemotherapy; diagnosis of the disease for at least 3 months; women and men over 18 years of age. Exclusion criteria: psychological disorders (Psychosis, dementia): Being in End stage.

Intervention groups

The intervention group will receive treatment based on Compassion-Focused Therapy. The control group does not receive any intervention and remains in the waiting list.

Main outcome variables

Reduce psychological symptoms: Improving the quality of life of cancer patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141108019855N4**

Registration date: **2018-07-19, 1397/04/28**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-19, 1397/04/28**

Update count: **0**

Registration date

2018-07-19, 1397/04/28

Registrant information

Name

Samira Masumian

Name of organization / entity

Tehran Psychiatry Institute

Country

Iran (Islamic Republic of)

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+98 21 3349 6990

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Compassion-Focused Therapy (CFT) on psychological Symptoms and Quality of Life on Patients with Cancer

Public title

Compassion-Focused Therapy (CFT) on Patients with Cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1) the age range of 18 years. 2) the possession of a minimum diploma. 3) the occurrence of any type of cancer based on a physician's diagnosis. 4) those who, according to the results of a pathological test, have at least two months The definitive history of their diagnosis passes. 5) Patients undergoing drug and chemotherapy.

Exclusion criteria:

mental retardation. Patients are not at the end stages of cancer.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The final sample will be included 30 participants who will be randomly assigned to both control and intervention groups. At first, the names of all the subjects will be written and be placed in a container, and in another there are 15 control sheets and 15 test sheets. Without naming the of individuals or groups, each name and group of containers are removed from each selection. This is repeated so that everyone is placed in the control and intervention groups.

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 Iran University of Medical Sciences

Street address

Shahid MNo. 1, ansouri Street, Niyayesh Street, Satarkhan Avenue, School of Behavioral Sciences and Mental Health, Tehran City

City

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Province

Tehran

Postal code

۱۴۴۵۶۱۳۱۱۱

Approval date

2018-04-21, 1397/02/01

Ethics committee reference number

IR.IUMS.REC.1397.098

Health conditions studied

1

Description of health condition studied

Depression Disorder

ICD-10 code

F32.2

ICD-10 code description

Major depressive disorder, single episode, severe without psychotic features

2

Description of health condition studied

Generalized anxiety disorder

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Depression

Timepoint

pretest.posttest (at the end of 8 session)

Method of measurement

DASS inventory

2

Description

Anxiety

Timepoint

pretest.posttest (at the end of 8 session)

Method of measurement

DASS inventory

3

Description

Stress

Timepoint

pretest.posttest (at the end of 8 session)

Method of measurement

DASS inventory

4**Description**

Compassion Focused Therapy

Timepoint

pretest.posttest (at the end of 8 session), 8 weeks following end of the treatments

Method of measurement

Self-Compassion Scale

5**Description**

Quality of life

Timepoint

pretest.posttest (at the end of 8 session)

Method of measurement

Quality of life inventory

Secondary outcomes

empty

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

Intervention group: Patients will participate in eight sessions of 2 hours of Group Therapy based on Compassion; at the first session, the group will respond to self-esteem, depression, anxiety and stress, and quality of life questionnaires. It will be performed for the group of compassion-based therapy; the first sessions, the rationale of compassion-based therapy, the concepts of compassion and compassion will be introduced; further, individuals are asked to try to think and behave towards themselves; During these meetings, some methods such as: picturing compassion of the species, relieving breathing, harmony, empathy, writing a compassionate letter, etc. Encouragement will be taught to the people themselves; in the final sessions, people will be encouraged to recognize and deal with factors that cause their fear and repulsion toward the component of compassion; at the last and second session Month after the end of the session (follow up), depression, anxiety, stress and quality of life will be re-tested.

Category

Treatment - Other

2**Description**

Control group: The control group will not receive any psychotherapy interventions and will respond only to all the questionnaires that the testing team will answer before and after the implementation.

Category

N/A

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

Emam Khomeini hospital

Full name of responsible person

Mahsa Mirzakhani

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

Vice Chancellor for Research of Faculty of Behavioral Sciences of Iran University of Medical Science

Full name of responsible person

Dr Gharraee

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

Yes

Title of funding source

Vice Chancellor for Research of Faculty of Behavioral Sciences of Iran University of Medical Science

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
Iran University of Medical Sciences
Full name of responsible person
Mahsa Mirzakhani
Position
Master's Degree in Clinical Psychology
Latest degree
Master
Other areas of specialty/work
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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

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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

Analytic Code

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

Data Dictionary

Not applicable

Title and more details about the data/document

Release in clinics and mental hospitals.

When the data will become available and for how long

Get started 6 months after printing results.

To whom data/document is available

Researchers working in academia and academia.

Under which criteria data/document could be used

More research in this area for researchers with email

requests.

From where data/document is obtainable

Mahsa mirzakhani: Email:

mahsa.myzakhany@gmail.com tel: 09122057154

What processes are involved for a request to access

data/document

Access is ultimately up to one month after the request by email.

Comments