

# 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)

##### Phone

+98 21 3349 6990

##### Email address

samira.masumian@yahoo.com

##### 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

Tehran

## 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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**Phone**

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**Email**

mahsa.myrzakhany@gmail.com

**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**  
Psychology  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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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**