

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Effectiveness of compassion focused therapy (CFT) and emotional schema therapy (EST) on cancer related fatigue, self-care behaviors and emotional self-regulation in cancer patients.

Protocol summary

Study aim

Comparison of the effectiveness of compassion-focused therapy and emotional schema therapy on cancer fatigue, self-care behaviors and emotional self-regulation in cancer patients

Design

A clinical trial with a control group, with parallel, randomized groups, on 45 patients, uses the website www.randomization.com for randomization.

Settings and conduct

All information and contents related to theoretical foundations are compiled using the library method and after reviewing books, articles and dissertations related to the research topic as well as information available in Internet databases, in order to achieve the results of existing hypotheses, The quasi-experimental method is used based on treatment protocols. The statistical population of the present study is all cancer patients referred to the non-governmental center of oncology in Urmia in 1399. After identifying cancer patients based on patient's records, 45 patients who met the inclusion criteria are identified and randomly assigned to the experimental and control groups

Participants/Inclusion and exclusion criteria

Entry criteria for subjects: 1. Minimum education at the diploma level 2. Conscious satisfaction with participating in research 3. Not receiving a psychotherapy at the same time
Criteria for leaving the subjects: 1. Existence of mental disorders requiring immediate treatment (such as symptoms of psychosis and substance abuse)

Intervention groups

Intervention group 1: Intervention group 1 receives compassion-focused therapy for 8 sessions. Intervention group 2: Intervention group 2 receives emotional schema therapy for 12 sessions. Intervention group 3: Intervention group 3 is the control group and does not receive any therapy.

Main outcome variables

Cancer related fatigue; self-care behaviors; emotional self-regulation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200108046059N1**

Registration date: **2020-09-09, 1399/06/19**

Registration timing: **retrospective**

Last update: **2020-09-09, 1399/06/19**

Update count: **0**

Registration date

2020-09-09, 1399/06/19

Registrant information

Name

Farinaz Tabibzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 44 3382 8912

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-05, 1399/05/15

Expected recruitment end date

2020-08-21, 1399/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of compassion focused therapy (CFT) and emotional schema therapy (EST) on cancer related fatigue, self-care behaviors and emotional self-regulation in cancer patients.

Public title

Comparison of compassion focused therapy (CFT) and emotional schema therapy (EST) in cancer patients.

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Minimum education at the diploma level Conscious satisfaction with participating in research With at least 6 months of illness and undergoing chemotherapy or radiation therapy Minimum age 40 and maximum age 60 years Not receiving a psychotherapy at the same time

Exclusion criteria:

Existence of mental disorders requiring immediate treatment (such as symptoms of psychosis and substance abuse)

Age

From **40 years** old to **60 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 randomization process is done using the site www.randomization.com. In order to hide the random allocation, a sealed envelope with a random sequence is used. In such way, that the number of sample volume is 45 people, the envelope is made By the person in charge of the reception center and each of the random sequences created is recorded on a card and the cards are placed in the letter envelopes. in order to maintain the random sequence, on the outer surface of the envelopes are numbered in the same way. Finally, the letter envelopes are glued and placed in a box, respectively. According to the order of entry of eligible participants to the study, one of the envelopes is opened and the assigned group of the participant is revealed. During this period, the researcher and participants are not aware of the assignment of the experiment and control group.

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 Tonekabon Azad University

Street address

3 km of Chalous road, Valiabad, Islamic Azad University of Tonekabon

City

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Province

Mazandaran

Postal code

4684161167

Approval date

2020-07-26, 1399/05/05

Ethics committee reference number

IR.IAU.TON.REC.1399.013

Health conditions studied**1****Description of health condition studied**

Cancer patients

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Self-care behaviors Score from the Esmi 2016 Questionnaire

Timepoint

Assessing self-care behaviors before and after the intervention

Method of measurement

Esmi Self-care behaviors in cancer patients questionnaire 2016

2**Description**

Cancer Fatigue Score from the Okoyama 2000 Questionnaire

Timepoint

Assessing cancer fatigue before and after the intervention

Method of measurement

Okoyama Cancer Fatigue Questionnaire 2000

3

Description

Emotional self-regulation score of Hoffman and Kashedan 2010 questionnaire

Timepoint

Assessment of emotional self-regulation before and after the intervention

Method of measurement

Hoffman and Kashedan Emotional Self-Regulation Questionnaire 2010

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group 1: Compassion-focused therapy group: Content of compassion-focused therapy intervention sessions: The first session. Performing a pre-test, therapeutic logic based on self-compassion and understanding compassion and self-compassion. Session 2. Patients are asked to try to identify how they think and behave towards themselves. Session 3. Use compassionate imaging skills and use soothing breathing techniques. Session 4. Using the technique of mindfulness for patients. Session 5. In this session, the technique of writing a letter of daily compassion and promoting self-compassion is done by emotional discharge. Sixth session. In this session, pathology of factors that cause fear and repulsion of patients to Self-compassion is checked. Seventh session. Teaching methods to deal with the factors of self-compassion and the use of relaxation techniques. Summarize the sessions, make final suggestions and practice, and finally perform a post-test.

Category

Behavior

2

Description

Intervention group: Intervention group 2: Emotional schema therapy group: Session 1. Establishing a therapeutic relationship, presenting treatment logic and therapeutic goals, presenting etiology and treatment model from the emotional schema therapy approach. Session 2. Normal and difficult emotions Well done, paying attention to the patient's painful emotions and normalizing them, emotional self-awareness, emotion education and introduction, identifying and labeling emotions, distinguishing between different emotions, identifying emotions in physical and psychological state. Session 3. Self-assessment with the aim of recognizing experience Self-assessment, self-assessment to identify the level of emotional vulnerability in the individual, self-assessment to identify emotion regulation strategies, cognitive consequences of emotional reactions, physiological consequences of emotional reactions,

behavioral consequences of emotional reactions and the relationship between the three. Anger excitement and ways to overcome anger. Session 4. Addressing the emotional schemas identified in the patient, verbal challenge and Socratic dialogue. Session 5. Addressing other emotional schemas identified in the patient and the verbal challenge and Socratic dialogue, teaching the technique of writing negative memories with the aim of facilitating emotional processing. Session 6. Preventing from social isolation. Avoidance, problem-solving strategy training, interpersonal skills training (dialogue, assertiveness and conflict resolution), introductory introduction to the concept of emotion acceptance and accreditation. Seventh session. Helping patients to generate and challenge emotions, identify assessments Mistakes and their effects on emotional states. Session 8. Introducing the types of negative beliefs about emotions and challenging them, identifying miscalculations and their effects on emotional states. Ninth session. Identifying the extent and method of using inhibition strategies And examining its emotional consequences, training to express emotion, exposure, training in emotional release and relaxation. Session 10. Discussion about the severity of schemas, before and after exposure, addressing the patient's remnant. Session 11. Review sessions and practice learned skills. Session 12. Work on treatment plan (recurrence prevention) , Planning for remedial sessions, homework, commitment to continuous use of treatment exercises.

Category

Behavior

3

Description

Control group:Control group: do not receive any intervention

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Non-governmental center of oncology in Urmia city

Full name of responsible person

Farinaz Tabibzadeh

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North Khayyam, in front of Quds Clinic

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tonekabon Azad University

Full name of responsible person

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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

Tonekabon Azad University

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**

Islamic Azad University of Tonekabon

Full name of responsible person

Farinaz Tabibzadeh

Position

Student

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

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