

# 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](http://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)

##### Phone

+98 44 3382 8912

##### Email address

tabibzadeh\_f@yahoo.com

##### 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](http://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**

Tonekabon

**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

##### **Street address**

North Khayyam, in front of Quds Clinic

##### **City**

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## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
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masoodghane@gmail.com

**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 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