

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Comparison of the efficacy of treatment based on acceptance and commitment and positive psychotherapy on the acceptance of Pain, self-compassion and affects control of cancer patients

#### Protocol summary

##### Study aim

Comparison of the efficacy of treatment based on acceptance and commitment and positive psychotherapy on the acceptance of pain, self-compassion and affects control of cancer patients

##### Design

Study groups will include people with cancer-based on inclusion criteria who will be non-randomly assigned to the experimental and control groups. The sample of the two groups will include 36 people. And will be selected voluntarily and in an accessible manner. Excel software rand function was used for randomization.

##### Settings and conduct

The present study is a quasi-experimental with a pre-test-post-test design with a control group and a one-month follow-up stage. Subjects are first selected by convenience sampling and randomly assigned to the experimental and control groups. Training is done in Kohgoluyeh city education counseling center.

##### Participants/Inclusion and exclusion criteria

Diagnosis of cancer by a specialist; Have a history of at least one year of cancer; Have at least an education level of diploma Age range 50-20 years; Severe mental disorders; Taking antipsychotic drugs; Having substance abuse.

##### Intervention groups

Control group, commitment and acceptance treatment group and positive psychotherapy group

##### Main outcome variables

Acceptance and commitment, Positive psychotherapy, Acceptance of pain, Self-compassion, Emotion control

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200802048274N1**

Registration date: **2020-09-05, 1399/06/15**

Registration timing: **retrospective**

Last update: **2020-09-05, 1399/06/15**

Update count: **0**

##### Registration date

2020-09-05, 1399/06/15

##### Registrant information

###### Name

Kouroush Fathi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 74 3226 3011

###### Email address

f\_korosh@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-02-19, 1397/11/30

##### Expected recruitment end date

2020-03-19, 1398/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the efficacy of treatment based on acceptance and commitment and positive psychotherapy on the acceptance of Pain, self-compassion and affects

control of cancer patients

### Public title

Comparison of the efficacy of treatment based on acceptance and commitment and positive psychotherapy on the acceptance of Pain, self-compassion and affects control of cancer patients

### Purpose

Education/Guidance

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Have a history of at least one year of cancer Have a minimum education level of diploma Age range 50-20 years

#### Exclusion criteria:

Do not have acute mental problem

### Age

From **20 years** old to **50 years** old

### Gender

Male

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **39**

### Randomization (investigator's opinion)

Not randomized

### Randomization description

### 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

Yasuj University of Medical Sciences

##### Street address

7 tir

##### City

Yasuj

##### Province

Kohgiluyeh-va-Boyrahmad

##### Postal code

7571865365

#### Approval date

2020-03-08, 1398/12/18

#### Ethics committee reference number

IR.YUMS.REC.1398.163

## Health conditions studied

### 1

#### Description of health condition studied

Cancer

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

One of the important concepts in contemporary theories is how a person reacts and adapts to chronic pain.

Accepting pain is the first step in adapting to changes in life in a way that allows the person to continue to work in the living environment and at the same time try to control pain.

#### Timepoint

At the beginning and before the intervention, immediately after the intervention and 2 months after the last intervention session

#### Method of measurement

The McCracken Pain Acceptance Scale and the Williams and Chambles Emotion Control Scale will be used to collect data. The McCracken & Wools Pain Acceptance Scale has two components: the tendency to accept pain and active participation and has a total of 20 items, 9 of which are related to the component of tendency to accept pain (items 4, 7, 11, 13, 14, 16, 17, 18 and 20) and its 11 items are related to the active participation component (items 1, 2, 3, 5, 6, 8, 9, 10, 12, 15 and 19). Scoring is done on a Likert scale of 7 degrees. This scale has well shown a good internal consistency with an alpha of 0.82 for the pain acceptance component and 0.78 for the active participation component. The results of factor analysis in the study of McCracken, McLeod and Ecclestone, (2008), confirmed the existence of two factors: the tendency to accept pain and active participation and the validity of this scale has also been confirmed. In Iran, Cronbach's alpha coefficient of this scale has been reported in research 0.87. Emotion Control Scale: This scale has 42 questions made by Williams and Chambles and its purpose is to evaluate the ability to control emotions from the basics of the 15th Amendment. Emotions have a valid internal consistency, the correlation of the test between the subscales of the test, and between the questions of the scale is significant at the level of 0.01 confidence. The validity of the emotion control test among students, teachers, nurses, and professors in Iran is relatively high and has an acceptable level and the test questions are correlated with each other, so the questions of this test are suitable for measuring emotion control.

### 2

#### Description

She has defined compassion as a three-component construct that includes kindness to oneself versus self-

judgment, human commonalities versus isolation, and awareness versus extreme assimilation

### **Timepoint**

Measurement periods at the beginning and before the intervention, immediately after the intervention and 2 months after the last intervention session

### **Method of measurement**

The McCracken Pain Acceptance Scale and the Williams and Chambles Emotion Control Scale will be used to collect data. The McCracken & Wools Pain Acceptance Scale has two components: tendency to accept pain and active participation, and has a total of 20 items, 9 of which are related to the component of tendency to accept pain (items 4, 7, 11, 13, 14, 16, 17, 18 and 20) and its 11 items are related to the active participation component (items 1, 2, 3, 5, 6, 8, 9, 10, 12, 15 and 19). Scoring is done on a Likert scale of 7 degrees. This scale has well shown a good internal consistency with alpha of 0.82 for the pain acceptance component and 0.78 for the active participation component. The results of factor analysis in the study of McCracken, McLeod and Ecclestone, (2008), confirmed the existence of two factors: the tendency to accept pain and active participation, and the validity of this scale has also been confirmed. In Iran, Cronbach's alpha coefficient of this scale has been reported in research 0.87. Emotion Control Scale: This scale has 42 questions made by Williams and Chambers and its purpose is to evaluate the ability to control emotions from the basics of the 15th Amendment. Emotions have a valid internal consistency, the correlation of the test between the subscales of the test, and between the questions of the scale is significant at the level of 0.01 confidence. The validity of the emotion control test among students, teachers, nurses and professors in Iran is relatively high and has an acceptable level and the test questions are correlated with each other, so the questions of this test are suitable for measuring emotion control.

## **3**

### **Description**

Emotion control includes controlling anger, depression, anxiety, and positive emotions

### **Timepoint**

Measurement periods at the beginning and before the intervention, immediately after the intervention and 2 months after the last intervention session

### **Method of measurement**

The McCracken Pain Acceptance Scale and the Williams and Chambles Emotion Control Scale will be used to collect data. The McCracken & Wools Pain Acceptance Scale has two components: tendency to accept pain and active participation, and has a total of 20 items, 9 of which are related to the component of tendency to accept pain (items 4, 7, 11, 13, 14, 16, 17, 18 and 20) and its 11 items are related to the active participation component (items 1, 2, 3, 5, 6, 8, 9, 10, 12, 15 and 19). Scoring is done on a Likert scale of 7 degrees. This scale has well shown a good internal consistency with alpha of 0.82 for the pain acceptance component and 0.78 for the active participation component. The results of factor analysis in the study of McCracken, McLeod and

Ecclestone, (2008), confirmed the existence of two factors: the tendency to accept pain and active participation, and the validity of this scale has also been confirmed. In Iran, Cronbach's alpha coefficient of this scale has been reported in research 0.87. Emotion Control Scale: This scale has 42 questions made by Williams and Chambers and its purpose is to evaluate the ability to control emotions from the basics of the 15th Amendment. Emotions have a valid internal consistency, the correlation of the test between the subscales of the test, and between the questions of the scale is significant at the level of 0.01 confidence. The validity of the emotion control test among students, teachers, nurses and professors in Iran is relatively high and has an acceptable level and the test questions are correlated with each other, so the questions of this test are suitable for measuring emotion control.

## **Secondary outcomes**

### **1**

#### **Description**

A term for theories and research about what makes life most valuable.

#### **Timepoint**

At the beginning and before the intervention, immediately after the intervention and 2 months after the last intervention session

#### **Method of measurement**

questionnaire

### **2**

#### **Description**

One of the therapies is the third wave, which emphasizes mindfulness, and is based on the acceptance of suffering (embedded in) life and committed action based on values to enjoy a richer life.

#### **Timepoint**

At the beginning and before the intervention, immediately after the intervention and 2 months after the last intervention session

#### **Method of measurement**

questionnaire

## **Intervention groups**

### **1**

#### **Description**

The following treatment protocol was performed in eight sessions. Session 1: 1- Presenting generalities of the group protocol, introducing the members and expectations of the group 2- Short mindfulness meditation 3- Written practice of self-affirmation and expression of values 4- Description of the exercise (homework) Three good events 5- Mindfulness meditation. Session 2: 1- Mindfulness meditation 2- Discussion about practicing three good events 3- Discussion about self-worthwhile results 4- Description of exercise (homework) Strengths 5- Mindfulness

meditation. Session 3: 1- Mindfulness meditation 2- Discussion about practicing the use of strengths 3- Description of exercise (homework) Enjoyment 4- Mindfulness meditation. Session 4: 1- Mindfulness meditation 3- Discussion about exercise (homework) Enjoyment 4- Description of exercise (homework) Having a good day 5- Mindfulness meditation. Session 5: 1- Mindfulness meditation 2- Discussion about exercise (homework) Having a good day 3- Introduction of exercise (homework) Appreciation meeting 4- Mindfulness meditation. Session 6: 1- Mindfulness meditation 2- Discussion about exercise (homework) Appreciation meeting 3- Introduction of exercise (homework) Active / constructive answer 4- Mindfulness meditation. Session 7: 1- Mindfulness meditation 2- Discussion about practice (homework) Active / constructive answer 3- Introduction of biography writing practice 4- Mindfulness meditation. Session 8: 1- Mindfulness meditation 2- Discussion about (homework) Writing a biography 3- Introducing positive service assignment 4- Mindfulness meditation 5- Discussion about the final session.

**Category**

Behavior

**2****Description**

Control group: will not receive any intervention.

**Category**

Behavior

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

Kohgiluyeh city hospitals and medical centers

**Full name of responsible person**

Kourosh Davari, PhD

**Street address**

Sepah street - Imam Khomeini hospital in Dehdasht

**City**

Dehdasht

**Province**

Kohgilouyeh-va-Boyrahmad

**Postal code**

7571865365

**Phone**

+98 74 3226 0000

**Email**

F\_korosh@yahoo.com

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

Islamic Azad University

**Full name of responsible person**

Masoud Shahbazi ph.d

**Street address**

Islamic azad University of Ahvaz

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

757180000

**Phone**

+98 74 3227 0000

**Email**

Masoudshahbazi66@yahoo.com

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

No

**Title of funding source**

does not have

**Proportion provided by this source**

1

**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**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Kouroush Fathi

**Position**

Employee

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

**Street address**

Dehdasht 7th of Tir street

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**Person responsible for scientific inquiries****Contact**

**Name of organization / entity**  
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**Full name of responsible person**  
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**Position**  
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**Latest degree**  
Master  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
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**Position**  
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**Latest degree**  
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**Other areas of specialty/work**  
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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

No - There is not a plan to make this available

### Clinical Study Report

No - There is not 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

Cannot share at this time.

### When the data will become available and for how long

Cannot share at this time.

### To whom data/document is available

Cannot share at this time.

### Under which criteria data/document could be used

Cannot share at this time.

### From where data/document is obtainable

Cannot share at this time.

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

Cannot share at this time.

### Comments

Cannot share at this time.