

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### The effectiveness of Acceptance and Commitment Therapy (ACT) on body image and marital satisfaction of patients with ostomy

#### Protocol summary

Registration timing: **prospective**

#### Study aim

Determining the effectiveness of Acceptance and Commitment Therapy (ACT) on body image fear and marital satisfaction in patients with ostomy.

Last update: **2021-05-16, 1400/02/26**

Update count: **0**

#### Registration date

2021-05-16, 1400/02/26

#### Design

An interventional study with control and parallel groups, with randomization, Phase 3 study will perform on 70 patients with ostomy.

#### Registrant information

##### Name

Raheleh Nejati

##### Name of organization / entity

Mashhad University of Medical Sciences, Ibn-e- Sina Psychiatric Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3711 2540

##### Email address

nejatir2@mums.ac.ir

#### Settings and conduct

This study will perform on 70 patients with ostomy referred to Ghaem Hospital in Mashhad. Patients will be randomly divided into control and intervention groups. Blinding would not be performed. Patients in the intervention group will have 8 sessions of consultation with the therapist, and in the control group, without any counseling sessions, body image fear and Enrich's marital satisfaction questionnaires will be completed for each patient in the intervention and control groups.

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Participants/Inclusion and exclusion criteria

All married people having an ostomy and fully satisfaction to enter the project.

#### Intervention groups

In the intervention group, patients are trained in the Acceptance and Commitment Approach Protocol (ACT) for 8 sessions and body image and marital satisfaction questionnaires are completed before and after the sessions. In the control group, people complete body image and marital satisfaction questionnaires without any counseling session.

#### Expected recruitment start date

2021-07-23, 1400/05/01

#### Expected recruitment end date

2021-10-23, 1400/08/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Main outcome variables

Fear of body image Marital satisfaction

#### Scientific title

The effectiveness of Acceptance and Commitment Therapy (ACT) on body image and marital satisfaction of patients with ostomy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20101130005280N37**

Registration date: **2021-05-16, 1400/02/26**

##### Public title

The effectiveness of acceptance and commitment therapy (ACT) on ostomy patients

### **Purpose**

Education/Guidance

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

Having an ostomy Married

#### **Exclusion criteria:**

Attending therapeutic sessions or psychotherapy training concurrently Taking psychotropic drugs or drug abuse for the past six months

### **Age**

No age limit

### **Gender**

Both

### **Phase**

3

### **Groups that have been masked**

No information

### **Sample size**

Target sample size: 70

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

Simple randomization with table of random numbers available at "www.randomization.com" website will be used. Numbers will be placed in sealed envelopes and each envelope is assigned to one participant placing them in one of the two 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 Ferdowsi University of Mashhad

##### **Street address**

Ferdowsi University of Mashhad, Azadi Square

##### **City**

Mashhad

##### **Province**

Razavi Khorasan

##### **Postal code**

9117948974

#### **Approval date**

2020-01-21, 1398/11/01

#### **Ethics committee reference number**

IR.HSU.REC.1398.028

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Rectal cancer

#### **ICD-10 code**

C19

#### **ICD-10 code description**

Malignant neoplasm of rectosigmoid junction

## **Primary outcomes**

### 1

#### **Description**

Fear of body image

#### **Timepoint**

At the beginning of the study (before the intervention) and after 8 counseling sessions in the intervention group and without consultation in the control group

#### **Method of measurement**

Fear of body image questionnaire

### 2

#### **Description**

Marital Satisfaction

#### **Timepoint**

At the beginning of the study (before the intervention) and after 8 counseling sessions in the intervention group and without consultation in the control group

#### **Method of measurement**

Enrich Marital Satisfaction Questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: In the intervention group, patients are trained in the Acceptance and Commitment Approach (ACT) Protocol for 8 sessions. Explaining the concept of acceptance and its difference with the concept of failure, identifying the values of patients' lives and specifying and focusing on these values, possible internal and external barriers to pursuing values and preparation to deal with them are expressed. Before and after the sessions, body image and marital satisfaction questionnaires are completed.

#### **Category**

Behavior

### 2

#### **Description**

Control group: In the control group, patients without any counseling sessions would complete, body image and

marital satisfaction questionnaires before and after the time duration of the sessions with the intervention group.

**Category**

Behavior

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Clinic of Ghaem Hospital

**Full name of responsible person**

Monire Pourfarahani

**Street address**

Ahmad abad AVE, Ghaem hospital

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Mashhad

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Razavi Khorasan

**Postal code**

99199-91766

**Phone**

+98 51 3801 2469

**Email**

farahanim4900@gmail.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177899191

**Phone**

+98 51 3841 2081

**Email**

ramresearch@mums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad University of Medical Sciences

**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**

Mashhad Ferdowsi University

**Full name of responsible person**

Hossein Share

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychology

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**Person responsible for scientific inquiries**

**Contact**

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**Full name of responsible person**

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**Position**

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**Contact**

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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**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not 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**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available