Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

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

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

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 wouldnot be perform. 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.

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.

Main outcome variables
Fear of body image Marital satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20101130005280N37**
Registration date: **2021-05-16, 1400/02/26**
Registration timing: **prospective**

Last update: **2021-05-16, 1400/02/26**
Update count: **0**

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

Registrant information

Name
Raheleh Nejati

Name of organization / entity
Mashhad University of Medical Scinces, Ibn-e- Sina Psychiatric Hospital

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

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

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

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

۹۱۷۷۹۴۸۹۷۴

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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99199-91766
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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
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Mashhad
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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
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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
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