

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Effectiveness of acceptance and commitment therapy enriched with compassion on body image, cognitive-behavioral avoidance and sexual satisfaction of patients with colorectal cancer after colostomy surgery

Protocol summary

Study aim

The aim of this study was the effectiveness of acceptance and commitment therapy enriched with compassion on body image, cognitive-behavioral avoidance and sexual satisfaction of patients with colorectal cancer after colostomy surgery.

Design

Clinical trial with purposeful sampling with no randomization, parallel groups, control group, no blinding, including 36 patients, outcome assessment

Settings and conduct

The location of research was MAKSA associated with ALA charity center in Isfahan.

Participants/Inclusion and exclusion criteria

-Entrance criteria: 1-Patients with colorectal cancer after colostomy surgery 2-Being married -Exit criteria: 1- Diagnosed with severe mental disorders 2-Concurrent use of psychological treatments 3-Use of psychiatric drugs from the 3 previous months 4-Have other cancers and severe physical diseases

Intervention groups

1-The experimental group received 10 sessions (weekly, 90-minute session) of acceptance and commitment therapy enriched with compassion. 2-Control group: received no treatment and standed in wait list.

Main outcome variables

body image; cognitive-behavioral avoidance; sexual satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200728048245N1**

Registration date: **2020-08-15, 1399/05/25**

Registration timing: **retrospective**

Last update: **2020-08-15, 1399/05/25**

Update count: **0**

Registration date

2020-08-15, 1399/05/25

Registrant information

Name

Sheida Jabalameli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3641 4663

Email address

sh-jabalameli@iaun.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-16, 1397/01/27

Expected recruitment end date

2018-06-18, 1397/03/28

Actual recruitment start date

2018-06-21, 1397/03/31

Actual recruitment end date

2018-09-22, 1397/06/31

Trial completion date

2019-01-20, 1397/10/30

Scientific title

Effectiveness of acceptance and commitment therapy enriched with compassion on body image, cognitive-behavioral avoidance and sexual satisfaction of patients with colorectal cancer after colostomy surgery

Public title

Effectiveness of acceptance and commitment therapy enriched with compassion on psychological symptoms of

patients with colorectal cancer after colostomy surgery

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with colorectal cancer after colostomy surgery
Being married

Exclusion criteria:

Diagnosed with severe mental disorders
Concurrent use of psychological treatments
Use of psychiatric drugs from the 3 previous months
Have other cancers and severe physical diseases

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 36

Actual sample size reached: 28

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

Ethics committee of Najafabad University

Street address

University Street

City

Najafabad

Province

Isfahan

Postal code

۸۵۱۴۱۴۳۱۳۱

Approval date

2019-01-03, 1397/10/13

Ethics committee reference number

IR.IAU.NAJAFABAD.REC.1397.093

Health conditions studied

1

Description of health condition studied

Colorectal cancer after colostomy surgery

ICD-10 code

C18.9

ICD-10 code description

Malignant neoplasm of colon, unspecified

Primary outcomes

1

Description

body image

Timepoint

Before and after treatment (2 months interval)

Method of measurement

Multi-dimensional questionnaire of individual's attitude about body image

2

Description

Cognitive-behavioral avoidance

Timepoint

before and after treatment (2 months interval)

Method of measurement

Young-Rygh Avoidance Inventory

3

Description

Sexual satisfaction

Timepoint

before and after treatment (2 months interval)

Method of measurement

Hudson Sexual Satisfaction Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: acceptance and commitment therapy enriched with compassion, 10 weekly sessions

Category

Behavior

2

Description

Control group: receive no treatment

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
MACSA
Full name of responsible person
-
Street address
Motahari street
City
Isfahan
Province
Isfahan
Postal code
8197113765
Phone
+98 31 3233 3029
Email
info@macsa.ir
Web page address
http://macsa.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University
Full name of responsible person
Sheida Jabalameli
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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
Islamic Azad University
Proportion provided by this source
70
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
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Position
Assistant Professor
Latest degree
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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