

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

A comparison of the effectiveness of acceptance and commitment therapy (ACT) and unified transdiagnostic treatment (UP) in psychological distress, meta-emotion beliefs, acceptance and post-traumatic growth in colorectal cancer patients comorbid with stress

Protocol summary

Study aim

A comparison of the effectiveness of acceptance and commitment therapy (ACT) and unified transdiagnostic treatment (UP) in psychological distress, meta-emotion beliefs, acceptance and post-traumatic growth in colorectal cancer patients comorbid with stress.

Design

This will be a quasi-experimental study based on pre-test and post-test with follow-up period and control group. There will be three groups (two experimental and one control).

Settings and conduct

This study will be performed on colorectal cancer patients in khorramabad. Participants are randomly divided into two intervention groups and one control group. And for the members of the first intervention group, 8 sessions of unified transdiagnostic treatment and for the second intervention group, 8 sessions of acceptance and commitment therapy are performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Have a minimum score of 19 or higher on the stress subscale of the DASS-21 questionnaire, age ranging from 30 to 60 years, starting treatment under 6 months. Exclusion criteria: Unwillingness to participate in treatment.

Intervention groups

The intervention group 1: Treatment sessions based on Unified Transdiagnostic Treatment book of Barlow & et al will be performed according to the protocol (1 session per week, each session about 90 minutes – 8 sessions during 2 months). group 2: Treatment sessions based on Acceptance and Commitment Therapy book of Hayes, Strosahl, & Wilson will be performed according to the protocol (1 session per week, each session about 90 minutes – 8 sessions during 2 months). but control group: doesn't receive any intervention.

Main outcome variables

Psychological Distress, Meta-Emotion Beliefs, Acceptance, Post-traumatic Growth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200213046480N1**

Registration date: **2021-01-09, 1399/10/20**

Registration timing: **prospective**

Last update: **2021-01-09, 1399/10/20**

Update count: **0**

Registration date

2021-01-09, 1399/10/20

Registrant information

Name

Ahmad Kazempour

Name of organization / entity

The university of Lorestan

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-23, 1399/11/04

Expected recruitment end date

2021-01-25, 1399/11/06
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparison of the effectiveness of acceptance and commitment therapy (ACT) and unified transdiagnostic treatment (UP) in psychological distress, meta-emotion beliefs, acceptance and post-traumatic growth in colorectal cancer patients comorbid with stress

Public title
Comparison of the effectiveness of acceptance and commitment therapy (ACT) and unified transdiagnostic treatment (UP) in colorectal cancer patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Have a minimum score of 19 or higher on the stress subscale of the DASS-21 questionnaire Age ranging from 30 to 60 years Starting treatment under 6 months
Exclusion criteria:
Unwillingness to participate in treatment

Age
From **30 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 block randomization method is performed by the statistical consultant as follows: randomization is performed in three groups: acceptance and commitment therapy, unified transdiagnostic treatment and control. First, a list of eligible individuals is provided and coded. In block randomization, the number of participants in all groups will be very close together by making blocks of sequences so that the same number of participants are assigned to study groups within each group. We first code the groups in Latin letters as follows: A = acceptance and commitment therapy, B = unified transdiagnostic treatment, and C = control group. In this study with three groups A, B and C, we create the following six groups and assign a number from 1 to 6 to each group: ABC-ACB-BAC-BCA-CAB-CBA, Then, using the table of random numbers, we contract that if the numbers 1, 2, 3, 4, 5, and 6 appear in order, one of these blocks will be selected, and if another number appears, we will assume it to be void and move on to the next selection. In fact, we have obtained a random sequence of numbers with a table of random numbers that for each

number we consider the desired order of assignment. In this way, the number of people in the groups will be approximately equal.

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 Lorestan University of Medical Sciences

Street address

Lorestan University of Medical Sciences, Anooshirvan Rezaei Square, Khorramabad, Lorestan.

City

khorrarnabad

Province

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Postal code

6813833946

Approval date

2020-02-22, 1398/12/03

Ethics committee reference number

IR.LUMS.REC.1398.275

Health conditions studied

1

Description of health condition studied

colorectal cancer

ICD-10 code

C18.9

ICD-10 code description

Malignant neoplasm of colon, unspecified

Primary outcomes

1

Description

Psychological distress

Timepoint

The middle of treatment, after treatment and two months after the end of treatment

Method of measurement

Depression Anxiety and Stress Scale

2

Description

Meta-emotion beliefs

Timepoint

The middle of treatment, after treatment and two months after the end of treatment

Method of measurement

Meta-Emotions Scale

3

Description

Acceptance

Timepoint

The middle of treatment, after treatment and two months after the end of treatment

Method of measurement

Acceptance and Action Questionnaire

4

Description

Post-traumatic growth

Timepoint

The middle of treatment, after treatment and two months after the end of treatment

Method of measurement

Post-traumatic Growth Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Treatment sessions based on Unified Transdiagnostic Treatment book of Barlow & et al will be performed according to the protocol (1 session per week, each session about 90 minutes – 8 sessions during 2 months). Measurements will be performed again in three times: the middle of treatment, the end of treatment and once in two months after the end of treatment.

Category

Diagnosis

2

Description

Intervention group 2: Treatment sessions based on Acceptance and Commitment Therapy book of Hayes, Strosahl, & Wilson will be performed according to the protocol (1 session per week, each session about 90 minutes – 8 sessions during 2 months). Measurements will be performed again in three times: the middle of treatment, the end of treatment and once in two months after the end of treatment.

Category

Rehabilitation

3

Description

Control group: This group of 15 randomly selected individuals will receive no treatment for two months. However, the control group, which has been bothering to participate in the research, at the end of the study period is freely and intensively subject to one of the treatments of Acceptance and Commitment Therapy or Unified Transdiagnostic Treatment.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rahimi Hospital

Full name of responsible person

Ahmad Kazemipour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Lorestan

Full name of responsible person

Mohammad Feizian

Street address

5th Kilometer of Khorramabad-Boroujerd Highway, Khorramabad, Lorestan

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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

The University of Lorestan

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

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Person responsible for updating data**Contact****Name of organization / entity**

The University of Lorestan

Full name of responsible person

Ahmad Kazemipour

Position

M.a in Psychology

Latest degree

Master

Other areas of specialty/work

Psychology

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

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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

Other areas of specialty/work

Psychology

Street address

No 3, West Lale, Velayat Blvd.

City

Khorramabad

Province

Lorestan

Postal code**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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Demographic data, methodical data, Data analysis

When the data will become available and for how long

As the results are published

To whom data/document is available

Researchers working in universities and medical centers

Under which criteria data/document could be used

In clinical and therapeutic work

From where data/document is obtainable

Email: A.kazemi04@yahoo.com Phone: 00989167491925

Kazemipour Ahmad

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

It will take a month to process.
Comments