

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 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**

Iran (Islamic Republic of)

##### **Phone**

+98 66 3326 9287

##### **Email address**

kazempour.ah@fh.lu.ac.ir

##### **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**  
khorramabad  
**Province**  
Lorestan  
**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

##### **Street address**

Azadi Square, Khorramabad

##### **City**

Khorramabad

##### **Province**

Lorestan

##### **Postal code**

5214632147

##### **Phone**

+98 61 3321 4596

##### **Email**

Shahidrahimi@yahoo.com

## **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

##### **City**

khorrabad

##### **Province**

Lorestan

##### **Postal code**

44316-68151

##### **Phone**

+98 21 3312 0097

##### **Email**

lorestanuni@lu.ac.ir

#### **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

44316-68151

**Phone**

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**Fax****Email**

kazemipour.ah@fh.lu.ac.ir

**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

**Street address**

No 3, West Lale, Velayat Blvd.

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**Postal code**

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**Phone**

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**Fax****Email**

kazemipour.ah@fh.lu.ac.ir

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

The University of Lorestan

**Full name of responsible person**

Ahmad Kazemipour

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

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**Person responsible for scientific inquiries****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

**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**