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**
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Name of organization / entity
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**Recruitment status**
Recruitment complete

**Funding source**

**Expected recruitment start date**
2021-01-23, 1399/11/04
**Expected recruitment end date**
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

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

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

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Khorramabad

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Sponsors / Funding sources

1
Sponsor

Name of organization / entity
The University of Lorestan

Full name of responsible person
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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

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
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Other areas of specialty/work
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Person responsible for scientific inquiries

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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