Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of Acceptance and Commitment Therapy (ACT) on Depression, Emotional regulation, Psychological well-being and Quality of life in the individual with Physical and motor disabilities

Protocol summary

Study aim

The specific purposes of the present study are to determine the effectiveness of acceptance and commitment therapy on depression, emotional regulation, psychological well-being, and quality of life.

Design

The present study is a clinical trial with control group, parallel group design. 60 participants were selected after evaluating and qualifying for inclusion in the study. In the present study, the simple randomization method was used, superiority, parallel-group trial in which the names of the subjects were first listed and then, each group was randomly assigned to treatment group (n=30) and a control group (n=30)

Settings and conduct

The study sample consisted of all persons with physical and motor disabilities who were lived in Kamyaran city.

Participants/Inclusion and exclusion criteria

Inclusion criteria are required moderate depression, having Physical Disability, having at least a high school diploma, aged between 18 and 40 years and not receiving psychotherapy in the past six months. Exclusion criteria include comorbidity with other psychiatric disorders, psychotic symptoms, mental disability and personality disorders

Intervention groups

Acceptance and commitment therapy (ACT), it is an empirically-based psychological intervention that uses acceptance and mindfulness strategies mixed in different ways with commitment and behavior-change strategies, to increase psychological flexibility. The approach was originally called comprehensive distancing. The objective of ACT is not the elimination of difficult feelings. The control group did not receive any intervention, in order to adhere to the research ethics, two sessions of psychological training skills will be provided the intervention

Main outcome variables

The effect of acceptance and commitment therapy on depression, emotion regulation, psychological wellbeing and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160625028633N2**
Registration date: **2019-12-28, 1398/10/07**
Registration timing: **retrospective**

Last update: **2019-12-28, 1398/10/07**
Update count: **0**

Registration date

2019-12-28, 1398/10/07

Registrant information

Name

Mahtab Sadeghi

Name of organization / entity

Kermanshah University Of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 83 3835 0177

Email address

kums2017@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-05-20, 1398/02/30

Actual recruitment start date
2019-04-21, 1398/02/01
Actual recruitment end date
2019-05-10, 1398/02/20
Trial completion date
2019-09-06, 1398/06/15

Scientific title
Effectiveness of Acceptance and Commitment Therapy (ACT) on Depression, Emotional regulation, Psychological well-being and Quality of life in the individual with Physical and motor disabilities

Public title
Effectiveness of Acceptance and Commitment Therapy (ACT) on Depression, Emotional regulation, Psychological well-being and Quality of life
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Moderate depression score based on the cut-off score of 17 on Beck Depression Inventory Physical disability (Medium Level), and having a Smart card for Disability by the National Welfare Organization Minimum diploma education No psychotherapy during the past six months
Exclusion criteria:
Co-morbidity with other mental disorders having psychotic symptoms (hallucinations and delusions) mental disability personality disorders
Age
From **18 years** old to **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **103**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The simple randomization method was used, in which the subjects' names were first listed and assigned a number from 1 to 60 for each one. We threw the numbers into a box and started removing the numbers from the box. The first 30 numbers were assigned to the experimental group and the remaining 30 numbers were assigned to the control group.
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 Kurdistan University
Street address
Kurdistan University, Pasdaran Blve., Sanandaj, Iran
City
Sanandaj
Province
Kurdistan
Postal code
66177-15175
Approval date
2019-01-05, 1397/10/15
Ethics committee reference number
IR.UOK.REC.1398.007

Health conditions studied

1

Description of health condition studied
Depression
ICD-10 code
F06.31
ICD-10 code description
Mood disorder due to known physiological condition with depressive features

2

Description of health condition studied
Emotional Regulation
ICD-10 code
R45
ICD-10 code description
Symptoms and signs involving emotional state

Primary outcomes

1

Description
Depression
Timepoint
Before the intervention, Eight weeks after the intervention and one month after the end of the intervention
Method of measurement
Beck Depression Inventory (BDI-II)

2

Description
emotional regulation

Timepoint
Before the intervention, Eight weeks after the intervention and one month after the end of the intervention
Method of measurement
Gross & John Emotion Regulation Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group: Acceptance and commitment therapy is an empirically-based psychological intervention that utilizes acceptance and mindfulness strategies. The experimental group received eight sessions of acceptance and commitment therapy (one session per week) for 90 minutes. These sessions are based on the guidelines of Hayes and Wilson (2006, 2012). Each session will be counseled and treated with mindfulness training, pre-session review, potential supportive exercises, and homework assignments.
Category
Behavior

2

Description
Control group: Routin care
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Tooska Disability Institute
Full name of responsible person
Hiva Shahweiss
Street address
Shariati Ave., Kamyaran, Kurdistan, Iran
City
Kamyaran
Province
Kurdistan
Postal code
66316-17156
Phone
+98 87 3553 5931
Email
malakikaveh4920@gmail.com
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kurdistan University
Full name of responsible person
Rahmat Sadeghi
Street address
Kurdistan University, Pasdaran Blve., Sanandaj, Iran
City
Sanandaj
Province
Kurdistan
Postal code
6617-15175
Phone
+98 87 3366 4608
Email
info@uok.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kurdistan University
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
Kurdistan University
Full name of responsible person
Mehdi Zemestani
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Kurdistan University, Pasdaran Blve., Sanandaj, Iran
City
Sanandaj
Province
Kurdistan
Postal code
66177-15175
Phone
00988733664600-8
Email
m.zemestan@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kurdistan University

Full name of responsible person
Mehdi Zemestani

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
Kurdistan University, Pasdaran Blve., Sanandaj, Iran

City
Sanandaj

Province
Kurdistan

Postal code
66177-15175

Phone
00988733664600-8

Email
m.zemestan@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Kurdistan University

Full name of responsible person
Sharmin Mozafari

Position
M.Sc., Student of Clinical Psychology

Latest degree
Master

Other areas of specialty/work
Psychology

Street address
Kurdistan University, Pasdaran Blve., Sanandaj, Iran

City
Sanandaj

Province
Kurdistan

Postal code
66177-5175

Phone
00988733664600-8

Email
sharmin70mozaffari@gmail.com

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
All potentially unrecognizable data is shareable and the necessary explanations are given in the SPSS file

When the data will become available and for how long
Other researchers have access to research data 2 months after the results are published

To whom data/document is available
Data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used
Used for educational and research programs

From where data/document is obtainable
Researchers can contact the author to obtain the required documentation or data. Sharmin Mozaffari, MA in Clinical Psychology, Kurdistan University Email: sharmin70mozaffari@gmail.com Contact Number: 00989187816605

What processes are involved for a request to access data/document
The research data includes SPSS software file with the necessary explanations

Comments