

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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

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Iran (Islamic Republic of)

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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

AgeFrom **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

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Sanandaj

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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

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Shariati Ave., Kamyaran, Kurdistan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kurdistan University

Full name of responsible person

Rahmat Sadeghi

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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

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

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Person responsible for updating data

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M.Sc., Student of Clinical Psychology

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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

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