

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Comparison effectiveness of acceptance and commitment therapy (ACT) and drug therapy on improving patients with major depression

#### Protocol summary

##### Summary

Introduction: In addition to traditional methods of drug therapy, a lot of discussion has been done recently about the third wave of cognitive and behavioral approaches for treating depression. Therefore this study was done aimed to compare effectiveness of acceptance and commitment therapy and drug therapy on improving patients with major depression. Methods: Design of this study was semi-experimental type as pretest-posttest with two experiment groups and one control group. Statistical population consisted of all patients with major depression treated in of Shahrekord city welfare centers in 2015 year. The sample studied were all 45 people of from patients who were selected through random sampling method and were divided into three groups- under training with acceptance and commitment therapy, drug therapy group and one control group. For collection data was used from Beck Depression Inventory (BDI). Data Analyzing was conducted with covariance and Scheffe post hoc test and SPSS. Results: The mean post-test of the psychotherapy group was 12/40, drug therapy group 23/13 and control group 36/27. The results showed there were significant differences between experiment groups of acceptance and commitment therapy and drug therapy and control group ( $F= 110/33$ ,  $p<0/001$ ) and acceptance and commitment therapy and drug therapy have significant effect in reducing of major depression. Also, the results showed that acceptance and commitment therapy have more effective than drug therapy in reducing depression. Conclusions: According to the findings this study, can suggested acceptance and commitment therapy and drug therapy as an effective way and a useful clinical intervention in improving depression besides drug therapy. Keywords: acceptance and commitment, psychotherapy, drug therapy, depression.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017070334862N1**

Registration date: **2017-07-19, 1396/04/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-07-19, 1396/04/28

##### Registrant information

##### Name

Rasoul Alipour

##### Name of organization / entity

Islamic Azad University, Bandar Abbas

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

research fellow

##### Expected recruitment start date

2015-03-30, 1394/01/10

##### Expected recruitment end date

2015-04-13, 1394/01/24

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison effectiveness of acceptance and commitment therapy (ACT) and drug therapy on improving patients with major depression

## Public title

Comparison effectiveness of acceptance and commitment therapy (ACT) and drug therapy on depression

## Purpose

Treatment

## Inclusion/Exclusion criteria

(1) Aims: The aim of this study was to compare the efficacy of group therapy based on admission and commitment and drug therapy on the improvement of patients with major depression. (2) Design: The research design was semi-experimental and pre-test-posttest with two experimental groups and one control group. (3) How to do it (3) Setting and conduct (4) Participants: The statistical population of the study included all patients with major depressive disorder in Shahrekord's well-being care centers in 1994. The study sample consisted of 45 patients who were selected by convenience sampling and randomly assigned to two experimental groups with acceptance and commitment and drug therapy and one control group. Beck Depression Scale (BDI) and Coopersmith's Self-Esteem Questionnaire were used for data collection in pre-test and post-test. Data were analyzed by analysis of univariate covariance and Scheffe post hoc test and SPSS software. (5) interventions: group therapy based on acceptance and commitment and medication (6) Main outcome variables: Signs of major depression, self-esteem

## Age

From **20 years** old to **40 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

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Other

## Other design features

The study sample consisted of 45 patients who were selected by convenience sampling and randomly assigned to two experimental groups with acceptance and commitment and drug therapy and one control group.

## Secondary Ids

### 1

#### Registry name

-

#### Secondary trial Id

-

#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Bandar Abbas Azad University

##### Street address

Bandar Abbas Crossroads Paladin Campus-Blvd  
Campus-Islamic Azad University Bandar Abbas

##### City

Bandar Abbas

##### Postal code

#### Approval date

2014-01-12, 1392/10/22

#### Ethics committee reference number

73/397158

## Health conditions studied

### 1

#### Description of health condition studied

Major depressive disorder

#### ICD-10 code

F32.2

#### ICD-10 code description

Severe depressive episode without psychotic symptoms

## Primary outcomes

### 1

#### Description

Symptoms of depression

#### Timepoint

Pre-test and post-test intervals of one month

#### Method of measurement

The Beck Depression Scale (BDI) was used to collect data. Data were analyzed by analysis of univariate covariance and Scheffe post hoc test and SPSS software.

## Secondary outcomes

### 1

#### Description

Self-esteem

#### Timepoint

Pre-test and post-test intervals of one month

## Method of measurement

The score is the score that the subjects earned in the Cooper Smith self-esteem questionnaire. Data were analyzed by analyzing univariate covariance and Scheffe post hoc test and SPSS software.

## Intervention groups

### 1

#### Description

Acceptance and Commitment Group Therapy: In this research, the Acceptance and Commitment-based Treatment Group (ACT) is an 8-session intervention program (90 minutes each week), in which the members of the group gather together, And with the help of the group leader, they will discuss issues related to the acceptance of emotions, achievement of goals, impulse control, awareness raising, access to emotional regulation strategies, and clarification and clarification of problems, and carry out related assignments.

#### Category

Treatment - Other

### 2

#### Description

Medication Constant dose intake of antidepressants including triple tyline (alivyl), trimimipramine (surmontelium) and alprazolam was monitored and administered by a psychiatrist by psychiatric and psychiatric patients who were diagnosed with major depressive disorder (MDD) Theoretical definition: The approach to drug therapy for mood disorders has transformed their treatment and reduced its inherent costs for the community. Antidepressants are increasingly prescribed to treat depression disorders. Among the most important of these are monoamine oxidase inhibitors, tri-drug drugs, serotonin reuptake inhibitors Operational Definition: A constant dose of antidepressants including triple tyline (alavil), trimimperamine (surmontelyl), and alprazolam were monitored and administered by a psychiatrist by psychiatric and psychiatric patients who were under the Major Depression Scale (MDD) under the well-being of Shahrekord.

#### Category

Treatment - Drugs

### 3

#### Description

The control group did not receive any kind of treatment, but the control group was told that after the research they could attend admissions and admission treatment sessions.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Welfare Organization of Shahrekord City

##### Full name of responsible person

Firuze maleki

##### Street address

Shahr-e-Kord: Northern Hafez Street above the post office of the 437th post office

##### City

Shahr-e-Kord

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Deputy of Research of Bandar Abbas Azad University

##### Full name of responsible person

Kobra Haji Alizadeh

##### Street address

Bandar Abbas Crossroads Paladin Campus-Blvd  
Campus-Islamic Azad University Bandar Abbas

##### City

Bandar Abbas

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Deputy of Research of Bandar Abbas Azad University

#### Proportion provided by this source

100

#### Public or private sector

*empty*

#### Domestic or foreign origin

*empty*

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Bandar Abbas Azad University

##### Full name of responsible person

Rasoul Alipour

##### Position

MA

##### Other areas of specialty/work

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Shahr-e-Kord - The western nation originates 16 meters second to the glass of Berri Bahramian

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
*empty*  
**Study Protocol**  
*empty*  
**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**  
*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*