

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Developing the integrated Package of compassion focused therapy with acceptance and commitment Therapy and Comparison its effectiveness with cognitive behavioral therapy on depression, Psychological Well-being, interpersonal forgiveness and HbA1C in Female Patients with Type II diabetes.

Protocol summary

Study aim

The purpose of this study is :The effectiveness of acceptance and commitment therapy and compassion focused therapy on depression of diabetic females.

Design

Semi experimental method with 3 experimental groups and 1 control group were assigned randomly.

Settings and conduct

Shahid Shabani diabetic center _ 61 diabetic females in 3 experimental groups and 1 control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria : patient's tendency to participate in the study and obtaining informed consent from them , being able to read and write (having literacy), age range 30 - 60 years old and being female. Exclusion criteria : refraining from participation in the research and absence from more than 3 sessions in the group therapy.

Intervention groups

"Intervention group 1" (ACT group - compassion focused } "Intervention group 2" (CFT group - ACT focused }
"Intervention group 3" (CBT group) and Control group.

Main outcome variables

Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180607039996N1**

Registration date: **2018-12-10, 1397/09/19**

Registration timing: **retrospective**

Last update: **2018-12-10, 1397/09/19**

Update count: **0**

Registration date

2018-12-10, 1397/09/19

Registrant information

Name

Shahin Khayatan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3264 1704

Email address

shahin.khayatan@khuisf.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-05-24, 1396/03/03

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Developing the integrated Package of compassion focused therapy with acceptance and commitment Therapy and Comparison its effectiveness with cognitive behavioral therapy on depression, Psychological Well-being, interpersonal forgiveness and HbA1C in Female Patients with Type II diabetes.

Public title

Developing the integrated Package of compassion focused therapy with acceptance and commitment Therapy and Comparison its effectiveness with cognitive behavioral therapy on depression, Psychological Well-being, interpersonal forgiveness and HbA1C in Female Patients with Type II diabetes.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Obtaining informed consent. The age range of 30 - 60 years old. Female patients.

Exclusion criteria:

Refraining from participation in the research. Absence from more than 3 sessions.

Age

From **30 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **61**

Randomization (investigator's opinion)

Randomized

Randomization description

61 subjects were randomly (through lottery) assigned to 3 experimental groups and 1 control group. Referring to Shahid Shabani diabetic center in Isfahan, 61 diabetic females who were referring to this center for treatment were purposefully selected for research, and after obtaining informed consents from them, were assigned randomly in four groups including three experimental groups and one 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

IR.IAU.KHUISF.REC.

Street address

Moshtagh-hamze-lane4-12

City

Isfahan

Province

Isfahan

Postal code

8158835441

Approval date

2018-04-16, 1397/01/27

Ethics committee reference number

IR.IAU.KHUISF.REC.1397.037

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E08.0

ICD-10 code description

Diabetes mellitus due to underlying condition with hyperosmolarity

Primary outcomes

1

Description

Depression

Timepoint

Pre-test post _test follow up

Method of measurement

Beck depression inventory

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group 1": { CFT group - ACT focused }

Category

Treatment - Other

2

Description

"Intervention group 2 ": { ACT group - CFT focused }

Category

Treatment - Other

3

Description

'Intervention group 3 ": { CBT group }

Category

Treatment - Other

4

Description

Control group: control group

Category

Other

Country of origin**Type of organization providing the funding**

Persons

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Shabani diabetic center

Full name of responsible person

DR. Roya Zolfaghari

Street address

Charbagh Street

City

Isfshsn

Province

Isfahan

Postal code

8158835441

Phone

+98 31 3265 7960

Email

AMOOZESHTAMIN@GMAIL.COM

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Researcher:Shahin Khayatan

Street addressIsfahan, Arghavanie Street, Islamic Azad University
(Isfahan) Branch**City**

Isfahan

Province

Isfahan

Postal code

81595158

Phone

+98 31 3535 4001

Email

shahin.khayatan@khuif.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

2**Sponsor****Name of organization / entity**

Islamic Azad University,Isfahan (Khorasgan)Branch

Full name of responsible person

Shahin Khayatan

Street address

isfahan.moshtagh,lane 4 ,12

City

Isfahan

Province

Isfahan

Postal code

8158835441

Phone

+98 31 3264 1704

Email

shahin.khayatan@khuif.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Islamic Azad University,Isfahan (Khorasgan)Branch

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Persons

3**Sponsor****Name of organization / entity**

IslamicAzad University,Isfahan (Khorasgan)Branch

Full name of responsible person

Shahin Khayatan

Street addressIsfahan, Arghavanie Street, Islamic Azad University
(Isfahan) Branch**City**

Isfahan

Province

Isfahan

Postal code

8158835441

Phone

+98 31 3264 1704

Email

shahin.khayatan@khuif.ac.ir

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 IslamicAzad University.Isfahan (Khorasgan)Branch
Proportion provided by this source
 100
Public or private sector
 Private
Domestic or foreign origin
 Domestic
Category of foreign source of funding
 empty
Country of origin
Type of organization providing the funding
 Persons

Person responsible for general inquiries

Contact
Name of organization / entity
 Islamic Azad University
Full name of responsible person
 Shahin Khayatan
Position
 psychologist
Latest degree
 Ph.D.
Other areas of specialty/work
 Psychology
Street address
 moshtagh - hamze - line 4 - 12
City
 Isfahan
Province
 Isfahan
Postal code
 5441 883 815
Phone
 +98 31 3264 1704
Email
 shahin.khayatan@khuisf.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
 Islamic Azad University
Full name of responsible person
 Asghar Aghaei
Position
 Asghar Aghaei: Professor, Department of educational science and psychology, Isfahan (Khorasgan) Bran
Latest degree
 Ph.D.
Other areas of specialty/work
 Psychology
Street address
 Arghavanie street Isfahan.Islamic University
City

Isfahan
Province
 Isfahan
Postal code
 81595158
Phone
 +98 31 3535 4001
Email
 aghaeipsy@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
 Islamic Azad University
Full name of responsible person
 Shahin Khayatan
Position
 Psychologist
Latest degree
 Ph.D.
Other areas of specialty/work
 Psychology
Street address
 Moshtagh Street
City
 Isfshsn
Province
 Isfahan
Postal code
 8158835441
Phone
 +98 31 3264 1704
Email
 SHAHIN.KHAYATAN@KHUISF.AC.IR

Sharing plan

Deidentified Individual Participant Data Set (IPD)
 Yes - There is a plan to make this available
Study Protocol
 Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
 Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
 Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
 Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
 Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
 Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
 DETAILS FROM RESEARCH
When the data will become available and for how long

6MONTHS AFTER PRINT OF RESULTS
To whom data/document is available
FOR RESEARCHES
Under which criteria data/document could be used
FOR RESEARCHES STUDIES
From where data/document is obtainable

SHAHIN.KHAYATAN@KHUISF.AC.IR
What processes are involved for a request to access
data/document
BY EMAIL
Comments