

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The comparison of the effectiveness of Acceptance and Commitment Therapy with the Lifestyle Intervention of promoting health on disease perception, disease adjustment, and HbA1c Levels in Type II Diabetes patients

Protocol summary

Study aim

The purpose of this study is to compare the efficacy of acceptance and commitment therapy with lifestyle intervention of promoting health in a sample of type II diabetes patients.

Design

60 type 2 diabetes patients who, after matching by age and gender, are divided to three groups, Two experimental and one control, will participate in the research

Settings and conduct

Diabetes and metabolic disorders specialty clinic

Participants/Inclusion and exclusion criteria

Sample persons are type II diabetes patients and should not have received psychological intervention since a year ago. People who can not participate in the study include those with type 1 diabetes or those who are suffering from mental disorders, as well as those who have physical problems culminating in type 2 diabetes.

Intervention groups

In the research, the first group will have psychological treatment of acceptance and commitment. The second group has the lifestyle intervention of promoting health for type 2 diabetes patients. The third group is the control group.

Main outcome variables

Disease perception ; Disease adjustment ; Level of Hb A1C

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180404039185N1**

Registration date: **2018-05-28, 1397/03/07**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-28, 1397/03/07**

Update count: **0**

Registration date

2018-05-28, 1397/03/07

Registrant information

Name

Nasim Soltanian

Name of organization / entity

Psychology and Education faculty of Semnan university

Country

Iran (Islamic Republic of)

Phone

+98 21 6161 1538

Email address

n.soltanian@semnan.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-08-11, 1397/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effectiveness of Acceptance and Commitment Therapy with the Lifestyle Intervention of

promoting health on disease perception, disease adjustment, and HbA1c Levels in Type II Diabetes patients

Public title
Effect of ACT on diabetes

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Type 2 diabetes patients lack of getting psychological treatment since a year ago
Exclusion criteria:
Type 1 diabetes patients Patients with Psychological disorders and Physical problems culminating in diabetes

Age
From **30 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method is simple random sampling. Having matched the samples in terms of age and gender, a number in the range of one to three will be given to every group. Then the numbers randomly will be assigned to the title of every group, like control group, ACT group and lifestyle group by a computerized program

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 Semnan University of Medical Science

Street address

Mahdishahr ;Education and psychology faculty of semnan university

City

Semnan

Province

Semnan

Postal code

3564111156

Approval date

2018-03-14, 1396/12/23

Ethics committee reference number

IR.SEMUMS.REC.1396.257

Health conditions studied

1

Description of health condition studied

diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Disease Perception

Timepoint

Before and after of Intervention

Method of measurement

The Brief Illness Perception Questionnaire (BIPQ)

2

Description

Disease adjustment

Timepoint

Before and after of Intervention

Method of measurement

Problem Areas in Diabetes Questionnaire(PAID)

3

Description

HbA1C

Timepoint

Before and after of Intervention

Method of measurement

Blood analysis

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Acceptance and commitment therapy (ACT). The name of ACT stemming from one of its main message: Accept what you can't change and control it and commit to improve everything you can enrich and change it in your life. The purpose of ACT is attaining psychological flexibility. ACT has six core processes:

Contacting the present moment; Defusion of thoughts; Acceptance; Values; Commitment and Self as a context. This protocol takes around two months to run. It has eight sessions. In fact the intervention aims at improving the quality of life of diabetes patients to cope with their disease toward having an active life. This program lays emphasis on medical issues along with psychological matters.

Category

Behavior

2

Description

Intervention group: Lifestyle intervention for promoting health. In fact this protocol is a medical approach for diabetes. It emphasizes on self-care behaviors like blood sugar tests, walking, mild exercise and diet. In this course patients will learn about risks and disease resulting from diabetes and will learn how to prevent them. This program comprises six sessions taking three weeks. This approach lays little emphasis on psychological variables.

Category

Lifestyle

3

Description

Control group: None intervention, only as evidence group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes and metabolic disorders speciality clinic

Full name of responsible person

Dr Fatemeh Bandarian

Street address

karegar-e-shomali Diabetes and metabolic disorders speciality clinic

City

Tehran

Province

Tehran

Postal code

1411715851

Phone

+98 21 8833 4192

Fax

Email

emri_diabetes@tumc.ac.ir

Web page address

http://emri.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The university of semnan- Psychology faculty

Full name of responsible person

Dr Eshagh Rahimian Bougar

Street address

Mahdishahr, Psychology faculty, Semnan University

City

Semnan

Province

Semnan

Postal code

356411156

Phone

+98 23 3362 4250

Email

psychology@semnan.ac.ir

Web page address

http://psy.semnan.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

This is a PHD Dissertation

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

Faculty of Psychology and Education of Semnan university

Full name of responsible person

Nasim Soltanian

Position

PHD Candidate

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

No.4, 9 laleh, 35 metrieh laleh, Marzadaran blvd, Tehran

City

Tehran

Province

Tehran

Postal code

1461874373

Phone
+98 21 4422 1959
Email
n.soltanian@semnan.ac.ir
Web page address
http://psy.semnan.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
The university of Semnan
Full name of responsible person
Eshagh Rahimian
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Mahdishahr, Education and Psychology faculty of Semnan university
City
Semnan
Province
Semnan
Postal code
3564111156
Phone
+98 23 3362 4250
Email
i_rahimian@semnan.ac.ir
Web page address
http://psy.semnan.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
The University of Semnan
Full name of responsible person
Nasim Soltanian
Position
PHD Candidate
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Mahdishahr, Semnan, Education and Psychology faculty of Semnan university
City

Semnan
Province
Semnan
Postal code
3564111156
Phone
+98 23 3362 4250
Email
n.soltanian@semnan.ac.ir
Web page address
http://psy.semnan.ac.ir

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

Not applicable

Title and more details about the data/document

Total research results will be published in scientific journals

When the data will become available and for how long

The documentation and research results are likely to be published in 2018-2019

To whom data/document is available

The full research document will be available to Semnan faculty of Psychology. Research results will be available to researchers as an article and book

Under which criteria data/document could be used

Using the results with the number and type of community and the research sample as well as the intervention can be used.

From where data/document is obtainable

Faculty of Psychology and Educational Sciences of Semnan University. Information and Documentation Center of Iran (IranDoc) Or sending a message to researcher : n.soltanian@semnan.ac.ir or n.soltanian@gmail.com

What processes are involved for a request to access data/document

Visiting the IranDoc center or Semnan University Library
Or one week after sending email to the writer

Comments