Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effectiveness of the Therapeutic Life-based Appearance Package Based on Adoption Therapy and the Special Therapeutic Commitment of Female Patients with Type 2 Diabetes and Its Comparative Effect with Mindfulness-Based Cognitive Therapy, Self-Care, Resilience, Depression, Adherence to Treatment, and Glycosylated Hemoglobin

Protocol summary

Study aim

The purpose of this study was to investigate the effect of the package of lifestyle-based health on the basis of treatment and acceptance and to compare the effect of this package with cognitive therapy on mind-awareness on self-care, resilience, depression, tolerance to treatment and glycosylated hemoglobin in women with type II diabetes Isfahan city. The intervention stage was a semi-experimental, pre-test, post-test, and follow-up period with a control group.

Design

Clinical trials with community based and pragmatic control group with parallel, blind, randomized groups

Settings and conduct

The efficacy of a phenomenal package of lifestyle based on the treatment of admission and special commitment of patients with type 2 diabetes and its comparison with cognitive therapy based on mind-awareness, the statistical population of women with type 2 diabetes in Isfahan and at a medical charity center

Participants/Inclusion and exclusion criteria

Women with type 2 diabetes

Intervention groups

Group 1: Health Lifestyle Intervene with Acceptance and Commitment, Group 2: Intervention of Cognitive Therapy Based on Mindfulness, Group III: Group on the waiting list of treatment and currently do not receive interventional control group.

Main outcome variables

depression, self-care, resilience, adherence to treatment and glycated hemoglobin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180522039786N1**
Registration date: **2018-08-27, 1397/06/05**
Registration timing: **retrospective**

Last update: **2018-08-27, 1397/06/05**
Update count: **0**

Registration date

2018-08-27, 1397/06/05

Registrant information

Name

Maryam Hor

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3338 4716

Email address

marya.hor@khuisf.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-06, 1397/03/16

Expected recruitment end date

2018-08-19, 1397/05/28

Actual recruitment start date

2018-06-05, 1397/03/15

Actual recruitment end date

2018-08-19, 1397/05/28

Trial completion date

empty

Scientific title

The Effectiveness of the Therapeutic Life-based Appearance Package Based on Adoption Therapy and the Special Therapeutic Commitment of Female Patients with Type 2 Diabetes and Its Comparative Effect with Mindfulness-Based Cognitive Therapy, Self-Care, Resilience, Depression, Adherence to Treatment, and Glycosylated Hemoglobin

Public title

Preparing a phenomenological package for Healthy Life Style Treatment Based on Acceptance and Combination and Compare the Effect of Its Combination with Mindfulness Based on Cognitive Therapy on Self-care,Ressilience,Depression,Adherence to Treatment & Glycated Hemoglobin

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent,. ,Definite diagnosis of type 2 diabetes is at least one year old, Age range between 35 and 69 years Medium to severe depression score and low or moderate score in resilience Access to patients and their lack of participation in other research projects simultaneously

Exclusion criteria:

Having acute psychiatric disorder based on clinical interview,

Age

From **35 years** old to **69 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **45**

More than 1 sample in each individual

Number of samples in each individual: **15**

Woman with type 2 diabetes

Actual sample size reached: **45**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Islamic Azad University,Isfahan(khorasgan)Branch

Street address

Islamic Azad University, Isfahan (Khorasgan) branch, Arqavanieh, Jay Street, Isfahan, Iran. Box: 81595-158

City

Isfahan

Province

Isfehan

Postal code

158-81595

Approval date

2018-04-13, 1397/01/24

Ethics committee reference number

IR.IAU.KHUISF.REC.1397.014

Health conditions studied

1

Description of health condition studied

Diabetes mellitus

ICD-10 code

7

ICD-10 code description

E10-E14

Primary outcomes

1

Description

Depression score in Beck questionnaire is higher than 10,

Timepoint

Trimester

Method of measurement

. Back depression inventory (1961)

2

Description

Resonance increase based on Connor and Davidson questionnaire above 30

Timepoint

Trimester

Method of measurement

Resilience Conner inventory (2003)

3

Description

Increased self-care based on the scale of self-care activities of diabetic patients (SDSCA) above 4

Timepoint

Trimester

Method of measurement

Tobert self-care inventory (2000),

Secondary outcomes

1

Description
Glycosylated hemoglobin decreased by less than 6.5
Timepoint
Trimester
Method of measurement
Electrophoresis test in medical diagnostic laboratory

Intervention groups

1

Description
Intervention group: Life style health package based on acceptance and commitment
Category
Lifestyle

2

Description
Intervention group: MBCT
Category
Lifestyle

3

Description
Control group: 15 people without medical intervention
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Charity Center for Training, Control, Prevention of Isfahan Diabetes
Full name of responsible person
Dr. Mohammad Ali Attari
Street address
street J, Lahore Street ،Isfahan,
City
Esfhan
Province
Isfehan
Postal code
158-81595
Phone
+98 31 1325 8444
Email
Diabetes_ngo@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr. Majid Touhyani
Street address
Isfahan (Khorasgan) branch, Arqavanieh, Jay Street, Isfahan, Iran
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158-81595
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+98 31 1535 4001
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Marya.hor@khuisf.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
personal
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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Maryam Hor
Position
Staff
Latest degree
Ph.D.
Other areas of specialty/work
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
Not applicable

Title and more details about the data/document
Part of the data can be shared after unidentifiable people

When the data will become available and for how long
2021

To whom data/document is available
For researchers, diabetes will be available at university institutes

Under which criteria data/document could be used
Use of any documentation is allowed for scholars.

From where data/document is obtainable
Maryam hor Marya.hor@khuisf.ac.ir

What processes are involved for a request to access data/document
Posting emails and surveys will allow the submission of documentation.

Comments