

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of Well being Therapy on Depression, Anxiety, Self-management and Blood Glucose Control in Women with Type 2 Diabetes

Protocol summary

Study aim

Determining the effect of well-being therapy on depression, anxiety, self-management and glycemic control in women with type 2 diabetes

Design

A Randomized, Controlled, Double-Blind, Parallel-Group Clinical Trial

Settings and conduct

Therapy is provided at Parsian Diabetes Center. Samples are selected according to the inclusion criteria and are divided into control and intervention groups. Depression, anxiety and self-management inventory and blood glucose test are completed as pretest. The inventories are completed again after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1-Gender: female 2-Age limit: minimum 35 years, maximum 65 years 3- Scores of higher than 19 on the Beck Depression Inventory (BDI). 4.Scores of higher than 16 on the Beck Anxiety Inventory (BAI). Exclusion criteria: 1. Exhibiting signs and symptoms of severe mental disorders including personality disorder. 2.Receiving other psychological and pharmacological treatments at the time of the research. 3.Taking psychiatric medications

Intervention groups

Intervention group:The well-being therapy program for diabetic patients is composed of 12 sessions of 90 minutes held once a week for three months. Early sessions (1-2): Preparing the group, building relationships, and introducing the logic of treatment. Middle session (2-6): Identifying existing barriers and removing irrelevant beliefs with the aim of self-observation of care seekers to achieve psychological well-being Last sessions (6-12): Introducing six dimensions of model of psychological well-being and changing six damaged dimensions of psychological well-being.

Main outcome variables

Self Management. Depression. Anxiety. Glycemic Control

General information

Reason for update

Acronym

بهزیستی درمانی

IRCT registration information

IRCT registration number: **IRCT20190929044918N1**

Registration date: **2019-11-11, 1398/08/20**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-11, 1398/08/20**

Update count: **0**

Registration date

2019-11-11, 1398/08/20

Registrant information

Name

Mahnaz Pazuheshgar

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3866 2507

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-21, 1398/07/29

Expected recruitment end date

2019-11-20, 1398/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Well being Therapy on Depression, Anxiety, Self-management and Blood Glucose Control in Women with Type 2 Diabetes

Public title

The effect of well-being on diabetes

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Gender: female Minimum 35 years, maximum 65 years, 3. Depression score of higher than 19 in the 21-item Beck Depression Inventory (BDI-21) .Anxiety score of higher than 16 in the 21-item Beck Anxiety Inventory (BAI-21) Minimum level of Education: high school diploma

Exclusion criteria:

Evidence of severe mental disorder (including personality disorder), Other simultaneous psychological and medicinal treatments, Psychiatric medications.

Age

From **35 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocking is used to make balance amongst the samples of each group under examination. This feature might be useful when meso-level analysis is needed during sampling process, so that each group is allocated the same amount of samples. In this design randomizing shall take place based on permuted blocking. Thus, patients will be grouped in 15 blocks, each comprising two people from the experimental group and two people from the control group. Finally, group 1 will be treated using Well-Being Therapy (WBT) and the control group shall receive no treatment.

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**

National Committee on Ethics in Biomedical Research

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Boulevard Emamieh 70

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Postal code

91899-13878

Approval date

2019-07-09, 1398/04/18

Ethics committee reference number

IR.IAU.MSHD.REC.1398.067

Health conditions studied**1****Description of health condition studied**

Diabetes

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Depression

Timepoint

At the beginning of the study, both experimental and control groups will be measured before and after the intervention.

Method of measurement

Beck Depression Inventory

2**Description**

Anxiety

Timepoint

Both case and control groups are measured at the beginning of the study, before the intervention and after the re-intervention.

Method of measurement

Beck Anxiety Inventory

3**Description**

Self-Management

Timepoint

Both case and control groups are measured at the beginning of the study, before the intervention and after the re-intervention.

Method of measurement

The Tobert & Thompson Self-Management Questionnaire

4

Description

Glycemic Control

Timepoint

Both case and control groups are measured at the beginning of the study, before the intervention and after the re-intervention.

Method of measurement

Blood sugar test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The well-being therapy program for diabetic patients is composed of 12 sessions of 90 minutes held once a week for three months. Early sessions (1-2): Preparing the group, building relationships, and introducing the logic of treatment. Clinical interview, getting identification data, information about feelings, current distress, previous distress, defining the curriculum process, defining the structure and conditions of well-being therapy, including the number of sessions, duration of sessions, interval between sessions. Middle session (2-6): Identifying existing barriers and removing irrelevant beliefs with the aim of self-observation of care seekers to achieve psychological well-being the role of lack of positive emotions, giving the first home workout, explaining the concept of optimal experiences, describing thoughts and behaviors that are detrimental to well-being, explaining the concept of self-therapy, explaining problem solving, self-acceptance and its role in mental relaxation. Last sessions (6-12): Introducing six dimensions of model of psychological well-being and changing six damaged dimensions of psychological well-being. environmental mastery as a component of mental health, initiating cognitive reconstruction of thoughts or behaviors that disrupt well-being, personal growth and exploring social cognitive development, the role of dysfunctional cognitions, providing autonomy components and positive relationships with others, summary, emphasizing the importance of continuing self-therapy after the sessions

Category

N/A

2

Description

This group receives routine caring actions like glycemic control, medical advice, and prescription of medication from the physician of Diabetes Center. However, it does not receive well-being therapy intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Parsian Diabetes Center

Full name of responsible person

Dr. Ali Rauf

Street address

Jam Street, University Road

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Hamid Shahabi

Street address

No. 2, Behvarz 9, Dr. Hesabi 4, Jam Junc., Daneshgah St.

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info@iautj.ac.ir

Web page address

<http://www.iautj.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

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

Other

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Person responsible for general inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Mahnaz Pzhuhsghar

Position

University Student

Latest degree

Master

Other areas of specialty/work

Psychology

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Latest degree

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Other areas of specialty/work

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City

Mashhad

Province**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

Not applicable

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

Not applicable

Data Dictionary

Not applicable