Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 callocatedthe same amount of samples. In this design randomizing shall take place based on permuted blocking. Thus, paitients will be grouped in 15 blocks, each comprisingtwopeople from the experimental group and two people from the control group.Finally, group 1 will be treated using Well-BeingTherapy(WBT) and the control group shall receive notreatment.
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
Street address
Boulevard Emamieh 70
City
Mashhad
Province
Razavi Khorasan
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 sessionsMiddle 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 relaxationLast 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
City
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m.p13978694@gmail.com
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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9576174814
Phone
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Fax
+98 51 5251 0080
Email
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

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Mahnaz Pzhuhshgar
Position
University Student
Latest degree
Master
Other areas of specialty/work
Psychology
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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