

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Assessing the Effectiveness of Integrated Psycho-Spiritual Care Package on Self-Efficacy, Self-Care and Health-Related Quality of Life in Adults with Type 2 Diabetes.

Protocol summary

Study aim

Determining the effect of an integrated psycho-spiritual care package on self-efficacy, self-care and health-related quality of life in adults with type 2 diabetes.

Design

a pre-test-post-test, single-blind clinical trial study in which the sample individuals are randomly allocated to two groups: control and intervention.

Settings and conduct

Authoritative content development and production, multistage sampling, conducting the first session both in-person and virtually, and completing informed consent forms and questionnaires, followed by 18 virtual training sessions via Eita, Telegram, and WhatsApp, administering post-intervention questionnaires immediately after the intervention and three months later, through virtual means or telephone contact.

Participants/Inclusion and exclusion criteria

Individuals with type 2 diabetes and covered by comprehensive health service centers under the supervision of Shahid Beheshti University of Medical Sciences Have not received any formal psychological or spiritual care or treatments in the past six months. Absence of severe mental illnesses such as psychotic disorders, memory disorders, PTSD or substance abuse; Participants must have been diagnosed with type 2 diabetes or started glucose-lowering medication at least five years prior. Have not received diabetes self-management education in the past six months. Possess the ability to utilize digital technology (mobile phones) and social networks. Primary exclusion criteria: unwillingness to continue participation in the study, or the occurrence of severe life stressors or unforeseen adverse events.

Intervention groups

The intervention group receives the psycho-spiritual care package for 8 weeks, with 18 training sessions, and the

control group will receive only 5 sessions of diabetes physical self-care training for 5 weeks.

Main outcome variables

Self-Efficacy, Self-Care, Health-Related Quality of Life.

General information

Reason for update

Change of supervisor, Change in methodology and change in sampling location.

Acronym

IRCT registration information

IRCT registration number: **IRCT20221013056164N1**

Registration date: **2022-11-15, 1401/08/24**

Registration timing: **prospective**

Last update: **2025-09-29, 1404/07/07**

Update count: **1**

Registration date

2022-11-15, 1401/08/24

Registrant information

Name

Yasamin Geloumaki Robati

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-05-22, 1402/03/01
Actual recruitment start date
2024-06-22, 1403/04/02
Actual recruitment end date
2024-10-09, 1403/07/18
Trial completion date
2025-04-25, 1404/02/05

Scientific title
Assessing the Effectiveness of Integrated Psycho-Spiritual Care Package on Self-Efficacy, Self-Care and Health-Related Quality of Life in Adults with Type 2 Diabetes.

Public title
Effectiveness of Integrated Psycho-Spiritual Care Package on Self-Efficacy, Self-Care and Health-Related Quality of Life of Adults with Type 2 Diabetes.

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Individuals with type 2 diabetes and covered by comprehensive health service centers under the supervision of Shahid Beheshti University of Medical Sciences Have not received any formal psychological or spiritual care or treatments in the past six months. Do not suffer from severe mental illnesses such as psychotic disorders and memory disorders, PTSD diagnosed by a psychiatrist or substance abuse (Based on information from the SIB system and a review of medical history through self-report via telephone contact or a demographic questionnaire). Participants must have been diagnosed with type 2 diabetes or started glucose-lowering medication at least five years prior Have not received diabetes self-management education in the past six months (excluding education provided by comprehensive health service centers or health posts). Having a smartphone Consented to participate in the study
Exclusion criteria:
Have severe mental, emotional and psychological disorders such as dementia. At the same time, suffer from debilitating diseases such as cancer, MS, stroke, end stages of liver and kidney diseases, etc. Have vision and hearing problems A pregnant woman with gestational diabetes Have other specific types of diabetes.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **118**
Actual sample size reached: **58**

Randomization (investigator's opinion)
Randomized

Randomization description
Following the selection of a comprehensive health service center via convenience sampling; the sampling will be random. Based on a list of contact information for individuals with Type 2 diabetes extracted from the electronic health records of the SIB system, and by contacting individuals to assess eligibility criteria, Participants will be selected from the list using a systematic random sampling method, alternating between the control and intervention groups. This process will continue until the sample size for each group is complete. The first individual will be assigned to the control or intervention group by random draw. If the number of individuals in the intervention and control groups does not reach the required sample size, another comprehensive health service center will be consulted, and this process will be repeated.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, a single-blind design means that the statistical analyst is unaware of the group allocation of the participants, which is incorporated to reduce bias in the data analysis process.

Placebo
Not used

Assignment
Parallel

Other design features
The study includes two groups (control and intervention). During the study, the intervention group will receive all three components: psychological care, spiritual care, and physical self-care in diabetes (Integrated Psycho-Spiritual Care Package). The control group will only receive the physical self-care component in diabetes.

Secondary Ids
empty

Ethics committees
1
Ethics committee
Name of ethics committee
Vice-Chancellor in Research Affairs - Shahid Beheshti University of Medical sciences
Street address
13th floor, Block A, Central Headquarters of the Ministry of Health, Treatment and Medical Education, Simaye Iran St., between South Flamek and Zarafshan, Quds town (west), Tehran
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2022-10-02, 1401/07/10
Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Self-Efficacy

Timepoint

Before the start of the intervention, immediately after the end of the intervention, 3 months after the end of the intervention

Method of measurement

Diabetes Management Self-Efficacy Scale (DMSES)

2

Description

Self-Care

Timepoint

Before the start of the intervention, immediately after the end of the intervention, 3 months after the end of the intervention

Method of measurement

Self-Care of Diabetes Inventory (SCODI)

3

Description

Health-Related Quality of Life

Timepoint

Before the start of the intervention, immediately after the end of the intervention, 3 months after the end of the intervention

Method of measurement

World Health Organization quality of life questionnaire - Brief version (WHOQoL-BREF)

Secondary outcomes

1

Description

fasting blood sugar

Timepoint

Twice weekly for eight weeks during the intervention period.

Method of measurement

Blood glucose monitoring by patients using a glucometer, and if a glucometer is unavailable, recording the patient's blood glucose test results during the

2

Description

Glycosylated hemoglobin (HbA1c)

Timepoint

Recording of patients' HbA1c values from 2024/9/22 to 2024/12/20, if tested

Method of measurement

blood test

Intervention groups

1

Description

Intervention Group: Content is provided to the research participants via video-sharing websites (Aparat and Namasha) and by sharing session links in virtual groups on social networks (Telegram, Eita, and WhatsApp), involving individuals with type 2 diabetes. This will be implemented in a scheduled manner (every other day, 18 training sessions) for eight weeks for the intervention group, in various multimedia formats, podcasts, educational posters, interactive text, and similar materials. To develop the educational content, the method of literature search, review of the latest evidence, and the opinions of experts in this field will be used. Ultimately, after content production, the content's validity will be confirmed by reviewing the opinions of 5 experts and 10 patients (with different educational levels and social classes, varying durations and severity of diabetes, and from both genders). The content production method for each of the 18 educational sessions will be approved by at least 2 specialists in the field of e-learning, and an agreement coefficient above 70% will be used for method selection. In cases of disagreement, a third party's opinion will be consulted.

Category

Lifestyle

2

Description

Control group: The control group will receive only one session per week for five weeks, covering the self-care in diabetes module of the care package, similar to the intervention group.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Ershad Comprehensive Health Services Centers

Full name of responsible person

Ms. Zahra Arghayi

Street address

Shariati Street, Opposite Hosseiniyeh Ershad, Hedieh Alley, Ershad Community Health Center- Number 9

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2**Recruitment center****Name of recruitment center**

Torab Comprehensive Health Services Center

Full name of responsible person

Ms. Sajedah Sadat Taavousi

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Shahid Kolahdouz (Dolat) Street - Corner of Fakourian - Number 352

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3**Recruitment center****Name of recruitment center**

Sabarou Comprehensive Health Services Center

Full name of responsible person

Ms. Leila Parsa

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Vanak Square - Vanak Street - After Al-Zahra University - Majidpour Street - Number 204

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4**Recruitment center****Name of recruitment center**

Jolfa Health Post

Full name of responsible person

Ms. Zahra ghazaghi

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Tehran - Shahid Chamran Highway, Yemen Street - Shahid Aerabi Street - Building No. 2 - 5th Floor

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Grant name

-

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

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

Street address

Shahid Beheshti University of Medical Sciences,
Faculty of Nursing and Midwifery, in front of Shahid
Rajaei Heart Hospital, Intersection of Niayesh
Highway (Ayatollah Hashmi Rafsanjani) and Vali Asr
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Person responsible for general inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Yasamin Geloumaki Robati

Position

Student of MSc of Psychiatric nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Shahid Beheshti University of Medical Sciences, in
front of Shahid Rajaei Heart Hospital, Faculty of
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Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

Student of MSc of Psychiatric Nursing

Latest degree

Bachelor

Other areas of specialty/work

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fataneh Ghadirian Baharanchi

Position

Faculty Member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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

Yes - There is a plan to make this available

Title and more details about the data/document

Raw and final dataset of the clinical trial study

When the data will become available and for how long

Access will only be granted upon formal request and with ethics committee approval.

To whom data/document is available

The data and documents related to the study will be accessible exclusively to researchers and members of the scientific community with legitimate research purposes. Access is contingent upon adherence to ethical guidelines, confidentiality agreements, and approval by the ethics committee.

Under which criteria data/document could be used

Data and documents may only be used for legitimate scientific research purposes and must comply with ethical standards. Applicants are required to submit a research proposal and commit to maintaining

confidentiality and respecting participants rights. Use of the data is contingent upon approval by the ethics committee and written consent from the study's principal investigators.

From where data/document is obtainable

The data and documents related to the study will be obtainable from the Shahid Beheshti University of Medical Sciences data repository as well as email at ghadirian.fataneh@gmail.com

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

Applicants must submit a formal request including their research objective, study proposal, and a commitment to confidentiality. The request will be reviewed by the research team and the ethics committee. Upon approval, access will be granted under specific and restricted conditions. Applicants are also required to sign a data use agreement, pledging to use the data solely for the stated purposes.

Comments