Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

Country

Iran (Islamic Republic of)

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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

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Postal code

1985717443

Approval date

2022-10-02, 1401/07/10

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.474

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 intervention period (if a test was performed) and record on Blood sugar registration form.

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. Sajedeh Sadat Taavousi
Street address
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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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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info@sbmu.ac.ir
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

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

Street address
Shahid Beheshti University of Medical Sciences, in front of Shahid Rajaei Heart Hospital, Faculty of Nursing and Midwifery, Intersection of Niayesh Highway (Ayatollah Hashmi Rafsanjani) and Vali Asr (AJ) Street, Tehran

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Fataneh Ghadirian Baharanchi

Position
Faculty Member

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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 (AJ) Street, Tehran

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
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Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Shahid Beheshti University of Medical Sciences, in front of Shahid Rajaei Heart Hospital, Faculty of Nursing and Midwifery, Intersection of Niayesh Highway (Ayatollah Hashmi Rafsanjani) and Vali Asr (AJ) Street, Tehran

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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

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