Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Sep 2026

Design and measuring the effect of an evidence-based Interventional Mapping on the level of self-management, self-efficacy, quality of life, distress, and experiences of living with type 2 diabetes of Iraqi employees: Mixed Method (hybrid design).

Protocol summary

Study aim
Evaluate the effect of a workplace evidence-based diabetes intervention mapping program on diabetes self-management, diabetes self-efficacy, diabetes-specific quality of life, and diabetes distress among Iraqi governmental employees with type 2 diabetes.

Design
Two-arm, parallel-group, randomized controlled trial with 60 participants, 30 per group, allocated by block randomization; no placebo and not blinded.

Settings and conduct
The trial will be conducted in approved governmental hospital sites in Baghdad, Iraq. After written informed consent and baseline assessment, eligible governmental employees with type 2 diabetes will be allocated to intervention or control groups using block randomization. The intervention group will receive a structured workplace evidence-based diabetes intervention mapping program plus usual care, while the control group will receive usual care only. Outcomes will be measured at baseline and post-intervention using validated Arabic questionnaires. No formal blinding will be implemented because the intervention is educational and behavioral, so participants and intervention providers will know group allocation.

Participants/Inclusion and exclusion criteria
Iraqi governmental employees aged 30–60 years with confirmed type 2 diabetes for at least six months. Exclusions include other diabetes types, healthcare professionals, severe illness preventing participation, inability to complete questionnaires, planned absence before follow-up, or withdrawal of consent.

Intervention groups
The intervention group will receive W-EBDIM plus usual care. The control group will receive usual care only. Allocation will use block randomization with a 1:1 ratio.

Main outcome variables
Main outcomes are diabetes self-management (DSMQ-R), self-efficacy (DSES), diabetes-specific quality of life (QOLSID), and diabetes distress (PAID-5), measured at baseline and post-intervention.

General information

Reason for update

Acronym
W-EBDIM

IRCT registration information
IRCT registration number: **IRCT20260610069736N1**
Registration date: **2026-06-14, 1405/03/24**
Registration timing: **prospective**

Last update: **2026-06-14, 1405/03/24**
Update count: **0**

Registration date
2026-06-14, 1405/03/24

Registrant information

Name
ANAS KARAGHOOL

Name of organization / entity
Tarbiat Modares University

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-09-01, 1405/06/10
Expected recruitment end date
2026-11-30, 1405/09/09
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Design and measuring the effect of an evidence-based Interventional Mapping on the level of self-management, self-efficacy, quality of life, distress, and experiences of living with type 2 diabetes of Iraqi employees: Mixed Method (hybrid design).

Public title
Public title - English:Effect of a workplace diabetes self-management program on employees with type 2 diabetes
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Iraqi governmental employee working in one of the approved study sites in Baghdad Confirmed diagnosis of type 2 diabetes mellitus by a physician or HbA1c/blood test for at least six months Aged between 30 and 60 years Receiving diabetes management through antidiabetic medication and/or lifestyle modification Able to read Arabic or complete the Arabic questionnaires with researcher assistance Willing to participate voluntarily and provide written informed consent
Exclusion criteria:
Diagnosis of type 1 diabetes, gestational diabetes, or any other type of diabetes other than type 2 diabetes mellitus Healthcare professionals, including physicians and nurses, or highly specialized clinical staff whose advanced medical knowledge may bias baseline scores Severe physical or mental illness that prevents participation in the intervention or follow-up assessment Inability to complete the questionnaires adequately, even with researcher assistance Transfer, resignation, migration, or planned absence from the study site before follow-up assessment Withdrawal of consent or discontinuation of participation during the study
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
After eligibility confirmation, written informed consent, and baseline assessment, eligible participants will be assigned to the intervention or control group using computer-generated permuted block randomization with a 1:1 allocation ratio. The unit of randomization will be the individual participant. The random allocation sequence will be prepared by an independent statistician who is not involved in recruitment, intervention delivery, or outcome assessment. Allocation concealment will be maintained using sequentially numbered, opaque, sealed envelopes or an equivalent secure computerized allocation system. Group assignment will be revealed only after eligibility confirmation, consent, and baseline assessment have been completed.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
This trial is the intervention evaluation stage of a multiphase mixed-methods study. The current registration covers only the randomized trial stage. Before the trial, quantitative and qualitative findings will be integrated to design a workplace evidence-based diabetes intervention mapping program. The final program will then be evaluated in a two-arm parallel randomized controlled trial comparing the program plus usual care with usual care only.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tarbiat Modares University
Street address
Tarbiat Modares University, Nasr Bridge, Jalal Al Ahmad Highway, Tehran, Iran
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Province
Tehran
Postal code
14115-111
Approval date
2026-02-07, 1404/11/18
Ethics committee reference number
IR.MODARES.REC.1404.241

2

Ethics committee
Name of ethics committee
Research Ethics Committee of the Iraqi Ministry of Health
Street address

Iraqi Ministry of Health, National Centre for Training and Human Development, Baghdad, Iraq

City
Baghdad

Postal code
10047

Approval date
2026-04-22, 1405/02/02

Ethics committee reference number
Decision No. 51/2026

Health conditions studied

1

Description of health condition studied
Type 2 diabetes mellitus

ICD-10 code
E11

ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Diabetes self-management

Timepoint
Baseline (T0) and post-intervention (T1)

Method of measurement
Diabetes Self-Management Questionnaire-Revised (DSMQ-R), Arabic version. The total score will be calculated according to the questionnaire scoring instructions; higher scores indicate better diabetes self-management.

Secondary outcomes

1

Description
Diabetes self-efficacy

Timepoint
Baseline (T0) and post-intervention (T1)

Method of measurement
Diabetes Self-Efficacy Scale (DSES), Arabic version. The total score will be calculated according to the scale scoring instructions; higher scores indicate greater diabetes self-efficacy.

2

Description
Diabetes-specific quality of life

Timepoint
Baseline (T0) and post-intervention (T1)

Method of measurement
Quality of Life Scale for Iraqi Diabetes Mellitus Patients (QOLSID), Arabic version. The total score will be calculated according to the scale scoring instructions; higher scores indicate better diabetes-specific quality of life.

3

Description
Diabetes distress

Timepoint
Baseline (T0) and post-intervention (T1)

Method of measurement
The 5-item Problem Areas in Diabetes Scale (PAID-5), Arabic version. The total score ranges from 0 to 20; higher scores indicate greater diabetes-related emotional distress.

Intervention groups

1

Description
Intervention group: Participants will receive the Workplace Evidence-Based Diabetes Intervention Mapping (W-EBDIM) program in addition to usual care. W-EBDIM is a structured workplace-based educational and behavioral diabetes self-management program developed using Intervention Mapping and integrated quantitative and qualitative findings. It includes group sessions, culturally adapted Arabic materials, goal-setting, self-monitoring, problem-solving activities, peer discussion, and guidance on workplace nutrition, physical activity, medication adherence, blood glucose monitoring, and prevention of hypo- and hyperglycemia.

Category
Behavior

2

Description
Control group: Participants will not receive the W-EBDIM educational program during the study period and will continue to receive only their standard routine care.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Baghdad Teaching Hospital

Full name of responsible person
Anas Karaghool

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2

Recruitment center
Name of recruitment center
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3

Recruitment center
Name of recruitment center
Ibn Al-Bitar Specialized Hospital for Cardiac Disease and Surgery
Full name of responsible person
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4

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

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Web page address
https://en-med.modares.ac.ir
Grant name
No external grant
Grant code / Reference number
Not applicable
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tarbiat Modares University
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
Tarbiat Modares University
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Anas Karaghool
Position
PhD Candidate in Nursing
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Deidentified individual participant data will not be shared because the study involves health-related data from employees recruited from specific workplace and hospital settings. Even after deidentification, there may be a risk of indirect identification. Data sharing is also limited by the informed consent conditions and ethical approvals. Only aggregated results will be reported in publications and academic outputs.

Study Protocol

No - There is not 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

Not applicable

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The study protocol, statistical analysis plan, and blank informed consent form will be shared. These documents will not include identifiable participant information or individual participant-level data.

When the data will become available and for how long

The documents will become available after publication of the main study results or completion of the doctoral dissertation, whichever occurs first, and will be available for five years.

To whom data/document is available

The documents will be available to qualified researchers affiliated with academic or research institutions upon reasonable request.

Under which criteria data/document could be used

Requests must include a clear academic or scientific purpose and must be consistent with ethical approvals, participant confidentiality, and institutional regulations. The documents may be used for research, protocol comparison, or methodological reference only.

From where data/document is obtainable

Requests should be sent by email to the principal investigator: anasramaid@gmail.com (or Anas.karaghool@modares.ac.ir). Requests may also be reviewed in consultation with the study supervisor and Tarbiat Modares University.

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

The applicant should submit a written request explaining the requested document, purpose of use, affiliation, and planned use. The research team will review the request and provide the approved documents electronically if the request is appropriate.

Comments

No deidentified individual participant data will be shared.