Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the Effect of an Educational Intervention Based on King's Theory of Goal Attainment on Self-Efficacy and Self-Care Behaviors in Patients with Type 2 Diabetes

Protocol summary

Study aim
To investigate the effectiveness of a King's Theory based educational program on improving self efficacy in patients with type 2 diabetes

Design
Two arm randomized controlled trial with pre test post test design and three month follow up in 80 patients; simple randomization via Excel; single blind

Settings and conduct
This two-arm randomized controlled trial at comprehensive health service After screening and applying criteria, 80 patients with type 2 diabetes will be individually allocated via simple randomization (Microsoft Excel) to either the intervention group (4-week King's Theory-based educational program) or control group (standard diabetes care). Data will be collected using the Diabetes Self-Efficacy Scale at three time points: Before, after and 3 months after intervention. employs single-blinding: outcome assessors and data analysts remain blinded to group allocation, while blinding of participants is not feasible due to the educational nature of the intervention

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients with type 2 diabetes mellitus aged 30 to 70 years providing written informed consent.Exclusion Criteria: History of severe psychiatric disorders or advanced cardiac/renal failure.

Intervention groups
Intervention group: type 2 diabetes patients receiving a 4-week King's Theory-based educational program (personal, interpersonal, social systems and purposeful transaction) via 90-minute interactive group sessions. Control group: patients receiving standard 45-minute diabetes counseling on diet, medications and blood glucose monitoring without theoretical content.

Main outcome variables
Self efficacy score for diabetes management & diabetes self care behaviors

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20160824029512N4**
Registration date: **2026-08-16, 1405/05/25**
Registration timing: **retrospective**

Last update: **2026-08-16, 1405/05/25**
Update count: **0**

Registration date
2026-08-16, 1405/05/25

Registrant information
Name
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Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-06-20, 1402/03/30
Expected recruitment end date
2026-05-16, 1405/02/26
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of an Educational Intervention Based on King's Theory of Goal Attainment on Self-Efficacy and Self-Care Behaviors in Patients with Type 2 Diabetes

Public title

King's Theory Based Educational Program for Improving Self Efficacy in Diabetic Patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with type 2 diabetes Age between 30 and 70 years Providing written informed consent Ability to read and comprehend questionnaires Attendees of selected comprehensive health service centers

Exclusion criteria:

History of severe psychiatric disorders Advanced cardiac or renal failure Recent surgery less than three months ago Unwillingness to continue participation throughout the study period

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, randomization at the individual level will be utilized to maintain a precise balance between the two groups throughout the recruitment period, and given this approach, no stratification will be applied. The random sequence will be generated using the random number generation function in Microsoft Excel software. To allocate 80 patients into two groups of 40 each, 20 blocks of four will be used. Within each block, two allocations are assigned to the intervention group and two to the control group, and their sequence will be completely randomized using the RAND function in Excel. This ensures that exactly 40 patients will ultimately be placed in each group, and no quasi-randomization methods, such as allocation based on the date of visit, medical record number, or alternation, will be employed. Regarding allocation concealment, which is a distinct process from blinding and is aimed at preventing selection bias, the standard method of sequentially numbered, opaque, sealed envelopes (SNOSE) will be implemented. The sequence generated in Excel will be written on identical cards and placed inside opaque envelopes so that the contents cannot be seen from the outside. The envelopes will then be sealed and numbered sequentially from 1 to 80, strictly according to the random sequence order, and kept securely by the principal investigator in a safe location. After verifying the inclusion criteria and obtaining written informed consent from each patient, the researcher will open the lowest available numbered envelope to determine the assigned group. Prior to opening the envelope, the next assignment will remain completely concealed and unpredictable to both the researcher and the patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the educational nature of intervention, blinding of participants and interventionist is not feasible. Outcome assessors (data collectors) and data analysts will be blinded to group allocation status.

Placebo

Not used

Assignment

Parallel

Other design features

A two arm parallel group randomized controlled trial with pre test post test design and three month follow up. Eighty patients with type 2 diabetes will be randomly allocated to intervention group (four week educational program based on King's Theory constructs including personal system, interpersonal system, social system and transaction) and control group (standard care). The study employs single blinding (outcome assessors and data analysts blinded).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Torbat Heydariyeh Medical Sciences

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Approval date

2023-02-13, 1401/11/24

Ethics committee reference number

IR.THUMS.REC.1401.036

Health conditions studied

1

Description of health condition studied
Type 2 diabetes mellitus
ICD-10 code
E1
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Self efficacy score for diabetes management
Timepoint
Pre test before intervention onset, post test immediately after completion of four week educational program, and three month follow up after intervention completion
Method of measurement
Diabetes Self Efficacy Scale

Secondary outcomes

1

Description
Diabetes self care behaviors
Timepoint
Before, after and 3-month follow-up after intervention
Method of measurement
Summary of Diabetes Self Care Activities questionnaire

Intervention groups

1

Description
Intervention group: Participants receiving a four-week educational program based on King's Theory of Goal Attainment, consisting of four weekly 90-minute group sessions with a maximum of 8 participants per group. Week 1 (Personal System): enhancing self-efficacy through identification of personal barriers, setting SMART goals for diabetes self-management, and mental imagery exercises for successful health behaviors. Week 2 (Interpersonal System): improving interaction with healthcare providers via role-playing simulated consultations with physicians and nurses, and training effective communication skills for expressing treatment needs. Week 3 (Social System): engaging family members in diabetes management, developing social support mapping, and resolving conflicts related to dietary and medication adherence. Week 4 (Purposeful Transaction): integrating all three systems into an individualized action plan, providing group feedback, and establishing a 3-month follow-up schedule. Educational methods include structured group discussion, role-playing exercises, case study analysis, and immediate feedback delivered by a nurse trained in King's Theory application.Control group: Participants receiving standard diabetes care consisting of a single 45-minute individual counseling session delivered by a center nurse, covering general principles of dietary management for type 2 diabetes, instructions on antidiabetic medication use (metformin, sulfonylureas), importance of regular blood glucose monitoring (fasting and postprandial), and basic recommendations for age-appropriate physical activity. This session lacks theoretical framework, interactive components, or repeated educational contacts. Participants retain access to routine primary care services (regular physician and nurse visits) throughout the study period.
Category
N/A

2

Description
Control group: Receiving standard diabetes care including single session general counseling on diet, anti diabetic medications and importance of blood glucose control without structured content based on King's Theory.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
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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
Torbate-Heidaria 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
Torbate-Heidaria University of Medical Sciences

Full name of responsible person
Mohammad hossien Delshad

Position
Assistant

Latest degree
Specialist

Other areas of specialty/work
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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

Study protocol and statistical analysis plan: The complete study protocol including objectives, methodology, inclusion/exclusion criteria, randomization and blinding procedures, and the statistical analysis plan detailing descriptive and inferential methods (independent and paired t-tests, analysis of covariance),all data , questionnaires will be made available six months after publication of the primary manuscript. The data dictionary will include variable definitions, measurement scales, and coding schemes used in questionnaires. The final clinical study report will be disseminated through publication in a peer-reviewed scientific journal. Availability timeframe: Six months after publication of the primary manuscript and until the end of the third year following study completion. Authorized recipients: Researchers holding valid ethics approval from an accredited academic institution with research objectives related to diabetes or health education. Access conditions: Submission of written request with research proposal and institutional ethics approval to the principal investigator; use strictly for non-commercial research purposes with proper citation of the original study. Request mechanism: Email request to the principal investigator (Dr. Mohammad Hossein Delshad) at delshad264@gmail.com including institutional affiliation and research purpose.

When the data will become available and for how long

Six months after publication of the primary manuscript until the end of the third year following study completion

To whom data/document is available

Researchers holding valid ethics approval from accredited academic and research institutions (universities and research centers under the supervision of the Ministry of Science or Ministry of Health) with research objectives related to diabetes, health education, or health psychology, requesting access solely for non-commercial research purposes.

Under which criteria data/document could be used

De-identified data and study documents may be used only for non-commercial academic research and educational purposes. Conditions for use include: Submission of valid institutional ethics approval from the requesting organization Provision of a research proposal related to diabetes, health education, or health psychology Mandatory citation of the original study in any resulting publications or presentations Prohibition of commercial use, marketing activities, or attempts to re-identify participants No redistribution of data to third parties without written permission from the principal investigator

From where data/document is obtainable

Principal Investigator: Dr. Mohammad Hossein Delshad, Assistant/Associate Professor, Department of Public Health, Research Center for Health Sciences, School of Public Health, Torbat Heydariyeh University of Medical Sciences Postal Address: Research Center for Health Sciences, School of Public Health, Torbat Heydariyeh University of Medical Sciences, Torbat Heydariyeh, Razavi Khorasan Province, Iran, Postal Code: 9417966579 Official Institutional Email: delshad@thums.ac.ir Office Phone: +98 51 52421 ext. 248(if applicable)

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

The data request process follows four sequential steps: Step 1) Submission of written request via institutional email including research proposal, valid ethics approval certificate, and institutional letter of introduction to the principal investigator's official email address; Step 2) Review by the Study Data Access Committee (comprising the principal investigator and two independent faculty members) within 15 working days; Step 3) Upon approval, signing of a Data Use Agreement that legally prohibits commercial use and any attempt to re-identify participants; Step 4) Delivery of de-identified data in Excel or SPSS format within 10 working days after agreement execution. The entire process typically takes 25 to 35 working days from initial submission to data delivery. Incomplete requests or those lacking valid ethics approval will be rejected without review.

Comments

Raw data containing personally identifiable information (name, medical record number, contact details) will be permanently deleted immediately after initial coding; only de-identified coded data will be retained for analysis. No fees will be charged to participants and participation is entirely voluntary. The study has no financial or organizational conflicts of interest and is fully funded by the Vice-Chancellor for Research and Technology of Torbat Heydariyeh University of Medical Sciences. All study procedures are conducted under the supervision of the University Ethics Committee (Code: IR.THUMS.REC.1401.036).