Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness of a nurse-led diabetes self-management education on glycosylated hemoglobin in Iranian Kurdish adults with type 2 diabetes

Protocol summary

Summary

Objective: The general objective of this research is to develop, implement and evaluate the effect of a nurse-led diabetes self- management education compared to an existing DSME program in Iran Kurdish Adults with T2DM on glycosylated hemoglobin (HbA1c) across the study period (baseline, 3 and 6 months follow-up). Design: A single-center, parallel group randomized control trial design with balanced randomization (1:1) will be conducted over a six months. Setting and conduct: This study will be conducted in an urban primary and secondary clinic in Ilam city, Iran. Recruitment will be conducted in two phases. The first phase involves placing an advertisement on the notice board of the clinic. In this phase interested eligible patients will be invited to contact the researcher to volunteer. A master list of interested participants will be provided. The second phase involves screening process of potential patients by the researcher to identify the eligibility to participate based on the study inclusion and exclusion criteria. The research assistant will contact eligible participants for enrollment. Those patients who agree to take part in the study will be provided with the information sheet and written consent form before baseline assessment at enrolment. 142 Patients with T2DM will be randomized sequentially at the time they provided baseline assessment. Randomization will be generated by permuted block randomization with allocation concealment. Participants will be divided into intervention or control groups. Participants inclusion major eligibility: Major inclusion criteria: Being Iranian people; Aged 18 years and above; Being clinically diagnosed with T2DM at least for 6 months; Have medical record showing HbA1c ≥ 8%; Being independent in activity of daily living; Having the ability to read and write the Persian; Have a telephone in their residence and be able to use it effectively; Participating in regular follow-up; at least two visits in the last year; No acute medical illness in the last 6 months. Major exclusion criteria: Have T2DM combined with severe complications which would interfere with self-care such as blindness, being on dialysis and severe stroke; Have medical history of cognitive deficits such as dementia; Have uncontrolled hypertension (blood pressure ≥ 180/110 mmHg); Known hearing impairment; Known vision impairment; Unable to participate in the educational program (for example are housebound or unable to communicate in Persian or Kurdish) or are participating in another research study; Have hemolytic anemias, hemoglobinopathies;. Interventions: Participants will be randomly allocated to either diabetes usual care in the existing program or to diabetes usual care plus 12-week nurse-led DSME intervention. Main outcome measures: The primary outcome of this study is glycosylated hemoglobin (HbA1c). Lipid profile, blood pressure, diabetes self-care behavior, self-efficacy, quality of life, depression and social support are the secondary measures.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062528627N1**
Registration date: **2016-09-24, 1395/07/03**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-09-24, 1395/07/03

Registrant information

Name

Golnaz Azami

Name of organization / entity

Medical University of Ilam

Country

Iran (Islamic Republic of)

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Recruitment status
Recruitment complete
Funding source
Ilam University of Medical Science, IR Iran, has a financial interest in this study

Expected recruitment start date
2016-11-01, 1395/08/11
Expected recruitment end date
2017-05-01, 1396/02/11
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of a nurse-led diabetes self-management education on glycosylated hemoglobin in Iranian Kurdish adults with type 2 diabetes

Public title
Diabetes Self-Management Education
Purpose
Supportive
Inclusion/Exclusion criteria
Major inclusion criteria: Being Iranian people; Aged 18 years and above; Being clinically diagnosed with T2DM at least for 6 months; Have medical record showing HbA1c ≥ 8%; Being independent in activity of daily living; Having the ability to read and write the Persian; Have a telephone in their residence and be able to use it effectively; Participating in regular follow-up; at least two visits in the last year ; No acute medical illness in the last 6 months;. Major exclusion criteria: Have T2DM combined with severe complications which would interfere with self-care such as blindness, being on dialysis, DKA, and the severe stroke; Have the medical history of cognitive deficits such as dementia; Have uncontrolled hypertension (blood pressure ≥ 180/110 mmHg); Known hearing impairment; Known vision impairment; Unable to participate in the education program (for example are housebound or unable to communicate in Persian or Kurdish or are participating in another research study); Have hemolytic anemias, hemoglobinopathies;
Age
From **18 years** old to **100 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **142**

Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
-
Secondary trial Id
-
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Medical University of Ilam
Street address
Ilam Medical University, 6939177143, Pajohesh Blvd, Bangangab, Ilam, Iran
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Ilam
Postal code
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Approval date
2016-03-10, 1394/12/20
Ethics committee reference number
22/40/94/5599

2

Ethics committee
Name of ethics committee
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Street address
University Putra Malaysia, 43400, Selangor Darul Ehsan, UPM Serdang, Malaysia
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Approval date
2016-07-27, 1395/05/06
Ethics committee reference number
UPM/TNCPI/RMC/JKEUPM/1.4.18.2

Health conditions studied

1

Description of health condition studied
Type 2 diabetes
ICD-10 code
E10, E11,
ICD-10 code description
Diabetes mellitus

Primary outcomes

1

Description
Glycosylated Hemoglobin (HbA1c)
Timepoint
Baseline, 3 months, 6 months
Method of measurement
Laboratory Measure

Secondary outcomes

1

Description
Lipid profiles (TG, Cholesterol,HDl, LDL
Timepoint
Baseline, 3 months, 6 months
Method of measurement
Laboratory Measures

2

Description
Blood Pressure
Timepoint
Baseline, 3 months, 6 months
Method of measurement
Clinical Measure

3

Description
Body Mass Index (BMI)
Timepoint
Baseline, 3 months, 6 months
Method of measurement
Clinical Measure

4

Description
Diabetes Self-Management Behavior
Timepoint
Baseline, 3 months, 6 months
Method of measurement
Diabetes Self-Management Questionnaire (DSMQ)

5

Description
Self-efficacy
Timepoint
Baseline, 3 months, 6 months
Method of measurement
Diabetes Management Self-Efficacy Scale (DMSES)

6

Description
Quality of life
Timepoint
Baseline, 3 months, 6 months
Method of measurement
World Health Organization Quality of Life Scale (WHOQOL-BREF)

7

Description
Depression
Timepoint
Baseline, 3 months, 6 months
Method of measurement
The Center for Epidemiology Studies Short Depression Scale (CES-D)

8

Description
Social Support
Timepoint
Baseline, 3 months, 6 months
Method of measurement
Medical Outcome Study (MOS) Social Support Survey (SSS) tool

9

Description
Outcome Expectation
Timepoint
Baseline, 3 months, 6 months
Method of measurement
The Perceived Therapeutic Efficacy Scale (PTES)

Intervention groups

1

Description
Intervention Group: Receiving the diabetes self-management booklet: The content of “diabetes self-care booklet” provided by Paul Tracy “learning about diabetes” (Tracy, 2015) and American Diabetes Association Website (ADA) (American Diabetes Association, 2015c). The booklet provides general information about how to perform daily self-management activities including diet control, physical activity, blood glucose monitoring, adherence to medication regimen, foot care and healthy living with diabetes. Booklet is

easy to read and understand with illustrations and photographs related to self-management of diabetes. The booklet will be given out in the first week of intervention. The content of the booklet will be used in the full-length of entire intervention to further their learning, discussion or to create resources for use.

Category

Behavior

2

Description

Intervention Group: Viewing four 10-min movie episodes: During the first 4 weeks of the intervention, participants will be invited to watch four 10-min movie weekly episodes with instructions to remember it. The content of the movie is based on the diabetes self-care booklet. The movie is designed to provide participants with verbal persuasion by describing what T2DM is, short term and long term complications, how to prevent or delay complications and the key steps to diabetes management (session 1), introduction to physical activity and foot care (session2), introduction to healthy eating (session 3), and how to healthy living with diabetes (session 4). The entire movie was created with Powtoon animated video. The movie content is inspired by "animated diabetes patient" website available at: (http://www.animateddiabetespatient.com/en/clist.aspx?c=patient%20video). A copy of the movie will be given to the participants at the end of forth group session.

Category

Behavior

3

Description

Intervention Group: Participating in four weekly group sessions: Four group sessions at weekly interval will be undertaken. The goal of group session is to help patients acquire the information, knowledge, self-management practices, goal setting, action plan, problem solving and coping skills required for the effective self-management of their diabetes. All group sessions will be held at times convenient to the participants and the seating will be limited to 10 participants. Each group session will be lasted 120 minutes (2 hours) and contain fostering self-efficacy enhancing skills, self-goal setting, action plan, problem solving, sharing and peer support for diabetes and will be facilitated by the researcher. The discussion will begin with introduction and explanation of the purpose of the meeting. Verbal informed consent will be obtained. Confidentially will be assured and all participants have same opportunity to share and discuss their opinions. A prepared moderator's guide will be applied to provide a semi-structured technique. The focus of the discussion will be (1) to introduce team members to each other (2) to uncover the participants' awareness and current level of knowledge about diabetes and importance of managing it (3) to set a SMART goals (S-specific (target a specific area for improvement), M- measurable (quantify or at least suggest an indicator of progress), A- assignable (specify who will do it), R-realistic (state what results can realistically be achieved, given available resources), T-time related (specify when the result(s) can be achieved), (4) to produce action plans (5) empowerment and problem-solving skills (6) invite recommendations for future programs including a discussion of motivations and barriers related to diabetes management. Open ended questions will be used to stimulate independent exploration and development of comments and ideas. Moreover, the material in the "Diabetes Self-management" booklets will be used in each session. Participants will be strongly encouraged to attend these sessions accompanied by one family member that will provide a beneficial family support for patient.

Category

Behavior

4

Description

Intervention Group: Participating in Telephone Follow-up: During the two months following the end of the focus group sessions, the researcher provided one call per week to participants in the experimental group. The length of each call varies depending on the participant. All telephone calls will be arranged at participants` convenience times. The purpose of calling is to foster continued performance accomplishment via verbal persuasion. In addition, Telephone follow-up will provide continuous enhancing skills fostering, goal-setting sharing and mental support for diabetics through the use of motivational interviewing (MI). Motivational interviewing will be use as tool for behaviour change. The MI counselling approach is patient oriented and it can be used to enhance patient adherence to diet, physical activity, and smoking counselling in daily routine (Miller & Rollnick, 2003). The initial step in MI is to set a specific agenda for consultation together with the participant (Miller & Rollnick, 2003). "Agenda setting" will be an issue to remember right from the beginning of the interview. The key question will be "what are we going to talk about?" Participants will be encouraged to choose one key item in the agenda setting. This make the telephone follow up more structured and will cause a more precise action plan. Then, the researcher will evaluate the patient current behavior and desire for change by rating and exploring confidence and importance regarding the selected key item. This will be done by asking open ended questions, affirmations, reflective listening, summaries, express empathy, develop discrepancy, role with resistance, support self-efficacy, and reinforcing positive change-talk and new behavior. If there is a need and adequate desire for change with the respect to the key item, the researcher will consult with the patient to choose an item as the goal for behavior change (Jansink et al., 2009).

Category

Behavior

5

Description

Control Group: Usual diabetes care will be provided for all patients regardless of group allocation. The usual

diabetes care practice is based on the Iranian Ministry of Health Guideline on the management of the T2DM, that involve education on self-care management, lifestyle modification (including diet, physical activity, monitoring, feet care) and medications. This education will be provided on an individual basis at three-monthly interval with the duration of 20 -30 minutes per appointment. Face to face lecturing method and pamphlets are used in content delivery. The content consisted of a small amount of information and is mostly confined to the five pillar of diabetes management, i.e.: diet, physical activity, medication, blood glucose monitoring and foot care. Clinical examination and laboratory tests are generally conducted during each visit in accordance with national diabetes guidelines. Based on the result of laboratory tests and examination, individual counseling, recommendation, and renewal of prescribed medication is given at these checkups. Usual diabetes care involves a multidisciplinary team care approach with the patient at the center of the team. Healthcare team includes an internist, a diabetes nurse educator, a nutritionist, a pharmacist and if necessary shared care with an ophthalmologist and endocrinologist.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Mostafa Khomeini Hospital

Full name of responsible person
Golnaz Azami

Street address
Shahid Mostafa khomeini Hospital, Ilam, Iran

City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Medical University of Ilam, Iran

Full name of responsible person
Dr Behzad Badakhsh

Street address
Ilam Medical University, 6939177143, Pajohesh Blvd, Bangangab, Ilam, Iran

City
Ilam

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for research, Medical University of Ilam, Iran

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty