ISRCTN15662612 https://doi.org/10.1186/ISRCTN15662612

Motivational interviewing in the management of type 2 diabetes mellitus

Submission date
01/04/2016

Recruitment status
No longer recruiting

Registration date
13/04/2016

Overall study status
Completed

Last Edited
18/11/2021

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Type 2 diabetes mellitus (T2DM) is a growing problem worldwide. People with T2DM have difficulty controlling their blood sugar (glucose) as they do not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). An important part of diabetes management maintaining a healthy lifestyle, namely eating well, exercising and taking medication properly. Transtheoretical Model (TTM)–based motivational interviewing is a technique used to change behaviour. It works by progressing gradually through a series of stages so that the patient is able to move from being uninterested or unwilling to change to considering to change and deciding and preparing to make a change. The aim of this study is to find out whether the TTM-based motivational interview method is an effective way of improving self-efficacy, metabolic control, and health behaviour in adults with T2DM.

Who can participate?
Men and women aged between 20 and 65 with type 2 diabetes

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group take part in the TTM-based motivational interview every 15 days or every month (depending on the needs of the individual) for six months. Through these sessions, the interviews focus on blood sugar monitoring, eating well and exercising, and taking medication properly. Participants in the second group continue to receive usual care alone for six months. At the start of the study and again after six months, participants in both groups complete a number of questionnaires in order to assess their lifestyle and self-efficiency, as well as having their blood sugar and weight measured.

What are the possible benefits and risks of participating?
Participants may benefit from being able to change their behaviour, which could have a positive impact on how well they are able to control their blood sugar. There are no notable risks involved with taking part in this study.

Where is the study run from?
Erciyes University Hospital (Turkey)

When is the study starting and how long is it expected to run for?
January 2013 to May 2013

Who is funding the study?
Erciyes University (Turkey)

Who is the main contact?
Dr Alime Selçuk-Tosun
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Project No: TDK-2013-4699

Study information

Scientific Title
The effect of transtheoretical model–based motivational interview on self-efficacy, metabolic control, and health behavior in adults with type 2 diabetes mellitus: A randomised control study

Study objectives
Hypotheses:
1. The self-efficacy scores of participants in the intervention and control groups do or do not

differ statistically at follow-up
2. The metabolic scores of participants in the intervention and control groups do or do not differ statistically at follow-up
3. The exercise behavior change stages of participants in the intervention and control groups do or do not differ statistically at follow-up
4. The nutrition behavior change stages of participants in the intervention and control groups do or do not differ statistically at follow-up
5. The medication use behavior change stages of participants in the intervention and control groups do or do not differ statistically at follow-up

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of University Clinical Studies (EUCS), 08/01/2013, ref: 2013/14

Study design
Interventional

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus

Interventions
Participants are randomly allocated to one of two groups.

Intervention group: Participants undergo a 30 to 45 minute TTM-based motivational interview every 15 days or monthly, depending on the participant's individual needs. Motivational interview methods such as expressing empathy, developing discrepancy, rolling with resistance, supporting self-efficacy, avoiding giving advice, providing simple decisional balance, using an importance-confidence scale, using open-ended questions, reflecting, and summarizing are used. Three forms are used in the motivational interviews, namely a blood glucose follow-up table, a medication use and walking form, and a food intake record form, which are used to ensure monitoring of blood glucose levels, medication use, and proper nutrition on a regular basis and to help participants exercise regularly.

Control group: Participants receive no TTM-based motivational interview and continue to receive usual care in the polyclinic.

Participants in both groups are followed up after six months.

Intervention Type
Behavioural

Primary outcome measure
Self-efficiency is measured using the Self-Efficacy Scale at baseline and six months.

Secondary outcome measures
1. Metabolic values (glycated hemoglobin (HbA1c), weight, body mass index, and waist circumference) is measured taking intravenous blood in the laboratory at baseline and six months
2. Number of steps is measured using a pedometer at baseline and six months
3. Behavior change stage of nutrition, exercise, and medication use is measured using Diagnosis Form for Behavioral Change Stage in Patients with Type 2 Diabetes Mellitus at baseline and six months

Overall study start date
01/01/2013

Completion date
10/05/2015

Eligibility

Key inclusion criteria
1. Type 2 diabetes mellitus diagnosis for 6 months or longer with hypertension or dyslipidemia
2. Aged between 20 and 65 years
3. Primary school graduates
4. Body mass index (BMI) of 25 kg/m2 or more (overweight or obese)
5. Glycated hemoglobin (HbA1c) level of 7% or more
6. Using oral diabetic medication or insulin or both

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
70

Key exclusion criteria

1. Medical problems that hinder exercise
2. Serious peripheral or autonomic neuropathy
3. Severe retinopathy
4. Psychiatric disorders

Date of first enrolment
08/01/2014

Date of final enrolment
18/11/2014

Locations

Countries of recruitment
Türkiye

Study participating centre
Erciyes University Hospital
Endocrinology and metabolism polyclinic
Feyzioğlu Street No. 42
Kayseri
Türkiye
38039

Sponsor information

Organisation
Erciyes University

Sponsor details
The Scientific Research Project Coordination Department
Köşk
Talas Blv
Kayseri
Türkiye
38039

Sponsor type
University/education

Website
http://bap.erciyes.edu.tr

ROR

https://ror.org/047g8vk19

Funder(s)

Funder type
University/education

Funder Name
Erciyes University (Erciyes Üniversitesi)

Alternative Name(s)
Erciyes University

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Türkiye

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/05/2019	18/11/2021	Yes	No