

# Motivational interviewing in the management of type 2 diabetes mellitus

<b>Submission date</b> 01/04/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 13/04/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/11/2021	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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  
alimetosun@selcuk.edu.tr

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Alime Selçuk-Tosun

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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-efficacy 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/m<sup>2</sup> 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

## 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?
<a href="#">Results article</a>		14/05/2019	18/11/2021	Yes	No