

# Peer support added to diabetes education to improve type 2 diabetes outcomes in a Mexican Mayan community

<b>Submission date</b> 12/07/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 18/07/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 02/03/2021	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Type 2 diabetes is a lifelong condition where the pancreas doesn't produce enough insulin or the body's cells don't react to insulin, causing a person's blood sugar level to become too high. Mexico has the highest levels of type 2 diabetes (14.7%) in all of the American Continent. In the Mexican Mayan population, factors like poverty and language barriers increase the problems of living with diabetes. Peer support is a promising approach to diabetes care as it helps diabetes patients to support each other throughout their everyday lives with self-management treatment. This program is the first of its kind in Mexico to include peer diabetes support. The aim of this study is to assess the effects of peer support when added to a diabetes education program on blood sugar control, in comparison to a conventional diabetes education program, in patients with type 2 diabetes in a Mexican Mayan community.

### Who can participate?

Adults living in the community of Komchen, who are over the age of 18 and who have a physician's diagnosis of type 2 diabetes

### What does the study involve?

The diabetes educational program is first promoted simply using a van with loudspeakers (which is the usual method to inform the community about new events). Posters are pasted in key places in the community (clinics, church, market) and also by word of mouth. Participants must have a previous diagnosis of type 2 diabetes which is corroborated in their health cards. Participants are randomly allocated to one of two groups. Those in the first group are asked to participate in the education program. Those in the second group are asked to participate in the education program and to attend peer-support meetings. The study lasts a total of 8 months. Participants are asked to give blood samples and to complete questionnaires and assessments three times during the study: at the beginning, and at 4 and 8 months.

### What are the possible benefits and risks of participating?

The benefits for the participants are that they had free access to diabetes education, physical activity and constant blood sugar measurements. There is no risk of participating in the

educational intervention. Giving blood samples has minimal risks; the blood sample collection guidelines are followed to avoid these risks.

Where is the study run from?

The study is run by the Universidad Autonoma de Yucatan and the Universidad Marista de Merida and takes place within the participants' community.

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

March 2015 to October 2015

Who is funding the study?

1. Fundacion Bepensa A. C
2. Universidad Marista de Merida
3. Consejo Nacional de Ciencia y Tecnología

Who is the main contact?

1. Prof. Karen Castillo-Hernandez  
nutricalli@gmail.com
2. Prof. Hugo Laviada Molina

## Contact information

**Type(s)**

Scientific

**Contact name**

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## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

FMED-CANH-2015-001

## **Study information**

**Scientific Title**

Peer support added to diabetes education to improve type 2 diabetes outcomes in a Mexican Mayan community: a randomized controlled trial

**Study objectives**

Peer education will lead to a more significant reduction in A1c levels at 4 and 8 months of follow-up in comparison to conventional diabetes education in patients with type 2 diabetes in a Mayan Mexican community.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics Committee of the Faculty of Medicine of the Universidad Autonoma de Yucatan (UADY), 21/11/2014, ref: 21-11-2014-FMed-UADY

**Study design**

Single-centre pragmatic randomized control trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Community

**Study type(s)**

Treatment

**Participant information sheet**

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

## **Health condition(s) or problem(s) studied**

Type 2 diabetes

## **Interventions**

Fifty-eight adults of the community of Komchen (Yucatan, Merida) with previous diagnosis of type 2 diabetes were recruited from the community clinics and randomized following simple randomization procedures using EpiInfo 6.04 statistical software in a 1:1 ratio to:

1. The Peer Support and Education Group (PSEG)
2. The Education-only Group (EG)

All participants in the study attended a four-month Diabetes Self-Management Education Program (DSMEP) delivered by a certified diabetes educator. The DSMEP consisted of 16 weekly group sessions of one hour duration. Additionally, all participants completed a comprehensive one-on-one nutrition counseling session with a dietitian during the first month of the study; and had access to four 50-minute weekly exercise sessions lead by certified trainers who had previous experience in working with adults with chronic diseases.

Participants in the PSEG also attended peer support meetings facilitated by nine leaders with type 2 diabetes.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

A1c level, measured from blood samples using NGSP-certified method at baseline, 4 and 8 months

## **Secondary outcome measures**

Measured at baseline, 4 and 8 months:

1. Systolic and diastolic blood pressure; average of two readings measured on an OMRON HEM-7220 Automatic BP monitor
2. BMI: weight measured on an OMRON F514 balance and height measured on a SECA 213 Mobile Stadiometer
3. Diet, assessed by trained dietitians
4. Physical activity, measured with the International Physical Activity Questionnaire
5. Diabetes-related self-care behaviors, assessed using the Summary of Diabetes Self-Care Activities Measure
6. Diabetes-related quality of life, measured using the Diabetes 39 Questionnaire

## **Overall study start date**

09/09/2014

## **Completion date**

29/10/2015

## **Eligibility**

### **Key inclusion criteria**

1. Physician diagnosis of type 2 diabetes
2. >18 years of age

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

52

**Key exclusion criteria**

1. Severe medical or psychiatric conditions such as hearing impairment or substance abuse
2. Pregnancy

**Date of first enrolment**

12/01/2015

**Date of final enrolment**

19/03/2015

## Locations

**Countries of recruitment**

Mexico

**Study participating centre****Ayudar es compartir**

Domicilio conocido Komchen

Yucatan

Merida

Mexico

97302

## Sponsor information

**Organisation**

Autonomous University of Yucatán

**Sponsor details**

Avenida Itzáes No. 498 x 59 y 59A Col. Centro  
Merida  
Mexico  
97000

**Sponsor type**

University/education

**Website**

<http://www.medicina.uady.mx/principal/index.php>

**ROR**

<https://ror.org/032p1n739>

**Organisation**

Universidad Marista de Merida

**Sponsor details**

Periférico Norte Tablaje Catastral 13941  
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Merida  
Mexico  
97300

**Sponsor type**

University/education

**Website**

<http://www.marista.edu.mx/>

**Funder(s)****Funder type**

University/education

**Funder Name**

Bepensa Foundation, A. C.

**Funder Name**

Marista University of Merida

**Funder Name**

Consejo Nacional de Ciencia y Tecnología

**Alternative Name(s)**

Consejo Nacional de Ciencia y Tecnología, National Council of Humanities, Sciences and Technologies, Mexican National Council of Science and Technology, National Council for Science and Technology (CONACyT), National Council of Science and Technology, Mexico, Conahcyt

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Mexico

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal.

**Intention to publish date**

31/07/2019

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Fernanda Molina (fmolina@marista.edu.mx). The type of data is numeric data on Excel sheets. Since data capture is finished, it is available from now on and until December 2017. Consent was obtained in the Informed Consent Letter which was read and explained to participants. In order to maintain data anonymisation, names were never captured on the computerized data sets, only the ID number. Due to the nature of the intervention which was educational, there were no other ethical or legal restrictions.

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>		25/01/2019	25/01/2019	No	No
<a href="#">Results article</a>	results	01/04/2021	02/03/2021	Yes	No