

# How effective is a 2-year peer-support diabetes education program, for type 2 diabetes, in a semi-rural Mayan community in the Yucatán, Mexico?

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<b>Registration date</b> 07/07/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 19/01/2024	<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

### Background and study aims

There is a lack of certified diabetes educators in Mexico. Diabetes is a burden to the national health budget and overcomes the capacity of Mexican public health infrastructure.

Peer leaders are people with diabetes who are trained to acquire skills designed to empower other people living with diabetes, amplify educational strategies, and improve outcomes of conventional diabetes education programs.

The investigators have previously proven, in the short term period, a model of Diabetes Education supported by peers resulting in better diabetes outcomes when added to a conventional diabetes education program in a semi-rural Mayan population (<http://isrctn.com/ISRCTN40146390>). However, there is no information yet on the sustainability of the effects on the outcomes for people with diabetes in a midterm time frame (2 years).

This study aims to determine the midterm effects of a diabetes education program supported by peers and its sustainability over this period of time.

### Who can participate?

Adults living in the community of Komchen, who are over the age of 30 and who have a physician's diagnosis of type 2 diabetes.

### What does the study involve?

Participants will be randomly allocated to one of two groups. Those in the first group will be asked to participate in the education program. Those in the second group will be asked to participate in the education program and to attend peer-support meetings. The study will last a total of two years. Participants will be asked to give blood samples every 4 months and to complete questionnaires and assessments at the start of the study and then at 12 and 24 months.

What are the possible benefits and risks of participating?

The benefits for the participants are free access to diabetes education, physical activity, and constant glucose measurements. There is no risk for participating in the educational intervention. Giving blood samples implies minimal risks; the blood sample collection guidelines will be followed to avoid these risks.

Where is the study run from?

The Universidad Marista de Merida (Mexico) and will be carried out within the community.

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

From November 2017 to November 2019.

Who is funding the study?

AstraZeneca S.A. de C.V. México (Mexico)

Who is the main contact?

1. Prof. Karen Castillo-Hernandez

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2. Prof. Hugo Laviada Molina

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## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

ESR-16-12030

## Study information

### Scientific Title

Effectiveness of a 2-year peer support diabetes education intervention, for type 2 diabetes, implemented in a semi-rural Mayan community in the Yucatán, Mexico: A randomised clinical trial

### Study hypothesis

People with type 2 diabetes exposed to an intervention program of diabetes education, which is reinforced by peer leaders, are able to achieve and maintain better metabolic control in the midterm, compared with a population of people living with type 2 diabetes who receive the conventional diabetes education provided by health authorities in rural communities in Yucatan, during the same period of time.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 03/02/2017, Marista University Ethics Committee (Periférico Norte; Tablaje catastral 13941, Carretera Mérida-Progreso, C.P. 97300 Mérida, Yucatán, México; +52 999 942 97 00), ref: CEUMM\_002\_2017

### Study design

Single-center prospective randomized controlled study

### Primary study design

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Community

## **Study type(s)**

Prevention

## **Participant information sheet**

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

## **Condition**

Type 2 diabetes

## **Interventions**

This is a trial with a 2-year duration for participants with a previous diagnosis of type 2 diabetes, recruited from the community clinics in Conkal, Yucatán.

Participants will be assigned, in a 1:1 ratio, to either the Peer Support and Education Group (PSEG) or the Education-only Group (EG):

1. The Peer Support and Education Group (PSEG) uses a cultural adaptation of an international proven strategy of a peer support diabetes self-management program that has been developed by the investigators. These materials were tailored to local culture and customs. This group of participants will follow this model of education for 2 years. Diabetes self-management education program (DSME) consists in one-hour group sessions, with option of morning or afternoon meeting, one day a week only, in the Municipal Office of National System for Integral Family Development (DIF) of the Villa de Conkal conducted by a certified diabetes educator. Following the education session, participants are invited to stay for a 50-minute physical activity period. Aside from DSEM general sessions, only participants in the PSEG are assigned to one of 13 peer leaders. Study design foresees weekly attendance to peer support meetings in the community premises or at leaders' homes, facilitated by their own peer leader without the presence of trial team members, but with the possibility to contact diabetes educator for doubts and reassurance.

Leaders were trained to start each meeting with an icebreaker introduction followed by a discussion session and a goal setting as described on the Peer Leader Manual [32]. The discussion segment is based on the DSME theme of the previous education session, or according to groups' needs and interests.

2. The Education-only Group (EG) will receive standard care, over the same 2 year time period, via the conventional diabetes education support group promoted by official health system authorities in Mexico (without peer leader support).

All participants will be asked to give blood samples every 4 months and to complete questionnaires and assessments at baseline, 12, and 24 months, for assessment of the effectiveness of the intervention.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Metabolic control assessed using glycated haemoglobin level (HbA1c) measured from blood samples taken at baseline, 4, 8, 12, 16, 20 and 24 months

### **Secondary outcome measures**

1. Quality of life measured using the SF-36 Health Survey at baseline, 12, and 24 months
2. Systolic and diastolic blood pressure measured using an average of two readings measured on an OMRON HEM-7220 Automatic BP monitor at baseline, 4, 8, 12, 16, 20 and 24 months
3. Body Mass Index (BMI) calculated from weight, which was measured on an OMRON F514 balance, and height, which was measured on a SECA 213 Mobile Stadiometer, at baseline, 4, 8, 12, 16, 20 and 24 months
4. Self-reported use of diabetes-related self-care behaviors measured using the Summary of Diabetes Self-Care Activities Measure (SDSCA) at baseline, 12, and 24 months

### **Overall study start date**

01/12/2016

### **Overall study end date**

28/11/2019

## **Eligibility**

### **Participant inclusion criteria**

1. Diagnosis of type 2 diabetes mellitus
2. Aged  $\geq 30$  years
3. Identified in community health centers of Conkal, Yucatán
4. Wish to participate in the study

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

152

### **Total final enrolment**

155

### **Participant exclusion criteria**

1. Diagnosis of physical disabilities and cannot be displaced from their homes
2. Diagnosis of a mental illness or severe learning difficulties
3. Pregnancy

### **Recruitment start date**

16/08/2017

**Recruitment end date**

15/11/2017

## Locations

**Countries of recruitment**

Mexico

**Study participating centre****DIF MUNICIPAL**

The Municipal Office of National System for Integral Family Development (DIF) of the Villa de Conkal

Mérida, Yucatán

Mexico

97345

## Sponsor information

**Organisation**

AstraZeneca (Mexico)

**Sponsor details**

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**Sponsor type**

Industry

**Website**

<https://www.astrazeneca.com/country-sites/mexico.html>

## Funder(s)

**Funder type**

Industry

## Funder Name

AstraZeneca (Mexico)

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

## Intention to publish date

30/08/2020

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Hugo Laviada (hlaviada@marista.edu.mx). The type of data will be that will be shared is data not protected by confidentiality. The data will become available after publication in a peer-reviewed journal, data will be available indefinitely

## 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>		12/01/2022	12/01/2022	No	No
<a href="#">Other publications</a>	Lessons learned from a peer-supported diabetes education program in two dissimilar Mayan communities	04/01/2024	19/01/2024	Yes	No