

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

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?

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Contact information

Type(s)

Scientific

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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 objectives

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

Health condition(s) or problem(s) studied

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 DSME 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

Completion date

28/11/2019

Eligibility

Key inclusion criteria

1. Diagnosis of type 2 diabetes mellitus
2. Aged ≥ 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

Key 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

Date of first enrolment

16/08/2017

Date of final enrolment

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?
Basic results		12/01/2022	12/01/2022	No	No
Other publications	Lessons learned from a peer-supported diabetes education program in two dissimilar Mayan communities	04/01/2024	19/01/2024	Yes	No