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Dulce Wireless Tijuana: Impact of the project Dulce TM and mobile technology on metabolic outcomes, quality of life and behaviors

Submission date
28/03/2014

Recruitment status
No longer recruiting

Registration date
17/04/2014

Overall study status
Completed

Last Edited
23/01/2019

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
This Project Dulce study will examine the impact of different strategies on glycemic control, diabetes self-management, quality of life and healthy life style for patients with type 2 diabetes (when the body does not produce enough insulin or the body does not react to insulin) in underserved communities in Mexico.

Who can participate?
Adults with type 2 diabetes, poor metabolic control and no current use of insulin.

What does the study involve?
Participants will be randomly allocated to one of three groups:
- Project Dulce only (PD): Clinical management by medical and nurse-certified diabetes educators and self-management education provided by community workers.
- Project Dulce + Technology Enhanced model (PD-TE): same as above plus use of Glucose meters with USB connections, cell phones with 3G technology for real-time data relay, alerts by text messages, wireless technology for improved communication between patients, doctors and community workers.
- Standard care (Control): monthly visit to doctor, access to laboratories and medications and educational classes.

What are the possible benefits and risks of participating?
Participants are able to receive additional educational and technological resources in order to improve the management of their condition, metabolic outcomes, healthy life style and quality of life. If participants are in the Control group, they are to receive the outreach education after the completion of the study. Apart from some discomfort due to glucose testing, there are no significant risks for the partcipants.

Where is the study run from?
The study is conducted in the largest Family Medicine Clinic of Mexico in Tijuana, Mexico.

When is the study starting and how long is it expected to run for?
The study started in November 2011 and will finish in March 2014.

Who is funding the study?
Private and public sector. The main financial sponsors are Qualcomm Inc. and IUSACELL. Other in-kind contributors are the Instituto Mexicano del Seguro Social (IMSS), the International Community Foundation (ICF), Universidad Autónoma de Baja California (UABC), Scrips Whittier Diabetes Institute (SWDI), Fronteras Unidas Pro Salud, (Pro Salud) and the Fundación Internacional de la Comunidad (FIC).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
CNIC-R-2011-785-019

Study information

Scientific Title
Dulce Wireless Tijuana: A randomized controlled trial studying the impact of the project Dulce TM and mobile technology on metabolic outcomes, quality of life and behaviors

Acronym
DWT

Study objectives
The benefit observed in metabolic control, lifestyle, quality of life, self-efficacy in the management and knowledge of the disease is higher in the intervention groups compared with the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Commission and its Bioethical Committee of the Instituto Mexicano del Seguro Social (IMSS); August 2011; ref: CNIC-R-2011-785-019

Study design
Clinical randomized controlled trial single blind single-centered with 3 parallell groups and a 10th month follow-up

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Diabetes Type 2

Interventions
The DWT study randomly assigned patients to the following three arms:
1. Project Dulce TM intervention only (PD)
2. Project Dulce + Technology Enhanced intervention(PD-TE)
3. Standard of care (Control)

1. The clinical education arm Project Dulce (PD) is based on the Project Dulce™ chronic care multidisciplinary model with peer-led diabetes education and consists of two components:
1.1. Clinical management by medical and nurse-certified diabetes educators trained in the multidisciplinary chronic care model and use of clinical algorithms.
1.2. Self-management education provided by community workers. The outreach workers follow the peer educational curriculum Diabetes Among FriendsTM. Patients receive eight diabetes self-management sessions and one orientation by the outreach workers during the first two months of the study. After these two months, patients are invited to participate in eight monthly support meetings.

2. The Project Dulce-Technology Enhanced (PD-TE) arm included the same Project Dulce Model as in PD plus the following technology:
2,.1. Glucose meters with USB connections: We provided glucose meters to patients. They measure their glucose levels twice a day during the first month and biweekly the second month. Measures were uploaded via a USB connection at the end of the week.
2.2 Cell phones with 3G technology that allow: An interactive motivational survey via 3G mobile cell phones able to relay data in real-time. This survey is sent once a day during the first month and twice a week the second month; culturally appropriate designed videos and educational materials uploaded to patients cell phones. Patients were encouraged to watch these videos and materials as they pleased in order to clarify the topics covered during classes.
2.3. Compatible electronic diabetes management registry able to send alerts and notifications via SMS . Patients received alerts via text messages when they reported glucose readings below or above the normal range. They also received notifications when they missed an appointment at the clinic, at the laboratory or a class.
2.4. Wireless technology will allow clinical, administrative staff and community outreach workers

to share patient information, avoid duplication and keep patients from falling through the cracks of an otherwise fragmented system of care. The technology-enhanced arm of the study works by consolidating and centralizing patient information and by extending diabetes education to communities via 3G services such as interactive surveys, relevant video content and community classes. Patients, promotores (community health workers), nurses, and doctors access the system via mobile devices such as cell phones, smartphones, netbooks and laptops. Technology facilitates communication among the different levels of care, including, primary care, community outreach and the patients home or work.

3. The Control Group (CG) received the standard of care provided by IMSS guidelines. The standard of care includes access to a monthly visit with a physician for an average of 15 minutes. It also includes access to laboratories and medications. Educational classes are available for patients that are willing and able to participate. Also, patients were able to participate in a model of group medical visits once a month under the program DiabetIMSS. Approximately half of the patients joined the medical group modality and the other half remained with the traditional one-on-one care.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Hb A1C measured using metabolic tests at baseline, fourth and tenth month

Key secondary outcome(s))
1. Quality of life (QoL) is evaluated using the Diabetes 39 instrument . This instrument has been validated in Spanish and in Mexico by Juan Manuel Lopez-Carmona and Raymundo Rodriguez-Moctezuma.
2. Lifestyles (LS) are evaluated using the IMEVID instrument (Instrument to measure lifestyle of type 2 diabetes mellitus patients). This instrument has been validated in Spanish and in Mexico by Juan Manuel Lopez-Carmona et.al.
3. Self efficacy is evaluated using the instrument Spanish Diabetes Self-Eficacy. This instrument was prepared by Stanford Patient Education Research Center and was adapted to Spanish.
4. Depression measured by the PHQ9 instrument at baseline and the tenth month. This instrument is developed by Spitzer et.al. and has been validated to Spanish.
5. Diabetes knowledge evaluated using the Diabetes Knowledge Questionnaire 24. This instrument was develop and validated to Spanish by Alexandra A. Gracia, et.al. (The Starr County Diabetes Education Study)
6. Total cholesterol, HDL, LDL and triglycerides measured at baseline, fourth and tenth month

Completion date
04/01/2014

Eligibility

Key inclusion criteria
1. Adults 18-75 years old
2. Diabetes Mellitus type 2
3. Glycated haemoglobin (HbA1c) ≥8%

4. No current insulin use
5. Member or holder of IMSS clinic 27 insurance

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Key exclusion criteria
1. Patients without insurance to IMSS UMF No. 27
2. Pregnant women
3. Patients without physical or mental capacity to attend clinic visits and self-care classes for reasons beyond diabetes

Date of first enrolment
11/01/2011

Date of final enrolment
04/01/2014

Locations

Countries of recruitment
Mexico

Study participating centre
Boulevard Diaz Ordaz S/N Km 11.5
Tijuana
Mexico
22650

Sponsor information

Organisation
Mexican Social Security Institute (Instituto Mexicano del Seguro Social) (Mexico)

ROR
https://ror.org/03xddgg98

Funder(s)

Funder type
Industry

Funder Name
Qualcomm Inc. (USA)

Funder Name
Iusacell (Mexico)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2016	23/01/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes