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Mobile Phone Diabetes Support Study

Submission date
29/11/2011

Recruitment status
No longer recruiting

Registration date
25/01/2012

Overall study status
Completed

Last Edited
30/10/2017

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
This project examines if the use of mobile phone communication between people with diabetes and their healthcare givers improves existing diabetes self-management programmes in Congo, Cambodia and the Philippines. Mobile phones will be given to people to enable them to call for support. They will receive messages and calls about behaviour change and results and reminders to appointments and taking of medication.

Who can participate?
People older than 18 years who are known to have (pre-)diabetes and who receive existing Diabetes Self-Management Education (DSME) in the participating study centres can participate. Diabetes education, also known as diabetes self-management training (DSMT) or diabetes self-management education (DSME), is defined as a collaborative process through which people with or at risk for diabetes gain the knowledge and skills needed to modify behavior and successfully self-manage the disease and its related conditions

What does the study involve?
The intervention involves the sending of Short Messages Services (SMS) to people with diabetes to support them in the self-management of their disease, on top of their routine care in the self-management programme. Sending a SMS intervention (the intervention group) will be compared with routine care only (the control group). All participants in the intervention group will receive SMS, but the content and frequency of the messages will be adjusted to the profile of the patient and of his diabetes, for instance the use of insulin or not.

What are the possible benefits and risks of participating?
The potential benefits for participating people in the intervention group are an increased capacity for self-managing their diabetes, increased quality of care and improved diabetes control. Participants in both groups will continue to receive their normal care and support in the pre-existing programme. The pre-existing programme will be analysed and where needed optimised, which will benefit all participants in the study. Other benefits for all participants are receiving a mobile phone for free and half-yearly determination of glycosated haemoglobin for free. The risks are similar to those of the usual care - such as the finger prick for blood tests - and risks related to the use of mobile phones, for instance the cost of making phone calls, the loss of the phone and the sharing of the phone with others.

Where is the study run from?
The study will take place in 3 countries, the Democratic Republic (DR) of Congo, Cambodia and the Philippines. There will be 480 participants in each country. In DR Congo, the participants will come from six health centres that are part of the diabetes care network (CS Esengo, CS Mokengeli, CS 2ème Rue, CS Lisanga, CS St Alphonse, CS Kinkenda). In Cambodia, they will come from four provinces (Takeo, BanteayMeanchey, KompongSpeu and Kompong Thom) and Phonm Penh. In the Philippines, participants will be identified by community health workers in Quezon City, Metro Manila, in the City of Batac, IlocosNorte and in Pagudpud, IlocosNorte.

When is study starting and how long is it expected to run for?
The recruitment of participants will be done in June and July 2012. The study will run until September 2014.

Who is funding the study?
This project is supported by a BRIDGES Grant from the International Diabetes Federation. BRIDGES, an International Diabetes Federation project, is supported by an educational grant from Lilly Diabetes.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
11245776

Study information

Scientific Title
Mobile Phone Diabetes Self-Management Support: a multi-country analysis of its implementation in existing Diabetes Self-Management Education Programmes in the Democratic Republic of Congo, Cambodia and the Philippines

Study objectives

The use of mobile phone communication, on top of an existing Diabetes Self-Management Education (DSME) strategy, can improve health outcomes, access to care and self-management for people with diabetes in those programmes, in Democratic Republic of Congo, Cambodia and the Philippines.

Please note that as of 19/10/2012, the target number of participants for this trial was updated from '1200 in the three countries in total: 400 in each country, of which 200 in the intervention and 200 in the control group' to '1320 in total: 480 in each country of which 240 in intervention and 240 in control group'

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Institutional Review Board of the Institute of Tropical Medicine Antwerp, Belgium, 02/08/2011, ref: 11245776 - approval of change 08/08/2012
2. Committee for Medical Ethics, University of Antwerp, Belgium, 03/10/2011, ref: B-300201111924
3. Ethics Committe of the School of Public Health, University of Kinshasa, Democratic Republic of Congo [Comité d'éthique de l'Ecole de Santé Publique (ESP) de l'Université de Kinshasa, Democratic Republic of Congo] 15/12/2011
4. National Ethical Committee for Health Research, Ministry of Health, Cambodia 15/12/2011
5. Research & Ethics Committee, Veterans' Memorial Medical Centre, Philippines 28/08/2012

Study design
Interventional randomised non-blinded multicenter study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Diabetes mellitus

Interventions
The project introduces a Diabetes Self-Management Support intervention in addition to an existing Diabetes Self-Management Education strategy in each country, by providing mobile phones to randomly chosen patients with diabetes to use this for support when needed and to communicate about behaviour change, results and reminders.

Control Group: Routine care only

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

Current primary outcome measures as of 19/10/2012:
The percentage of people with a controlled HBA1c level; controlled being defined as <7.0%.

Previous primary outcome measures until 19/10/2012:
Mean change in glycosated haemoglobin (HbA1C) at the last available time-point after start of the intervention

Key secondary outcome(s))
1. Health outcomes:
1.1. Mean blood pressure
1.2. Mean body mass index (BMI)/waist circumference
1.3. Diabetic foot lesions
2. Access and quality of care:
2.1. Failure to attend rate: number of planned versus actual contacts between patient and educator in the last year
2.2. Perceived quality of care (adapted Patient Assessment of Chronic Illness Care - PACIC)
2.3. Direct and indirect health care expenditure in the last month
3. Enablement:
3.1. Level of knowledge on diabetes and diabetes care (adapted from Michigan Diabetes Research & Training Centers Brief Diabetes Knowledge Test & the Diabetes Knowledge Questionnaire)
3.2. Self-management and feeling of coping (Howie score)
3.3. Adherence to glucose monitoring and control regimes - adherence to healthy lifestyle
4. Process indicators:
4.1. Number and type (conversation or SMS) of Project Initiated Communications towards the person with diabetes
4.2. number and type (conversation or SMS) of Patient Initiated Communications towards educators and other patients
4.3. Intervention cost at the level of the DSMS programme

Completion date
30/09/2014

Eligibility

Key inclusion criteria
1. Diagnosed as having (pre-)diabetes based on the WHO/IDF guidelines
2. Above 18 years old
3. Presently included in an existing Diabetes Self-Management Education strategy in a participating centre
4. Having received at least one session with an educator in the DSME strategy
5. Willing and able to provide written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/06/2012

Date of final enrolment
31/07/2012

Locations

Countries of recruitment
Belgium

Cambodia

Congo, Democratic Republic

Philippines

Study participating centre
Nationalestraat 155
Antwerpen
Belgium
2000

Sponsor information

Organisation
Institute of Tropical Medicine, Antwerp (Belgium)

ROR
https://ror.org/03xq4x896

Funder(s)

Funder type

Government

Funder Name
International Diabetes Federation (Belgium) - Long term Bridges Project (ref: LT10-341)

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	03/01/2017		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes