ISRCTN15790927 https://doi.org/10.1186/ISRCTN15790927

Effect on glucose control and quality of life for people with type 2 diabetes of using a device to measure glucose levels at home and send them to the clinic, rather than attending an out-patient clinic for blood tests

Submission date
23/12/2018

Recruitment status
No longer recruiting

Registration date
25/01/2019

Overall study status
Completed

Last Edited
21/09/2021

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
Diabetes mellitus is a long-lasting disease in which the level of blood sugar is higher than normal. High level of sugar in the blood can lead to serious consequences, including blindness, kidney failure, amputation of limbs, coma and death. Patients with diabetes need to regularly take their medicine and to make sure they monitor the level of sugar in their blood on daily basis. This can affect their quality of life. The aim of this study is to understand if telemedicine (monitoring and treatment without patients having to attend a healthcare facility) and home-based care is more effective than traditional GP and outpatient care in terms of patients taking medication regularly and their quality of life.

Who can participate?
Men and women who live in the study area, have been diagnosed with type 2 diabetes at least 1 year before the start of the study and have been on the same treatment for at least 3 months.

What does the study involve?
The participants will be recruited by GPs and doctors working in diabetes centres. Participants will be randomly assigned to one of two groups. One group will be treated and followed according as usual. They will test their blood sugar level at home and record it on paper. They will attend a diabetes outpatient clinic for follow-up. The other group will record the level of blood sugar using a digital home-based system that will send data to the diabetes clinic for follow-up. All participants will receive treatment as appropriate from the clinic. At the end of the study (after 18 months), the two groups will be compared to assess which group achieved a better control of their blood sugar level and which experienced a better quality of life, assessed using a questionnaire. The participants will also have their height, weight, waist circumference, blood pressure, cholesterol and blood fats measured at the beginning and end of the study.

What are the possible benefits and risks of participating?
All patients will receive medication as usual and the control group will continue to attend outpatient clinic, so there are no additional risks associated with participating in the trial. The telemedicine group might benefit from avoiding the inconvenience of having to attend outpatient clinics and from a more rapid response to changes in their blood sugar level from the clinic.

Where is the study run from?
Catanzaro Health Authority (Italy)

When is the study starting and how long is it expected to run for?
March 2018 to May 2020

Who is funding the study?
GPI SpA, a company that develops telemedicine systems

Who is the main contact?
Dr Maurizio Cipolla (cipolla.maurizio54@gmail.com)

Study website
http://www.ehealth.study/dc20

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EudraCT/CTIS number
2018-002223-41

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2018-DC-2-0

Study information

Scientific Title
Use of telemedical models and devices in the home management of type 2 diabetes mellitus to improve diabetic control - measured as blood sugar and glycated hemoglobin levels - and the patients' perceived quality of life

Acronym
Diabetes CALABRIA 2.0 Project

Study objectives
Patients with Type 2 diabetes mellitus uploading data on a telemedicine system achieve a glycemic control, evaluated in terms of glycated hemoglobin levels, similar to that of patients followed in a traditional diabetes outpatient department, with improvements to quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regione Calabria, Sezione Area Centro Ethics Committee, 21/06/2018, ref: 176 - 21/6/2018

Study design
Longitudinal case-control observational study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
GP practice

Study type(s)
Diagnostic

Participant information sheet
A copy of the information sheet (in Italian) is available for download from: www.ehealth.study/dc20

Health condition(s) or problem(s) studied
Type 2 Diabetes Mellitus (T2DM)

Interventions
Researchers perform a general examination at baseline and measure the following parameters (baseline values) and perform the following investigations for all participants (T2DM adult patients enrolled in GP practices belonging to the Health Units of the Catanzaro area involved in the study [about 35,000 patients]) in both the intervention and control group:
- Weight
- Height
- BMI
- Abdominal circumference
- Winsor Index
- ECG
- Retinography
- Blood level of (fasting values): total cholesterol, HDL cholesterol, LDL cholesterol, blood sugar, triglycerides, glycated hemoglobin
These parameters will be checked again at 3, 6 and 18 months.

During the study patients in the telemedicine group will measure at home:
- Blood sugar (two measurements per week). Participants can measure blood sugar more often that that at their wish or according to a personalized treatment scheme. These data will be part of the dataset and can be analysed thoroughly in retrospect as part of future research). Blood sugar level is measured in mg/dl in a drop of capillary blood with the use of standard glucose meter.
- Body weight (weekly)
- Blood pressure (weekly)
Use of devices that allow the automatic upload of data via wi-fi or web is allowed

The control group will attend their routine appointments scheduled by their GPs and specialists in outpatient clinics and will record blood sugar levels according to the traditional method as per GP or specialist physician's indications. Blood sugar level is measured in mg/dl in a drop of capillary blood with the use of standard glucose meter.

Intervention Type
Behavioural

Primary outcome measure
Level of glycated hemoglobin (GlyH) at the end of the study (18 months) in patients followed with telemedicine and in the control group when compared to baseline, with normal GlyH defined as <5.6%.

Secondary outcome measures
1. Quality of life as perceived by the patients measured using the SF-36 questionnaire at baseline, 6 months and at the end of the study (18 months)
2. BMI calculated from height and weight at baseline and at the end of the study (18 months)
3. Abdominal circumference at baseline and at the end of the study (18 months)
4. Blood triglyceride level at baseline and at the end of the study (18 months)
5. Blood LDL-cholesterol level at baseline and at the end of the study (18 months)
6. Systolic blood pressure at baseline and at the end of the study (18 months)
7. Diastolic blood pressure at baseline and at the end of the study (18 months)

8. Compliance with blood glucose testing, with participants divided into four groups: poor (<50%), mediocre (50-70%), good (70-90%), optimal (90-100%)
9. Hyperglycemic events, defined as a spot measure of fasting blood sugar >300 mg/dl

Overall study start date
01/03/2018

Completion date
31/05/2020

Eligibility

Key inclusion criteria
1. Patients with type 2 diabetes mellitus (T2DM)
2. Diagnosis of DM made at least 1 year before the start of the study
3. Hypoglycemic treatment remained the same in the 3 months preceding the start of the study

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
350

Total final enrolment
161

Key exclusion criteria
1. Diabetes other than T2DM
2. Pregnant women
3. Chronic conditions other than T2DM
4. Unable to give informed consent
5. Dementia or psychiatric conditions that can affect a person's will or ability to participate in the study

Date of first enrolment
01/07/2018

Date of final enrolment
31/10/2018

Locations

Countries of recruitment
Italy

Study participating centre
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GPI SpA

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
GPI SpA

Results and Publications

Publication and dissemination plan
Data and results of the study to be published on peer-reviewed scientific journals covering telemedicine, diabetes and chronic conditions.

Intention to publish date
01/06/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from DIGITCAL (digitcal01@gmail.com). Anonymised data will be made available to recognised research institutions for research purposes. Written request is required, and data will be shared after approval of the scientific and ethical committees of DIGITCAL. Criteria for data sharing are under discussion at the moment.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/02/2021	21/09/2021	Yes	No