ISRCTN51677359 https://doi.org/10.1186/ISRCTN51677359

The effect of Telehealth on community delivered diabetes care: a cross sectional study

Submission date
21/01/2014

Recruitment status
No longer recruiting

Registration date
11/03/2014

Overall study status
Completed

Last Edited
18/08/2020

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Type 2 diabetes (T2DM) is a common cause of illness and death, with sufferers being extensive users of the healthcare system. Studies have suggested that telemonitoring (Tm) can deliver clinical benefits to patients living with chronic conditions including T2DM. However, what has not been clearly established for best clinical benefit is:
Which should be the ideal target patient population?
What is the best duration for comprehensive Tm on an ongoing basis?
How could Tm be better utilised to reflect an individual patients health status at any given time, i.e. can it be flexible and evolve continuously as the patients status changes rather than staying rigid.?
This study aims to address these issues.

Who can participate?
T2DM patients over the age of 18 years who monitor blood glucose levels at home and residing within the Hywel Dda University Health Board area. In addition, 400 historical controls with T2DM who monitored their blood glucose levels at home within the Hywel Dda University Health Board area during the 12 months before the study started. The controls will not be receiving any sort of additional intervention as part of this study other than their usual healthcare usage and access. They will be used as a comparison group only.

What does the study involve?
All study subjects will receive instruction on the use of a provided blood glucose monitoring device and will be sent reminders to perform blood glucose checks by an automated programme. This programme analyses the data according to an individualised set of parameters and provides instant feedback to the patient via their gateway device along with locally agreed advice messages if required. Should a parameter be critically breached the study participant will be advised on immediate action and who to contact. An alert message will also be sent to their primary health care provider which can be reviewed immediately (or the next working day if the anomalous parameter occurs out of working hours).
The controls will not receive any intervention (i.e., Tm), but their medical notes will be used to establish if there has been a reduction in the number of GP appointments.

What are the possible benefits and risks of participating?
The aim will be to deliver a more efficient and effective service for patients. It will be emphasised to patients that the Tm is not a replacement for their usual service delivery, rather that is in combination with standard support. Furthermore, all patients will be treated according to the clinical discretion of their primary care doctors, specialist nurses and hospital specialists. There should be no risks in participating, the interventions provided are intended to supplement rather than replace existing clinical supervision.

Where is the study run from?
The study will be run from the Hywel Dda University Health Board in Wales, UK.

When is the study starting and how long is it expected to run for?
It is expected that the recruitment will begin in early 2014, with the aim of recruiting all patients over a 12-month period. Recruits to the study will then be followed up for 12 months post recruitment. The study will run until December 2016,.

Who is funding the study?
European Commission.

Who is the main contact?
Dr Sam Rice
sam.rice@wales.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Sam Rice

Contact details
Hywel Dda University Health Board
Prince Philip Hospital
Dafen
Llanelli
United Kingdom
SA14 8QF
+44 (0)1554 783598
sam.rice@wales.nhs.uk

Additional identifiers

Protocol serial number
14/WA/0014

Study information

Scientific Title

Does blood glucose telemonitoring (Tm) and remotely delivered lifestyle advice improve self management in Type 2 Diabetes (T2DM)? A cross-sectional study

Study objectives
It is hypothesised that the introduction of home blood glucose Tm coupled with automated health coaching reduces face-to-face primary care contacts over a 12-month period.

The null hypothesis is that there will be no difference in the number of face-to-face GP contacts between those receiving Tm and those not receiving Tm.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Dyfed Powys Research Ethics Committee (Wales REC 7), 14/02/2014, ref: 14/WA/0014

Study design
Non-randomised cross-sectional study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Study subjects will be connected to the backend monitoring via a usual primary care visit and set up through Florence©, Simple Telehealth, Web-based monitoring system (Stoke on Trent, NHS England) (www.florence.co.net). Test runs undertaken locally confirm that the system is 3G compatible so does not require 4G or WiFi but does require a reliable mobile phone signal. The patient will be trained in the use of the Tm equipment and will need to demonstrate satisfactory understanding of text messaging before the patient consents to use.

The study subject will use a provided blood glucose monitoring device for the measurement of blood glucose levels and will be sent reminders to perform their blood glucose readings by an automated programme. The device feeds back the blood glucose level to the patient who then uses a gateway device manually or automatically to transmit the data to an automated programme. This programme analyses the data according to an individualised set of parameters and provides instant feedback to the patient via their gateway device along with locally agreed advice messages if required. Should a parameter be critically breached the patient will be advised on immediate action and who to contact. An alert message will also be sent to their primary health care provider which can be reviewed immediately (or the next working day if the anomalous parameter occurs out of working hours). During the study, the subject will also receive standardised, weekly, health coaching messages and study subjects will be reminded upon entering the study and through the Patient Information Sheet that if they require the attention of a healthcare professional in relation to their diabetes and the message that they have received, that it is their responsibility to make the contact.

The devices used for the Tm will be the patients own unless they do not already have one, in which case one will be supplied by their GP surgery as part of their routine care. The mobile phone used to transmit the glucose readings will once again be the patients own if they do not possess one they will be provided with one ('Huawei' HB4J14 Huawei Technologies) by the lead Research Nurse. Transmission of the results is provided via a free number and so there are no cost implications for patients. Patients who are provided with a phone will only be able to use it to send and receive Tm messages it will not have the capability to send or receive telephone calls, additional text messages etc, and the participant must return it at the end of the study period.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Number of face-to-face primary care contacts between the Intervention and Comparator Groups over 12 months

Key secondary outcome(s))
Assessed 12 months after recruitment

1. Health data:
1.1 HbA1c level
2. Health contacts:
2.1. Number of admissions to secondary care
2.2. Number of bed days
2.3. Number of emergency room visits
2.4. Number of elective and emergency visits to GPs and primary health care
2.5. Number of specialist nurse home visits
2.6. Number of clinic visits to secondary care
3. Other outcomes:
3.1. Cost per avoided face-to-face primary care contact
3.2. Qualitative reporting of the barriers to implementing Tm
3.3. Adverse events attributed to Tm
4. Organisational outcomes:
4.1.To determine whether the required organisational changes can be implemented at scale and in a timely fashion. The Tm will result in a workload for the staff involved that is acceptable to them.
4.2. The required organisational changes and new ways of working are agreed and approved by the appropriate management structures within the relevant agencies involved in the delivery.
4.3. The intervention models can be successfully transferred to other regions and mainstreamed as part of usual care.
5. Economic outcomes
To evaluate the cost-effectiveness of Tm in aT2DM care pathway.
6. Other outcomes
To determine if a new Tm service is acceptable to all stakeholders including patients and health professionals.

Completion date

01/12/2016

Eligibility

Key inclusion criteria
1. Clinical diagnosis of T2DM
2. Currently using self monitoring blood glucose monitors
3. Capability to use Tm and mobile phones including for the use of text messaging
4. Cognitively able to provide informed consent
5. Aged more than 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Unwilling or unable to provide written consent
2. Lack of mobile phone signal where they reside normally
3. Clincian's discretion based on behaviour, social circumstances etc.

Date of first enrolment
01/03/2014

Date of final enrolment
01/12/2016

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre

Hywel Dda University Health Board
Llanelli
United Kingdom
SA14 8QF

Sponsor information

Organisation
Hywel Dda University Health Board (UK)

ROR
https://ror.org/012gye839

Funder(s)

Funder type
Government

Funder Name
European Commission (Belgium) - The Information and Communication Technologies Policy Support Programme Project reference: 325215

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?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes