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The impact of a telemetric monitoring service in type 2 diabetes

Submission date	Recruitment status
06/05/2011	No longer recruiting
Registration date	**Overall study status**
06/05/2011	Completed
Last Edited	**Condition category**
20/09/2016	Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.telescot.org/diabetes.html

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
9556

Study information

Scientific Title
The impact of a telemetric monitoring service in type 2 diabetes: a randomised controlled trial

Acronym
Telescot Diabetes Study

Study objectives
As the population ages, more people are living with long term conditions. Current methods of management, relying on clinicians to monitor patients, are becoming unsustainable. There is potential for people to monitor their own condition with appropriate supervision and support, but so far there is little good evidence that this helps them achieve better control. Systems are now available which allow patients with diabetes to monitor their own illnesses and automatically send the information to a secure website, which they and their clinicians can view. The system can provide reminders to take measurements and medication, and alert patients and clinicians if additional treatment is required.

Aim: We want to find out if a telemetry system can help reduce blood glucose, blood pressure and weight of diabetics who have poor control of their symptoms. We also wish to find out if telemetry can help improve the quality of life of diabetics, and save patients and their clinicians' time.

Method: We will do this by running a randomised controlled trial in which patients whose diabetes is poorly controlled are randomised to one of two groups: one group who get the telemetry (the intervention group) and the other group who continue to receive their usual care (the control group). We will collect data at the start and at the end of the study to see if those in the intervention group are better able to control and manage their diabetes with the supported self monitoring which telemetry provides.

Potential benefits: Diabetes affects an increasing number of people, with large numbers having problems controlling their blood glucose levels and blood pressure. This is responsible for a heavy workload in primary care. We believe that telemetry has the potential to improve the quality of life for diabetics; however before equipment is purchased it is vital that the potential benefits are assessed.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Scotland Research Ethics Committee 2, First MREC approval date 25/11/2010, ref: 10/S1102160

Study design
Randomised; Interventional; Design type: Process of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information material can be found at http://www.telescot.org/diabetes.html

Health condition(s) or problem(s) studied
Topic: Diabetes Research Network, Primary Care Research Network for England, Scottish Primary Care Research Network and Scottish Diabetes Research network ; Subtopic: Not Assigned; Disease: Diabetes

Interventions
The control group do not receive an intervention other than an appointment at the beginning for optimisation of care and self management education.

Telemetric monitoring: Patients in the intervention group will be given blood pressure (BP) and blood glucose monitors and weighing scales which use Bluetooth to transmit readings via a (supplied) modem to a remote server. The user may securely access their record on the server at any time (either at home if they have internet access, or in a library or other public internet access point). Their general practitioner (GP) and practice nurse will also be able to access this record via the internet. Users will also receive regular (monthly) feedback; Follow Up Length: 9 month(s); Study Entry : Single Randomisation only

Intervention Type
Device

Primary outcome measure
Difference in mean HbA1c between intervention and control groups; Timepoint(s): 9 months

Secondary outcome measures
1. Difference in mean daytime diastolic BP measured by Ambulatory Blood Pressure Monitoring (ABPM); Timepoint(s): 9 months
2. Difference in mean daytime systolic BP measured by ABPM; Timepoint(s): 9 months
3. Difference in mean weight between intervention and control groups; Timepoint(s): 9 months
4. Incremental cost-effectiveness measured as Cost per Quality Adjusted Life Year; Timepoint(s): 9 months

Overall study start date
01/03/2011

Completion date

30/11/2011

Eligibility

Key inclusion criteria
Patients registered with general practices in the selected areas who:
1. Are on their practice diabetes registers
2. Have type 2 diabetes which is managed mainly in general practice
3. Are aged bewteen 18 and 79 years
4. Have a last recorded haemoglobin A1c (HbA1c) measurement > 7.5% (>59 mmol/mol)
5. Have a last recorded blood pressure > 135/80mmHg and average daytime self monitored systolic blood pressure >1 30/75 mmHg
6. Have given informed consent
7. Have a mobile telephone signal available from home.; Target Gender: Male & Female; Upper Age Limit 79 years ; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 320; UK Sample Size: 320

Key exclusion criteria
Patients who:
1. Are aged 80 and above
2. Have an average systolic blood pressure =120/70 or > 210/135 mmHg taken by the research nurse at the consent visit
3. Have HbA1c < 7.5% (< 59 mmol/mol)
4. Have hypertension or renal disease being managed in secondary care
5. Have had treatment for a cardiac event, or other life-threatening illness within the past 6 months or have had surgery within the last 3 months
6. Are unable to consent
7. Are unable to use self-monitoring equipment;
8. Have atrial fibrillation
9. Are pregnant

Date of first enrolment
01/03/2011

Date of final enrolment
30/11/2011

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
The University of Edinburgh
Edinburgh
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EH8 9AG

Sponsor information

Organisation
University of Edinburgh (UK)

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Sponsor type
University/education

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office (ref: ARPG/07/03)

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	06/07/2013		Yes	No
Results article	results	23/12/2015		Yes	No
Results article	results	26/07/2016		Yes	No