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Diasend study: Does nurse advice using blood glucose data uploaded to the Diasend website improve blood glucose control for insulin-treated diabetes patients, and their well-being, compared with standard care, where blood glucose data are taken from journals or meters?

Submission date
23/08/2012

Recruitment status
No longer recruiting

Registration date
19/09/2012

Overall study status
Completed

Last Edited
07/12/2016

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Blood glucose levels obtained by self monitoring are the main source of information on which changes in management and behaviour designed to improve diabetes control are based. However, these decisions, for practical reasons, often use only a very limited sample of the potential data available. An increasing number of devices are being marketed to convert all available data into a clinically useful form. DIASEND is one such device, enabling blood glucose data to be uploaded from most meters to a website, where it is analysed and presented in various ways to give maximum clinical benefit. Both the patient and a healthcare advisor, with permission, can access the same information simultaneously from different sites in order to enrich discussion. The study aims to demonstrate that the use of this enhanced information by diabetes specialist nurses (DSNs) confers benefit to patients both in terms of improved blood glucose control and in confidence to self-manage.

Who can participate?
The Diasend Study aims to recruit 294 people with poorly-controlled (HbA1c between 58 and 97 mmol/mol) type 1 and insulin-treated type 2 diabetes over the age of 21 years.

What does the study involve?
Over the six months of the study, participants will have a 2-3 weekly consultation, either face-to-face or over the telephone, with a diabetes specialist nurse, with the aim of improving their diabetes control. At the beginning of the study, people will be randomly allocated either to the Diasend or the usual care group. At each contact with a diabetes nurse, the usual care group will discuss their diabetes control and any changes in management using blood glucose readings stored in the blood glucose meter and/or recorded in a monitoring book. The Diasend group will

upload their blood glucose readings each week from their meters memory to a secure, encrypted website using special software. The uploaded information can be displayed on screen in a number of ways, making it easier to analyse problems or detect trends. With the permission of the patient and the necessary password, the diabetes nurse can access the website, either with the patient in the clinic or remotely, and use the information to help in understanding the reasons for poor diabetes control and discuss how they might be tackled.
Participants will fill in a short questionnaire at the beginning and end of the study to assess their confidence in self-management and will have a blood test at the beginning, middle and end of the study. They will also be required to monitor their blood glucose levels at least twice daily. Other aspects of care will be as normal.

What are the possible benefits and risks of participating?
It is hoped that both groups will benefit from regular diabetes specialist nurse advice over the 6 months of the study, but that there will be a greater improvement in control and confidence in self-management and less use of resources in the Diasend group. There are no obvious risks to participation.

Where is the study run from?
Fieldhead Hospital

When is study starting and how long is it expected to run for?
It is anticipated that the study will begin in early 2013 and run for approximately a year to eighteen months.

Who is funding the study?
Funding is being applied for through Research for Patient Benefit.

Who is the main contact?
Dr Keith Sands
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised trial comparing the outcomes of specialist diabetes nurse advice to patients with insulin-treated diabetes and Diasend, a telehealth system, at home with a matched group of patients receiving advice based on a conventional, clinic-based approach

Study objectives
The use of the Diasend system as part of normal care results in improved outcomes in terms of blood glucose control, use of resources and patient confidence in self-management.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Open randomised possibly multi-site trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
Diasend or the usual care group.

The study will involve 294 people of either sex with poorly controlled type 1 or insulin-treated type 2 diabetes. It will use the widely-used and validated Diabetes Treatment Satisfaction Questionnaires, administered at the beginning and end of the six month study period.

Patients will have study contact with their diabetes specialist nurse (DNS) fortnightly until the End of Study visit at 24 weeks. Contact may be face-to-face or by telephone, as determined by the DNS.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Change in HbA1c between first contact and the end of the study

Secondary outcome measures
1. Use of resources
2. Patient confidence in self-management

Overall study start date
01/02/2013

Completion date
01/08/2014

Eligibility

Key inclusion criteria
1. Type 1 (not receiving insulin via a pump) or insulin-treated type 2 diabetes with an HbA1c (documented within the previous 3 months) of between 7.5% (58 mmol/mol) and 11.0% (97 mmol/mol)
2. Aged 21 years or more
3. Duration of diabetes of at least 2 years
4. BMI <40 kg/m2
5. In patients with insulin-treated type 2 diabetes, oral medication (ie no changes in dosage) must have been stable for at least 6 weeks
6. Able to attend clinic and be available for telephone consultations at the requisite times
7. Able and willing to perform blood glucose monitoring using a blood glucose meter at least twice every other day and, ideally, four times daily
8. Appropriate equipment at home to upload blood glucose levels to the Diasend web-site using the Diasend uploader
9. Willing to monitor and record signs and symptoms of hypoglycaemia

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
294

Key exclusion criteria
1. Type 1 diabetes receiving insulin via a pump
2. Treatment with a glucagon-like peptide-1 (GLP-1) receptor agonist
3. Pregnancy
4. Disruption of liver (ALT and/or AST greater than three times the upper limit of normal at screening) or kidney (eGFR less than 50 mls/min/1.72m^2) function that might affect insulin action
5. Clinically relevant cardiovascular, respiratory, hepatic, neurological, endocrine or other major disease making implementation of the protocol or interpretation of the study results difficult
6. Any condition that, in the investigators judgement, is likely to cause the patient to be unable to understand the information in the Patient Information Sheet or provide informed consent or to cooperate fully with the protocol
7. History of drug or alcohol abuse

Date of first enrolment
01/02/2013

Date of final enrolment
01/08/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Medical Directorate
Barnsley
United Kingdom
S70 3RD

Sponsor information

Organisation
South West Yorkshire Partnership NHS Foundation Trust (UK)

Sponsor details

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Sponsor type
Hospital/treatment centre

Website
http://www.southwestyorkshire.nhs.uk

ROR
https://ror.org/02m7qex15

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit Programme

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