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# Digital Diabetes Project

**Submission date**
26/09/2013

**Recruitment status**
No longer recruiting

**Registration date**
17/03/2014

**Overall study status**
Completed

**Last Edited**
06/02/2017

**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
NHS Highland is the largest Health Board in the UK geographically speaking. It covers an area of over 300,000km2 including many outlying Scottish islands and some of the remotest parts of the British mainland. Within this area there are around 14,000 patients with diabetes, of which around 1,500 have a diagnosis of type 1 diabetes. Access to specialist clinical services are limited to central clinics in Inverness and outreach clinics in Skye, Fort William and Wick. Follow up between these clinic appointments is delivered by community based Diabetes Specialist Nurses. At present, these contacts are conducted by traditional face-to-face clinic visits then, perhaps, telephone visits if required in between. This type of interaction invariably requires patients and staff to travel potentially great distances, often on poor roads or during inclement weather conditions. It is also worth noting that type 1 diabetes is a disease predominantly of the young and certainly of those of working age, or those engaged in education. The requirement for clinical consultation to be face-to-face currently requires the patient to take time off work or out of education.
This study will investigate the usability and acceptability of digital communication methods to patients with indifferent control of their type 1 diabetes. The type of clinic that is proposed will enable the same functionality of a 'traditional' diabetes clinic, but it will not require patients or staff to meet face-to-face. Patients views on the digital means of communication will be captured with questionnaires. Phase 1 and 2 will develop a technology acceptance questionnaire to be used in the main study (phase 3). Digital means of communication will be video consultation, email, text and phone. All treatment offered, or blood samples taken, will be in accordance with standard clinical practice for patients with indifferent control of their diabetes.

Who can participate?
Adults who have had a diagnosis of type 1 diabetes for more than 12 months. Participants must have access to the internet, a PC or laptop with a webcam, an email address and a mobile phone and be able to give informed consent.

What does the study involve?
Patients meeting the criteria will be identified by members of the Diabetes Specialist Service within NHS Highland. These patients will either be approached at clinic or invited by letter to participate in the study. They will be given a copy of the Patient Information Sheet to read and consider. A period of at least 24 hours will be allowed for this.
Phase 1 & 2: participants will only complete a questionnaire.

Phase 3: participants will then be invited to attend a meeting with the research practitioner in person to discuss the study in more detail before being consented for it. After giving consent, the participant will complete 3 questionnaires and will be shown how to use WebEx software (videoconsultation platform which has been approved for NHS use by NHS Highland eHealth Dept.). Text number, phone number and email address of the research practitioner will be given to the participant. A mutually agreeable date will be set for the 1st virtual clinic consultation using WebEx. Further dates will be set up at 3 and 6 months, again at mutually agreeable times. Prior to the 1st meeting, the participant will be required to have an HbA1c blood test completed by their GP if their last test was more than 6 weeks before the clinic appointment. The participants will be required to have HbA1c blood tests completed at 3 and 6 months, again prior to the WebEx consultation. Between the video consultations the patients will be invited to communicate with the research practitioner via text, email or phone for treatment advice and help to optimise treatment. Participants' self- monitoring of blood glucose results will be shared between the participant and the research practitioner via WebEx 'share' function (where one person on the call shares their computer screen or document on their computer with another person). After the final clinic visit, the participant will be contacted by a research fellow and asked to complete 3 questionnaires.

What are the possible benefits and risks of participating?
Participation will help our researchers to advance understanding of the acceptability of digital methods of communication for running a diabetes clinic. There are no anticipated risks.

Where is the study run from?
The study is being run within the Highland Clinical Research Facility, Inverness (UK).

When is study starting and how long is it expected to run for?
Phase 1 and 2 of the study will be open from October 2013 and Phase 3 of the study will start in March 2014. Recruitment will be open for up to 1 year. Each participant recruited will be in the study for 6 months.

Who is funding the study?
The Scottish Diabetes Group (UK)

Who is the main contact?
Gordon Rushworth, Lead Pharmacist Diabetes, +44 (0)1463 279586

# Contact information

### Type(s)
Scientific

### Contact name
Prof Sandra MacRury

### Contact details
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
409SM

# Study information

### Scientific Title
A pilot study to test the usability and acceptability of virtual support for patients with type 1 diabetes in Highland region

### Acronym
DDP

### Study objectives
To determine the usability and acceptability of a variety of digital communication modes between the specialist diabetes team and patients with diabetes.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
NRES Committee London-Bloomsbury, ref: 13/LO/1232

### Study design
Mixed methods study

### Primary study design
Observational

### Secondary study design
Mixed methods study

### Study setting(s)
Other

### Study type(s)
Treatment

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

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

### Interventions
The type of clinic that is proposed will enable the same functionality of a traditional diabetes clinic, but it will not require patients or staff to meet face-to-face. Phase 1 and 2 will develop a technology acceptance questionnaire to be used in the main study (phase 3). Digital means of communication will be video-consultation, email, text and phone. All treatment offered, or blood samples taken, will be in accordance with standard clinical practice for patients with indifferent control of their diabetes. Patients' views on the digital means of communication will be captured with questionnaires.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
To determine the usability and acceptability of a variety of digital communication modes between the specialist diabetes team and patients with diabetes.

An elicitation questionnaire exploring patients' views on a digital diabetes clinic will be used in phase 1 of the study to develop an evaluation questionnaire to be piloted in phase 2 of the study. The method to be used to measure the outcomes for the main part of the study (phase 3) will be 3 questionnaires. There will be a self-efficacy for diabetes questionnaire, summary of diabetes self-care activities questionnaire and the evaluation questionnaire which has been validated in phase 1 and 2.

### Secondary outcome measures
To determine if secure, reliable methods can be established for sharing blood glucose data and for assimilating different modes of communication into patient records in addition to assessment of change in glycaemia control.

### Overall study start date
01/10/2013

### Completion date
01/10/2014

## Eligibility

### Key inclusion criteria
1. Type 1 diabetes
2. Over 18
3. Glycosylated hemoglobin (HbA1c) > 64mmol/mol (8%)
4. Diabetes duration of more than 12 months
5. Access to the internet
6. Ability to give informed consent
7. Access to a personal computer (PC) or laptop with a webcam

8. Have an email address
9. Have a mobile phone

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Phase 1 & 2 = 25, phase 3 = 20.

### Key exclusion criteria
1. Any form of diabetes other than type 1
2. Those on insulin pump therapy
3. HbA1c ≤ 64mmol/mol (≤8%)
4. Diabetes duration of less than 12 months
5. Those without access to a PC or laptop which includes a webcam
6. Those without internet access
7. Those without an email address
8. Those without a mobile phone
9. Unable to use a PC, mobile phone or email

### Date of first enrolment
01/10/2013

### Date of final enrolment
01/10/2014

## Locations

### Countries of recruitment
Scotland

United Kingdom

### Study participating centre
**Highland Clinical Research Facility**
Inverness
United Kingdom
IV2 3JH

# Sponsor information

**Organisation**
University of the Highlands and Islands (UK)

**Sponsor details**
c/o Jeff Howarth
VP Research and Enterprise
UHI Executive Office
Ness Walk
Inverness
Scotland
United Kingdom
IV3 5SQ

**Sponsor type**
University/education

**ROR**
https://ror.org/02s08xt61

# Funder(s)

**Funder type**
Other

**Funder Name**
Scottish Diabetes Group (UK)

# 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? |
| --- | --- | --- | --- | --- | --- |
| HRA research summary | | | 28/06/2023 | No | No |