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A web-based self management programme (HeLP-Diabetes) for people with type 2 diabetes in primary care

Submission date
12/02/2013

Recruitment status
No longer recruiting

Registration date
14/02/2013

Overall study status
Completed

Last Edited
11/09/2018

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims

Type 2 diabetes is one of the commonest long term health conditions in the UK, affecting over 2 million adults. Many people with type 2 diabetes need help and support to live a healthy, happy life. The NHS recommends that every person with type 2 diabetes should have the opportunity to attend a self-management course on diabetes when first told they have diabetes, and once a year thereafter. But not everybody who needs these courses gets them - either because there are not enough courses locally, or because the courses are hard to get to, or because patients aren't offered them. An additional way of helping people with diabetes get the support and information they need to live a healthy, happy life is through the internet. We have developed two websites (one complex; one simple) offering help and support for people with type 2 diabetes. The aims of thise study are to see if either website improves people's wellbeing and clinical outcomes and if they are cost-effective compared to usual care.

Who can participate?

The HeLP-Diabetes study aims to recruit about 400 people with type 2 diabetes, aged 18 or over from General Practices across England.

What does the study involve?

Participants will be asked to complete a baseline assessment. This involves completing some questionnaires online and the practice nurse taking some clinical measurements like height, weight and blood pressure. The nurse will also take a blood sample to measure HbA1c and cholesterol levels. After this assessment has been completed participants will be randomly (by chance) allocated to use one of two websites. One website will be more complicated with lots of online tips and tools to help them manage their diabetes while the other will be simpler, focusing on the essential information everybody with type 2 diabetes needs to know. Participants will be asked to use the website as much or as little as they like for 12 months. Their use of the website (number of logins, pages visited) will be automatically recorded by the computer. After 3 months and 12 months they will be asked to complete the same questionnaires again and to see the practice nurse again to check their blood pressure and weight, and to take some blood tests (HbA1c and cholesterol). At the end of the study, HbA1c

levels and measures of well-being will be compared in people asked to use the complicated website versus those asked to use the simpler, information only website.

What are the possible benefits and risks of participating?
Participants will have the opportunity to use a web-based education site (HeLP-Diabetes) for people with type 2 diabetes for a year. There is some research evidence to show that people who are given diabetes related information have better health outcomes than people who receive no information. It is very unlikely that participants will be at risk as a result of taking part in the study. The information on both websites has been developed by a team of doctors, nurses, dieticians and researchers. It reflects current best practice in the NHS.

Where is the study run from?
University College London in collaboration with The Whittington NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
It is anticipated that General Practice recruitment will start in March 2013 until September 2013. Participant recruitment will then start for another 6 months (September 2013 - March 2014). Participants will be enrolled on the study for one year.

Who is funding the study?
National Institute of Health Research Programme Grant for applied research (UK)

Who is the main contact?
Dr Charlotte Dack
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13563

Study information

Scientific Title
Randomised controlled trial of a web-based self management programme (HeLP-Diabetes) for people with type 2 diabetes in primary care

Acronym
HeLP-Diabetes

Study objectives
The trialists have developed a web-based self-management programme for people with type 2 diabetes (called HeLP-Diabetes). The aim is to determine the effectiveness and cost-effectiveness of HeLP-Diabetes through a randomised controlled trial in general practice. Participants will be randomised to using either the HeLP-Diabetes programme or a comparator website (information only). A pilot study will run for 6 months prior to the main RCT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Camden and Islington National Research Ethics Committee, 06/12/2012, ref: 12LO1571

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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
Type 2 diabetes

Interventions

Comparator website: This will be an information only website created by the study team to compare with HeLP-Diabetes

HeLP-Diabetes: HeLP-Diabetes is a web-based self-management programme we have developed for adults with type 2 diabetes

Follow Up Length: 12 month(s)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Glycaemic control (HbA1c) and health-related quality of life, measured by the Problem Areas in Diabetes (PAID) scale Timepoint(s): Baseline, 3 months, 12 months

Secondary outcome measures
1. Body mass index (BMI); Timepoint(s): Baseline, 3 months, 12 months
2. Completion of "9 essential processes"; Timepoint(s): 12 months
3. Cost of developing intervention; Timepoint(s): Baseline, 3 months, 12 months
4. Cost of supported access; Timepoint(s): Baseline, 3 months, 12 months
5. Costs of maintaining and updating the intervention; Timepoint(s): Baseline, 3 months, 12 months
6. Costs of training NHS staff in using intervention and training patients to use intervention; Timepoint(s): Baseline, 3 months, 12 months
7. Disability Management Self Efficacy Scale (DMSES); Timepoint(s): Baseline, 3 months, 12 months
8. Diabetes Treatment Satisfaction Questionnaire change version (DTSQc); Timepoint(s): 12 months
9. DTSQs; Timepoint(s): Baseline, 3 months, 12 months
10. EQ-5D to calculate Quality-Adjusted Life Years (QALYs); Timepoint(s): Baseline, 3 months, 12 months
11. Hospital Anxiety and Depression Scale (HADS); Timepoint(s): Baseline, 3 months, 12 months
12. Health service utilisation during the study period; Timepoint(s): Baseline, 3 months, 12 months
13. Systolic and diastolic blood pressure; Timepoint(s): Baseline, 3 months, 12 months
14. Total cholesterol and HDL; Timepoint(s): Baseline, 3 months, 12 months
15. Use of website; Timepoint(s): Throughout

Overall study start date
01/03/2013

Completion date
01/09/2015

Eligibility

Key inclusion criteria

1. Adults, male and female, aged 18 or over
2. With type 2 diabetes

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 398

Key exclusion criteria
1. Unable to provide informed consent, e.g. due to psychosis, dementia or severe learning difficulties
2. Terminally ill with less that 12 months life expectancy
3. Unable to use a computer due to severe mental or physical impairment
4. Insufficient mastery of spoken English to use the intervention
5. Current participation in a trial of an alternative self-management programme

Date of first enrolment
01/03/2013

Date of final enrolment
01/03/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
London
United Kingdom
NW3 2PF

Sponsor information

Organisation
University College London (UK)

Sponsor details
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Sponsor type
University/education

Website
http://www.ucl.ac.uk

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Central Commissioning Facility; Grant Codes: GZHN

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	29/12/2015		Yes	No
Results article	results	27/09/2017		Yes	No
Results article	cost-effectiveness results	08/06/2018		Yes	No
Results article	results	01/09/2018		Yes	No