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The Study of Health trainers Improving Patient Self management support

Submission date
16/01/2012

Recruitment status
No longer recruiting

Registration date
16/01/2012

Overall study status
Completed

Last Edited
24/08/2016

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
Diabetes mellitus (DM) is a common disorder that affects around 2.3 million people in the UK. DM control is linked with peoples understanding of DM and self-management. Evaluation of the local (Blackpool) X-PERT diabetes education programme suggests that there remain gaps in provision for people from disadvantaged communities with low literacy and numeracy levels. We plan to use Health Trainers (HTs) to improve engagement with supported self-management in people with type 2 DM by developing individually tailored management plans based on patients priorities and locally available options, with ongoing HT support over six months.
HTs are a Government initiative designed to reduce health inequalities. They are trained to help patients change behaviours based on psychological and behavioural theories; they have not been used specifically with patients with diabetes. Interventions aimed at improving provisions for marginalised populations need to be tested, and often are not.
The purpose of this study is to see if people with diabetes find HTs useful in helping them to live healthily with their diabetes.

Who can participate?
Patients over 18 years of age, on the practice register for DM, and whose diabetes is currently poorly controlled (as measured by routine blood tests undertaken by their practice) will be eligible to participate.

What does the study involve?
Patients who agree to take part in this study will be contacted by a researcher from Keele University who will arrange to visit them (at home or in the surgery) to explain the study, answer any questions, obtain written consent, and then ask some baseline questions. Questions will be asked by the researcher and the patients answers entered directly into a database by the researcher (using face-to-face data collection ensures patients with low basic skills are not excluded).
Patients will then be randomly assigned to either the intervention group or to continue with usual general practitioner care. Patients in the intervention group will be contacted by the HT who will arrange an appointment to see him/her. At this meeting the patient and the health trainer will develop an individually tailored self-management plan according to patient priorities and goals. He/she will arrange further contact either face-to-face or by telephone on two or

more occasions over the following six months.
The researcher will contact the patient again about seven months after her first visit and arrange to visit or telephone to collect follow-up questionnaire data.

What are the possible benefits and risks of participating?
Having a healthy lifestyle is very important when you have diabetes. It is not always easy to manage to have a healthy lifestyle HTs, although not medically qualified, do understand the challenges in achieving a healthy way of life. They are trained in helping people to achieve their goals.
There are no risks associated with seeing a HT.

Where is the study run from?
Keele University, UK.

When is the study starting and how long is it expected to run for?
The study will start to recruit patients in March 2012 and will run until July 2013.

Who is funding the study?
National Institute of Health Research (NIHR) (UK).

Who is the main contact?
Dr Joanne Protheroe, PI
Ms Shirley Caldwell, study coordinator
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Contact information

Type(s)
Scientific

Contact name
Ms Jacqueline Gray

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10855

Study information

Scientific Title
A pilot study to examine the feasibility of improving engagement with supported self-management in diabetic patients in disadvantaged populations

Acronym
SHIPs

Study objectives
Diabetes Mellitus (DM) is a common disorder that affects 2.3 million UK people. DM control is linked with peoples understanding of DM & self-management. We plan to use Health Trainers (HTs) to improve engagement with supported self-management in people with type 2 DM by developing individually tailored management plans based on patients priorities & locally available options, with ongoing HT support over 6 months.

This study is a pilot randomised controlled trial (RCT) of the HT intervention vs usual general practitioner (GP) care; recruited patients will be randomised to see the HT or continue with usual GP care. The project is in NHS Blackpool which has high levels of DM & low levels of basic skills. Type 2 DM (85% of DM) is linked with obesity & lifestyle.

1. We will conduct interviews with Patients, HTs and GPs to refine the intervention
2. Evaluate the intervention through a pilot trial (using face to face data collection to ensure patients with low basic skills are not excluded) & qualitative interviews
3. Collect basic cost evaluation data outcomes. We will compare the intervention with usual care. Outcome measures will include diabetes self-care behaviours, self-efficacy, glucose control & quality of life.The potential impact will be better DM self-management & health in people with type 2 DM, patients empowered to take more control of their health, a potential role for HTs to support people with type 2 DM and reduced health care costs.

Please note that as of 15/03/2013, the anticipated end date for this trial was updated from 30/09/2013 to 31/07/2013

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East Midlands - Derby 2; First MREC approval date 16/08/2011, ref: 11/EM/0294

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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
Topic: Diabetes Research Network, Primary Care Research Network for England; Subtopic: Type 2, Not Assigned; Disease: Diabetic Control, All Diseases, Education

Interventions
Structured interview: The intervention is a structured interview with the Health Trainer to develop an individualised patient self managment plan utilising a locally developed menu of options. The HT will follow up 1-2 times either face to face or by telephone depending on patient preference over following 6
months.; Follow Up Length: 7 month(s); Study Entry : Registration only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Diabetes Self Care Activities Measure (DSCAM); Timepoint(s): Baseline and 7 months follow up (FU)

Secondary outcome measures
1. Demographic information
1.1. Age; Timepoint(s): Baseline
1.2. Education; Timepoint(s): Baseline
1.3. Ethnicity; Timepoint(s): Baseline
1.4. Sex; Timepoint(s): Baseline
2. Depression using QOF screening questions; Timepoint(s): Baseline and 7 months FU
3. Health economic information-health service use; Timepoint(s): Baseline and 7 months FU
4. Health Status - SF12; Timepoint(s): Baseline and 7 months FU
5. Health-related Quality of Life; Timepoint(s): Baseline and 7 months FU
6. Length of time since diagnosis.; Timepoint(s): Baseline
7. Self-efficacy and Illness Perception Questionnaires; Timepoint(s): Baseline and 7 months FU
8. Socio-economic information
8.1. Employment status; Timepoint(s): Baseline
8.2. Housing; Timepoint(s): Baseline
8.3. Receipt of benefits; Timepoint(s): Baseline
9. Tests of Health Literacy; Timepoint(s): Baseline

Overall study start date
01/03/2012

Completion date
31/07/2013

Eligibility

Key inclusion criteria
1. Adult patients >18yrs with poorly controlled type 2 DM (defined as having an HbA1c greater than 7.5 at their last two
measurements
2. Target Gender: Male & Female; Upper Age Limit 110 no age limit or unit specified ; Lower Age Limit 18 no age limit or unit specified

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 120; UK Sample Size: 120

Key exclusion criteria
1. Patients deemed ineligible for the study by practice staff
1.1. Include patients with terminal illness
1.2. Those unable to participate due to deafness, blindness or
cognitive dysfuncton

Date of first enrolment
01/03/2012

Date of final enrolment
31/07/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Arthritis Research UK Primary Care Centre
Newcastle-Under-Lyme
United Kingdom
ST5 5BG

Sponsor information

Organisation
Keele University (UK)

Sponsor details
Keele
Newcastle
England
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ST5 5BG

Sponsor type
University/education

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Government

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

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