

The Study of Health trainers Improving Patient Self management support

Submission date 16/01/2012	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 16/01/2012	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 24/08/2016	Condition category Nutritional, Metabolic, Endocrine	☐ 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

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised; Interventional; Design type: Process of Care

Study type(s)

Quality of life

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 management 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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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 dysfunction

Date of first enrolment

01/03/2012

Date of final enrolment

31/07/2013

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Arthritis Research UK Primary Care Centre

Newcastle-Under-Lyme

United Kingdom

ST5 5BG

Sponsor information**Organisation**

Keele University (UK)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration