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Looking after yourself when you have diabetes

Submission date
26/10/2012

Recruitment status
No longer recruiting

Registration date
21/01/2013

Overall study status
Completed

Last Edited
04/06/2018

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
This study involves people with learning disabilities who also have type 2 diabetes. There are high rates of poorly-controlled type 2 diabetes in adults with learning disability - this includes high levels of obesity and poor dietary habits; prescription medications that increase risk; and poor self-management skills. Finding those with diabetes, for service planning and for research purposes, is greatly helped in the UK by the fact that general practitioners (GPs) are required to maintain a register of all patients with diabetes. However, learning disability is less straightforward to define and identify, especially at the milder end of the spectrum. The aim of this study is thus, in phase 1, to develop and test a simple case-finding method to identify participants who have both mild/moderate Learning Disability and Type 2 diabetes who are not taking insulin and who might be suitable for the study intervention. Phase I of the study also aims to:
1. Develop a manual to aid supported self-management of diabetes
2. Assess the feasibility of delivering the intervention
3. Develop a simple measure of adherence to the manual
4. Develop procedures for determining and recording capacity and obtaining consent.
The aims of Phase 2 of the study are to:
5. Estimate recruitment and retention rates
6. Assess the feasibility of collecting a range of outcome measures from participants and from medical records.
7. Test the effectiveness of the data collection forms developed
8. Assess the feasibility of delivering the intervention
9. Provide a detailed description of what treatment is delivered to each group.
This work will enable development of a large scale study to test the clinical and cost-effectiveness of the intervention.

Who can participate?
Patients aged 18 and over who have type 2 diabetes which is not treated with insulin, have mild to moderate learning disability (not related to a disease acquired in adult life - e.g. adult-onset dementia), and live in the community (not in a hospital).

What does the study involve?
The first phase of the study involves developing best methods for identifying eligible people, and then conducting interviews with consenting participants. The interview includes questions

about how they currently manage their diabetes, consent for access to health care records, and identification of a supporter who might help them if they take part in the second phase of the study. They are also asked whether they would be interested in taking part in helping with the development of the intervention, and being involved in the second part of the study. The intervention consists of 'supported self-management' materials, developed by reviewing the literature and materials that are already in use to help people manage their diabetes. Participants who are willing to be involved in this process are consulted to further develop the intervention. In the phase 2 of the study participants are randomly allocated to receive either the supported self-management intervention that has been developed in phase 1, or usual care.

What are the possible benefits and risks of participating?
It is hoped that some participants may benefit directly from the study materials. Very few risks are anticipated at any point in the study, but any changes in mood or behaviour are monitored.

Where is the study run from?
Diabetes services in primary and secondary care in Bradford, Leeds and Wakefield will be involved. The study researcher will be based at the University of Leeds (UK).

When is the study starting and how long is it expected to run for?
February 2013 to January 2016

Who is funding the study?
NIHR Health Technology Assessment Programme (UK)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 10/102/03

Study information

Scientific Title
Managing with learning disabilities and diabetes (feasibility study)

Study objectives
This research involves two phases. In Phase I potential participants will be identified and characterised, and a self-management manual and adherence measure will be developed. Phase II will be a feasibility Randomised Controlled Trial (RCT).

Phase 1:
1. Develop a manual to aid supported self-management of diabetes
2. Assess the feasibility of delivering the intervention
3. Develop a simple measure of adherence to the manual
4. Develop procedures for determining and recording capacity and obtaining consent

Phase 2:
1. Estimate recruitment and retention rates to inform a definitive trial.
2. Assess the feasibility of collecting a range of outcome measures from participants and from medical records.
3. Test the effectiveness of the data collection forms developed
4. Assess the feasibility of delivering the intervention
5. Provide a detailed description of what treatment is delivered to each arm

More details can be found at https://www.journalslibrary.nihr.ac.uk/programmes/hta/1010203/#/
Protocol can be found at https://njl-admin.nihr.ac.uk/document/download/2006978

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & The Humber - Humber Bridge, 09/07/2012, ref: 12/YH/0304

Study design
Phase 1: prospective case-finding survey and development of materials
Phase 2: individually-randomised feasibility randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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, learning disabilities

Interventions
Phase 1:
1. A simple checklist will be developed to enable staff working in primary care (and in a range of other NHS and non-NHS settings) to identify potential participants as they undertake Quality and Outcomes Framework (QoF) diabetes checks
2. Self-management materials will be developed - from existing literatures in Learning Disability and diabetes and chronic disease self-management, and from content of related care pathways such as that for obesity in Learning Disability. The manualised self-management intervention will have selectable components to allow variable involvement with a supporter. It will have a component for the participant, for a supporter, and for shared activities
3. An adherence measure will be developed.

Procedures: All potential participants will be interviewed to
1. Identify those who meet entry criteria
2. Establish current diabetes management and current physical health state from QoF measures
3. Identify supporters and their role in diabetes management
4. Elicit preferences for further assistance and potential for recruitment into Phase II. Interviews will then be conducted by the Study Researcher with the diabetes specialist nurses to identify any barriers to delivery.

Phase 2 of the study, the randomised feasibility element:
For those randomised to active intervention the professional support element will be arranged

via a routine diabetes specialist nurse who will be hospital or community based. The nurse will introduce manualised supported self-management of diabetes to the person with diabetes and their supporter, explaining how to use the materials and suggesting some initial actions and activities. Further contact will be negotiated but we anticipate 2-3 further meetings of 30-60 minutes over the next 6-8 weeks, followed by telephone support and advice - the balance offered to the person with diabetes or their supporter to be decided by negotiation.

Those randomised to usual treatment will receive standard education materials produced by the NHS, or charities such as Diabetes UK will be provided according to local service policy. Different nurses will be involved in providing the intervention and control. A single session with the diabetes specialist nurse will be arranged; a DVD may be provided. Little is currently known about the general level of care delivered at a local level. One of the objectives of Phase II will be to provide a detailed description of what is delivered to each arm, including a checklist of health care professionals involved, by centre and level (primary, secondary and third sector organisation), and a list of their associated tasks. The trialists will talk to professionals about how their service operates and what difficulties or barriers they face.

Follow-up at 6 months

Intervention Type
Other

Phase
Phase I/II

Primary outcome measure
Phase I:
1. Estimate the number of people who meet the inclusion criteria, and the numbers willing to consider change and to participate in further research
2. Characterize the population in terms of important characteristics such as diabetes control, living circumstances and presence and involvement of a supporter in diabetes management
3. Develop self-management materials and adherence measure and field-test them for acceptability in a case series of six people

Phase 2:
In the definitive trial HbA1c would be used at 12 months as the primary outcome, to estimate treatment differences between arms. A 12 month follow up interval will allow comparison with other published diabetes trials. It will also be compatible with an intervention the main effect of which is measured through routine NHS service delivery in the QOF system. For the feasibility RCT there will be 6 months follow up, which will be adequate for the main outcomes:
1. Variability of:
1.1. HbA1c
1.2. Blood pressure (BP)
1.3. Body mass index (BMI)
2. Recruitment rates
3. 6 months follow up rates

Secondary outcome measures
Phase 2 secondary outcomes are:
1. Patient and supporter costs
2. Participant and supporter reported adherence to diet and activity (Summary of Diabetes Self-

Care Activities)
3. Participant and Carer Mood (PHQ9)
4. Health Related Quality of Life (HRQL) (SF12 and EQ5D)
5. Medication use

Feasibility and data quality outcomes are:
1. Feasibility of collecting 6 month outcome measures based on blood tests from routine data from QOF reviews
2. Feasibility of collecting data on adherence to the intervention
3. Data quality for vascular risk markers collected from GP databases: Fasting triglycerides; fasting glucose; markers of microvascular disease (microalbuminuria)

Data quality for other outcomes collected at 6-month interview

Overall study start date
01/02/2013

Completion date
31/01/2016

Eligibility

Key inclusion criteria
Phase 1:
1. Aged 18 years or over
2. Suffering from Type 2 diabetes which is diet-controlled or treated with hypoglycemic agents other than insulin
3. With a mild to moderate Learning Disability, defined by functional deficits (in daily activities, educational and social attainment and support needs, day-to-day cognitive functions of memory and knowledge) attributable to primary or secondary (acquired) cognitive impairment determined by consensus review
4. Living in the community (not in a hospital setting)

Phase 2:
Participants found to be eligible in phase I, meeting the following criteria, are eligible for entry, providing they do not meet any of the exclusion criteria:
1. Providing written informed consent (assessment of mental capacity to consent will be repeated by the Study Researcher)
2. Having inadequate diabetes control defined as HbA1c >7.5% taken from the latest QOF review where this is available in the last 3 months prior to randomisation or from a baseline blood test, taken just prior to randomisation, if not

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
350 in phase 1, 80 in phase 2.

Key exclusion criteria
Phase 1:
1. Insufficient mental capacity to consent or to participate in the research, as assessed by the Study Researcher following guidelines using the Mental Capacity Act (2005) with people with learning disabilities (http://www.scie.org.uk/publications/mca/files/bild-mca.pdf). Study Researchers will be trained by LD consultant to undertake this assessment.
2. Problems acquired from disease in adult life, defined as 16 years or over, such as learning difficulty due to adult-onset dementia or stroke
3. Secondary diabetes (such as steroids, pancreatitis, endocrine disorders etc.) and rare causes of diabetes (such as MODY: maturity onset diabetes of the young)

Phase 2:
1. Referred for insulin or put on insulin between identification (Phase I) and randomisation
2. Participated in development of the self-help materials, adherence measure or health economics analyses in Phase I

Date of first enrolment
01/09/2014

Date of final enrolment
30/04/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Leeds
Leeds
United Kingdom
LS2 9LJ

Sponsor information

Organisation
University of Leeds (UK)

Sponsor details
Governance
Woodhouse Lane
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LS2 9JT

Sponsor type
University/education

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

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The trialists plan to publish four more articles in high-impact peer-reviewed journals

Intention to publish date

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/08/2015		Yes	No
Results article	results	06/10/2016		Yes	No
Results article	results	01/05/2018		Yes	No
Results article	results	01/12/2018		Yes	No
Results article	results	01/12/2018		Yes	No