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Embedding diabetes education

Submission date	Recruitment status	[_] Prospectively registered
19/06/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/07/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/06/2020	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
Diabetes is a serious and progressive disease that causes blood sugar levels to be uncontrolled. This can lead to complications like heart attacks, stroke, kidney failure, and a shorter span of life. Managing diabetes well is the key to living a healthy life and self-management education programmes are the best way to gain the knowledge and skills necessary to live well with diabetes. So our study is particularly relevant to anyone with diabetes, as well as the general public. There is good evidence that diabetes education works well. The aim of this study is to increase the number of people with type 2 diabetes who go to self-management education programmes by testing the components of an embedded package of diabetes education.

Who can participate?
Medical practices and primary care stakeholders involved in the provision of diabetes structured education. Patients aged 18 and older who are diagnosed with type 2 diabetes.

What does the study involve?
Participating centres receive an 'Embedding package' which is an online resource given to practices for a six month period. This includes a clear marketing strategy, user friendly and effective referral pathways, new and amended roles including a local clinical champion and a toolkit of resources for patients, healthcare professionals and other key stakeholders. Eligible patients are asked to complete questionnaires, take part in observations and interviews relating to structured diabetes education and provide consent to access medical information.

What are the possible benefits and risks of participating?
There are no notable benefits or risks with participating.

Where is the study run from?
This study is being run by the University of Leicester (UK) and takes place in seven medical centres/hospitals in the UK.

When is the study starting and how long is it expected to run for?
May 2012 to January 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Mrs Kyla Harrington
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
34445

Study information

Scientific Title
Increasing uptake of self-management education programmes for Type 2 Diabetes in multi-ethnic primary care settings: A feasibility study

Study objectives
The aim of this feasibility study is to test the components of the Embedding Package intervention prior to conducting a stepped wedge randomised controlled trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber – Leeds West Research Ethics Committee, 03/05/2017, ref: 17/YH/0135

Study design

Non-randomised; Both; Design type: Prevention, Education or Self-Management, Qualitative

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Treatment

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
Specialty: Diabetes, Primary sub-specialty: Type 2; UKCRC code/ Disease: Metabolic and Endocrine/ Diabetes mellitus

Interventions
The Embedding Package is implemented in each practice for a six month period during the feasibility study. An integrated ethnographic element, using observation and semi-structure interviews, are conducted to provide detailed contextually-sensitive data about the process of implementation, sustainability of the change and the 'fit' of the Embedding Package within routine practice.

The Embedding Package comprises of four key components which have been collated in to an online resource:
1. A clear marketing strategy
2. User friendly and effective referral pathway
3. New/amended roles including a local clinical champion and an 'Embedder'
4. Toolkit of resources (for patients, healthcare professionals and other key stakeholders

Packages of support and resources, resources developed in an earlier part of our research project that deals with a wide variety of needs, from training GPs and nurses in how to explain the benefits of diabetes education to improving the way that information about diabetes education is made available in local communities. A skilled person described as an 'Embedder' is provided to centres to support practices with ideas and skills. Information from patients with type 2 diabetes and healthcare staff is collected through a variety of different methods, including a patient questionnaire, interviews and observations and pseudonymised electronic patient data. Eligible patient participants are asked to complete a questionnaire, take part in observations and interviews relating to diabetes structured education and provide consent to access medical information.

The information gathered is used to to develop the resources ready for a larger scientific trial in 80 more GP practices around the UK in 2018.

Intervention Type

Other

Primary outcome measure
The feasibility and suitability of the components of the Embedding Package within the participating practice and wider host organisations as assessed using ethnographic methods throughout the duration of this feasibility study.

Secondary outcome measures
1. Optimisation of observational methods in a range of contexts for use in the main trial, are assessed using ethnographic methods throughout duration of feasibility
2. The completeness and quality regarding outcomes required for the RCT is assessed using data extracted from primary care by PRIMIS between months 2 and 6 of the feasibility study.
3. Referral and uptake practice level data from providers of SME are assessed for availability at the end of the study
4. Response rate to the questionnaire are recorded as the number of completed questionnaires returned by the end of the recruitment period
5. Patient preferences for the delivery of SME is assessed via the questionnaire responses at the end of the study
6. Consent rate for accessing medical records will be recorded as the number of completed consent forms returned by the end of the recruitment period
7. Costing for the component of the Embedding package will be assessed using a practice level proforma and interviews at the end of the feasibility study period

Overall study start date
01/05/2012

Completion date
31/01/2018

Eligibility

Key inclusion criteria
Practice Inclusion criteria:
1. Use either EMIS Web or TPP System One (required for data extraction)
2. Located within the participating CCGs
3. Able to refer patients with type 2 diabetes to a structured education programme.
4. Willing to sign a data sharing and remote data collection agreement with PRIMIS allowing the collection of one line per patient anonymised and, where patient consent is given, identifiable data as required for analysis.

Primary Care stakeholder eligibility criteria:
1. Employed by, or involved in the delivery of/or commissioning of any aspect of the Embedding Package at a participating practice/CCG
2. Willing and able to give informed consent (written or verbal)

Patient participant eligibility criteria:
1. Aged ≥18 years old
2. Coded in their primary care medical record as diagnosed with T2DM, before or during the study
3. Registered at a participating practice

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 200; UK Sample Size: 200

Total final enrolment
423

Key exclusion criteria
Practice exclusion criteria:
1. Does not use EMIS Web or TPP System One
2. Located outside of participating CCG
3. Unable to refer patients with type 2 diabetes to a structured education programme
4. Not willing to sign a data sharing and remote data collection agreement with PRIMIS

Primary care stakeholder exclusion criteria:
1. Not employed by or involved in the delivery or commissioning of any aspect of the Embedding Package at participating practice or CCG
2. Not willing or able to give informed consent

Patient participant exclusion criteria:
1. Aged under 18 years old
2. A record of a terminal illness
3. Life expectancy < 12 months
4. Coded in their primary care medical records as housebound or in residential care
5. A dissent code in their primary care medical records to sharing data as part of a research study

Date of first enrolment
08/06/2017

Date of final enrolment
30/11/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals Leicester (Lead site)
Gwendolen Road
Leicester
United Kingdom
LE5 4PW

Study participating centre
St Georges Medical Practice
93 Musters Road
West Bridgford
Nottingham
United Kingdom
NG2 7PG

Study participating centre
West Bridgeford Medical Centre
97 Musters Road
West Bridgford
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NG2 7PX

Study participating centre
East Leake Health Centre
Gotham Road
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LE12 6JG

Study participating centre
Danes Camp Medical Centre
Rowtree Road
Northampton
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NN4 0NY

Study participating centre
Albany House Medical Centre
Queen Street

Wellingborough
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NN8 4RW

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Sponsor information

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Sponsor type
University/education

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer review journal.

Intention to publish date
31/01/2019

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
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/05/2020	02/06/2020	Yes	No
HRA research summary			28/06/2023	No	No