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Embedding Diabetes Education (RCT)

Submission date
26/03/2018

Recruitment status
No longer recruiting

Registration date
05/04/2018

Overall study status
Completed

Last Edited
13/02/2025

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 is part of a complex research project aiming to increase the number of people with type 2 diabetes who go to self-management education programmes. Diabetes is a serious and progressive disease which can lead to complications like heart attacks, stroke, kidney failure, and a shorter lifespan. 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. This study is not about testing a particular diabetes education programme, as very good evidence about these programmes already exists. The researchers will be working with education providers, CCG staff (local NHS providers of primary healthcare) and 66 GP practices to improve the opportunities provided for people with diabetes to attend education programmes.

Who can participate?
Patients aged 18 and over with type 2 diabetes who are registered at participating practices

What does the study involve?
Participating practices are randomly allocated to either the immediate group or the wait-list group. The immediate group provide usual care data at the start of the study and then receive the intervention immediately. The wait-list group also provide usual care data at the start of the study and receive the intervention at a later date. The intervention involves a package of support and resources, the 'Embedding Package', developed in an earlier part of the research project. The Embedding package 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. It also includes a skilled person described as an 'Embedder' to support both providers and practices with ideas and skills. Information is collected from patients and healthcare staff through a variety of different methods, including a patient questionnaire, interviews, observations and electronic patient data. Through this data the effectiveness, cost-effectiveness and sustainability of the Embedding Package is assessed in comparison with usual care.

What are the possible benefits and risks of participating?
The benefits for practices and providers taking part is that they receive access to the evidence-based embedding package and to the Embedders who work with them to ensure all possible avenues for increasing uptake are explored and tested over the course of the study. The

Embedders are available to each provider service for about 1 day per week, this work will in the main be remote working. This helps provider organisations and referring practices to see the following benefits: increased capacity (decrease in nurse time and appointments required by patients), informed patients (leading to better quality appointments), help to better achieving treatment targets, assisting the practice in meeting the Improvement and Assessment Framework (IAF) targets, help to fulfil National Diabetes Audit (NDA) requirements in primary care, and improvements in coding of referral and uptake to structure education. Access to the Embedding Package (minus the Embedders/personnel) will also be available indefinitely after the study. Benefits for patients are that they will be helping the researchers to understand the current picture of diabetes education in a more rounded way, as rather than just relying on information from GP systems the researchers will ask patients to give their thoughts and current understanding. Risks for the patients are minimal as all data provided by them in questionnaires is anonymised and is only identifiable if permission is granted by them through the use of a pseudonymised-scrambled NHS number, which without the algorithm for unlocking is a meaningless 64-digit code. The risks for practices and providers is minimal – some time will be required to help the Embedders gather an understanding of the current local landscape for diabetes education and where possible to support the work of the Embedder throughout the course of the study.

Where is the study run from?
University Hospitals of Leicester NHS Trust (UK)

When is the study starting and how long is it expected to run for?
December 2017 to January 2021

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

Who is the main contact?
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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
CPMS 37222

Study information

Scientific Title
Evaluating the impact of an intervention to increase uptake of self-management education programmes for type 2 diabetes in primary care: a wait-list cluster randomised controlled trial

Study objectives
Diabetes is a serious and progressive disease which 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 this study is particularly relevant to anyone with diabetes, as well as the general public. This study is part of a complex research project aiming to increase the number of people with type 2 diabetes who go to self-management education programmes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands – Edgbaston REC, 05/02/2018, ref: 18/WM/0036

Study design
Randomized; Both; Design type: Process of Care, Education or Self-Management, Complex Intervention, Management of Care, Qualitative

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus

Interventions
Randomisation is at practice-level stratified by CCG and will be performed prior to baseline in a 1:1 fashion to either the immediate group or the wait-list group.

The immediate group will provide usual care data at baseline and will then receive the intervention immediately. The wait-list group also provide usual care data at baseline and will NOT receive the intervention after 9 months.

This study is not about testing a particular diabetes education programme; very good evidence about these programmes already exists. The trialists will be working with education providers, CCG staff (local NHS providers of primary healthcare) and 66 GP practices to improve the opportunities provided for people with diabetes to attend education programmes. They will offer a package of support and resources, the 'Embedding Package', developed in an earlier part of the research project. The Embedding Package 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 etc. It also includes a skilled person described as an 'Embedder' to support both providers and practices with ideas and skills. The trialists will collect information from patients with type 2 diabetes and healthcare staff through a variety of different methods, including a patient questionnaire, interviews and observations and pseudonymised electronic patient data. Through this data the study will assess the effectiveness, cost-effectiveness and sustainability of the Embedding Package in comparison to usual care.

The total study is 30 months:
Month 0 – baseline data extraction and randomisation
Month 0-9 – immediate arm receive intervention
Month 9-18 – immediate and wait-list arm receive intervention
Month 18-30 – both arms going into Sustainability phase of the study – the Embedder personnel are removed but access to website (embedding toolkit) is still available to all sites

Intervention Type
Other

Primary outcome measure
Patient-level HbA1c compared between the control (months 0-3 in immediate group and months 0-12 in wait-list group) and intervention (months 3-21 in immediate group and 12-21 in wait-list group) conditions in the RCT

Secondary outcome measures
Measured at month 0 (baseline), Month 0-9, Month 9-18 and Month 18-30:
1. Body mass index, if not available in GP system calculated from weight and height
2. Weight and height, as per method recorded in GP system
3. Total, LDL and HDL cholesterol, as per method recorded in GP system
4. Systolic and diastolic blood pressure, as per method recorded in GP system
5. Glucose, blood pressure and lipid lowering medications, as per method recorded in GP system
6. Smoking status, as per method recorded in GP system

7. Hospital admissions, as per method recorded in GP system – using appropriate Read-code to identify
8. QRisk2 score (a measure of cardiovascular risk), as per method recorded in GP system

Secondary process outcomes:
1. Whether or not the patient was referred to and attended, measured using Read-code from GP system at Month 0 (baseline), Month 0-9, Month 9-18 and Month 18-30; self-reported by patient in questionnaire at beginning of study; on receipt of self-report from patients education providers will be asked (will vary per site)
2. Percentage of eligible individuals referred to education, measured using Read-code from GP system at Month 0 (baseline), Month 0-9, Month 9-18 and Month 18-30
3. Percentage of eligible individuals who attended education, measured using Read-code from GP system at Month 0 (baseline), Month 0-9, Month 9-18 and Month 18-30
4. Percentage of eligible individuals who declined education, measured using Read-code from GP system at Month 0 (baseline), Month 0-9, Month 9-18 and Month 18-30
5. Number, timing and venue of available education sessions, measured using education provider questionnaire monthly
6. Number of trained educators, measured using education provider questionnaire monthly

Secondary psychosocial and process outcomes:
1. Where the patient has previously received diabetes information from, measured using self-report questionnaire at single time-point during month 0-9
2. Patient Activation Measure, measured using validated P.A.M questionnaire at single time-point during month 0-9
3. Well-being, measured using validated W-BQ12 questionnaire at single time-point during month 0-9
4. Problem Areas in Diabetes (PAID) score, measured using the validated PAID questionnaire at single time-point during month 0-9

Overall study start date
01/12/2017

Completion date
28/02/2022

Eligibility

Key inclusion criteria
Patients – data extraction and mail-out:
All patients registered at a participating practice and meeting the following eligibility criteria will have pseudonymised one line per patient data extracted, and will be mailed an invitation pack which includes an invitation letter, PIS and questionnaire booklet. The questionnaire booklet contains a self-report questionnaire and a consent form which gives patients the option to have their questionnaire responses linked to their attendance data in their practice and Provider records.

Patient inclusion criteria:
1. Registered at a participating practice
2. Aged ≥18 years old
3. Coded in their primary care medical record as diagnosed with T2DM before or during the study period (to be reassessed at each data extraction point)

4. Willing and able to provide informed consent (Applicable to optional consent form and questionnaire booklet only)
5. Able to understand written English to a level sufficient to enable an understanding of the research and their participation within it (applicable to optional consent form and questionnaire booklet only)

Patients – ethnographic sub-study:
Patients who express an interest to participate in the ethnographic sub-study and meet the following eligibility criteria will be eligible for the ethnographic sub-study

Patient inclusion criteria:
1. Meet all of the above patient eligibility criteria
2. Is able to attend the practice unaided or with a carer or support (applicable to observations of consultations only)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 2000; UK Sample Size: 2000

Total final enrolment
2308

Key exclusion criteria
Practice exclusion criteria:
1. Unable to make contact with practice manager or equivalent

Patient exclusion criteria - data extraction and mail-out:
1. Coded in their primary care medical records as having a terminal illness
2. Coded in their primary care medical records as housebound or in residential care
3. A dissent code in their primary care medical records for researcher to access clinical data

Patient exclusion criteria - ethnographic sub-study:
1. Unable to understand spoken English to a level sufficient to enable an understanding of the research and their participation within it

Stakeholder exclusion criteria:
1. Unable to understand written and spoken English to a level sufficient to enable an understanding of the research and their participation within it

Date of first enrolment

01/05/2018

Date of final enrolment
01/11/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals of Leicester NHS Trust
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Sponsor information

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University of Leicester

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Sponsor type
University/education

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-1212-20004

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal in approximately Summer 2021. Additionally a baseline paper is being considered for publication in early 2019.

Intention to publish date
01/03/2024

Individual participant data (IPD) sharing plan
The data that supports the findings of this trial will not be publicly available as consent for data sharing was not obtained.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V2.0	22/01/2018	05/04/2018	No	Yes
Participant information sheet	version V2.0	22/01/2018	05/04/2018	No	Yes
Participant information sheet	version V2.0	22/01/2018	05/04/2018	No	Yes
Protocol file	version V1.0	14/12/2017	05/04/2018	No	No
Protocol article	protocol	07/11/2019	11/11/2019	Yes	No
HRA research summary			20/09/2023	No	No
Results article		25/04/2024	26/04/2024	Yes	No
Other publications	Cost-utility analysis	11/02/2025	13/02/2025	Yes	No