ISRCTN70402110 https://doi.org/10.1186/ISRCTN70402110

A feasibility study of the effect of proactive diabetes specialist nurse reviews of patients with diabetes in hospital

Submission date
01/02/2022

Recruitment status
No longer recruiting

Registration date
21/02/2022

Overall study status
Completed

Last Edited
19/06/2024

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[_] Results

[_] Individual participant data

[_] Record updated in last year

Plain English summary of protocol

Background and study aims

The number of people diagnosed with diabetes has more than doubled in the last 20 years. This is a lifelong condition leading to high blood sugar levels. With an aging population and people with diabetes living longer more people admitted to hospital will have diabetes. Most people admitted to hospital with diabetes are not admitted because of diabetes, meaning that they are typically under the care of health care professionals who are not specialised in diabetes management. Because activity levels, food intake and general well-being are different in hospital compared to home, diabetes management is challenging and often outside of the experience of those providing inpatient care. Many hospitals have inpatient diabetes specialist nurses, despite this, good blood sugar levels are achieved for less than half of the hospital inpatient days. Furthermore, 20% have an episode of dangerously low blood sugar, during hospital admission.

Diabetes specialist nurses currently are usually only informed about diabetes inpatients after they have had dangerously low or high blood sugar levels. Inpatient specialist nurses are thus attempting to ‘fix’ rather than prevent diabetes complications. Diabetes specialist nurses could proactively assess the potential risk for these low or high blood sugar levels and recommend actions to help prevent them. This could mean that more specialist nurses would need to be employed, but money could also be saved as people with diabetes will have better glucose control, meaning their discharge is not delayed.

My study aims to explore whether a proactive (rather than reactive) review of patients with diabetes in hospitals is potentially beneficial in a large teaching hospital. I want to find out what staff and patients think of this approach and test whether a larger study could directly compare proactive reviews by diabetes nurses to what happens usually in hospital (reactive “after an event” reviews). I will do this by allocating at random (e.g. through the toss of a coin) four wards to receive the proactive reviewing service while another four wards will continue to receive usual care.

Who can participate?

Patients will be included if they are adults (16 years and older), have diabetes and are not already being looked after by the diabetes doctors.

What does the study involve?
Patients will automatically be reviewed by a diabetes specialist nurse if they have diabetes and are admitted to a ward randomly allocated to proactive reviewing. If a patient has diabetes and is admitted to a ward randomly allocated to usual care, they will only receive the review if their doctors or nurses requests it (current practice).
Routinely available Information will be collected such as blood glucose test results and the length of time the patient spends in hospital. I will then compare the outcomes for the patients that received the proactive reviewing against the outcomes for patients on the wards that did not. While this initial study will not be big enough to test if proactive review is better than current clinical practice, it will help inform if a larger trial is possible.
I am also interested in how well the diabetes specialist nurses deliver the proactive review and what staff and patients think of it. The inpatient diabetes specialist nurses will be observed delivering the proactive review to ensure that they all complete it to the same high standards. The patient and the diabetes nurse will then be invited to take part separately in a debrief interview. This will explore their experience of their view. Ward doctors, nurses and managers will also be interviewed

What are the possible benefits and risks of participating?
The risks of this study are considered minimal and there will be no interventions provided /recommended beyond those already available as part of clinical care. Possible disadvantages would include use of time and receiving advise individuals may prefer not to follow, however participants can accept or refuse any part of their clinical care in line with normal practice. The information we get from this study though may benefit other people who have diabetes and the staff and services who work in the specialty by providing much needed evidence to support the best way of working.

Where is the study run from?
Addenbrookes Hospital (UK)

When is the study starting and how long is it expected to run for?
June 2020 to December 2022

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

Who is the main contact?
Andrea Lake, a.lake@uea.ac.uk

Contact information

Type(s)
Public

Contact name
Mrs Andrea Lake

ORCID ID
http://orcid.org/0000-0002-2901-7020

Contact details

Wolfson Diabetes & Endocrine Clinic - Box 281
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ
+44 7852353760
a.lake@uea.ac.uk

Type(s)
Scientific

Contact name
Mrs Andrea Lake

Contact details
Wolfson Diabetes & Endocrine Clinic - Box 281
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ
+44 7852353760
a.lake@uea.ac.uk

Type(s)
Principal Investigator

Contact name
Mrs Andrea Lake

Contact details
Wolfson Diabetes & Endocrine Clinic - Box 281
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ
+44 7852353760
andrea.lake@nhs.net

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
302069

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
IRAS 302069, CPMS 51167

Study information

Scientific Title
Proactive review for people with diabetes in hospital: a cluster randomised feasibility study and process evaluation

Acronym
PREP-D

Study objectives
It is feasible to conduct a cluster randoimised controlled trial testing the efficacy of the Proactive diabetes review care model (PDRM)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/01/2022, East of England - Cambridge Central Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +442071048384; cambridgecentral.rec@hra.nhs.uk), ref: 21/EE/0275

Study design
A cluster randomized feasibility trial with parallel process evaluation

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Interventions

The Proactive Diabetes Review Model (PDRM) is a complex intervention delivered by diabetes inpatient specialist nurses for patients with diabetes admitted to hospital. PDRM consists of a patient centred diabetes assessment undertaken within one working day of admission and aims to identify risk and prevent diabetes related harm.
Overall responsibility for the patient will remain with the primary ward team (patients admitting specialty doctor and ward nurses as is currently the case). Therefore, as part of this process, support for the patient's primary team will be provided through expert recommendations, on the spot education as needed, and an increased visibility of the diabetes inpatient specialist nurses on the wards. After the first review the patient will then be triaged into one of two groups: no further review required (re-refer as needed) or ongoing review (the diabetes inpatient specialist nurse team will provide ongoing reviews). PDRM differs from usual care as we will aim to review all patients with diabetes, not just those who have been referred. Other differences include the structure, timing and aims of the review itself.

Feasibility trial:
Eight wards will be recruited and then randomised to receive either the PDRM intervention or usual care. The Proactive Diabetes Review Model (PDRM) (n=4 wards) is a complex intervention delivered by diabetes inpatient specialist nurses for patients with diabetes admitted to hospital. PDRM consists of a single patient centred diabetes assessment undertaken within one working day of admission and aims to identify risk and prevent diabetes related harm. This review will include an enhanced clinical assessment of the patient's diabetes related biomarkers, history, and relevant physical exam. PDRM differs from usual care (n=4 wards) as we will aim to review all patients with diabetes, not just those who have been referred. Other differences include the structure, timing and aims of the review itself. There is no specified follow up visits in accordance with the protocol. Any patient clinical follow up will be organised at the discretion of the individual diabetes specialist nurse undertaking the review and in line with usual care processes. All patients will be followed up in the study until discharged from hospital (this is the end point of their participation in the study regardless of study arm and regardless of decisions made by DSNs).

Randomisation will be stratified by ward type (medical or surgical). Wards will be randomly allocated to receive either usual care or the PDRM intervention. The Ralloc procedure in Stata® will be used for randomisation. Block randomisation will limit imbalance in trial arms. Randomisation will take place following ward recruitment, baseline data collection and training.

Process Evaluation:
Underpinned by ethnographic methodologies, a parallel process evaluation will investigate both the delivery and acceptability of the PDRM intervention as well as trial feasibility to identify how to refine the intervention and trial design to optimise implementation in a future definitive trial. Methods will include single episodes of direct observations of the intervention delivery and semi structured interviews with patients, healthcare professionals and managers. A thematic approach to analysis is planned.

Intervention Type
Other

Primary outcome measure
1. Evaluate and describe the feasibility of a cluster randomised design within an acute trust setting recorded as:
1.1. the proportion of eligible wards, healthcare professionals and patients who consent to take part in the study by 8 months

1.2. the completion of the randomisation process and review of the equilibrium between arms
1.3. the number of eligible diabetes specialist nurses undertaking the training and contributing to the delivery of the study by 8 months
2. Assess the extent to which the PDRM is delivered as intended
3. Assess acceptability of the PDRM intervention and trial processes, including recruitment and consent
4. Identify any potential sources of contamination in the usual care arm
5. Identify contextual barriers and facilitators of delivery
6. Identify outcomes that are important to patients
For points 2-6 the methods used will include:
• Direct non participatory observations at the point of intervention delivery followed by debrief interviews
• Semi structured interviews with patient, healthcare professionals and managers

Secondary outcome measures
Evaluate availability and integrity of data relating to measures of glycaemic control through:
1. monthly ward level and individual patient admission incidence of hypoglycaemia defined as a glucose result<4.0 mmol/L
2. monthly ward level and individual patient admission incidence of hyperglycaemia >15.0 mmol /L
3. monthly ward level and individual patient admission incidence of positive capillary ketones >1. 5 mmol/L
4. monthly ward level and individual patient admission length of hospital stay
5. monthly ward level and individual patient admission incidence of hospital acquired foot ulceration

Overall study start date
01/06/2020

Completion date
19/12/2022

Eligibility

Key inclusion criteria
The main trial will recruit both wards (clusters) and patients:
1. Wards: General adult medical and surgical wards are eligible. The specialist diabetes wards, day-case units, maternity wards and paediatric areas (age <16 years) are excluded.
2. Patients: Adult patients with a diagnosis of diabetes documented on their problem list admitted to one of the included wards will be eligible. Inpatients already under the care of the specialist diabetes team in hospital will be excluded.

The process evaluation will include both a sub-sample of patients from the trial and health care professionals:
1. Patients: All patients with diabetes admitted to an included ward and taking part in the trial will be eligible.
2. Healthcare professionals: Nurses and Doctors that are permanent members of staff on an included ward will be eligible, along with all members of the diabetes inpatient specialist nurse team responsible for delivering the proactive diabetes review model (intervention). As key

stakeholders, divisional leads with service development, budget assignment and strategic decision-making responsibilities will also be eligible and known as managers for the purpose of this protocol.

Participant type(s)
Patient, Health professional

Age group
Adult

Sex
Both

Target number of participants
8 clusters. 250-500 trial participants and 22 participants in the process evaluation

Total final enrolment
287

Key exclusion criteria
1. Inpatients already under the care of the specialist diabetes team in the hospital
2. <16 years old

Date of first enrolment
25/04/2022

Date of final enrolment
02/12/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrookes Hospital
Cambridge University Hospitals NHS Foundation Trust
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

Sponsor details
Research & Development Department - Box 277
S Block, Level 4
Addenbrooke’s Hospital
Hills Road
Cambridge
England
United Kingdom
CB2 0QQ
+44 1223256620
andrea.lake@addenbrookes.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.cuh.org.uk/

ROR
https://ror.org/04v54gj93

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

This study will provide evidence for the feasibility of a definitive cluster randomised controlled trial of PDRM and its design. Dissemination will focus on diabetes specialists, key stakeholders, study participants and members of the public. The chief investigator expects to produce a minimum of three open access publications: one each to describe trial results, process evaluation outcomes and barriers and facilitators to the trial design. Further dissemination strategies will include presentation of results at relevant conferences and relevant local and national meetings (during site visits and Diabetes UK clinical study group meetings) and utilising patient and public communication strategies employed by Diabetes UK, such as social media and their website. These dissemination strategies will be detailed in the participant information sheets for both patients and staff.

Intention to publish date

01/09/2024

Individual participant data (IPD) sharing plan

The 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?
HRA research summary			28/06/2023	No	No
Protocol article		11/06/2024	19/06/2024	Yes	No