ISRCTN14918517 https://doi.org/10.1186/ISRCTN14918517

Preventing cardiovascular and renal complications in patients with type 2 diabetes and microalbuminuria: the GP-Prompt study

Submission date
11/05/2015

Recruitment status
No longer recruiting

Registration date
09/06/2015

Overall study status
Completed

Last Edited
04/03/2021

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Type 2 diabetes mellitus is a lifelong condition which causes a person's blood sugar level to become too high. People are more likely to develop diabetes if they are overweight, do not exercise, eat an unhealthy diet or are of an older age. Some people with type 2 diabetes also show signs of microalbuminuria, a term used to describe an increase of albumin protein detected in a person's urine. Microalbuminuria does not have any specific symptoms itself, and is usually only diagnosed by urine test. However, the presence of microalbuminuria is associated with a higher risk of heart and kidney disease in people with type 2 diabetes. Identifying microalbuminuria in patients with type 2 diabetes early can lead to faster treatment, decreased costs and hospital visits, and improved long term health. Unfortunately, there is currently no routine way for general practitioners (GPs) and practice nurses to review all the risk factors that they need to consider during consultations with patients diagnosed with type 2 diabetes and microalbuminuria. The aim of this study is to test new software which aims to bring these factors together and alert the healthcare professional that the patient has a high risk of heart and kidney disease. This will assist the health care professional in targeting the many risk factors involved to improve heart and kidney health in people with type 2 diabetes and microalbuminuria.

Who can participate?
Leicester GP practices and attached patients diagnosed with type 2 diabetes and microalbuminuria.

What does the study involve?
Participating GP practices are randomly allocated into one of two groups. GP practices in group 1 (intervention group) have customised software installed on their computers. The software highlights patients with type 2 diabetes and microalbuminuria to the GP and/or practice nurse. Practice staff are also given educational training on how to manage these patients better, and receive regular feedback on how these patients are being treated. GP practices in group 2 (control group) continue to provide standard care for their patients. The health of patients included in the study is assessed 2 years later using anonymised data.

What are the possible benefits and risks of participating?
Patients treated by GP practices using the computerised ‘prompting’ system may have better health outcomes. If this is the case, the results of this study will be used to recommend that all GP surgeries are provided with this training and information to improve patient outcomes.

Where is the study run from?
Leicester Diabetes Centre - Leicester General Hospital (UK)

When is the study starting and how long is it expected to run for?
June 2015 to June 2017

Who is funding the study?
Collaboration for Leadership in Applied Health Research and Care - East Midlands (UK)

Who is the main contact?
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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
0513

Study information

Scientific Title
An implementation strategy for reducing cardiac and renal complications in people with type 2 diabetes: the GP-Prompt study

Study objectives
Does a multifaceted intervention consisting of an automated software package operating within GP practice IT systems, education and training for practice staff and enhanced audit and feedback increase the proportion of eligible patients meeting enhanced targets for blood pressure and total cholesterol?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Lancaster, 16/04/2015, ref: 27/4/15.

Study design
Two-arm cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
The intervention being tested is aimed at general practitioners and practice nurses. The intervention will support practices in managing patients with type 2 diabetes and microalbuminuria.

Interventions
The intervention consists of three separate parts:
1. A software alert/template: the software alert will sit on the GP Practice computer and will trigger when eligible patients attend the surgery. The alert will encourage GPs/nurses to treat blood pressure (BP)/HbA1c/total cholesterol (TC) to target
2. Enhanced training for healthcare professionals: an educational intervention - two members of practice staff will be invited to attend a 1/2 day training session. Content will focus on justification for tighter targets for TC, BP and HbA1c in addition to case based discussion
3. Follow up email support for case based discussion: intervention practices will be able to access advice from a diabetes consultant via email in relation to specific queries

Intervention Type
Mixed

Primary outcome measure
Proportion (%) of patients meeting both of the following targets: BP <130/80 mmHg and total cholesterol <3.5mmol/l measured 24 months post-intervention.

Secondary outcome measures
1. Incidence of CV events and all-cause mortality
2. Glycaemic control assessed by HbA1c
3. Progression in microalbuminuria assessed via albumin-creatinine ratio (ACR)
4. Kidney function measured via estimated glomerular filtration rate (eGFR)
5. Current type 2 diabetes mellitus medications (use of metformin, Sulphonylureas (SUs), insulin, thiazolidinediones (TZD), glucagon-like peptide-1 (GLP1), dipeptidyl peptidase-4 inhibitor (DPP4) or sodium-glucose linked transporters (SGLT2))
6. Current BP or cholesterol medications (use of ACE inhibitors, ARBs, beta blockers, alpha blockers, aspirin, statins or exenatide)
7. Current smoking status

Overall study start date
01/06/2015

Completion date
30/06/2017

Eligibility

Key inclusion criteria
We aim to recruit 24 practices (12 intervention & 12 control) we will collect anonymised data from eligible patients registered at participating practices. Patients will be eligible if they have type 2 diabetes and microalbuminuria and are not excepted from quality outcomes framework (QOF) (whole domain diabetes) for any reason.

Participant type(s)
Health professional

Age group
Mixed

Sex
Both

Target number of participants
24

Key exclusion criteria
1. GP practices not located in Leicester City CCG, Leicester county east CCG or Leicester county west CCG will not be invited to take part in the study
2. GP practices with a list size of <6500 patients will not be invited to take part in the study

Date of first enrolment
15/06/2015

Date of final enrolment
31/07/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leicester Diabetes Centre - Leicester General Hospital
Gwendolen Road
Leicester
Leicester
United Kingdom
LE5 4PW

Sponsor information

Organisation
University of Leicester

Sponsor details
Leicester General Hospital
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England
United Kingdom
LE2 3JE

Sponsor type
University/education

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

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Research organisation

Funder Name
Collaboration for Leadership in Applied Health Research and Care - East Midlands (UK)

Results and Publications

Publication and dissemination plan
We plan to publish results of the study in high impact peer reviewed journals.

Intention to publish date
01/08/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol and baseline characteristics	08/06/2018		Yes	No
Results article	results	01/08/2020	04/03/2021	Yes	No