ISRCTN75386686 https://doi.org/10.1186/ISRCTN75386686

Reducing variability and improving diabetes care in general practices in deprived and ethnic areas

Submission date
19/11/2015

Recruitment status
No longer recruiting

Registration date
19/01/2016

Overall study status
Completed

Last Edited
18/10/2017

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Diabetes is an expensive and difficult condition to manage and there is variation in how effectively people with diabetes are looked after. People in poorer, multi-ethnic areas have a lower life expectancy than those in richer areas and there has not been any attempt to address this imbalance. This study aims to identify those patients most at risk of poor management of their diabetes, and to provide extra training and support for the staff who look after them. Link workers who are able to speak the same language as the patient will be key to this process.

Who can participate?
Patients aged 18 or over with diabetes, and general practice staff who provide diabetes services to ethnic minority people with diabetes and/or have commissioning responsibility for diabetes services within the locality.

What does the study involve?
Participating GP practices are randomly allocated into two groups. The extra training and support is rolled out to one group of GP practices over 12 months, then it is rolled out to the other group of practices over the following 12 months. Most of the information is gathered using a computer system which is already in use across the region. The researchers are also interested in speaking to a small number of patients about their experiences and how care might be improved. This involves meeting in a group or having a one-to-one interview where the researcher can ask some questions about the patient's experience. Staff members who participate are asked how diabetes care would benefit from being located mainly in the community rather than in a hospital.

What are the possible benefits and risks of participating?
The benefits would be an improvement in diabetes care for all patients in the area. There are no risks involved.

Where is the study run from?
University Hospitals Coventry and Warwickshire NHS Trust (UK)

When is the study starting and how long is it expected to run for?
February 2016 to January 2018

Who is funding the study?
External funding application underway

Who is the main contact?
Dr Joseph Paul O'Hare
j.p.o-hare@warwick.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Joseph Paul O'Hare

Contact details
University of Warwick
Warwick Medical School
Coventry
United Kingdom
CV4 7AL
+44 (0)2476 573086
j.p.o-hare@warwick.ac.uk

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Reducing variability and improving diabetes care in general practices in deprived and ethnic areas

Study objectives
To investigate whether an intervention of intensive support reduces the variability in diabetes care and improves its performance in UK general practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands – Solihull Ethics Committee, 25/04/2016, Ref: 16/WM/0074

Study design
Interventional and observational study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Diabetes

Interventions
Phase 1 will be a 3-month run-in for the project that will employ the project team in developing the application of the intervention in two practices similar to the 16 practices but not to be part of the analysis. This will involve training and applications of the Eclipse tool to capture the quantitative data needed for evaluation and in identification of the patients at risk, care finding and then care management. The acceptability and frequency of the team visits to practice and the virtual reinforcement through Eclipse, are additional areas requiring development and careful strategy including in this phase the development of the intervention tools.

Recruitment and any training of the Community Pharmacist and Link Worker, Community Dietician and Project Quality Team, will need to commence and be complete by the end of 6 weeks. Selection of practices after stratification by size to ensure a randomised equal sample, so that the comparator practices and those that have the intervention can be legitimately compared.

During the following 12 months the roll-out to the 8 practices will take place, continuing with the cross-over to the other 8 practices over the next 12 months; the support to reach all key performance indicators will also be carried out. After 14 months there will be a 6-week data collection and qualitative data for the intervention and control group.

1. A pre-evaluation group meeting with patients with diabetes and staff (duration 60-90 mins). The qualitative researcher (PZ) will facilitate the meeting, supported by a second researcher. Informed consent will be taken from all new participants. Meetings will be audiotaped.
2. Two to three observations involving patients and staff (duration 2-4 hours). Observations will be arranged via the clinical staff member(s) delivering the intervention. Where appropriate, permission to observe will be granted by both the patient and staff. The observation will be conducted in line with Good Clinical Practice (GCP) guidelines throughout. Only field notes will be taken.
3. A post-evaluation group meeting with patients and diabetes staff (duration 60-90 mins). The qualitative researcher (PZ) will facilitate the meeting, supported by a second researcher. Informed consent will be taken from all new participants. Meetings will be audiotaped.
4. Semi-structured 1:1 interviews (duration 45-60 mins). Approximately 20 of the participants (who took part in the evaluation meetings interviews and any addition) who give their consent to take part in semi-structured interviews about their experiences in the diabetes intervention. The interviews will take place at locations convenient to the participant, either within the Coventry and Rugby CCGs or their home or UHCW. Meetings will be audiotaped with participants' consent. The researchers will arrange meetings using the contact details the patients have provided.

Intervention Type
Other

Primary outcome(s)
Improvement in key performance indicators following intervention and in qualitative measures of patient and staff satisfaction

Key secondary outcome(s))
The secondary outcome measures of this study aims to evaluate the experience of staff and patients who participated in the intervention within the Coventry & Rugby CCGs, using qualitative methods.

We will conduct a qualitative study in parallel to the trial, the aim of which is to provide insight into participants' experiences of taking part in the experimental intervention. As the trial has two arms (intervention and control groups), three qualitative methods (group evaluation meetings [one pre-intervention and another post-intervention], observation, and 1-1 semi-structured face-to-face interviews) will be used to understand both the patients and staff views regarding the intervention. The research will be carried out by a researcher trained and experienced in qualitative research methodologies, supported by second researcher as follows:

1. First, a one-off purposive evaluation group meeting involving both patients and staff will be organised prior to the intervention with 8-12 key participants. The researcher will share existing evidence of some of the benefits of implementing diabetes services in the primary care settings rather than in hospital clinics. The meeting will then seek the views and reasons for participation and what the participants intend to achieve. Participants will be engaged to identify and discuss the types of clinical sessions that can be removed from hospital clinics and transferred into general practices as part of the integrated Community Diabetes Service, and the potential benefits.

2. Observations - Observations will take place at the beginning, middle and towards the end of the of the intervention at 2-3 clinics/consultations to make comparisons of what has been said /agreed or done to what actually happened during the intervention duration, whilst making notes on the changes or differences. This approach is useful in collecting data in naturally occurring behaviours and contexts and will enable the researcher to question, understand and document how things work in their natural settings. It will also complement the study by enriching all the other qualitative data (evaluation meetings and the semi-structured interviews).

3. At the end of the intervention, another one-off evaluation meeting will be organised with all those who participated at the initial meeting, including two additional participants. This meeting will seek to understand the views/experiences of the participants and whether the intervention met their expectations – what was planned and achieved or planned but not achieved or subsequently changed. The additional two new participants will be able to follow the discussion and comment from a neutral view point.

4. All participants who participated in the post evaluation meeting, plus any other key stakeholder (maximum of 20 participants and/or reach achieve data saturation) will be invited to take part in a 1-1 face-to-face semi-structured interviews using topic guide questions to provide a level of consistency between interviews, whilst maintaining some flexibility to capture ideas raised by the interviewees. The interview topic guides will used mostly open-ended questions to focus the discussion on the phenomena of interest. The interviews will address some of the issues that were not fully explored at the evaluation meetings, what worked and/or did not work in the intervention, how could the intervention be improved and sustained to become a truly

integrated Community Diabetes Service to benefit patients and the community at large and be transferable nationally. It is also give opportunity to some of the participants who may not have been fully opened to express their views in the group settings about our studied phenomenon.

Regarding 4 above, we will interview participants until we feel confident that we have reached data saturation. Based on our previous experiences we anticipate that the above stated maximum of 20 participants will be sufficient. Sampling in 1 – 4 will be purposive and will be aimed at reflecting the population of the intervention arm of the trial in relation to gender, ethnicity and social class both for the patients and staff. Pseudonyms will be used and any other identifying information will be anonymised to ensure participants' confidentiality is maintained. Evaluation and interview transcripts and field notes will be uploaded into NVivo (QSR), a computerised programme for qualitative data, to assist with data management and analysis.

Our approach to data analysis will be thematic and will broadly follow the principles of grounded theory (Charmaz, 2006).

The meetings will be conducted at convenient locations of the participants but away from clinical areas in order to minimise any interruptions. The 1-1 interviews will be held at locations preferable to the participants, either in their office or home or NHS buildings within Coventry and Rugby CCGs. The duration of evaluation meetings will range from 60-90 minutes, interviews 45-60 minutes and the observations last between 2-4 hours each.

To ensure that participants are fully aware of their rights and responsibilities in the study, a detailed PIL/SIL will be giving to them - clarifying the objectives of the study, assuring them of their confidentiality and of the fact that participation in the study was entirely voluntary and of their right to withdraw at any stage without affecting their NHS care.

Completion date
31/01/2018

Eligibility

Key inclusion criteria
1. Participants will comprise both patients and general practice staff
2. Patients should have a diagnosis of diabetes and be aged 18 years or over
3. General practice staff should be responsible for providing diabetes services to ethnic minority people with diabetes and/or having commissioning responsibility of diabetes services within the locality, and should have been in their post for at least 6 months

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients who are not adults and who do not have diabetes
2. General practice staff who do not provide diabetes service to ethnic minority communities and who have been in post for less than 6 months

Date of first enrolment
01/02/2016

Date of final enrolment
30/04/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
United Kingdom
CV2 2DX

Sponsor information

Organisation
University Hospitals Coventry and Warwickshire NHS Trust (UK)

ROR
https://ror.org/025n38288

Funder(s)

Funder type
Other

Funder Name
External funding application underway

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes