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Supervised pharmacy student led medication review of patients with diabetes in primary care.

Submission date
13/08/2015

Recruitment status
No longer recruiting

Registration date
13/08/2015

Overall study status
Completed

Last Edited
01/09/2016

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Medication reviews are beneficial to patients by making sure that the medications they are taking and the monitoring of their condition is appropriate, the patient knows how and why they are taking their medication and the medicines are being taken appropriately. Although pharmacists have good drug knowledge and are trained to help patients to take their medicines, research has shown that to regularly provide medication reviews pharmacists need to develop their communication skills and work more closely with medical practices. We believe that pharmacy student experience of undertaking real medication reviews under close supervision in a medical practice and a later related patient consultation is an innovative model which could provide significant patient benefit at relatively small cost. The aim of this study is to identify the potential patient benefits of these medical reviews and to describe it so that its easily repeated across other schools of pharmacy in the UK.

Who can participate?
Participants with type 2 diabetes taking non-insulin antidiabetes medication

What does the study involve?
First of all, a review of previous work is done alongside focus groups with doctors, patients, pharmacists and students. Patients from four medical practices are then recruited and then randomised to one of two groups. Those in group 1 undergo a student led medication review. Those in group 2 receive usual care. Pairs of students from the University of East Anglia are allocated 4 participants from group 1 to review under supervision at the patient's medical practice. Students discuss their findings with the participants GP. Six weeks later supervised face to face medicines related consultations with reviewed participants are carried out at the University. A questionnaire is sent to all participants from both groups six months after the interviews and the results between the two groups compared. Focus groups are then held again in order to learn from the process.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
School of Pharmacy, University of East Anglia (UK)

When is the study starting and how long is it expected to run for?
February 2011 to November 2012

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

Who is the main contact?
Mr Rick Adams
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Contact information

Type(s)
Public

Contact name
Mr Rick Adams

Contact details
School of Pharmacy, University of East Anglia
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
9933

Study information

Scientific Title
Supervised pharmacy student led medication review of patients with diabetes in primary care:a pilot study to ascertain the potential costs and effects.

Study objectives
Pilot study to identify if there are any benefits to type 2 diabetes patients in undertaking a student led medication review. In addition we will establish if there are any benefits in terms of education for the student.

Ethics approval required
Old ethics approval format

Ethics approval(s)
10/H0306/77

Study design
Randomised; Interventional; Design type: Process of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Topic: Primary Care; Subtopic: Other Primary Care; Disease: All Diseases

Interventions
1. Each intervention arm patient received a medication review of their medication by a student pharmacist, using their medical records. Any potential action forwarded to the patient's GP. Each intervention arm patient then met a student pharmacist for a one to one medication review.
2. Control patients received usual care.
Follow Up Length: 3 month(s); Study Entry : Single Randomisation only

Intervention Type
Other

Primary outcome measure
HbA1c; Timepoint(s): Pre intervention and 6 months post intervention

Secondary outcome measures
1. Blood pressure; Timepoint(s): Pre intervention and 6 months post intervention
2. Lipid profile; Timepoint(s): Pre intervention and 6 months post intervention
3. Medication adherence (MARS); Timepoint(s): Pre intervention and 6 months post intervention
4. Patient beliefs about medicines (BMQ); Timepoint(s): Pre intervention and 6 months post intervention
5. Quality of life (EQ5D); Timepoint(s): Pre intervention and 6 months post intervention
6. Satisfaction with diabetes treatment (DTSQ); Timepoint(s): Pre intervention and 6 months post intervention

7. Satisfaction with information about medicines (SIMS); Timepoint(s): Pre intervention and 6 months post intervention

Overall study start date
14/02/2011

Completion date
30/11/2012

Eligibility

Key inclusion criteria
1. Prescribed non insulin medication for type 2 diabetes for at least 2 years
2. Willing to give consent
3. Registered with one of the 4 participating GP practices

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 160; UK Sample Size: 160; Description: 80 control and 80 intervention

Key exclusion criteria
1. Deemed unsuitable for inclusion in the study for any reason by their GP
2. Enrolled in other clinical trials
3. Suffering from terminal illness

Date of first enrolment
14/02/2011

Date of final enrolment
30/11/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

School of Pharmacy, University of East Anglia
Earlham Road
Norwich
Norfolk
United Kingdom
NR4 7TJ

Sponsor information

Organisation
NHS South Norfolk CCG

Sponsor details
Research & Development
NHS South Norfolk Clinical Commissioning Group
Lakeside 400
Old Chapel Way
Broadland Business Park
Thorpe St Andrew
Norwich
England
United Kingdom
NR7 0WG

Sponsor type
Hospital/treatment centre

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
1. Dissemination meetings with patient participants (both groups) July 2014
2. Documentation of results to participating medical practices - July 2014
3. Copies of any publications sent to those participants requesting this at recruitment. date to be confirmed at a later date
4. Attendance at scientific conferences as appropriate. Date to be confirmed at a later date
5. Publication in appropriate journals

Intention to publish date
01/08/2015

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?
Results article	results	04/11/2015		Yes	No