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Vascular Intervention Program: a strategy of medication management for cardiovascular risk in people with type 2 diabetes

Submission date
17/02/2006

Recruitment status
No longer recruiting

Registration date
19/04/2006

Overall study status
Completed

Last Edited
25/05/2017

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
Heart disease and stroke have a significant impact on the patient and the health care system. People with diabetes are at higher risk of developing heart disease, perhaps because they are more likely to have other risk factors such as high blood pressure and high cholesterol. Recognizing this, the Canadian Diabetes Association recommends aggressive management of all risk factors. Given the complex medication treatments often required for management, pharmacists may provide a unique contribution to overall patient care. The aim of this study is to assess the impact of pharmacist care on heart disease risk in people with type 2 diabetes.

Who can participate?
Patients with type 2 diabetes, who are not considered for urgent assessment by the Regional Diabetes Program

What does the study involve?
Participants are randomly allocated to either the intervention group or the control group. For the intervention group the intervention is essentially the addition of a pharmacist to a care team within community family physician clinics. The pharmacist works as a member of the care team to provide information on drug treatment and take responsibility for monitoring outcomes for all of the patient's conditions to ensure effective use of medications. During the first visit, the pharmacist obtains a complete medication history to identify all prescription, non-prescription, herbal, and homeopathic drug products the patient currently uses. The pharmacist obtains the patient's medical history. A limited physical examination is performed to measure the patient's blood pressure. A survey is used to identify any difficulties with medication adherence. The pharmacist records his/her observations and identifies any actual or potential drug-related problems. Recommendations for changes to the patient's drug treatment are communicated by the pharmacist directly to the health care team in the physician office. Improvement of medication adherence is the first major focus of the pharmacist intervention. The pharmacist educates the patients about the name, purpose, and appropriate use of each prescription medication. The patient is encouraged to ask questions about their medications and the pharmacist takes the time to address these concerns. Recommendations to simplify the

medication are made where needed. For example, drugs that are administered once-daily and combination drug formulations are recommended where possible. Cuing techniques (e.g. coordinating taking medication with a daily event, use of blister packaging) are used to incorporate medication consumption into the patient's daily routine. Support mechanisms, such as close telephone follow-up, involvement of the patient's family, and group teaching sessions are used. The second major focus of the pharmacist intervention is to identify and resolve drug-related problems. Interventions to resolve these problems include: education on diabetes, heart disease risk factors, and the importance of reaching treatment goals for blood pressure and cholesterol, education on the impact of lifestyle choices (diet, exercise and smoking) on heart disease risk, education on the benefits and risks of drug treatment, and treatment recommendations for the patient's primary care physician. Interim visits with the intervention group participants are arranged as needed. These visits may be conducted either over the phone, or in-person. This contact time is used to identify any patient concerns about the medication and determine if an in-person follow-up visit is required. In-person follow-up visits, estimated to take 15-20 minutes, include a shortened medication history to update any changes in drug treatment since the last visit and a limited physical examination to obtain the patient's current blood pressure. The pharmacist then determine if there are any drug-related problems, most notably to determine if the treatment target for blood pressure has been achieved. At the 12-month follow-up visit, the patient is asked to complete the same survey given at the start of the study. The pharmacist obtains a blood pressure measurement and a blood sample is taken. Patients enrolled in the control group do not interact with the pharmacist until the end of the 12-month follow-up period. Their care is managed by the care team. Information on current prescription medications and clinical data, including blood pressure, are obtained. At the end of the 12-month follow-up, all patients are asked to attend an in-person clinic visit with the pharmacist. The pharmacist conducts an interview similar to the interview for the intervention group participants. A blood sample is also taken.

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

Where is the study run from?
University of Alberta (Canada)

When is the study starting and how long is it expected to run for?
February 2006 to June 2007

Who is funding the study?
1. Canadian Diabetes Association (Canada)
2. Institute of Health Economics (Canada)

Who is the main contact?
Dr Scot H Simpson

Contact information

Type(s)
Scientific

Contact name
Dr Scot H Simpson

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Vascular Intervention Program: a strategy of medication management for cardiovascular risk in people with type 2 diabetes

Acronym
VIP

Study objectives
Addition of a pharmacist to the interdisciplinary primary care team will improve blood pressure control in patients with type 2 diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Health Research Ethics Board (Biomedical), University of Alberta, February 2004, ref: 5137

Study design
Randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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
Type 2 diabetes mellitus

Interventions
Intervention programs that successfully improve management of chronic diseases share similar characteristics. First, a framework of explicit care plans (or critical pathways) is used to guide patient care. Second, the practice setting is restructured to involve an interdisciplinary team approach that will meet the needs of the patients. Third, attention is given to the information and support needs of the patient as they change health-related behaviours. Fourth, access to necessary expertise should be available for both the patient and the health care providers when needed. Fifth, an integrated information system is used for record-keeping and coordinating provision of ongoing care and follow-up. The environment created by the Primary Care Networks in our health region facilitates the development of these characteristics.

The intervention is essentially the addition of a pharmacist to an interdisciplinary care team within community family physician clinics. The pharmacist will work as a member of the interdisciplinary care team to provide information on drug therapy and take responsibility for monitoring therapeutic outcomes for all of the patients conditions to ensure effective use of medications. Activities specifically related to this study include:
1. Identification of any patient-perceived barriers to medication use and provision of patient-specific instructions to improve adherence
2. Identification of any drug-related problems pertaining to blood pressure control and provision of any necessary recommendations to optimize therapy
3. Recommendations to use acetylsalicylic acid, if indicated. These activities will be provided to the patient in addition to the regular services provided by the interdisciplinary care team.

During the first visit, which is expected to take 1 hour, the pharmacist will obtain a complete medication history to identify all prescription, non-prescription, herbal, and homeopathic drug products the patient currently uses. The pharmacist will obtain the patients medical history from discussion with the interdisciplinary team members, the physician office chart, and patient report. A limited physical exam will be performed to obtain the patients current blood pressure using the BpTRU. The BpTRU is an automated blood pressure device that has good accuracy and reliability compared to a mercury sphygmomanometer. Responses to the Barriers to Medication Use component of the baseline survey will be used to identify any difficulties with medication adherence. The pharmacist will record his/her observations on standardized report forms and use a systematic approach to process the information to identify any actual or potential drug-related problems. Recommendations for changes to the patients drug therapy will be communicated both verbally and in writing by the pharmacist directly to the health care team in the physician office.

Improvement of medication adherence will be the first major focus of the pharmacist intervention. Based on recent systematic reviews in adherence, a multifaceted approach is the most effective for improving adherence rates. The pharmacist will use written and verbal instructions to educate the patients about the name, purpose, and appropriate use of each

prescription medication. The patient will be encouraged to ask questions about their medications and the pharmacist will take the time to address these concerns. Recommendations to simplify the medication will be made, where indicated. For example, drugs that are administered once-daily and combination drug formulations will be recommended where possible. Cuing techniques (e.g. coordinating administration time with a daily event, use of blister packaging) will be used to incorporate medication consumption into the patients daily routine. Support mechanisms, such as close telephone follow-up, involvement of the patients family, and group teaching sessions will be used. We have found in discussions with heart failure patients that these techniques helped them maintain good adherence rates.

The second major focus of the pharmacist intervention is to identify and resolve drug-related problems. Interventions to resolve these problems would include, for example:
1. Comprehensive and individualized education on diabetes, cardiovascular risk factors, and the importance of reaching treatment goals for blood pressure, cholesterol, and acetylsalicylic acid use
2. Education on the impact of lifestyle choices (diet, exercise, and smoking) on cardiovascular risk
3. Education on the benefits and risks of drug therapy
4. Treatment recommendations for the individuals primary care physician

Treatment recommendations for hypertension and hypercholesterolemia management and acetylsalicylic acid use will be based on management algorithms. These algorithms are being developed from current Canadian guidelines, existing algorithms, treatment protocols from randomized controlled studies, and advice from local opinion leaders, family physicians, and allied health care professionals. For example, recommendations for hypertension management will follow a stepped care approach and an algorithm to determine indications for prophylactic use of acetylsalicylic acid was recently published.

Interim visits with the intervention group subjects will be arranged as clinically necessary. These visits may be conducted either over the phone, or in-person. This contact time will be used to identify any patient concerns about the medication regimen and determine if an in-person follow-up visit is required. In-person follow-up visits, estimated to take 15-20 minutes, will contain an abbreviated medication history to update any changes in drug therapy since the last visit and perform a limited physical exam to obtain the patients current blood pressure. The pharmacist will then determine if there are any drug-related problems; most notably to determine if the treatment target for blood pressure has been achieved.

At the 12-month follow-up visit, the patient will be asked to complete the same self-administered survey given at enrollment. The pharmacist will obtain a blood pressure measurement and a fasting blood sample will be drawn to determine blood glucose levels, A1c, and a lipid profile.

Control group:
Patients enrolled in the control group will not interact with the clinic pharmacist until the end of the 12-month follow-up period. Their care will be managed by the interdisciplinary care team. Baseline information on current prescription medications and clinical data, including blood pressure, will be obtained from the office chart. At the end of the 12-month follow-up, all patients will be asked to attend an in-person clinic visit with the pharmacist. The pharmacist will conduct an interview similar to the baseline interview for the intervention subjects. Fasting blood sample will be drawn to determine blood glucose levels, A1c, and a lipid profile.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Proportion of subjects achieving a 10% reduction in systolic blood pressure from baseline

Secondary outcome measures
Outcome-based variables:
1. Differences in systolic blood pressure (BP) changes between groups
2. Proportion of subjects achieving the BP target of <130/80
3. Differences in A1c changes between groups
4. Differences in low-density lipoprotein (LDL) changes between groups
5. Difference in 10-year risk of cardiovascular disease as calculated by:
5.1. Framingham risk score
5.2. United Kingdom Prospective Diabetes Study (UKPDS) risk equation

Process-based variables, adjustment in drug therapy
6. Initiate regular aspirin use for cardiovascular disease prevention
7. Initiate angiotension-converting enzyme (ACE) inhibitor therapy for vascular protection
8. Change to antihypertensive therapy
9. Change to lipid-lowering drug therapy
10. Difference in adherence rate to antihypertensive drug therapy between groups
11. Difference in proportions of subjects having Canadian Diabetes Association guideline-based recommendations in past year
12. Measurement of A1c (outside of protocol-driven measure at study end)
13. Measurement of fasting lipid profile (outside of protocol-driven measure at study end)
14. Measurement of creatinine ratio (ACR)
15. Measurement of urinary albumin
16. Eye examination for retinopathy
17. Foot examination by a health care professional

Overall study start date
21/02/2006

Completion date
30/06/2007

Eligibility

Key inclusion criteria
Patients with type 2 diabetes, who are not considered for urgent assessment by the Regional Diabetes Program (i.e. those with A1c <0.08, blood pressure <220/120, or triglycerides <15 mmol /l)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
400 (200 in intervention arm and 200 in control arm)

Key exclusion criteria
1. Subjects currently followed in specialty clinics for management of hypertension, hyperlipidemia, or diabetes
2. Those who decline an invitation to participate
3. Those who are cognitively impaired (i.e. unable to give informed consent)
3. Those who are not responsible for their own medication consumption
4. Those who are unable to communicate in English

Date of first enrolment
21/02/2006

Date of final enrolment
30/06/2007

Locations

Countries of recruitment
Canada

Study participating centre
University of Alberta
Alberta
Canada
T6G 2N8

Sponsor information

Organisation
Canadian Diabetes Association

Sponsor details
1400 - 522 University Avenue
Toronto
Ontario
Canada
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Sponsor type
Charity

Website
http://www.diabetes.ca

ROR
https://ror.org/00arvcr78

Funder(s)

Funder type
Charity

Funder Name
Canadian Diabetes Association

Alternative Name(s)
Association Canadienne du Diabète, The Canadian Diabetes Association, CDA

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
Canada

Funder Name
Institute of Health Economics

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2012		Yes	No