ISRCTN90211238 https://doi.org/10.1186/ISRCTN90211238

Pharmacist-involved collaborative care In the management of patients with diabetes

Submission date	Recruitment status	[_] Prospectively registered
05/11/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/11/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/05/2020	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
Diabetes is one of the common chronic health problems that affects many people in Singapore. Uncontrolled diabetes, where patients have persistently high levels of sugar in the blood, can harm important organs such as heart and the kidneys, and the management of diabetes-related complications is costly. People with diabetes, however, can still live a long and healthy life if their diabetes is well-controlled. Well-controlled diabetes requires healthy diet and active lifestyle, and optimal use of medications is also essential in ensuring timely control of diabetes. The purpose of this study is to find out the value of a new care approach which involves pharmacists, in addition to nurses, dieticians and other healthcare professionals, to support physicians in caring for patients with uncontrolled diabetes.

Who can participate?
Patients aged at least 21 years with uncontrolled type 2 diabetes, and other uncontrolled co-morbidities (other health conditions).

What does the study involve?
Patients are randomly allocated to one of two groups. Those in group 1 receive the active involvement of the pharmacist in drug optimization. Referrals to nurses and dieticians are actively made by the pharmacist and vice versa as required. Patients in group 2 (the control group) receive their usual or conventional care from the physician with as needed referral at the discretion of the physician to the nurses and dieticians. These patients are seen by different physicians at each visit, and pharmacists are not involved in drug optimization except for dispensing.

What are the possible benefits and risks of participating?
Patients who participate in this study may reasonably expect to benefit from the pharmacist-involved healthcare model in that the pharmacists will be able to assist patients in reviewing and explaining their blood glucose results, optimize medications, provide a cost-effective medication regimen, assist in setting goals to improve patients' conditions, answer questions related to medications and empower patients' knowledge on medications. There will not be any possible risks or side effects for participating in this study. Because the involvement of pharmacist is to provide an added value, patients' standard of care or routine care is still being preserved.

Where is the study run from?
National Healthcare Group Health Institutions (Singapore)

When is study starting and how long is it expected to run for?
December 2012 to November 2015

Who is funding the study?
Singapore Ministry of Health

Who is the main contact?
Professor Joyce Lee
phalycj@nus.edu.sg

Contact information

Type(s)
Scientific

Contact name
Prof Joyce Lee

ORCID ID
https://orcid.org/0000-0003-2620-555X

Contact details
Department of Pharmacy
Faculty of Science
National University of Singapore
Block S4, 18 Science Drive 4
Singapore
Singapore
117543
+6565168014
phalycj@nus.edu.sg

Additional identifiers

Protocol serial number
HSRG10MAY020

Study information

Scientific Title
The effectiveness of pharmacist-involved collaborative care model in the management of patients with diabetes mellitus in Singapore

Study objectives

The hypothesis of this study is that patients with diabetes under pharmacist-involved collaborative care will have greater improvements in all the clinical, humanistic and economic outcomes assessed than those under the conventional care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National University of Singapore Institutional Review Board and National Healthcare Group Domain Specific Review Board, 20/12/2012, 2012/01037

Study design
Multicenter, prospective, open-label, parallel-arm, randomized controlled study.

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Type 2 diabetes and other chronic comorbidities such as hypertension and dyslipidemia

Interventions
Eligible patients will be randomized into the intervention or control arms:
1. Patients assigned to the intervention arm will receive active involvement of the pharmacist in drug optimization. The clinical interventions carried out by the pharmacist include but are not limited to counseling patients about drug therapy, performing simple physical assessments, ordering pertinent follow-up visits and laboratory tests on behalf of the physicians, and initiating, titrating, and terminating medications per clinical protocol and under the supervision of the physicians as appropriate. As needed, referrals to nurses and dieticians will also be actively made by the pharmacist and vice versa. The pharmacist will schedule clinic appointments approximately every six weeks, with a total of 4 pharmacist visits in the 6-month follow-up period. If the patient’s diabetes is well-controlled, i.e. with stable improvements in clinical measures, the pharmacist may replace one or two clinic visits with telephone counseling at his /her discretion.
2. Patients assigned to the control arm will receive the usual or conventional care from the physician with as needed referral at the discretion of the physician to the nurses for soft skill-related diabetes counseling and dietitians for diet control. These patients may be seen by different physicians at each visit, and pharmacists will not be involved in drug optimization except for dispensing.

Intervention Type
Other

Primary outcome(s)
1. Glycated hemoglobin (HbA1c),
2. Systolic blood pressure (SBP),
3. Low-density lipoprotein (LDL),
4. Triglycerides (TG)

Will be measured at baseline, three- and six-months

5. Incidence of minor and major hypoglycemia,
6. Appropriateness of aspirin and ACEI/ARB use,
7. Diabetes-related clinical visit and hospitalization
8. Morisky Medication Adherence Scale (MMAS),
9. Euro Quality of Life Five Dimensions (EQ-5D),
10. Audit of Diabetes-Dependent Quality of Life (ADDQoL),
11. Problem Areas in Diabetes (PAID),
12. Diabetes Treatment Satisfaction Questionnaires (DTSQ)
13. Direct and indirect costs

Will be measured at baseline and six-months

Key secondary outcome(s))
N/A

Completion date
13/11/2015

Eligibility

Key inclusion criteria
1. 21 years and above
2. Diagnosed with type 2 diabetes
3. HbA1c ≥ 7%
4. Uncontrolled co-morbidities such as hypertension (>130/80 mm Hg) and dyslipidemia (LDL > 2.6 mmol/L and TG > 2.3 mmol/L)
5. Characteristics of CAREPILLS (defined as Closer monitoring, Adherence problem, Resistance to drug therapy, Empowerment in patient's own therapy, Polypharmacy, Insulin titration, Lack in drug knowledge, Lack in drug administration techniques and Switching of drugs)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
441

Key exclusion criteria
1. Diagnosed with type 1 diabetes
2. Unable to communicate independently

Date of first enrolment
01/05/2013

Date of final enrolment
01/04/2015

Locations

Countries of recruitment
Singapore

Study participating centre
National Healthcare Group Health Institutions
Singapore
138543

Sponsor information

Organisation
National University of Singapore

ROR
https://ror.org/01tgyzw49

Funder(s)

Funder type
Government

Funder Name
Singapore Ministry of Health

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?
Results article	results	01/08/2017	21/05/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes