Diabetes Project Leuven, Belgium.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21652

Source
NTR

Brief title
DPL (Diabetes Project Leuven)

Health condition

Diabetes mellitus type 2, adherence to guidelines, clinical inertia, primary care

Sponsors and support

Primary sponsor: National Institute for Health and Disability Insurance, Belgium
Source(s) of monetary or material Support: National Institute for Health and Disability Insurance, Belgium

Intervention

Outcome measures

Primary outcome

The primary endpoints of the study are the proportion of patients reaching the ADA-targets for three bio-clinical outcomes:

1. HbA1c < 7%

2. SBD

3. LDL-C < 100mg/dl.

Secondary outcome

Secondary endpoints are individual improvements of 12 validated parameters, i.e.

- HbA1c

- LDLC

- HDL-C

- Total Cholesterol

- SBP

- Diastolic Blood Pressure (DBP)

- Weight

- Physical exercise

- Healthy diet

- Smoking status

- Statin

- Anti-platelet therapy.

Study description

Background summary

ABSTRACT

Objective

To evaluate the effectiveness of a two- arm quality improvement programme in diabetes care on improvements in adherence to evidence-based guidelines and a reduction in the rate of clinical inertia in primary care physicians.

Methods:

Clustered randomized trial with 18-month intervention period. The “UQIP” group (53 GPs, 918 patients) was subjected to basic re-structuring of care. The “AQIP" Programme” group (67 GPs 1577 patients) in addition received more cost-intensive interventions both at the GP’s (patient centred feedback, peer review, education on motivational interviewing) and the patient’s level (group education by nurse educators at home and interventions of a health psychologist).

Primary therapeutic targets were:

HbA1c < 7%; LDL-Cholesterol < 100 mg/dl ; Systolic Blood Pressure

Results :

The proportion of patients on target before and after intervention significantly increased in the UQIP and the AQIP groups respectively from 53 to 66% and 55 to 68% (HbA1c), from 41 to 55% and 42 to 60% (LDL-C), from 48 to 53% and 50 tot 60% (SBP). Evolutions over time in these three targets were significant ($p<0.0001$) but not different in the two groups. UQIP and AQIP differed only in two secondary endpoints, i.e. a higher increase in the latter of the proportion of patients receiving anti-platelet therapy and in those doing physical exercise. Higher initial values were associated with better improvement.

Conclusion:

The restructuring of a healthcare setting that is not well adapted to chronic care delivery results into significant positive outcomes and thus better quality of care. Cost-intensive interventions show little additional benefit.

Study objective

A first hypothesis is that an advanced quality improvement program (AQIP) significantly improves clinical outcomes in persons with type 2 diabetes compared to a usual quality improvement program (UQIP).

The second hypothesis is that persons with type 2 diabetes who make use of a Diabetes Care Team (DCT) have significant better patient related outcomes compared to non-users of the DCT.

A third hypothesis is that primary care physicians who participate in the AQIP implementation

program have better process outcomes compared to physicians who participate in the UQIP.

Study design

T0 (January 2005-June 2005)

T1 (end of project)

Intervention

Type of interventions:

Two separate groups are randomly defined. The first group receives an advanced quality improvement program (AQIP-program) whereas a second group receives a usual quality improvement program (UQIP-program). Physicians can make use of the services of the programs on a voluntary basis.

In a first intervention arm a set of ‘usual’ quality improvement interventions (UQIP) will be implemented with the aim to improve adherence to evidence-based guidelines and to reduce the rate of clinical inertia in primary care physicians (PCP’s). The term ‘usual’ is applied since these interventions address the principal factors contributing to clinical inertia (physician, patient and office system factors) and represent standard requirements for what is considered quality of diabetes care in most health care systems according to international clinical guidelines and theoretical frameworks on quality of diabetes care in particular.

In addition to interventions as defined in the UQIP, PCP’s and their patients of the second intervention arm will receive supplementary and more experimental interventions that we refer to as ‘advanced’ quality improvement interventions. The interventions of this Advanced Quality Improvement Program (AQIP) aim at improvements in adherence to evidence-based guidelines and a reduction of the rate of clinical inertia in PCP’s by means of an extended focus on behavior changes in patients and providers. Interventions that focus on the patient aim at a more active involvement of the patient in his/her treatment regimen with a special focus on lifestyle attitude changes. Interventions that target the provider (PCP’s) focus on improvements in communication patterns with patients, interdisciplinary shared care and the involvement of PCP’s in community campaigns.

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Eligibility criteria

Inclusion criteria

All 379 primary care physicians (PCP's) that actively execute their profession in the project region were invited to participate.

These PCP's work in a semi-rural setting with 357.000 inhabitants in Belgium and predominantly serve Caucasian patients with diabetes mellitus type 2.

Primary care physicians provide care for approximately 80% of patients with type 2 diabetes, and are often the sole providers of care.

The only inclusion criterion for the providers is the agreement to bring in all their known patients with type 2 diabetes mellitus. In this way selection bias is prevented. In addition, PCP's will be asked to screen more systematically for new type 2 diabetes mellitus patients during 7 months after the start of the registration period.

Diabetes is defined in accordance to the 2003 ADA criteria with PCP's to take the final decision about the diagnosis of type 2 diabetes.

Exclusion criteria

Type 1 diabetes mellitus patients. Patients not capable to provide informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2005
Enrollment:	120
Type:	Actual

Ethics review

Positive opinion

Date:	07-07-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1320
NTR-old	NTR1369
Other	: ML 2719
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A