

Diabetes Care Implementation Study.

No registrations found.

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

Summary

ID

NL-OMON27595

Source

Nationaal Trial Register

Brief title

DIS

Health condition

Diabetes mellitus type 2, Primary care, Decision Support System (Clinical), Delegation, Quality of Health Care.

Nederlands:

Diabetes Mellitus type 2, Eerste lijnsgezondheidszorg, Beslissing ondersteunende systemen, Taak delegatie, Kwaliteit van zorg

Sponsors and support

Primary sponsor: Prof. dr. G.E.H.M. Rutten

Source(s) of monetary or material Support: Julius Center for Health Sciences and Primary Care
University Medical Center Utrecht
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Intervention

Outcome measures

Primary outcome

1. Change in:
 - a. HbA1c%;
 - b. Blood pressure;
 - c. Total cholesterol.

Secondary outcome

1. Change in cardiovascular risk;
2. Effects on quality of life and patient treatment satisfaction;
3. Effects on proces of care.

Study description

Background summary

The quality of care for patient with type 2 diabetes mellitus (DM2) in the Netherlands is still not optimal.

About 30% of these patients do not meet target values for blood glucose as recommended in the national guide lines.

Patients with diabetes have a 2-3 times increased risk for cardiovascular disease. When all cardiovascular risk factors, blood pressure and cholesterol are treated adequately, in time this will lead to less diabetes related complications.

There have been many projects on improving care for patient with diabetes. Beside these projects, guidelines have been developed to improve the quality of diabetes care. Most projects were only temporary and often there is insufficient support for implementation in daily primary care practice.

Diagnosis4Health (D4H) developed the Diabetes Care Protocol (DCP) in order to optimise diabetes care in general practice. DCP consist of a computerised decision support system, delegating routine task in diabetes care to a practice nurse, and starting a categorical diabetes consultation hour under responsibility of the primary care physician. Every three months the primary care physician becomes benchmark information. DCP is based on the

Dutch primary care guidelines on diabetes mellitus type 2.

Aim of the study:

To study the effectiveness of the Diabetes Care Protocol as it is implemented by Diagnosis4Health.

Methods:

DIS is a cluster randomised intervention trial in 55 primary care practices. In 25 practices the Diabetes Care Protocol is implemented, the other 30 practices form the control group. They perform usual diabetes care. After one year DCP is also implemented in the control group.

Population:

Patients with type 2 diabetes mellitus treated by their primary care physician and able to visit the primary care practice.

Intervention:

Implementation of the Diabetes Care Protocol. The primary care practices are analysed to make a practice improvement plan. These improvements are necessary for optimal diabetes care. The practice nurse is schooled in performing a categorical diabetes consultation hour, and in using the computerised decision support DCP software. Every three month the primary care physician becomes benchmark information.

Primary endpoint:

Change in cardiovascular risk (factors): HbA1c, blood pressure and cholesterol.

Secondary endpoints:

Changes in process of care, quality of life, and quality of care.

Possible profits:

Improvement in quality of care, with improvements in primary endpoint.

Improvement in quality of life for patients with type 2 diabetes mellitus with equal or improved satisfaction about the quality of care.

This method, delegating routine chronic care to a practice nurse, using computerised decision support, may be used for other chronic illnesses. (COPD and/or cardio vascular disease)

Study objective

Diabetes care can be improved by task delegation to a practice nurse supported by computerised decision support and benchmarking.

Study design

N/A

Intervention

Implementing the diabetes care protocol (DCP) developed by Diagnosis 4 Health.

Characteristics: consultation hour exclusively scheduled for DM2 patients and delegation of routine diabetes care tasks to a trained practice nurse who uses the DCP software that supports management and medical decisions.

Contacts

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Eligibility criteria

Inclusion criteria

Diabetes mellitus type 2.

Exclusion criteria

1. Under treatment of medical specialist;
2. Terminally ill patients;
3. Patients with complex multi morbidity;
4. Patients not able to visit the general practice.

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):	01-03-2004
Enrollment:	3500
Type:	Actual

Ethics review

Positive opinion	
Date:	20-02-2007

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	NL891
NTR-old	NTR915
Other	:
ISRCTN	ISRCTN21523044

Study results

Summary results

N/A