

The effectiveness of case management in addition to disease management: a study in patients with diabetes mellitus and comorbidity as an example.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28219

Source

NTR

Health condition

Care for diabetics with comorbidity.

Sponsors and support

Primary sponsor: NIVEL (Netherlands Institute for Health Services Research)

Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Score on 'tailored care' scale of the Consumer Quality Index for general practitioner's care.

Secondary outcome

1. Quality of care;
2. Health status;
3. Diabetes control;
4. Health care utilisation.

Study description

Background summary

BACKGROUND

For many patients suffering from multiple chronic diseases, participating in several single-disease oriented disease management programmes leads to uncoordinated care. The single-disease management programmes are not well prepared for coordinating care between programmes. Therefore, these patients are at risk for suboptimal treatment, unsafe care, unnecessary use of health care services, and consequently higher costs. Health care providers are convinced that for patients with multiple health problems tailored care is most appropriate, such as an individualised care programme ('case management'). This programme includes evidence based optimal care, but is tailored to the individual patient's preferences, especially if the optimal care for the various chronic diseases leads to contradictory or non-feasible treatments and recommendations. However, the additional value of such a case management programme has not been scientifically proven.

OBJECTIVE

The proposed study aims at establishing the added value of a case management programme additional to a single-disease management programme compared to this single-disease management programme alone. The study will be carried out among patients with diabetes mellitus and at least one other chronic disease.

RESEARCH QUESTIONS

1. What is the effectiveness of a case-management programme superposed on a single-disease management programme compared to a single-disease management programme alone for patients with diabetes mellitus and at least one other chronic disease regarding the quality of care (from the patient and the professional perspective), their health status, and their health care utilisation?

2. For which patients with diabetes mellitus and at least one other chronic disease is a case management programme superposed on a single-disease management programme more effective than the single-disease management programme?
3. Which factors favour or hamper the implementation of the case management programme superposed on the single-disease diabetes management programme?

STUDY PLAN

The study includes a cluster-randomized controlled clinical trial. Randomisation takes place on the level of general practices. The intervention includes the application of a case management programme by a trained practice nurse in general practice additional to a diabetes management programme. The case management programme includes 6 elements (assessment, design of a care plan, monthly monitoring of the care plan, coordination of care of all care professionals involved, facilitating access to health care providers and community services, recording and documentation). The patients in the control group will continue their participation in the diabetes management programme and receive care-as-usual by their general practitioner. The effectiveness of the combination of a case management programme in addition to the diabetes management programme compared to the diabetes management programme alone will be established after 12 months after the start of the case management programme.

POPULATION

Patients with diabetes mellitus and at least one of the following diseases will be eligible for the study: chronic ischaemic heart disease, stroke, depression, rheumatoid arthritis, osteoarthritis of hip or knee, cancer or chronic obstructive pulmonary disease. Patients will be recruited among the participants of the diabetes management programme "Diabetes Zorgsysteem West-Friesland".

OUTCOME MEASURES AND MEASUREMENTS

The main outcome measure is the quality of care as perceived by the patient. For this, the 'tailored care' subscale of the Consumer Quality Index, will be used, a validated questionnaire on quality of care. The primary outcome measure is the difference of this subscale score of the intervention and control group at inclusion and after 12 months. Secondary outcome measures include the quality of care from the professional perspective (the degree to which the delivered care for diabetes mellitus and the other chronic disease(s) is according to professional guidelines as measured with previously developed quality indicators), health status (on the basis of SF-36 scores, a generic health status questionnaire), diabetes control (Hb1Ac), and the use of health care services (on the basis of

patient questionnaires). Data will be collected through patient questionnaires at the start of the study and after 3 and 12 months. Additional data will be derived from the patients' medical records of the diabetes management programme and the general practices. Information about factors favouring or hampering the implementation will also be collected via interviews with patients, practice nurses, diabetes nurses and general practitioners.

Study objective

Care supported by case management and diabetes management for diabetics with comorbidity is perceived as better coordinated than care supported by disease management only.

Study design

0, 6 and 12 months after the start of the intervention.

Intervention

Case management programme.

Contacts

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Eligibility criteria

Inclusion criteria

Patients with diabetes mellitus and comorbidity participating in the diabetes management programme provided by the Diabetes Research Centre in Hoorn (NL).

Exclusion criteria

A health problem probably leading to death within 1 year.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2009
Enrollment:	258
Type:	Anticipated

Ethics review

Positive opinion	
Date:	08-06-2009
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	NL1737
NTR-old	NTR1847
Other	ZonMW : 300020003
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A