Implementation of a nurse-led self-management support programme among patients with diabetes in primary care: inquiry into efficiency

Published: 18-11-2010
Last updated: 19-03-2025

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON34709

Source
ToetsingOnline

Brief title
Implementation of Self-Management Support in primary care

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Mood disorders and disturbances NEC
- Lifestyle issues

Synonym
depressive symptoms, diabetes-specific distress

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: diabetes mellitus type 2, implementation, primary care nurses, self-management

Outcome measures

Primary outcome

Effect evaluation

The primary outcome of the RCT is perceived daily functioning, measured by means of a VAS-scale (DFT).

Cost-effectiveness evaluation

The cost-effectiveness evaluation includes program costs of implementing SMS, costs of training, direct health care costs, direct non health care costs and indirect costs (production losses relating to both paid and unpaid work, measured by SF-HLQ).

Process evaluation

Questionnaires completed by the practice nurse and patients will enable construction of several composite variables like the proportion of patients receiving the intervention as intended, the proportion of patients who refused and their reasons, and patients* ability to understand and implement the intervention. Interviews and focus groups with patients, practice nurses and GPs will provide insight into experiences and satisfaction with SMS, obstacles

to administering SMS and possible solutions for large scale implementation.

Secondary outcome

1. Autonomy and Participation

2. Satisfaction with care

3. Quality of life

4. Disease-specific quality of life

5. Self-efficacy

6. Glycaemic control

Demographic factors are age and gender of the POH and type of practice (solo, duo, group). Patient demographics are age, gender, marital status, income, education, year of diagnosis. The 4DSQ during follow up (at T3 and T12) gives insight in mental health problems.

Study description

Background summary

The increased risk for mental health problems in a chronic patient is at least twice as high as in the general population. The mutual relation between psychological problems and disease management leads to a downward spiral, disempowering the people involved and negatively influencing the course of the chronic disease. The consequences can be translated in terms of decreased individual well-being as well as increased social cost.

Given the increasing number of chronic patients, the need for a significant transformation of health care is recognized. Current health policy stresses the importance of a pro-active approach that supports patients in day-to-day management of their chronic condition. However, treatment is yet mainly focused on the biomedical or clinical aspects of the chronic disease itself rather than on its psychosocial consequences. Psychosocial problems often remain unrecognized and are under-treated in current health care. If

co-occurring mild or moderate mental problems are detected, they have increasingly been prescribed antidepressants and benzodiazepines. It does not support patients to handle impaired abilities in daily life by learning how to self-manage them.

Integrating diagnostics and psychological counselling in routine care is essential to actively prevent a downward spiral in chronic patients. We will evaluate the integration of an (cost) effective nurse-led intervention into the regular encounters between patients with diabetes mellitus type 2 and practice nurses. The intervention will be supplemented by a feasible (stepped) screening method to examine patients* need for self-management support. It primarily aims to improve daily functioning of patients. The practice nurse facilitates that patients explore possible solutions for their problems themselves, so the individual context of patients will be taken into account.

Study objective

Our pragmatic trial aims to integrate a cost-effective innovative care intervention in regular primary care. The intervention needs to be adapted for practice nurses to detect mental health problems in physical chronic patients and to provide, according to one*s needs, support in self-management, during regular consultations. Integrating this pro-active approach in routine care has to enable a shift towards integral chronic care, with simultaneous attention to both somatic and psycho-social aspects of a chronic physical disease. This approach intends to improve daily functioning of chronic patients.
The primary objective of this study is to evaluate the implementation of SMS provided by practice nurses during regular diabetes check-ups. The following questions will be addressed:
1. What is the effect of implementation of SMS in regular primary care on perceived problems in daily functioning (primary outcome) and on the secondary outcome parameters participation and autonomy, control over the disease, self-efficacy, quality of life, and appreciation of care of diabetes type II patients? (effect evaluation)
2. In what extent is it, from a societal perspective, cost-effective to deliver SMS in the primary care setting? (economic evaluation)
3. What are barriers hampering the integration of SMS in regular care at the level of the practice organization, practice nurses, general practitioners and the patients involved? (process evaluation)

After successful implementation, care for mental health problems can easily be permanently integrated in the regular payment system, not only for diabetes but also in the future for COPD and CVD.

Study design

The design involves a pragmatic, 2-armed randomized trial with an intervention

arm of 23 practice nurses applying SMS added to usual care, and a control arm of 23 practice nurses providing care as usual. A cluster randomisation on POH level is necessary as the POH is a unit of analysis. Usual care consists of 3-monthly check-ups conforming to diabetes guidelines. SMS will be integrated in the regular encounters between diabetes type 2 patients and practice nurses in general practice. Practice nurses in the intervention arm will be trained to carry out SMS. Practice nurses in the control arm receive training after T12. Follow-up measurements will be carried out by patient questionnaires at baseline, and 3 and 12 months after inclusion. Cost measurements will be carried out by means of random cohort measurement (3 subgroups retrospectively measure 3 random months a year). Process evaluation will focus on actual performance and possible barriers/facilitators for the implementation of SMS. Both quantitative and qualitative information will be collected among practice nurses, patients and GP*s.

To maintain the desirable contrast between intervention and control group, and to guarantee comparability between both groups, practice nurses will not be involved in the detection of patients with mental problems. Recruitment of patients will be carried out equally for both groups by the researcher. Patients who visit their practice nurse for a diabetes check-up within the next two months will be sent the Distress Screener (DS, 3 items), and the Daily Functioning Thermometer (DFT), a VAS-scale indicating problems with daily functioning. Patients give informed consent to use the scores for recruitment of eligible patients. For each practice nurse, 10 consecutive patient with moderate or severe mental problems (DS > 3 and/or DFT < 6) will be asked to participate in the study and give informed consent for participation.

Intervention

After training, a practice nurse is supposed to be competent regarding the following elements:

1. Each patient who visits a practice nurse will be examined for problems with daily functioning following the limitations of their diabetes. If applicable the Distress Screener (DS) and Daily Functioning Thermometer (DFT) will be administered and, if indicated (with DS > 3 and/or DFT < 6), patients complete the 4DSQ, a self-report questionnaire that distinguishes between patients with mild, moderate or severe mental health problems. Patients with severe problems will be referred to the GP.
2. Providing patients having moderate problems of functioning with Problem Solving Support, unless their problems are too emotional. Problem Solving Support consists of 7 stages that efficiently address psychosocial problems: (a) defining the problem, (b) setting achievable goals, (c) generating alternative solutions, (d) evaluating pro*s and cons, (e) choosing solutions, (f) implementing the preferred solution and (g) evaluating the outcome.
3. Use of reattribution in patients with strong emotional involvement. Practice nurses will take the problems of daily functioning as a starting point and will

aim at reattribution of negative cognitions, by stimulating positive behaviours.
An essential characteristic of SMS, as the practice nurse will be trained for, is to tailor it to the specific needs and context of a patient. Problems and solutions are mainly defined by patients themselves. The practice nurse only facilitates decision making about action plans by the patient him/herself.

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Study burden and risks

Experiences with SMS in the previous study DELTA show that the perceived burden is very low. Chronically ill elderly patients were satisfied and would recommend the intervention to other patients with a chronic condition. More than 90% of the participating patients suggested implementation of the intervention in regular care.

In our pragmatic trial, the effect of this innovative care intervention integrated in regular care will be evaluated. SMS will be integrated in the daily work of POH's in the intervention group. It takes place during regularly diabetes check-ups. If necessary, the (three-quarterly) consultation will be advanced.Practice nurses in the control arm will be trained in SMS after follow-up.

Patients will be recruited for the two trial arms using two short self-administered questionnaires (DS and DFT). Patients in the control group do not complete the 4DSQ at T0, to prevent patients' awareness of mental health problems without providing self-management support from trained practice nurses. However, we do not keep patients from psychosocial care.
Follow-up measurements will be carried out after the inclusion visit, and 3 and 12 months after inclusion. Data will be collected using self-administered questionnaires. With regard to the process evaluation, some patients will be invited for a semi-structurered interview (after T12) . Besides, communication between POH and patient during the diabetes check up will be audio recorded after patients' informed consent.

Contacts

Public
Universiteit Maastricht

Postbus 616
6200 MD Maastricht
NL
Scientific
Universiteit Maastricht

Postbus 616
6200 MD Maastricht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Both the intervention group as the control group consist of
- type 2 diabetes mellitus patients,
- who receive regular diabetes care from the POH in the general practice,
- and have moderate or severe problems of daily functioning (<6 Daily Functioning Thermometer DFT and/or >=4 Distress Screener DS).

Exclusion criteria

No exclusion criteria. We will send the short questionnaire to all patients who consecutively will visit their POH for a regular diabetes check-up within the next two months.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-09-2011
Enrollment:	460
Type:	Actual

Ethics review

Approved WMO

Date:	18-11-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 25250
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL31235.068.10
OMON	NL-OMON25250

Study results

Date completed:	01-11-2013
Actual enrolment:	264