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Original Article

A disease management programme for patients with diabetes mellitus is associated with improved quality of care within existing budgets

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Abstract

Aim To assess the impact of a disease management programme for patients with diabetes mellitus (Type 1 and Type 2) on cost-effectiveness, quality of life and patient self-management. By organizing care in accordance with the principles of disease management, it is aimed to increase quality of care within existing budgets.

Methods Single-group, pre-post design with 2-year follow-up in 473 patients.

Results Substantial significant improvements in glycaemic control, health-related quality of life (HRQL) and patient self-management were found. No significant changes were detected in total costs of care. The probability that the disease management programme is cost-effective compared with usual care amounts to 74%, expressed in an average saving of 117 per additional life year at 5% improved HRQL.

Conclusion Introduction of a disease management programme for patients with diabetes is associated with improved intermediate outcomes within existing budgets. Further research should focus on long-term cost-effectiveness, including diabetic complications and mortality, in a controlled setting or by using decision-analytic modelling techniques.

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Keywords cost utility, diabetes mellitus, disease management,

Abbreviations BMI, body mass index; DMP, disease management programme; DNS, diabetes nurse specialist; GP, general practitioner; HRQL, health-related quality of life; QALY, quality-adjusted life year; SCBC, Self-Care Behaviour Checklist; SF-36, Short-Form 36; VAS, visual analogue scale

Introduction

In the last decade, disease management programmes (DMPs) for patients with diabetes mellitus have gained attention in the belief that redesigning health care according to principles of disease management would improve patient outcomes and mitigate costs [1–3]. DMPs seek to identify chronic conditions more quickly and treat them more effectively, thereby slowing the progression of the disease. This is pursued through a combination of enhanced screening, monitoring and education, the co-ordination of care between providers and settings, and standardization of care using evidence-based guidelines [4,5]. The assumption is that, for the increasing number of chronically ill patients, better care today will result in better health and less expensive care in the future [5].

Thorough evaluation of the impact of DMPs on processes and outcomes of care is important, because the prevalence of diabetes and the burden of diabetes-related costs on scarce health care resources is rising [6]. Until now, many DMPs have been introduced without critical examination of the actual value of such programmes. Recently, the US Congressional Budget Office published a report stressing that 'to date there is insufficient evidence to conclude that DMPs can generally reduce the overall cost of healthcare services' [5]. Most studies do not directly address costs [5], and no significant improvements have been shown for outcomes such as mortality, hospital

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admission, patient satisfaction, patient knowledge and patient self-management [7]. As a result, decision making regarding the allocation of scarce resources for this purpose is difficult. Apart from methodological problems in assessing such comprehensive programmes [8], this is also because definitions and components of DMPs vary widely. Failure to recognize this may lead to inappropriate conclusions about the cost-effectiveness of these programmes [9].

A population-based DMP for patients with diabetes mellitus has been implemented in the region of Maastricht (the Netherlands) [10]. The programme aims to improve quality of care [11] within existing budgets [10]. This study reports on its impact on cost-effectiveness, health-related quality of life (HRQL) and patient self-management, as compared with usual care over a period of 2 years.

Patients and methods

Patients and setting

The region of Maastricht encompasses *c*. 120 000 inhabitants, 90 general practitioners (GPs) and one university hospital. GPs interested in participating in the programme were selected on condition that they offered a part-time working place to a nurse specialist within their practice. Currently, 63 of 90 GPs are taking part in the DMP. Between April 2001 and February 2002, patients were recruited from a convenience sample of nine randomly chosen general practices (12 GPs) and the hospital's outpatient department. Subsequently, patients with a diagnosis of diabetes mellitus and aged ≥ 16 years were invited to participate. As the programme aimed to cover the entire population of diabetic patients (including patients with complications and/or co-morbidity), only patients with severe co-morbidity such as pre-terminal renal failure or carcinoma and/or patients needing dialysis were excluded.

Study design

As the programme was implemented region wide and a 'fair' comparison region was not available, a single-group pre-post test design was applied [12]. In all potential comparison regions, innovations that would bias the measure of usual care such as self-management programmes or electronic patient record devices (e-health) were being implemented.

Disease management programme

The programme concerns all patients with diabetes Type 1 or Type 2 who are known to the GP, who is the gatekeeper of the Dutch health care system. Main features of the programme are: use of evidence-based clinical practice guidelines [13–15], central co-ordination of care, assignment of patients to either the GP, diabetes nurse specialist (DNS) or endocrinologist according to complexity of problems, and central data collection with yearly individual feedback to care providers of, among others, clinical outcomes, number of consultations, referrals and hospital admissions.

The DNSs see patients in the practices of the GPs and function as a liaison between endocrinologists, working in the hospital, and GPs. Apart from diagnostic and therapeutic tasks listed in the international guidelines for endocrinologists and GPs, the DNSs pay specific attention to patient education and promotion of self management. During their 30-min consultations, DNSs provide tailored information about the nature of the condition, explore self-efficacy and medication compliance of the patient, discuss the lifestyle of the patients (e.g. dietary habits and physical exercise) and identify 'pros and cons' for change herein. The population of patients diagnosed with diabetes mellitus was identified using databases of GPs and the database of the hospital. After obtaining written informed consent, patients were invited for an initial consultation, carried out by the DNS within the GP office. During this consultation, the DNS registered demographic and clinical characteristics of patients and made an inventory of previous and/or current complications, such as vascular complications, retinopathy, neuropathy, hypertension, etc. Based on these data, a core team (GP, endocrinologist, DNS) confirmed or reconsidered the diagnosis. They classified disease complexity and required intensity of care in accordance with national and international guidelines [13–15], leading to a proposal concerning the assignment of the patient. If patients agreed, those with newly diagnosed diabetes mellitus Type 1 or poorly regulated diabetes Type 1 or 2 with serious complications or co-morbidity were assigned to the endocrinologist. Patients with stable diabetes mellitus using insulin and/or suffering from serious psychosocial complications with which the GP did not have sufficient experience (as judged by the GP), received quarterly outpatient appointments with the DNS within the practice of the GP. All other patients were assigned to the GP. The stratification was based on Dutch guidelines for diabetes [13–15], research justifying the management of diabetic patients by DNSs [16,17] and local agreements concerning optimal organization of diabetes care given the availability of medical facilities in primary and secondary care. By means of individual feedback from the chief endocrinologist, care providers were stimulated to follow the multidisciplinary protocol, consisting of the clinical practice guidelines, description of task division as well as the local agreements, thus increasing uniformity in treatment policy.

The contrast between usual care and the care by the DMP concerned central co-ordination, uniform treatment policy, reassignment of patients, introduction of the DNS in this role and annual feedback. Within usual care, patients were either managed by the GP or the endocrinologist, while no structured feedback systems existed.

Measurements

Quality of care was defined according to the paradigm of Donabedian [11]. Effectiveness and efficiency are regarded as quality attributes [11]. Regarding effectiveness, clinical parameters, HRQL [18–20] and patient self management [20,21] were measured; regarding efficiency, data on resource use were collected to assess indirect costs of care [20,22].

Data collection covered a period of 6 months before patients entered the programme and 24 months afterwards. Laboratory data [glycated haemoglobin (HbA_{1c}), blood pressure, cholesterol, etc.] and clinical data were obtained from caregivers' registries.

All other data were collected by means of a postal questionnaire. Resource use was measured retrospectively every 6 months, starting at entry of the programme. Clinical data, laboratory data, HRQL and self-management were measured immediately prior to entry (T0) and after 24 months (T1).

Outcome measures

The main clinical outcome measure was change in glycaemic control, defined as the change in HbA_{1c}. Glycaemic control was assessed as the proportion of patients with good control ($HbA_{1c} < 7.0\%$), moderate control ($7.0\% \leq HbA_{1c} < 8.5\%$) or poor control ($HbA_{1c} \geq 8.5\%$) [13]. Clinical status was further determined by systolic and diastolic blood pressure, body mass index (kg/m^2), total cholesterol concentration and high-density lipoprotein. All laboratory measures were performed by standard techniques in one laboratory.

HRQL was measured with a Dutch version of the Short Form-36 (SF-36). Scores range between 0 and 100, with a higher score indicating a better health-related quality of life [18,19]. Additionally, a Visual Analogue Scale (VAS), was applied as single-item measure of quality of life. Self-management of patients was measured using the Self-Care Behaviour Checklist (SCBC), a validated Dutch diabetes-specific instrument [21]. The SCBC comprises four domains: dietary adherence, self-control of glucose levels, physical activity and self-performed foot control. Each domain was measured with two questions. For example, 'do you control your glucose levels yourself'? yes/no; and 'How often do you control your glucose levels yourself?' with an answer on a five-point scale from 'every day' to 'less than once a month'. Scores for each domain are computed (range 1–5). Patient adherence to medication schemes, scored on a five-point Likert scale, was measured with three items referring to the extent to which patients adhere to the scheme and take either more or less medication than prescribed. Scores are computed as the sum score of the three items (range 3–15). Reliability analysis on the data of this study yielded a Cronbach's alpha of 0.82.

Statistical analysis

All presented analyses were based on intention to treat. Missing response was handled by using the last observed response (carry forward procedure) [23]. Before–after comparisons were analysed using paired-samples *t*-tests and Wilcoxon signed rank tests (two-sided; $\alpha = 0.05$) where appropriate. Post-hoc subgroup analyses were performed to assess the relative contribution of each of the patient groups to the overall effect of the programme. All data are presented as mean ± SD unless stated otherwise. Data processing and analysis was performed using SPSS 12 for Windows (SPSS Inc., Chicago, IL, USA).

Economic analysis

The economic analysis was carried out from a societal perspective, meaning that all healthcare costs related to diabetes were included in the analysis. Cost calculations were based on actual resource use as measured with a 15-item questionnaire and verified with administrative data from care providers. Direct healthcare costs were calculated by using current prices, when available, or tariffs [22]. For costs of medication, cost prices as provided in the Dutch Pharmacotherapeutic Compass were applied. Productivity losses were measured in terms of sick-leave days, and calculated using the age-dependent friction cost method [24]. Overhead costs comprise costs for the employment of a medical and project coordinator, continuing education of the DNSs, costs of an administrative support office, maintenance costs of the electronic patient record system, telephone and travel costs of the DNSs and salary costs of the unit leader. Not included in this analysis were costs of informal care provided by family members, long-term disability and premature death, as information on these parameters was not available. The number of quality-adjusted life years (QALYs) was adopted as outcome measure for effectiveness as it incorporates both effects on survival and quality of life in a single index [25]. As the follow-up was limited to 2 years, the product of the VAS score and the duration of life up to 2 years represents the QALYs produced for each subject.

The difference in number of QALYs generated by the two strategies (i.e. usual care and DMP) and the difference in overall costs were used to produce the cost per QALY ratio. Because the sampling distribution of this value is unknown, the non-parametric bootstrap method has been applied to estimate its sampling distribution. The resulting estimates of the differences in costs and QALYs are plotted on the cost-effectiveness plane [26]. From the amount of estimates ending up in the south-east quadrant, the probability that the DMP provides an increase in QALYs at lower costs (i.e. dominance) can be calculated.

Sensitivity analysis

The following input parameters were univariately varied to assess the robustness of the findings: (i) consultation costs; (ii) medication costs; and (iii) costs for hospital admission. Two-year follow-up values of consultation, medication and hospital admission costs were varied by ±20% per cent. Subsequently, productivity losses were excluded from the analysis to address the insurance perspective.

Results

Patient inclusion and response rates

Based on GP and hospital registries, 521 eligible patients were identified, of whom 473 agreed to participate in the study (91%). Mean age of patients was 69 years, average duration of diabetes 9.8 ± 6.8 years. Half of the patients were male, 97% had Type 2 diabetes and 23% were current smokers. Of the included patients, 12% (Type 2 : Type 1 = 47 : 12) was assigned to the endocrinologist, 34% (Type 2 : Type 1 = 156 : 4) to the DNS and 54% (Type 2 : Type 1 = 253 : 1) to the GP. Although the assignment was altered substantially after 2 years, with 11% of the patients assigned to the endocrinologist, 66% to the DNS and 23% to the GP, the results of these patients were subscribed to the initial assignment group (intention to treat).

Clinical data were available for 82% ($n = 386$) of the patients after 24-month follow-up. Data from questionnaires

were available from 319 patients at T = 0 (67%) and 245 patients at T = 1 (52%). Main reasons for not returning the questionnaires were unwillingness to complete any questionnaires (also directly at the start of the study) and loss of interest. Patients who did not respond to the questionnaires were more likely to be assigned to the GP ($P < 0.05$), had lower mean HbA_{1c} ($\Delta -0.7 \pm 0.02$; $P < 0.05$) and 1.5 ± 0.03 years shorter duration of diabetes ($P < 0.05$). Comparison of results based on observed cases only against all cases (including imputed values) did not show significantly different cost and effect estimates.

Clinical parameters

Mean HbA_1 was $7.5 \pm 1.3\%$ at baseline, and improved significantly by $-0.2 \pm 1.2\%$ ($P < 0.001$; Table 1). The proportion of patients with poor glycaemic control decreased by 15%, while the proportion of patients with moderate control increased by 40%. The 25% decrease in the proportion of patients with good glycaemic control (Table 1) is the result of the decrease in glycaemic control in patients assigned to the GP. This deterioration was the main reason for reassigning a substantial part of these patients to the DNS. Total cholesterol and high-density lipoprotein levels decreased significantly, as did systolic and diastolic blood pressure. No significant changes in body mass index (BMI) were observed in any of the subgroups.

Health-related quality of life

VAS scores increased significantly from 5.4 ± 2.4 at baseline to 5.8 ± 1.5 ($P = 0.002$). This effect was mainly driven by the large improvement within the DNS subgroup (from 5.0 ± 2.4 to 5.9 ± 1.4; $P < 0.001$). Overall, scores on the SF-36 domains increased from 65 ± 16 to 70 ± 8 ($P < 0.001$). The largest improvement was found on the domain 'general health' (from 54 ± 11 to 63 ± 12; $P < 0.0001$), the smallest on the domains 'role limitation physical' and 'physical functioning' (both $\Delta+2$; $P > 0.05$).

Patient self management

Overall, scores for medication and dietary adherence, glucose self-control and foot control improved significantly by a mean of 15% (Table 2). Scores for physical activity did not change in patients assigned to GP or DNS and decreased significantly for patients assigned to the endocrinologist. The largest and most significant improvements in self management were measured in the DNS-subgroup (Table 2).

Costs and cost utility

Overall, the number of diabetes-related consultations with GPs and endocrinologists decreased while more (routine) consultations with the DNS took place. For patients assigned

Table 1 Effects on clinical outcome measures

	All patients ($n = 473$)			Patients assigned to: GP ($n = 254$)			DNS ($n = 160$)			Endocrinologist ($n = 59$)		
Variable*	Baseline	2 years	*P*-value	Baseline	2 years	*P*-value	Baseline	2 years	*P*-value	Baseline	2 years	*P*-value
HbA_{1c} (%)	7.5 ± 1.3	7.3 ± 0.8	< 0.001	6.7 ± 0.7	7.1 ± 0.7	< 0.001	8.1 ± 1.4	7.3 ± 0.6	< 0.001	8.8 ± 0.6	8.1 ± 0.8	< 0.001
Proportion of patients with: (%)												
good glycaemic control ($HbA_{1c} < 7.0\%$)	47	21	0.02	78	20	< 0.001	17	27	0.00	0	9	< 0.001
moderate glycaemic control ($7.0\% \leq HbA_{1c} < 8.5\%$)	33	73		20	75		59	71		15	70	
bad glycaemic control ($HbA_{1c} \geq 8.5\%$)	20	6		2	5		24	2		85	21	
Total cholesterol (mmol/l)	6.0 ± 1.6	5.0 ± 1.0	0.03	5.1 ± 1.2	5.1 ± 1.0	0.95	5.9 ± 3.9	4.9 ± 1.0	0.04	5.1 ± 1.2	5.1 ± 1.1	0.95
HDL (mmol/l)	1.3 ± 0.4	1.2 ± 0.4	< 0.001	1.3 ± 0.4	1.2 ± 0.4	< 0.001	1.2 ± 0.5	1.1 ± 0.4	< 0.001	1.4 ± 0.4	1.1 ± 0.3	< 0.001
LDL (mmol/l)	4.7 ± 1.4	3.8 ± 1.1	0.02	3.8 ± 0.9	3.9 ± 0.8	0.32	4.7 ± 2.0	3.8 ± 0.7	0.01	3.7 ± 0.9	4.0 ± 1.0	0.10
Systolic blood pressure (mmHg)	154 ± 22	144 ± 20	< 0.001	150 ± 22	142 ± 20	< 0.001	160 ± 21	146 ± 19	< 0.001	145 ± 18	146 ± 22	0.86
Diastolic blood pressure (mmHg)	85 ± 15	77 ± 11	< 0.001	86 ± 19	76 ± 10	< 0.001	83 ± 10	78 ± 12	0.01	81 ± 9	71 ± 11	0.21
Body mass index (kg/m^2)	29.8 ± 5.6	29.3 ± 5.0	0.05	29.2 ± 4.1	28.9 ± 4.3	0.22	30.2 ± 6.6	29.5 ± 5.4	0.12	31.8 ± 7.4	31.5 ± 6.7	0.72

* All variables are presented as mean ± SD unless stated otherwise.
HbA_{1c} glycated haemoglobin; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

Table 2 Effects on patient self management

	All patients (n = 473)			Patients assigned to: GP (n = 254)			DNS (n = 160)			Endocrinologist (n = 59)		
Variable*	T0	T1†	P-value	T0	T1	P-value	T0	T1	P-value	T0	T1	P-value
Compliance (3–15)	10.7 ± 2.0	11.1 ± 2.0	0.006	10.5 ± 2.2	10.1 ± 2.2	0.105	10.7 ± 1.9	11.9 ± 1.7	< 0.001	11.6 ± 1.8	11.4 ± 1.2	0.468
Dietary adherence (1–5)	2.3 ± 0.8	2.9 ± 1.0	< 0.001	2.3 ± 0.9	2.6 ± 0.8	0.013	2.1 ± 0.6	3.1 ± 1.2	< 0.001	3.1 ± 0.5	3.0 ± 0.2	0.102
Self control glucose (1–5)	2.3 ± 0.6	2.7 ± 1.0	< 0.001	2.1 ± 0.5	2.3 ± 0.9	0.031	2.2 ± 0.7	2.9 ± 1.2	< 0.001	2.8 ± 0.6	3.0 ± 0.4	0.140
Physical activity (1–5)	3.0 ± 1.2	3.0 ± 1.2	0.513	3.1 ± 1.3	3.1 ± 1.2	0.555	2.8 ± 1.2	2.9 ± 1.3	0.287	3.4 ± 1.0	2.7 ± 1.0	0.002
Foot control (1–5)	2.3 ± 0.7	2.6 ± 1.2	< 0.001	2.2 ± 0.7	2.4 ± 1.2	0.169	2.1 ± 0.6	2.6 ± 1.2	< 0.001	3.1 ± 0.6	3.1 ± 0.5	0.660

*All data were approximately normally distributed and expressed as mean ± SD.
†The number of observed cases on T1 ranges from 239 for physical activity to 245 for compliance and glucose self-control.

to the DNS, this led to a significant rise of consultation costs. Patients assigned to the GP began to use more self-care devices. Patients assigned to the DNS used less oral medication but more insulin. Furthermore, a 54% decrease in hospital admission costs was found within the DNS subgroup. Total costs did not change significantly within the 2-year period (Table 3). However, the cost-effectiveness plane in Fig. 1 shows that the DMP is the dominant strategy in 74% of the bootstrap simulations, saving on average 117 per patient per year, while HRQL increases by 5%.

Results sensitivity analysis

The DMP remained the most cost-effective strategy in all sensitivity analyses. Decision uncertainty surrounding overall cost-effectiveness is most sensitive to changes in productivity losses followed by consultation costs and costs for hospital admission, while it is least sensitive to changes in medication costs. After excluding productivity losses from the analysis, the percentage of bootstrap simulations that indicates the DMP to be dominant, compared with usual care, decreased from 74 to 64%, still suggesting that the benefits of the DMP extend beyond the health-care and insurance system.

Discussion

The objective of this study was to assess the 2-year impact of a DMP for patients with diabetes mellitus on cost-effectiveness, HRQL and self-care behaviour, in comparison to care delivered before implementation of the programme. The introduction of the DMP is associated with improvements in glycaemic control, except for patients assigned to the GP. Although room for improvement was limited in this subgroup of patients given their relatively low values of HbA_{1c} at baseline (6.7 ± 0.7%), the deterioration of glycaemic control was still worrying and led to reassignment of a substantial number of the patients from the GP to the DNS.

VAS and SF-36 scores show a significant improvement in HRQL of *c*. 5% for the total population. Patient self management also improved after introduction of the DMP, except for physical activity. This might be explained by the relatively high mean age of the study population. Total costs did not change significantly within the 2-year period, although in the DNS subgroup significantly lower costs for hospital admission were found. As the SF-36 was not devised for use in economic analysis [27], the VAS scores, representing the most conservative estimations of HRQL gained, were used to analyse cost utility in terms of costs per QALY. The DMP proved to be the 'dominant' strategy in 74% of simulations, meaning that there is a probability of 74% that the disease management strategy for patients with diabetes improved HRQL while saving money (on average 117 euro per patient) as compared with usual care.

Although the study design does not allow us to attribute the results to any specific element of the DMP in particular, it seems most likely that the augmented follow-up of patients,

Table 3 Effects on costs (in euros, costs per 3 months)

Variable*	Unit costs	All patients (*n* = 473)			Patients assigned to: GP (*n* = 254)			DNS (*n* = 160)			Endocrinologist (*n* = 59)		
		UC	DMP	Δ (95% CI)	UC	DMP	Δ (95% CI)	UC	DMP	Δ (95% CI)	UC	DMP	Δ (95% CI)
Overhead costs		0	21	21	0	21	21	0	21	21	0	21	21
Consultations with													
GP	20,20	21 ± 24	13 ± 26	–8 (–4,–12)	23 ± 21	25 ± 35	3 (–4,10)	20 ± 26	7 ± 16	–12 (–17,–7)	24 ± 26	6 ± 15	–18 (–27,–9)
DNS	32,80	16 ± 25	26 ± 28	10 (7,15)	12 ± 18	16 ± 30	5 (–2,11)	21 ± 30	36 ± 24	16 (10,22)	6 ± 15	13 ± 22	7 (–2,15)
Endocrinologist	100	31 ± 65	20 ± 48	–11 (–19,–3)	2 ± 20	4 ± 28	2 (–5,9)	38 ± 65	14 ± 40	–24 (–35,–13)	74 ± 99	121 ± 67	7 (–28,43)
Medication use													
Oral medication	NA†	26 ± 34	22 ± 29	–4 (–8,–1)	24 ± 28	25 ± 31	1 (–4,6)	26 ± 36	18 ± 22	–8 (–13,–2)	32 ± 40	29 ± 41	–3 (–12,6)
Insulin	NA	34 ± 57	41 ± 53	7 (2,13)	6 ± 28	8 ± 30	1 (–4,5)	28 ± 51	43 ± 44	15 (6,24)	129 ± 40	123 ± 46	–6 (–22,11)
Self-control dev.	NA	28 ± 77	37 ± 37	9 (0,17)	8 ± 22	20 ± 38	12 (4,20)	37 ± 75	47 ± 35	11 (–1,22)	43 ± 40	34 ± 28	–9 (–51,34)
Paramedical care‡	NA	18 ± 25	24 ± 34	6 (–4,22)	16 ± 27	28 ± 44	12 (–8,54)	26 ± 62	28 ± 64	2 (–6,23)	13 ± 36	27 ± 57	14 (–20,86)
Home care	40,40	58 ± 81	87 ± 133	50 (–46 152)	34 ± 95	38 ± 101	4 (–6,15)	56 ± 148	88 ± 172	32 (–29,69)	118 ± 221	154 ± 338	36 (–53,87)
Hospitalization	476/day	162 ± 444	104 ± 411	–57 (–115,88)	53 ± 220	47 ± 192	–6 (–64,51)	171 ± 447	78 ± 396	–93 (–171,–15)	289 ± 691	244 ± 690	–45 (–309 219)
Productivity loss	35/h	88 ± 448	62 ± 19	–27 (–81,27)	32 ± 162	37 ± 246	4 (–53,62)	66 ± 160	40 ± 147	–26 (–88,37)	122 ± 343	180 ± 131	–58 (–107 183)
Total costs	NA	482 ± 575	453 ± 569	–29 (–106,47)	210 ± 306	269 ± 541	59 (–94,139)	489 ± 543	420 ± 467	–69 (–188,7)	849 ± 901	952 ± 719	103 (–151, 105)

*All data are expressed in euros.
†NA, no fixed unit cost available.
‡Includes costs for podiatrist, dietician, pedicure and social work.
dev., devices; DMP, disease management programme; DNS, diabetes nurse specialist; GP, general practitioner; UC, usual care.

FIGURE 1 Cost-effectiveness plane of usual care vs. diabetes disease management. QALY, quality-adjusted life year.

as reflected in an increased number of consultations with the DNS, in combination with improved self management of patients, pays off in better glycaemic control within a period of 2 years. The DNS subgroup also seemed to benefit most for other outcomes from the introduction of the DMP. This is an important finding with regard to decision making, as the stratification of the patient population by disease severity and the key role of the DNS within the collaborative practice model are the most important differences with usual care. The increased attention to patient education and self management probably plays an important role herein, as does the combination of nursing and medical skills of the nurses. Because provider adherence to the protocol, for example in terms of number of consultations provided and type of medication prescribed, is highest within this group, this might further explain the beneficial effects found in these patients. Notwithstanding the positive outcomes in the DNS subgroup, the data also show that the natural deterioration of the condition was not sufficiently slowed in patients assigned to the GP. This indicates that more attention should be paid to secondary prevention for currently relatively well-controlled patients in order to prevent deterioration in HbA_{1c}, health status and quality of life in the early stages of the disease, and prevent complications in the future. In addition, primary prevention, aimed at patients 'at risk', would potentially further increase the benefits of the disease management approach. This could be achieved by mobilizing community resources to expand the health systems' care for these patients. For example, the DMP might form a partnership with a community centre that provides exercise classes as an option for elderly patients.

Given the limitations of the study design, no causal relationship between the introduction of the DMP and the observed changes in costs and effects of care can be demonstrated. As no comparable, parallel control group was available, the results from this study might be biased by, for example, regression to the mean [28]. Without underestimating the power of this phenomenon, we are confident that the observed results can, at least to a large extent, be attributed to the introduction of the DMP. Regression to the mean, for example, would have biased the results in all patients; not only of patients assigned to the DNS in whom the largest changes are observed. Also, no co-interventions that could interfere with our measurements (e.g. changes in discharge policy, introduction of screening programmes or availability of new drugs) occurred during the study period. Furthermore, given the magnitude of the observed changes in, for example, glycaemic control, self-care behaviour and a mean decrease in hospital admission costs of 54% in patients assigned to the DNS, we believe this cannot be explained by the natural course of the disease or by international trends. Another concern of this study is the missing values. Although the response and completion rates seen in this study reflect the values commonly observed in longitudinal studies of individuals with chronic diseases [29], the missing data selectively affect measurements within the disease management strategy. Because patients with missing data were more likely to be those patients with relatively low HbA_{1c}, high HRQL and low costs (i.e. patients being assigned to the GP), the estimates of costs and effects of the DMP are, if anything, underestimated.

In light of these study limitations, we recommend further analysis of diabetes DMPs, wherein DNSs play a key role, and suggest that future studies should focus on the long-term cost-effectiveness of DMPs including diabetic complications and mortality. These studies should preferably be carried out in a controlled setting, but without compromising daily practice with artificial research conditions. Performing practice-based research in various settings to accurately and representatively reflect 'programme–context interactions' and circumstances in which the results of research are to be applied [30,31] is the best way forward in studying real-world, population-based interventions as DMPs. Additionally, decision analysis enables us to combine data on a range of effectiveness, resource use and value parameters to support decision making under conditions of uncertainty, and facilitates the extrapolation of data beyond the relatively limited time horizons of clinical trials [32].

Competing interests

None to declare.

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Appendix 1

Outline of the 'Maastricht' disease management programme

In the region of Maastricht, the Netherlands, a population-based disease management programme for patients with diabetes has been implemented. The programme is aimed at all people that are currently diagnosed with diabetes or will be diagnosed in the future. Main features of the programme are:

1. central co-ordination of care;
2. protocolized assessment of diabetes and its complications;
3. classification of disease complexity;
4. assignment of patients to either general practitioner (GP), diabetes nurse specialist (DNS) or endocrinologist;
5. specific attention to patient education and promotion of self management;
6. central data collection with yearly feedback to individual care providers regarding clinical outcomes, number of consultations, referrals and hospital admissions;
7. regular training and education of care providers.

Special attention is given to the role of the DNS. The DNSs function as a liaison between central organization, endocrinologists and GPs (see Fig. S1). They are employed by the central organization (i.e. the integrated care department of the hospital), hosted in the hospital, but see patients in the offices of the GPs. Apart from the diagnostic and therapeutic tasks listed in the (inter)national guidelines for endocrinologists and GPs, the DNSs focus on patient education and promotion of self management. To fulfil these tasks, their consultation time was scheduled for 30 min. The scheduled duration of consultations with GP or endocrinologist was not changed. Patients that agreed to participate in the programme were invited for an initial consultation that was carried out by the DNS within the office of the patients' own GP. During this consultation, the DNS registered demographic and clinical characteristics of patients and made an inventory of previous and/or current complications such as vascular complications, retinopathy, neuropathy, hypertension, etc. Based on these data, the core team (GP, DNS and endocrinologist) confirmed or reconsidered the diagnosis. They classified disease complexity and required intensity of care in accordance with the international diabetes guidelines, leading to a proposal concerning the assignment of the patient (Table 1). If patients agreed, those with low disease complexity and requiring low intensity of care were assigned to the GP, patients needing medium intensity of care received quarterly outpatient appointments from the DNS within the practice of the GP, while patients requiring high intensity of care received health care from the endocrinologist. Endocrinologists and GPs were encouraged to follow the (inter)national guidelines for diabetes management. The protocol for care delivery by the DNS was based on the Dutch guidelines for GPs.

The contrast between usual care and the care as delivered within the disease management programme concerns the central coordination, the reassignment of patients and the introduction of the DNS in this role. Within usual care, patients are either managed by the GP (low to medium complexity) or the endocrinologist (medium to high complexity).

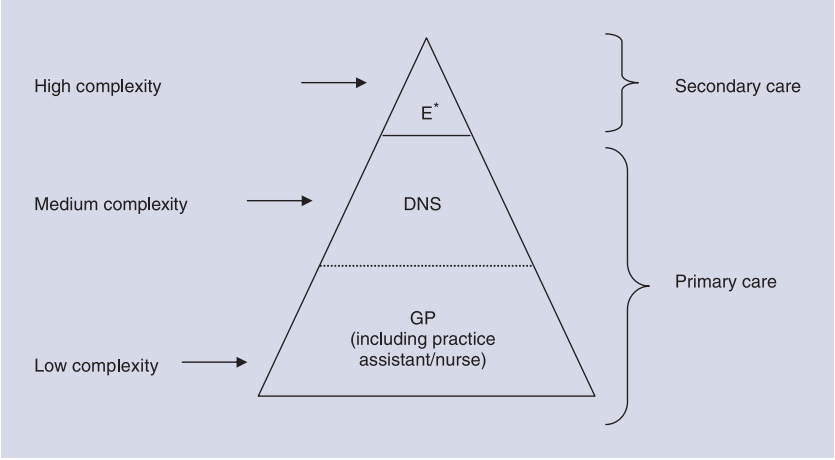

FIGURE S1 Outline of the 'Maastricht' disease management programme. E, endocrinologist.

Table S1 Patient assignment algorithm

Disease complexity	Assignment criteria
Low	Newly diagnosed Type 2 or well-regulated Type 1 patients with few or no complications are treated by the general practitioner, supported by a practice assistant or practice nurse, in his or her practice
Medium	Stable Type 2 diabetes patients with stable complications or patients with a complex treatment pattern in which the general practitioner has little experience are treated by the diabetes nurse specialist
High	Newly diagnosed Type 1 or badly regulated Type 2 diabetes patients or those with severe complications and severe co-morbidity are treated by endocrinologists in hospital care, supported by a nurse from the hospital

