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Cost and benefits of a multidisciplinary intensive diabetes education programme

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Abstract

Objectives To determine the cost and benefits of an intensive diabetes education programme for patients with prolonged self-management problems and to determine the inclusion criteria for optimal outcomes. **Methods** Sixty-one participants of a multidisciplinary intensive diabetes education programme (MIDEP) were measured before they started the intervention (T0), and at 1-year follow-up (T1). Data on glycaemic control (HbA1c), diabetes-related distress (PAID) and costs were obtained. Changes over time were analysed and means at T0 and T1 were compared to a reference group of 230 non-referred consecutive outpatients. The number needed to treat (NNT), that is, the number of patients to be treated to achieve one successful case, was calculated for different baseline values of HbA1c and PAID to determine optimal inclusion criteria. **Results** Diabetes-related costs decreased significantly and participants improved significantly in HbA1c and diabetes-related distress following MIDEP. HbA1c and distress reached the levels of the reference group. The T1 costs remained higher than in the reference group, but the reduction in costs outweighed the intervention costs. Including patients with baseline HbA1c ≥8.0% and/or PAID scores ≥40 would improve the NNT to achieve clinically relevant outcomes, while 76% of the patients matched these inclusion criteria. **Conclusions** MIDEP is effective in improving glycaemic control and diabetes-related distress for patients with prolonged self-management difficulties. Besides the immediate reduction in costs found in the present study, improved glycaemic control may reduce future costs of diabetic complications. Stricter inclusion criteria with respect to HbA1c and PAID scores may further improve the programme's efficiency.

Introduction

Diabetes mellitus is a growing public health issue (Mandrup 1998), predominantly because of the growing prevalence of type 2 diabetes and to a lesser extent by the increasing prevalence of type 1 diabetes (International Diabetes Federation 2003). Diabetes requires a complex and demanding treatment and behavioural regimen (Steed *et al*. 2003) and generates high direct and indirect medical costs (Niessen & Casparie 2001). Both in type 1 and type 2 diabetes, poor glycaemic control resulting in prolonged high

blood glucose levels (measured by glycated haemoglobin: HbA1c) is strongly related to the development of diabetic complications [Diabetes Control and Complications Trial Research Group (DCCT) 1993; UKPDS 1998], such as retinopathy, neuropathy and cardiovascular disease. These complications are associated with high medical costs (DCCT 1996), disability and a reduction in quality of life (DCCT 1996; Rubin & Peyrot 1999; UKPDS 2000).

Maintaining acceptable blood-glucose levels largely depends on self-management, which requires daily and life-long efforts from patients. They have to inject insulin or take blood-glucose-lowering tablets, keep a healthy and regular diet and exercise regularly and above all balance these elements in any possible situation. For example, stress influences insulin sensitivity and blood glucose levels (Surwit *et al.* 2002) requiring adjustments in self-management. Besides avoiding high blood-glucose levels in order to prevent long-term diabetic complications, the occurrence of hypoglycaemia (too low blood glucose levels) causes several immediate inconvenient effects, ranging from dizziness to coma. Hypoglycaemia can be a serious barrier in self-management (Cox *et al.* 1994). A dilemma, however, is that tight glycaemic control increases the number of hypoglycaemic episodes (UKPDS 1998). Given the heavy demands diabetes puts on patients, it is not surprising that a considerable number of diabetic patients experience difficulties in maintaining adequate self-management, manifesting in poor glycaemic control (Lloyd *et al.* 1993; Dalewitz *et al.* 2000) and psychosocial distress (Jacobson 1996; Snoek *et al.* 2000; Macrodimitris & Endler 2001; Pouwer *et al.* 2001).

Interventions to improve glycaemic control may help to prevent long-term complications, which may, in the long term, lead to cost savings that outweigh the costs of the intervention (DCCT 1995, 1996; Trento *et al.* 2002). The investment costs and postponed benefits, however, can present a major barrier to the implementation of such interventions (Sadur *et al.* 1999), although a few intervention studies showed more immediate cost reductions. Testa & Simonson (1998) conducted a medical intervention that resulted in improved glycaemic control, which led to beneficial labour-related outcomes and less ambulatory care visits compared to a placebo group. Some studies showed that lifestyle interventions for diabetic patients reduced medical costs and are cost-effective within a reasonably short time frame by reducing hospital admissions and unplanned visits to health care professionals (Sadur *et al.* 1999; Gozzoli *et al.* 2001). Lifestyle interventions conducted in group settings are particularly cost-effective (Rickheim *et al.* 2002).

To support patients with prolonged self-management difficulties, we developed a 12-day outpatient multidisciplinary intensive diabetes education programme (MIDEP) (Keers *et al.* 2004a), based on the empowerment approach (Funnell *et al.* 1991; Anderson *et al.* 2000). MIDEP resulted in improved glycaemic control and health-related quality of life (Links *et al.* 2003). Several important elements that contribute to the effectiveness of diabetes lifestyle interventions were incorporated in the design of the programme. MIDEP goes beyond improving knowledge, because mere knowledge does not result in improved glycaemic control nor behaviour change (Clement 1995; Coates & Boore 1996; Brown 1999) and isolated diabetes educational interventions probably only lead to additional costs (Gozzoli *et al.* 2001). To achieve durable changes in self-management, changes in patients' attitudes and motivation are more important than purely improving knowledge (Norris *et al.* 2001). Thus, intervention programmes must focus on patients' personal lifestyles, respect individual habits, incorporate social support and be reinforced over time (Anderson 1990). Treatment that combines attention to glycaemic and psychosocial factors is likely to be most effective, which requires close collaboration between diabetologists, diabetes nurse specialists, psychologists and other team members (Snoek & Skinner 2002). The contents of MIDEP will be discussed in more detail in the *Method* section. Obviously, such a relatively time-consuming and expensive intervention should be reserved for patients at particular high risk and for whom intensive standard care (Glasgow 1995; Sadur *et al.* 1999), that is, regular medical check-ups and consultations of a diabetes nurse specialist, is insufficient.

Careful selection of patients and an estimation of the costs in relation to its effects is needed to optimize MIDEP's efficiency. Therefore, we studied firstly the cost-effectiveness of the education programme by comparing costs and savings of the inter-

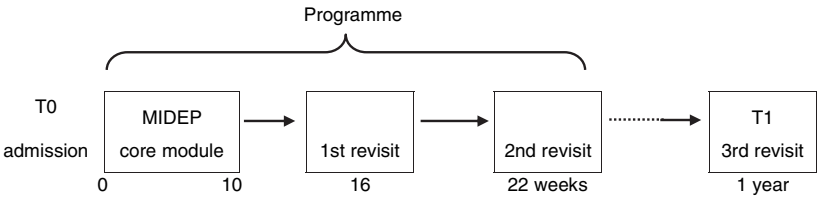

Figure 1 Schedule of the multidisciplinary intensive diabetes education programme.

vention. Secondly, we determined the patients for whom the intervention was most effective in achieving relevant improvements in HbA1c and diabetes-related distress.

Methods

The multidisciplinary intensive diabetes education programme

The Centre for Rehabilitation of the Groningen University Hospital offers an MIDEP for patients with diabetes mellitus with prolonged self-management difficulties manifesting in poor glycaemic control or diabetes-related psychosocial problems. Patients are referred from most outpatient clinics in the region. Figure 1 gives an outline of the programme. MIDEP comprises a core module of 10 whole days of group sessions (fixed groups of six to nine patients) and some individual support in a 10-week period. Follow-up visits take place at 6 and 12 weeks and 1 year after the core module, of which the 1-year follow-up session is not considered treatments, because it is used only for receiving and giving feedback and patients return to regular diabetes care after the second follow-up visit. In effect, participants are withdrawn from their regular outpatient care for a period of 5 months. The diabetes education team consists of a diabetes nurse specialist, an endocrinologist, a dietician, a social worker, a psychologist, a physiotherapist, an occupational therapist and an activity therapist, who work together closely.

The programme aims to empower patients to set and attain their own treatment goals. MIDEP highlights a range of diabetes-related topics and has sessions on self-management, diet, exercise, daily activities and employment, psychosocial aspects of diabetes and behavioural coping strategies. The programme uses a four-phase learning sequence. First a topic is introduced, followed by group discussion or practice. In the third phase, patients plan how to fit in a certain aspect in their own daily lives, which will subsequently be evaluated in the fourth phase. Using this approach, the patients' own experiences and goals that patients set at admission to MIDEP are taken into account. We provided an educational framework that covers all relevant topics of diabetes self-management, because education directed solely at patients' own priorities contains a risk of missing essential aspects of diabetes self-management (Colagiuri *et al*. 1995).

Patients

Of the 80 patients who had an admission interview of MIDEP, 11 did not start MIDEP or prematurely aborted the programme within the first 3 weeks. HbA1c was obtained from all 69 participants who completed MIDEP. Sixty-three patients completed the questionnaire at T1 and 56 patients completed cost questionnaires at both T0 and T1. A total of 330 consecutive non-referred outpatients from the Groningen University Hospital diabetes clinic were approached to serve as a reference group, using the same exclusion criteria as MIDEP. A total of 230 patients (70%) gave informed consent, their HbA1c values were obtained and they completed the same questionnaire as MIDEP participants did.

Glycaemic control and diabetes-related distress

Glycaemic control was measured by means of HbA1c, a standard measure in diabetes for the percentage of glycated haemoglobin, indicating glycaemic control in the past 6–8 weeks. An HbA1c of ≥8.0% is considered to reflect poor glycaemic control (American Diabetes Association 2001). The number of hypoglycaemia during the previous 4 weeks and the number of severe hypoglycaemia for which assistance was required were obtained by self-reports.

The Problem Areas in Diabetes questionnaire (PAID) (Welch *et al*. 1997; Snoek *et al*. 2000) mea-

sured the diabetes-related distress. The PAID consists of 20 Likert scale items and has subscales for 'diabetes-related emotional problems' (12 items), 'treatment-related problems' (three items), 'food-related problems' (three items) and 'social support-related problems' (two items) and the 20 items can be summed to a total diabetes distress score. All scales range from 0 to 100, with higher scores indicating more diabetes distress. PAID scores of ≥40 indicate high diabetes-related distress (Snoek *et al*. 2000).

Statistical testing

Effects of MIDEP were determined by comparing means of HbA1c, hypoglycaemia and PAID scores at baseline and 1 year follow-up, using paired samples *t*-tests. The magnitude of the changes was quantified by calculating effect sizes (ES), which were obtained by dividing the mean change (T1–T0) by the standard deviation (SD) of that change. ESs of around 0.20 are considered small, ESs of around 0.50 medium and ESs of around 0.80 are considered large (Cohen 1992). Severe hypoglycaemia were expected to occur only in a relatively small part of the patients and to be non-normally distributed. For these reasons, the percentage of patients having 1 or more severe hypoglycaemia was calculated. The participants of MIDEP were compared with the reference group of average outpatients at T0 and T1 using independent samples *t*-tests.

The number needed to treat (NNT), a measure of treatment success, is the number of patients who need to be treated in order to have a successful treatment outcome in one case (Laupacis *et al*. 1988; Cook & Sackett 1995). The NNT was determined for a clinically relevant improvement in HbA1c and in the total PAID score. The criteria for successful treatment in glycaemic control were a decrease of ≥0.5 HbA1c, which is considered clinically relevant (Diabetes Control & Complications Trial Research Group 1993; Cook & Sackett 1995), or a 1-year post-treatment HbA1c of <8.0%, considered fair glycaemic control (American Diabetes Association 2001). The criteria for successful treatment in diabetes-related distress were a reduction in PAID scores of 1 SD of the reference group and a post-treatment score of <40 [non-severe diabetes-related distress (Snoek *et al*. 2000)] were used as criteria for successful treatment.

The NNTs for subgroups with HbA1c ≥7.5, ≥8.0, ≥8.5 and ≥9.0 and for PAID ≥30, PAID ≥40 and PAID ≥50 were calculated to determine success rates when these different inclusion criteria would have been applied. In addition, we calculated the NNT for the combined success criteria of a ≥0.50% reduction in HbA1c and/or 1 SD improvement in the total PAID score. NNTs were determined for all participants of MIDEP and for the subgroup of patients with HbA1c ≥8.0% and/or PAID ≥40. The NNT for the combined criteria indicates the ratio of patients who were successfully treated with respect to at least one of the two main outcomes.

Economic evaluation

The aim of the economic evaluation was to assess the costs of MIDEP per patient. The economic evaluation was based on the data gathered for 69 programme participants and 230 non-participants from the diabetes outpatient department of the University Hospital. They filled in a cost questionnaire allowing an economic evaluation from a limited societal perspective. Both direct medical costs and direct and indirect non-medical costs were included as described below. In addition to the questionnaire data, expert opinions from two experienced diabetologists were obtained regarding time spent on outpatient visits by various disciplines.

Programme costs were calculated on the basis of a programme schedule provided by the centre for rehabilitation, detailing the time spent by the various disciplines involved. Programme overhead costs (rooms, cleaning, etc.) were calculated by means of a 35% surcharge on total personnel costs. This was not applied for costs of the use of sports and fitness facilities as well as swimming pool, for which current rental rates were used. For the calculation of costs per patient an average group size of seven patients was applied.

Costs of hospital admission were calculated on the basis of the actual number of admission days and the recommended Dutch unit price (indexed to price levels of the year 2003) for hospitalization per day for university hospitals and general hospitals (Oostenbrink *et al*. 2000). For health care consumption outside of the hospital, the recommended Dutch unit price for a GP visit was used. For consultation by

telephone, half the price of a visit was used. Travel costs were calculated on the basis of distances from postal code to postal code and data on mode of transportation used by the patients. For data on the latter, 61 randomly chosen programme participants were interviewed separately. All 230 patients in the reference group also provided these data. The costs of productivity losses were calculated according to the friction cost method, on the basis of data regarding sick leave from the questionnaire. Standard prices from the Dutch guideline, specified by sex and age, were used.

The costs of following the education programme were compared to the difference in health care consumption costs between T0 and T1. For the follow-up period, costs for successful and unsuccessful patients were compared as well. Participants were considered to be withdrawn from regular care while following the programme. The follow-up consisted of two 6-month assessments, totalling 1 year. Because of the short time horizon discounting was not applied.

Statistical testing of costs

The effects in diabetes-related costs were tested non-parametrically, because the distributions of cost data were skewed. We used Wilcoxon signed rank tests, the non-parametric alternative for the paired samples *t*-test, to compare pre- and post-measures of costs for outpatient clinic contacts, general practitioner contacts, hospital admissions, direct non-medical costs, indirect non-medical costs and total costs. To test differences in the reduction of the total costs for patients who were successfully treated by MIDEP and those who were not, Mann–Whitney tests for two independent samples were used.

Results

Study sample

Fifty-six of the 69 participants of MIDEP filled in a questionnaire at both T0 and T1, which means a response rate of 81%. HbA1c was obtained from all 69 participants at both measurements. Table 1 presents demographic characteristics of the participants and the 230 outpatients. Participants of MIDEP were more recently diagnosed, which was not considered to influence the results because no patients were newly diagnosed (<1 years). No other significant differences in demographics were found between participants and the consecutive outpatients.

Effects of MIDEP on glycaemic control, diabetes-related distress and cost parameters

One year after the intervention, the participants of MIDEP had improved significantly on most measures for glycaemic control, diabetes distress (Table 2), and medical costs (Table 3). At T0, participants of MIDEP had worse glycaemic control and more diabetes-related distress than the reference group. One year post-MIDEP, participants did not differ significantly from the reference group in any of these measures.

The costs for hospital admissions, costs for outpatient clinic contacts and the indirect non-medical costs declined considerably in the participants of MIDEP (see Table 3). Totalled up, at T1 the costs measured per patient were €1469 lower than costs generated in the year previous to MIDEP. The non-parametric tests (Wilcoxon singed ranks tests) show that the ranks of the post-MIDEP costs are signifi-

Table 1 Demographic characteristics of the study population

	MIDEP participants (n = *69*)	*Outpatients* (n = *230*)
Gender (% male/female)	49/51	46/54
Age (years ± SD)	44 ± 13	48 ± 13
Type of diabetes (% type 1/type 2)	63/37	68/32
Duration of diabetes (years ± SD)	13 ± 11*	18 ± 13
Employed (%)	65	55
Living with a partner (%)	78	76

MIDEP, multidisciplinary intensive diabetes education programme.
*$P < 0.05$.

Table 2 Effects of MIDEP: 1-year (T1) compared to baseline (T0) and participants at T0 and T1 compared to reference group

	T0†	*T1*†	*ES*‡	*Reference group (*n = *230)*
HbA1c (*n* = 69)	8.5 ± 1.3**	8.1 ± 1.2	0.32**	8.0 ± 1.2
Number of hypoglycaemia§	9.3 ± 8.1**	5.7 ± 5.9	0.53***	5.6 ± 6.8
≥1 severe hypoglycaemia§	18%	12%	–	14%
PAID (*n* = 56)				
PAID total	38 ± 22***	22 ± 15	0.81***	25 ± 18
Emotional problems	44 ± 26***	25 ± 16	0.88***	29 ± 21
Treatment-related problems	28 ± 22***	20 ± 17	0.40**	20 ± 22
Food-related problems	31 ± 24***	21 ± 19	0.44**	22 ± 21
Social support-related problems	22 ± 26**	12 ± 19	0.57***	13 ± 21

MIDEP, multidisciplinary intensive diabetes education programme.
*$P < 0.05$; **$P < 0.01$; ***$P < 0.001$.
†Means compared to the reference group by independent samples *t*-tests.
‡Effect sizes calculated by dividing the mean change by the SD of that change, and significances of differences between pre- and post-measurement were calculated with paired samples *t*-tests.
§In past 4 weeks.

cantly lower than the pre-MIDEP ranks of costs, but the magnitude of the differences in means could not be tested. Both at T0 and T1, participants generated significantly more costs than the reference group. However, the differences in costs became much smaller at T1.

Table 4 shows that the total costs of MIDEP were €1327, consisting of €1023 for running the programme and of €304 for travel expenses. The costs of MIDEP were compensated by the reduction in costs between T0 and T1.

Number needed to treat

Table 5 shows that in all MIDEP participants the NNT for a ≥0.5% HbA1c reduction was 2.88, which means that to realize this target in one patient, 2.88 patients had to be treated. One in every 2.09 patients had an HbA1c of <8.0% at T1. One in every 1.64 patients achieved at least one of both targets. Furthermore, Table 4 shows that patients with a higher HbA1c at inclusion have lower NNTs for the target of ≥0.50 reduction. However, less patients would achieve an HbA1c <8.0%.

In general, the NNTs for PAID scores were lower than for HbA1c targets; a higher percentage of patients achieved the targets in diabetes distress. Overall, one in every 2.24 patients achieved a reduction of >1 SD (≥18) of the reference group and one in every 1.19 patients achieved a PAID score <40. Including patients with baseline scores of, respectively, ≥30, ≥40 or ≥50 would lead to a substantial decline in the NNT for a > 1 SD reduction without a large increase of the NNT for the <40 target (see Table 5).

Combining the success criteria for HbA1c and PAID (an improvement of ≥0.5 HbA1c or ≥18 points at the overall PAID score or both), an NNT of 1.80 (95% CI = 1.46–2.41) for all participants of MIDEP was found, that is, one in every 1.80 patients improved relevantly in at least one of the two main outcomes. Seventy-six percent of the participants had a baseline HbA1c ≥ 8.0% and/or baseline PAID ≥ 40. The NNT for the combined outcome in this subgroup of patients was 1.48 (95% CI = 1.23–1.95). For a ≥0.5% HbA1c reduction alone the NNT was 2.38 (95% CI = 1.73–3.71) and for ≥18 reduction at the PAID the NNT was 1.72 (95% CI = 1.37–2.38).

NNT and cost reductions

The comparisons of subgroups based on the success criteria for clinically relevant reductions in HbA1c and or diabetes-related distress revealed some interesting associations between clinical outcomes of MIDEP and cost reductions, expressed as the mean

Table 3 Average diabetes-related costs per MIDEP participant in the year pre-MIDEP (T0) and the year post-MIDEP (T1)

	T0 (n = *56*) (€)	*T1* (n = *56*) (€)	P-*value**	*Reference group* (n = *230*) (€)
Outpatient clinic contacts				
Mean ± SD	49 ± 58	29 ± 21	0.003	23 ± 21
Median	27	18		18
n′	0	0		0
P-value†	<0.001	<0.001		
Diabetes-related general practitioner contacts				
Mean ± SD	20 ± 43	6 ± 19	0.013	9 ± 37
Median	0	0		0
n′	34	47		187
P-value†	<0.001	0.46		
Diabetes-related hospital admissions				
Mean ± SD	1357 ± 4588	718 ± 2994	0.035	48 ± 389
Median	0	0		0
n′	42	50		224
P-value†	<0.001	0.006		
Direct non-medical costs (travel expenses)				
Mean ± SD	23 ± 23	16 ± 12	0.002	20 ± 51
Median	18	12		6
n′	0	0		0
P-value†	<0.001	<0.001		
Diabetes-related indirect non-medical costs (friction costs)				
Mean ± SD	1472 ± 4165	929 ± 3452	0.15	158 ± 945
Median	0	0		0
n′	45	46		206
P-value†	0.073	0.107		
Total				
Mean ± SD	2991 ± 6174	1522 ± 5021	0.001	289 ± 1050
Median	126	73		55
n′	0	0		0
P-value†	<0.001	0.001		

MIDEP, multidisciplinary intensive diabetes education programme; *n*′, number of patients generating no costs.
*Wilcoxon signed ranks test comparing T1 with T0.
†Mann–Whitney test comparing participants of MIDEP with the reference group.

Table 4 Costs of MIDEP per participant

	Costs
Group education by MIDEP team (personal + 35% overhead costs)	€908
Individual counselling	€102
Use of facilities	€13
Travel expenses	€304
Total	€1327

MIDEP, multidisciplinary intensive diabetes education programme.

total costs at T1 minus the mean total costs at T0 (costs mentioned in Table 3). Patients with a clinically relevant reduction in HbA1c had a mean reduction in costs of €2144 in the year post-MIDEP, compared to €509 in the group of patients that did not achieve this improvement in HbA1c ($P = 0.30$; Mann–Whitney test). Comparing subgroups of participants who did achieve a ≥1 SD reduction in PAID and those who did not, gave similar results: a €2535 reduction was found in patients with relevant PAID improvement compared to €408 in the patient not achieving this PAID reduction ($P = 0.088$). Combin-

Table 5 Number needed to treat for various inclusion criteria of HbA1c and PAID score

		HbA1c		
Inclusion criterion	n *(%)*	*<8.0% at T1 (95% CI)*	*≥0.5 reduction (95% CI)*	<8.0% and/or *≥0.5 reduction (95% CI)*
all patients	69 (100)	2.09 (1.66–2.81)	2.88 (2.12–4.22)	1.64 (1.38–2.07)
HbA1c ≥ 7.5	54 (78)	2.70 (1.95–4.13)	2.70 (1.95–4.13)	1.86 (1.48–2.53)
HbA1c ≥ 8.0	44 (64)	3.14 (2.10–5.39)	2.20 (1.63–3.30)	1.91 (1.48–2.73)
HbA1c ≥ 8.5	31 (45)	3.88 (2.23–8.53)	1.94 (1.43–3.04)	1.94 (1.43–3.04)
HbA1c ≥ 9.0	23 (33)	3.29 (1.88–7.68)	1.77 (1.30–2.92)	1.77 (1.30–2.92)
		PAID		
		<40 at T1 (95% CI)	*>1 SD* reduction (95% CI)*	*<40 and/or >SD reduction (95% CI)*
all patients	56 (100)	1.19 (1.08–1.40)	2.24 (1.71–3.20)	1.08 (1.02–1.21)
PAID total ≥ 30	31 (55)	1.24 (1.08–1.60)	1.41 (1.16–1.93)	1.07 (1.01–1.28)
PAID total ≥ 40	27 (48)	1.27 (1.09–1.70)	1.17 (1.04–1.49)	1.08 (1.01–1.32)
PAID total ≥ 50	14 (25)	1.40 (1.09–2.41)	1.17 (1.01–1.77)	1.08 (1.00–1.53)

CI, confidence interval.
*SD of reference group.

ing the criteria for HbA1c and PAID gave a €2025 reduction for the successfully treated patients and a €499 reduction for the non-successfully treated patients ($P = 0.13$). In sum, patients achieving clinically relevant outcomes in HbA1c and PAID had greater, although not statistically significant, cost reductions than patients who did not achieve these HbA1c and PAID outcomes.

Discussion

The present study shows beneficial effects of an MIDEP for patients with prolonged diabetes self-management difficulties 1-year post-treatment. An improvement in glycaemic control, as indicated by the reduction in HbA1c, and a reduction in diabetes-related distress were found. These improvements were achieved for reasonable intervention costs that were outweighed by the substantial reduction in costs generated by participants in the year post-MIDEP.

The high costs MIDEP participants generated in the year before the intervention were substantially reduced, although remaining significantly higher than the costs of the reference group. The reduction in costs measured in this study equalled the costs of the intervention. Because the participants were withdrawn from their regular diabetes care during MIDEP, they did not generate outpatient clinic costs, direct non-medical costs and patients had no hospital admissions during approximately 5 months. The net costs of MIDEP then would be lower than €1327, which means a further improvement of the programme's cost-effectiveness. A relatively small proportion of the MIDEP participants generated the major part of the costs. The non-parametric tests performed on this skewed data confirmed that the observed differences in mean costs indeed indicate lower diabetes-related costs post-treatment.

The present study does not give an exhaustive description of the cost involved in diabetes care, but the most important variable costs in these relatively young diabetic patients without established diabetic complications were measured. We did not measure the costs for materials used for self-testing of blood glucose, although the improved HbA1c in the MIDEP participants could suggest an increase in self-testing. In our opinion however, these costs would be relatively small in comparison to for instance the costs of hospital admissions. The improved HbA1c, when sustained over time, will greatly reduce future health care costs by lowering

the risks for diabetic complications (DCCT 1993; UKPDS 1998).

From an efficiency perspective, not only the cost-effectiveness of the intervention is a matter of concern. The growing prevalence of diabetes (International Diabetes Federation 2003) puts an increasing load on outpatient diabetes clinics with some subgroups of patients showing a pattern of increased health care utilization (El Fakiri *et al*. 2003). The target group of MIDEP demands particularly much care, with more outpatient visits and more patients having hospital admissions than average outpatients do. Taking over this care for 5 months produces a considerable temporally relief of the outpatient clinic in itself besides the more lasting reduction of health care consumption of these patients after MIDEP.

Besides determining the costs and benefits of MIDEP, an important aim of the present study was to determine for which patients the programme is most effective in achieving clinically relevant improvements in HbA1c and diabetes-related distress. The effect of MIDEP in HbA1c and diabetes-related distress were satisfying in the whole group of participants, with one in less than three patients having a ≥0.5% reduction in HbA1c and one in slightly more than two patients reporting a decrease of >1 SD at the PAID (diabetes-related distress). Nevertheless, the selection of patients with higher baseline HbA1c and higher baseline distress would lead to lower NNT to achieve clinically relevant improvements. With respect to HbA1c, selection of patients with HbA1c ≥ 8.0% does result in a fairly considerable reduction in the NNT. Further restriction of inclusion on basis of HbA1c would not lead to large improvements of MIDEP's efficacy on glycaemic control outcomes. Interestingly, guidelines of the American Diabetes Association define an HbA1c ≥ 8.0% as poor control (American Diabetes Association 2001). The NNTs for >1 SD reduction in PAID scores declined considerably when selecting patients on, respectively, baseline scores of ≥30 and ≥40, without the NNTs for achieving PAID scores < 40 increasing much. In patients with high diabetes-related distress indicated by PAID scores ≥ 40 (Snoek *et al*. 2000), one in every 1.17 achieved a >1 SD reduction and one in every 1.27 achieved a PAID score of <40 at 1-year follow-up. Using these two inclusion criteria would further increase MIDEP's efficiency without excluding many patients; 76% of the participants had either HbA1c ≥ 8.0% and/or PAID ≥ 40.

Participants of MIDEP with clinical relevant improvements in HbA1c and/or diabetes-related distress had a greater reduction in the diabetes-related costs than patients who did not improve relevantly. Decreasing the NNT by stricter selection of patients as shown in Table 4, thus would not only increase MIDEP's effectiveness in glycaemic control and diabetes-related distress, but in cost-effectiveness as well. In successfully treated patients, the costs of running MIDEP, being €1327, are more than compensated by the costs reductions, whereas for non-successfully treated patients this is not the case.

Policy implications

To conclude with, this present study hands some valuable clues for the improvement of outpatient care for diabetic patients with prolonged self-management problems, both from the patients' perspective and from a cost-effectiveness perspective. The postponed cost reduction of diabetes interventions can present a serious barrier for implementation of the intervention (Sadur *et al*. 1999). Like a few other interventions (Testa & Simonson 1998; Sadur *et al*. 1999), we found MIDEP to be cost-effective within a year, which makes it an attractive intervention for patients with prolonged self-management difficulties. This holds not only for patients with poor glycaemic control (Sadur *et al*. 1999), but also for patients with diabetes-related distress. In contrast to most other cost-effectiveness studies of diabetes interventions, this study focused not only on the efficacy of the intervention, but also on improving this efficacy by exploring optimal inclusion criteria for MIDEP.

The present study shows that MIDEP results in clinically relevant improvements while the programme costs were almost entirely compensated by reduced medical consumption in the year post-MIDEP. The effects in the patients-related outcomes glycaemic control and diabetes-related distress can be further enhanced by selecting patients with either HbA1c ≥ 8.0% or PAID scores ≥ 40. With this, the reduction in diabetes-related medical and non-medical costs will further improve as well. Using these criteria more strictly in clinical practice can

help to solve another efficiency problem in the utilization of additional diabetes care for patients with self-management problems as well, that is, non-referral of patients who are actually in need of additional care. In particular, patients with high levels of diabetes-related distress are not recognized as needing MIDEP at the outpatient clinic (Keers *et al.* 2004b), although the present study shows beneficial effects for these patients as well.

Intensive outpatient programmes can improve diabetes care and relieve the occupied outpatient clinics that have to treat the growing number of diabetic patients. For this, these programmes have to be focused on patients with prolonged high levels of diabetes self-management problems and who generate high costs even without having established diabetes complications yet.

References

American Diabetes Association (2001) Standards of medical care for patients with diabetes mellitus. *Diabetes Care* **24** (Suppl. 1), S33–S49.

Anderson L. (1990) Health-care communication and selected psychosocial correlates of adherence in diabetes management. *Diabets Care* **13**, 66–77.

Anderson R.M., Funnell M.M., Carlson A., Saleh-Statin N., Cradock S. & Skinner T.C. (2000) Facilitating self-care through empowerment. In *Psychology in Diabetes Care* (eds F.J. Snoek & T.C. Skinner), pp. 69–98. John Wiley & Sons, Ltd, Chichester.

Brown S.A. (1999) Interventions to promote diabetes self-management: state of the science. *Diabetes Educator* **25**, 52–61.

Clement S. (1995) Diabetes self-management education. *Diabetes Care* **18**, 1204–1214.

Coates V.E. & Boore J.R. (1996) Knowledge and diabetes self-management. *Patient Education and Counselling* **29**, 99–108.

Cohen J. (1992) A power primer. *Psychological Bulletin* **112**, 155–159.

Colagiuri R., Colagiuri S. & Naidu V. (1995) Can patients set their own educational priorities? *Diabetes Research and Clinical Practice* **30**, 131–136.

Cook R.J. & Sackett D.L. (1995) The number needed to treat: a clinically useful measure of treatment effect. *British Medical Journal* **310**, 452–454.

Cox D.J., Gonder F.L., Julian D.M. & Clarke W. (1994) Long-term follow-up evaluation of blood glucose awareness training. *Diabetes Care* **17**, 1–5.

Dalewitz J., Khan N. & Hershey C.O. (2000) Barriers to control of blood glucose in diabetes mellitus. *American Journal of Medical Quality* **15**, 16–25.

Diabetes Control and Complications Trial Research Group (DCCT) (1993) The effects of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *New England Journal of Medicine* **329**, 977–986.

Diabetes Control and Complications Trial Research Group (1995) Resource utilization and costs of care in the diabetes control and complications trial. *Diabetes Care* **18**, 1468–1478.

Diabetes Control and Complications Trial Research Group (1996) Lifetime benefits and costs of intensive therapy as practiced in the diabetes control and complications trial. The diabetes control and complications trial research group [see comments] [published erratum appears in *JAMA* 1997 July 2;278(1):25]. *Journal of the American Medical Association* **276**, 1409–1415.

El Fakiri F., Foets M. & Rijken M. (2003) Health care use by diabetic patients in the Netherlands: patterns and predicting factors. *Diabetes Research and Clinical Practice* **61**, 199–209.

Funnell M.M., Anderson R.M., Arnold M.S., Barr P.A., Donnelly M., Johnson P.D., Taylor M.D. & White N.H. (1991) Empowerment: an idea whose time has come in diabetes education. *Diabetes Educator* **17**, 37–41.

Glasgow R.E. (1995) A practical model of diabetes management and education. *Diabetes Care* **18**, 117–126.

Gozzoli V., Palmer A.J., Brandt A. & Spinas G.A. (2001) Economic and clinical impact of alternative disease management strategies for secondary prevention in type 2 diabetes in the Swiss setting. *Swiss Medical Weekly* **131**, 303–310.

International Diabetes Federation (2003) *Diabetes e-Atlas.* [WWW document]. URL http://www.idf.org/e-atlas

Jacobson A.M. (1996) The psychological care of patients with insulin-dependent diabetes mellitus. *New England Journal of Medicine* **334**, 1249–1253.

Keers J.C., Blaauwwiekel E.E., Hania M., Bouma J., Scholten-Jaegers S.M.H.J., Sanderman R. & Links T.P. (2004a) Diabetes rehabilitation: development and first results of a multidisciplinary intensive education programme for patients with prolonged self-management difficulties. *Patient Education and Counselling* **52**, 151–157.

Keers J.C., Links T.P., Bouma J., Gans R.O.B., Maaten J.C.t., Wolffenbuttel B.H.R., Sluiter W.J. & Sanderman R. (2004b) Do diabetologists recognise self-management

problems in their patients? *Diabetes Research and Clinical Practice* **66**, 157–161.

Laupacis A., Sackett D.L. & Roberts R.S. (1988) An assessment of clinically useful measures of the consequences of treatment. *New England Journal of Medicine* **318**, 1728–1733.

Links T.P., Keers J.C., Bouma J., Maaten J.C.t., Gans R.O.B., Sanderman R. & Wolffenbuttel B.H.R. (2003) Long-term effects of diabetes rehabilitation for patients with prolonged self-management difficulties [Abstract]. *Diabetologia* **46**, A422.

Lloyd C.E., Wing R.R., Orchard T.J. & Becker D.J. (1993) Psychosocial correlates of glycaemic control: the Pittsburgh epidemiology of diabetes complications (EDC) study. *Diabetes Research and Clinical Practice* **21**, 187–195.

Macrodimitris S.D. & Endler N.S. (2001) Coping, control, and adjustment in type 2 diabetes. *Health Psychology* **20**, 208–216.

Mandrup P.T. (1998) Diabetes. *British Medical Journal* **316**, 1221–1225.

Niessen L.W. & Casparie A.F. (2001) *Effecten en Kosten van de Herziene Richtlijnen voor Diabetes (Effects and Costs of the Revised Diabetes Guidelines)*. Institute for Medical Technology Assessment, University of Rotterdam, Rotterdam.

Norris S.L., Engelgau M.M. & Narayan K.M. (2001) Effectiveness of self-management training in type 2 diabetes; a systematic review of randomized controlled trials. *Diabetes Care* **24**, 561–587.

Oostenbrink J.B., Koopmanschap M.A. & Rutten F.F.H. (2000) *Handbook for Cost Studies, Methods and Guidelines for Economic Evaluation in Health Care [Handleiding Voor Kostenonderzoek: Methoden en Richtlijnprijzen Voor Economische Evaluaties in de Gezondheidszorg]*. PB – College voor zorgverzekeringen, Amstelveen.

Pouwer F., Snoek F.J., van-der-Ploeg H.M., Ader H.J. & Heine R.J. (2001) Monitoring of psychological well-being in outpatients with diabetes: effects on mood, HbA(1c), and the patient's evaluation of the quality of diabetes care: a randomized controlled trial. *Diabetes Care* **24**, 1929–1935.

Rickheim P., Weaver T., Flader J. & Kendall D. (2002) Assessment of group versus individual diabetes education: a randomized study. *Diabetes Care* **25**, 269–274.

Rubin R.R. & Peyrot M. (1999) Quality of life and diabetes. *Diabetes Metababolism Research and Reviews* **15**, 205–218.

Sadur C.N., Moline N., Costa M., Michalik D., Mendlowitz D., Roller S., Watson R., Swain B.E., Selby J.V. & Javorski W.C. (1999) Diabetes management in a health maintenance organization. Efficacy of care management using cluster visits. *Diabetes Care* **22**, 2011–2017.

Snoek F.J., Pouwer F., Welch G. & Polonsky W.H. (2000) Diabetes related emotional distress in dutch and US diabetic patients. A cross-cultural validity of the problem areas in diabetes scale. *Diabetes Care* **23**, 1305–1309.

Snoek F.J. & Skinner T.C. (2002) Psychological counselling in problematic diabetes: does it help? *Diabetic Medicine* **19**, 265–273.

Steed L., Cooke D. & Newman S. (2003) A systematic review of psychosocial outcomes following education, self-management and psychological interventions in diabetes mellitus. *Patient Education and Counselling* **51**, 5–15.

Surwit R., van-Tilburg M., Zucker N., McCaskill C., Parekh P., Feinglos M., Edwards C., Williams P. & Lane J. (2002) Stress management improves long-term glycaemic control in type 2 diabetes. *Diabetes Care* **25**, 30–34.

Testa M.A. & Simonson D.C. (1998) Health economic benefits and quality of life during improved glycaemic control in patients with type 2 diabetes mellitus: a randomized, controlled, double-blind trial. *Journal of the American Medical Association* **280**, 1490–1496.

Trento M., Passera P., Bajardi M., Tomalino M., Grassi G., Borgo E., Donnola C., Cavallo F., Bondonio P. & Porta M. (2002) Lifestyle intervention by group care prevents deterioration of type II diabetes: a 4-year randomized controlled clinical trial. *Diabetologia* **45**, 1231–1239.

UKPDS (1998) Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). UK Prospective Diabetes Study (UKPDS) Group [see comments]. *Lancet* **352**, 837–853.

UKPDS (2000) Quality of life in type 2 diabetic patients is affected by complications but not by intensive policies to improve blood glucose or blood pressure control (UKPDS 37). UK Prospective Diabetes Study Group. *Diabetes Care* **22**, 1125–1136.

Welch G.W., Jacobson A.M. & Polonsky W.H. (1997) The problem areas in diabetes scale. An evaluation of its clinical utility. *Diabetes Care* **20**, 760–766.