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Diabetes specialist nurse as main care provider for patients with type 2 diabetes

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ABSTRACT

Background: The objective of this study was to determine whether the management of type 2 diabetes (DM2) can be transferred from an internist to a nurse specialised in diabetes (NSD).

Methods: Ninety-three patients with DM2 referred by their general practitioner were randomised; 84 patients completed the study. The intervention group received care from an NSD who treated glycaemia, blood pressure and lipid profile by protocol. The control group received care from an internist. The primary endpoint was the main decrease in HbA1c. Secondary endpoints included blood pressure, lipid profile, healthcare costs, QOL, and patient satisfaction.

Results: HbA1c, total cholesterol, LDL cholesterol and cholesterol/HDL ratio decreased significantly in both study populations after a follow-up time of 12 months. Cholesterol/HDL ratio decreased by 0.4 and 0.9 in the NSD and control group respectively (p=0.034 for the difference between groups). The decreases (95% confidence interval) in systolic blood pressure were 8.6 mmHg (2.6, 14.7) in the NSD group and 4.0 mmHg (-0.9, 8.9) in the control group, without a significant difference between groups. After one year, 33.3% of the patients in the NSD group achieved an HbA1c level <7% compared with 2.2% at baseline (p=0.002). Healthcare costs were less and patient satisfaction with the NSDs was significantly better (p<0.001), while maintaining the same QOL.

Conclusion: NSDs using treatment protocols are able to provide effective care for patients with DM2, comparable with the care provided by an internist, with respect to clinical parameters, and superior with respect to healthcare costs and patient satisfaction.

KEYWORDS

Diabetes mellitus type 2, nurses, randomised controlled trial

INTRODUCTION

Type 2 diabetes is a chronic, progressive illness which causes considerable morbidity and premature mortality.[1,2] The worldwide prevalence of type 2 diabetes is high and is increasing steadily, also in the Netherlands.[3,4] The burden of type 2 diabetes on healthcare has also increased because of the intensified cardiovascular risk management being practised to prevent macrovascular morbidity and mortality in these patients.[5] In the treatment of type 2 diabetes, tight guidelines are increasingly recommended for optimising glycaemia, blood pressure and lipid profile.[6] Therefore, the burden of treatment has increased and will further increase per patient as well as per population with type 2 diabetes. In order to meet this problem, in the current study, we tested the hypothesis that well-defined routine aspects in diabetes care, previously only handled by medical doctors in the secondary care setting, may be safely transferred to supervised nurses specialised in diabetes (NSD), including the prescription of medication, resulting in at least the same quality of clinical care, healthcare costs, health-related quality of life (HRQOL), and patient satisfaction.

MATERIALS AND METHODS

The study population consisted of patients with type 2 diabetes who were referred by general practitioners to the

diabetes outpatient clinics of two different hospitals in the northeast region of the Netherlands: the Isala Clinics in Zwolle and the Bethesda General Hospital in Hoogeveen. Patients were referred between March 2002 and January 2004. An internist saw all patients prior to randomisation and excluded patients in whom treatable comorbidity was found, such as macroalbuminuria, serum creatinine level >135 mol/l, Cockcroft <50 ml/min, and/or alanine aminotransferase (ALAT) >120 U/l. Pregnant patients were also not eligible. The study was approved by the local Medical Ethics Committee of the Isala Clinics. All participants provided written informed consent. Overall, 95 patients were recruited and randomised (*figure 1*). Eighty-four subjects, 46 in the intervention group and 38 in the control group, completed the study and were included in the analysis. Both groups were comparable for age, type 2 diabetes duration, body mass index (BMI), blood pressure, HbA1c, and lipid profile (*table 1*). The gender distribution was slightly different in the two groups.

Figure 1. *Flow of patients through the study*

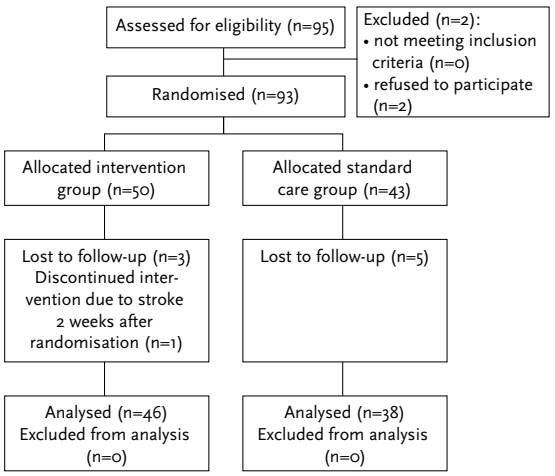

Table 1. *Baseline characteristics per group*

	NSD (n=46)	Standard care (n=38)
Gender (male)	43.5%	50.0%
Age (year) (mean ± SD)	63.1 ± 10.6	59.6 ± 10.6
Diabetes duration (year) (median (25-75%)	7.5 (4.0-13.0)	6.0 (3.5-10.5)
BMI (kg/m^2) (mean ± SD)	30.5 ± 5.6	30.1 ± 5.6
SBP (mmHg) (mean ± SD)	154.9 ± 23.3	156.3 ± 19.9
DBP (mmHg) (mean ± SD)	86.6 ± 10.9	85.6 ± 9.4
HbA1c (%) (mean ± SD)	8.9 ± 1.2	8.6 ± 1.3
Total cholesterol (mmol/l) (mean ± SD)	4.9 ± 0.8	5.2 ± 1.2
LDL cholesterol (mmol/l) (mean ± SD)	2.6 ± 0.9	2.7 ± 1.0
Cholesterol/HDL ratio (mean ± SD)	4.1 ± 1.2	4.4 ± 1.9

BMI = body mass index; SPB = systolic blood pressure; DBP = diastolic blood pressure; LDL = low-density lipoproteins; HDL = high-density lipoproteins.

Intervention and control group

The intervention group was primarily treated and educated by NSDs. NSDs were trained to follow a detailed treatment and management protocol aimed at optimising glycaemia, blood pressure, and lipid profile.[7] These protocols are based on the guidelines from the Dutch College of General Practitioners and those from the Dutch Diabetes Federation.[6,8] These protocols allowed the NSDs to prescribe medication and to order laboratory tests. They were permitted to initiate therapy with 14 different medications and to change dosages for a further 30. In some cases, the protocol indicated that consultation of an internist was necessary. All of the patients in the intervention group saw only one care provider (the NSD). The control group received standard care, in which an internist was responsible for treating type 2 diabetes and a 'standard' nurse specialised in diabetes was responsible for educating the patients.

Primary and secondary outcome measures

The primary endpoint was the mean decrease in HbA1c from baseline to one year after randomisation. Secondary endpoints were mean decrease in blood pressure, total cholesterol, LDL cholesterol and cholesterol/HDL ratio, proportion of patients achieving ranges of glycaemic control (HbA1c below 7 and 8.5%, respectively), of blood pressure (below 140/90 mmHg), and of lipid profile (individual target values according to the Dutch guidelines from 1999 to 2005 in which treatment is indicated in men between 50 and 70 years of age and women between 50 and 75 years of age with a 25% risk of developing cardiovascular disease in ten years) from baseline to one year after randomisation. Other secondary endpoints included measures of HRQOL, diabetes-related symptoms, patients' satisfaction, and healthcare consumption and costs (number of patient visits, number of contacts between NSD and internist, medication adjustments, costs of the prescribed medication, costs associated with requested lab work, and the costs of actual patient contact).

Measures

All subjects were seen prior to any intervention and before randomisation by an independent medical investigator and after six months (T6) and after 12 months (T12). These visits were planned independently from the visits to the care providers. At baseline, the duration of type 2 diabetes, any diabetes medication(s), general medication(s), and insulin-dose requirements were assessed. The patients were weighed dressed but without shoes. Height was measured without shoes, and blood pressure was measured with the patient in a sitting position. The mean of the two blood pressure readings was calculated. A calibrated and validated Omron M5-I (HEM-757) automatic blood pressure device was used to measure blood pressure.[9] HbA1c, serum total cholesterol, low-density lipoprotein (LDL), high-density

lipoprotein (HDL), triglycerides, ALAT, and creatinine levels were measured according to standard hospital procedures. HRQOL was assessed with the Short Form-36 questionnaire (SF-36). The SF-36 is a validated generic health-related quality-of-life questionnaire that includes both mental and physical factors.[10,11] To measure the presence and the perceived burden of diabetes-related symptoms, the revised version of the Type 2 Diabetes Symptom Checklist (DSC-type 2) was used.[12] Satisfaction with diabetes care was assessed using the Patients' Evaluation of the Quality of Diabetes Care (PEQD).[13]

Healthcare costs were determined at three levels: average cost per patient per month of the prescribed medication according to the prices as they are listed in the Dutch Pharmacotherapeutic Compass 2003 (analogous to the CPS in North America), the costs associated with requested lab work, based on the prices as listed in the Diagnostic Compass 2003, and the costs of actual patient contact which is calculated according to the salaries of the healthcare workers involved: internists € 60,00 per hour, and NSD and standard diabetes nurses € 23,00 per hour.[14,15]

Randomisation and power calculation

The patient population was randomised using non-transparent closed envelopes, with sequential numbers enclosed. Subjects with even numbers were assigned to the intervention group, and those with odd numbers were assigned to the control group. According to earlier study results, power analysis revealed that 81 patients would be required in order to have an 80% chance of detecting a significant (at the two-sided 5% level) 0.5% difference in mean HbA1c at T12 between the two groups, assuming a standard deviation of 0.75 and a 10% loss to follow-up.

Statistical analyses

Statistical analyses were performed using SPSS 11.0 for Windows. For longitudinal analyses we used the general linear model (GLM repeated measures) for continuous variables and the McNemar test for changes in dichotomous variables. To study changes in HRQOL, diabetes-related symptoms, and quality of diabetes care, we used the Mann-Whitney U tests for analyses between groups and the Wilcoxon signed-rank tests for changes from baseline within groups because of some skewed outcomes. To study changes in medical services and medication adjustments, we used Student's t-test for variables with a normal distribution, the Mann-Whitney U test for non-normal distributed variables, and the χ^2 test for categorical variables. All reported P values are two-tailed. To allow for multiple comparisons we adjusted the outcome analyses using the Bonferroni correction.

RESULTS

At T6 and T12, mean HbA1c, total cholesterol, LDL cholesterol and cholesterol/HDL ratio declined significantly in both groups (*table 2*). In the intervention group the systolic blood pressure was significantly lower at both T6 and T12, and the diastolic blood pressure was only significantly lower at T6. In the control group, the decreases

Table 2. *Mean change scores of outcome variables and percent of patients meeting outcome targets by treatment group*

		NSD			Standard care			p value†
		Difference between To-T6*	Difference between To-T12*		Difference between To-T6*	Difference between To-T12*		
SBP (mmHg)		-9.5 (-3.8, -15,2)	-8.6 (-2.6, -14.7)		-7.2 (-2.4, -12.1)	-4.0 (0.9, -8.9)		NS
DBP (mmHg)		-3.1 (-0.3, -5.9)	-1.4 (1.4, -4.1)		-1.0 (2.7, -4.8)	-2.4 (0.8, -4.9)		NS
BMI (kg/m²)		-0.1 (-0.5, 0.3)	0.4 (-0.1, 0.9)		0.1 (-0.3, 0.6)	0.2 (-0.3, 0.8)		NS
HbA1c (%)		-1.5 (-1.4, -1.9)	-1.5 (-1.0, -1.9)		-1.2 (-0.9, -1.6)	-0.9 (-0.5, -1.3)		NS
Total cholesterol (mmol/l)		-0.3 (-0.1, -0.6)	-0.4 (-0.2, -0.6)		-0.6 (-0.2, -1.1)	-0.9 (-0.5, -1.3)		NS
LDL cholesterol (mmol/l)		-0.1 (-0.3, 0)	-0.3 (-0.1, -0.5)		-0.3 (-0.6, 0.1)	-0.6 (-0.2, -0.9)		NS
Cholesterol/HDL		-0.3 (-0.1, -0.6)	-0.4 (-0.1, -0.6)		-0.7 (-0.4, -1.1)	-0.9 (-0.5, -1.4)		p=0.034‡
	Target	To	T12	p value	To	T12	p value	p value§
HbA1c	<7.0	2.2%	33.3%	p=0.002	10.5%	26.3%	NS	NS
	≤8.5	40.0%	93.3%	p<0.001	44.7%	81.6%	p<0.001	NS
SBP (mmHg)	<140	23.9%	32.6%	NS	23.7%	31.6%	NS	NS
DBP (mmHg)	<90	65.2%	63.0%	NS	65.8%	73.7%	NS	NS
BP (mmHg)	<140/90	21.7%	26.1%	NS	23.7%	23.7%	NS	NS
Dutch lipid profile	||	76.1%	91.3%	p=0.016	70.3%	91.9%	p=0.008	NS

SBP = systolic blood pressure; DBP = diastolic blood pressure, BMI = body mass index; LDL = low-density lipoproteins; HDL = high-density lipoproteins. *Mean with 95% CI. †Difference between NSD and standard care. ‡Difference between NSD and standard care in change between To and T12. §p value general linear model (GLM) between groups. || Individual target values according to Dutch guidelines from 1999-2005 in which treatment is indicated in men between 50 and 70 years and women between 50 and 75 years with a 25% chance of developing cardiovascular disease in ten years. During treatment, the target value for the cholesterol level is <5 mmol/l.

in blood pressure at both T6 and T12 were not significant. None of the differences between the two groups were significant except for the cholesterol/HDL ratio, which was lower in the control group. After one year, significantly more patients in the intervention group achieved the target HbA1c level of less than 7% compared with baseline. A majority of patients in both groups (93 and 82%) achieved an HbA1c <8.5% and the target for the lipid profile at T12 (91 and 92%). Between the groups, no differences were found in target levels.

Seventy-eight of the 84 patients completed the SF-36 and the Diabetes Symptom surveys at follow-up (T12), and 80 patients completed the satisfaction survey (data not shown). There were no differences in HRQOL or diabetes-related symptoms over time between the two groups. The patients' evaluations of care received from the NSD were significantly more positive than the evaluations reported by the control group (p<0.001). The total satisfaction sum score for the NSD was 73.9%, for the internist 53.3%, and for the 'standard' diabetes nurse 59.9%.

The use of medical services and the number of medication adjustments are presented in *table 3*. There was a significant difference in the number of visits between the two groups (lower in the NSD group) but not in the duration of the visits. In some cases, the protocol being followed by the NSDs indicated that consultation of an internist was necessary. In the intervention group, the total number of these consultations was 57, and the median number per patient was 1.0 (interquartile range: 0.0 to 2.0). The NSDs referred significantly more patients back to the GP within 12 months (38 patients (82.6%) *vs* 9 patients (23.7%); p<0.001). The NSDs only referred patients back to their GP when the treatment goals of glycaemic control, blood pressure and lipid profile had been met. The intensity of glucose-lowering therapy increased in both groups. Most patients were switched to insulin therapy. During the study period the NSD prescribed significantly more antihypertensive agents, and the internist prescribed significantly more cholesterol-lowering agents. The difference between the two groups was only significant for the cholesterol-lowering agents.

Table 3. *Medical utilisation, medication adjustments and healthcare costs*

	NSD			Standard care			p value
Number of visits ± SD	7.4 ± 3.0			9.8 ± 3.8 (total) 5.2 ± 1.4 (internist) 4.7 ± 3.3 (standard nurse)			p=0.002
Total duration of visits (minutes ± SD)	272.0 ± 120.5			249.2 ± 110.7 (total) 67.6 ± 17.5 (internist) 180.8 ± 104.8 (standard nurse)			
Number of consultations with internist (median (25-75%))	1.0 (0-2.0)			-			-
Percent of patients referred back to the GP <12 months	82.6%			23.7%			p<0.001
Percentage patients	**Baseline**	**T12**	**p value**	**Baseline**	**T12**	**p value**	**p value***
OHA without insulin	91.3%	34.8%	p<0.001	89.5%	34.2%	p<0.001	NS
Insulin without OHA	6.5%	19.6%	NS	2.6%	7.9%	NS	NS
Insulin with OHA	2.2%	45.7%	p<0.001	5.3%	57.9%	p<0.001	NS
AHA	67.4%	84.8%	p=0.016	55.3%	71.1%	NS	NS
CLA	45.7%	54.3%	NS	34.2%	68.4%	p<0.001	p=0.006
Total salary costs in euros (mean ± SD) [median, 25-75%]	114.6 ± 50.4 [101.0, 70.1-147.2] (total) 106.0 ± 46.9 [96.4, 68.7-140.2] (patient visits) 8.6 ± 10.1 [7.0, 0-13.9] (consultations with internist)*			138.3 ± 48.3[126.8, 96.8-175.2] (total) 67.9 ± 17.7 [60.0, 50.0-80.0] (internist) 70.5 ± 40.8 [58.5, 35.1-105.2] (standard DN)			p=0.032
Total lab costs in euros (mean ± SD) [median, 25-75%]	64.9 ± 34.5 [60.0, 36.3-82.4]			91.5 ± 36.7 [83.8, 73.0-116.6]			p=0.001
Medication costs per month	**Baseline**	**T12**	**p value**	**Baseline**	**T12**	**p value**	**p value***
Total costs (mean ± SD and median (25-75%))	57.5±44.3 50.5 (27.0-77.3)	136.3±91.9 110.2 (66.5-202.7)	p<0.001	49.6±39.4 38.6 (19.7-78.4)	149.0±94.4 136.0 (72.2-188.7)	p<0.001	NS
HA (mean ± SD and median (25-75%))	24.1±30.9 11.6 (8.9-26.9)	89.3±77.6 67.8 (17.9-163.6)	p<0.001	21.8±22.7 12.7 (8.9-27.1)	88.6±79.6 81.8 (12.5-133.0)	p<0.001	NS
AHA (mean ± SD and median (25-75%))	14.5±15.4 7.4 (0-27.6)	21.5±19.7 19.1 (4.8-32.4)	p=0.001	11.3±14.0 4.7 (0-19.1)	23.7±23.0 18.9 (0-39.3)	p<0.001	NS
CLM (mean ± SD and median (25-75%))	18.9±24.6 0 (0-48.6)	25.5±29.6 23.2 (0-51.3)	p=0.011	16.5±27.3 0 (0-30.8)	36.7±34.4 35.1 (0-48.6)	p<0.001	p=0.005

***p value GLM between groups. OHA = oral hypoglycaemic agents; HA = hypoglycaemic agents; AHA = antihypertensive agents; CLA = cholesterol-lowering agents.**

The costs for the consumption of medical services are also listed in *table 3*. It is clear from this table that the personnel costs and the costs associated with laboratory testing are significantly lower in the intervention group when compared with the control group ($p<0.001$). The average per month increase in medication costs are not significantly different between the two groups, except for the cost increase associated with cholesterol-lowering medications, which shows a greater increase in the control group ($p=0.005$).
As mentioned, the gender distribution was slightly different in the two groups. In order to investigate whether the results were applicable for both men and women, we performed additional analyses for these groups separately (data not shown). These analyses revealed that the results did not differ when stratifying for gender.

DISCUSSION

This is the first randomised controlled study in which the following two strategies of treatment in patients with type 2 diabetes have been compared in a secondary healthcare setting: the strategy with an almost complete shift of diabetes care from doctors to nurses versus the conservative strategy. The results of this study show that an NSD, following tight protocols, achieves results which are equal to those achieved by an internist working with a 'standard' nurse in the treatment of patients with type 2 diabetes without serious diabetic complications who have been referred by their general practitioners to the hospital. Both patient groups were successfully treated, considering the improvements in clinical parameters. Both groups showed comparable numbers of patients with values within the target range at one year after randomisation for: HbA1c, blood pressures, and lipid profiles. While the patients in the NSD group were more satisfied with the care they received than the patients in the control group, their HRQOL levels remained equal.
Healthcare costs appeared to be lower in the NSD group than in the control group. This study also shows that there is a time saving on the part of the internist. For each patient who is primarily treated by the NSD, the average time saving for the internist is 61.4 minutes (difference of the mean internist-patient contact time per patient between the groups minus difference of the mean consultation time between NSD and internist per patient between the groups). This means that the internist would be able to supervise the treatment of almost eleven patients by the NSD in the same amount of time that he or she would require to treat a single patient.
In this study patients treated by an internist achieved a lower cholesterol/HDL ratio. However, an equal number of patients with lipid profile within the target range were found in both groups after one year (91.3 and 91.9%). This means that internists prescribed more cholesterol-lowering medicines than was dictated to the NSDs by the protocol. One has to remember that the protocol used in this study is based on older guidelines. The treatment goals for the lipid profile in patients with type 2 diabetes have become more stringent nowadays. Another difference between both groups is the proportion of patients referred back to the general practitioner within 12 months. In our opinion, both differences are probably caused by strictly following the study protocol in the NSD group.
What is already known about this topic? A Cochrane review from 2003 looked at the effect of treatment by NSDs on the metabolic regulation of patients with diabetes.[16] Only six studies were included in this review including 1382 participants. The conclusion was that NSDs were better at regulating glucose in the short term (six months) but not in the long term (12 months). None of these studies systematically examined the effect of assigning the treatment of patients with type 2 diabetes to NSDs in a randomised controlled design. Three of the studies in the review included only patients with type 1 diabetes. In the other three studies, the nurse was only responsible for delivering treatment recommendations to the primary physician, without being responsible for treating the patient. All the studies up to 2002 were included in the Cochrane review. In addition to this review, we found six randomised studies in Medline, which were published between 2002 and 2009.[17-21] In three of these studies, nurses were assigned specific tasks in the treatment of patients with type 2 diabetes.
New *et al*. studied the effect of lipid lowering and antihypertensive treatment regimens by nurses in specialist nurse-led clinics according to protocols on treatment efficacy compared with that of standard regimens by physicians.[19] These specialist nurses titrated medications according to the local protocol, but did not initiate additional therapy when necessary. Overall, specialist nurse-led clinics were associated with a significant improvement in patients achieving the target.
The study by Taylor *et al*. examined the effects of assigning a nurse-care manager who, according to specific protocols, was permitted to titrate medications for glycaemic control, blood pressure and lipid profile.[20] Patients randomised to usual care were instructed to remain under the treatment of their primary care physician. The patient's primary care physician was called if a new medication was indicated. At one year, the mean reductions in HbAlc, total cholesterol, and LDL cholesterol were significantly greater for the intervention group compared with the usual care group.
The effect of antihypertensive treatment regimens by home care nurses who titrated drug regimen according to an algorithm, was investigated by Tobe *et al.*[21] After each medication change, follow-up was arranged with the patient's primary care physician. Participants assigned to the control group were treated by their primary care

physician. Both groups experienced a significant reduction in systolic blood pressure (between the groups not significant) and patients in the intervention group had a larger decrease in diastolic blood pressure over time than did those in the control group.

All of these studies were trying to determine if interventions involving a nurse would lead to improved care for the patient with diabetes. Our primary goal was not to improve the quality of care. We essentially questioned whether NSDs are able to offer diabetes care with maintenance of its actual quality and with relief of its increasing burden in a cost-effective way.

CONCLUSION

Standardised care, in patients without serious diabetic complications, delivered by a specially trained NSD is a good alternative to standard care by an internist, with comparable results after one year of treatment in treatment goals, and even better results in patient goals and goals for cost-effectiveness.

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