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BMJ 2001;323:970-5

Randomised controlled trial of structured personal care of type 2 diabetes mellitus

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Abstract

Objective To assess the effect of a multifaceted intervention directed at general practitioners on six year mortality, morbidity, and risk factors of patients with newly diagnosed type 2 diabetes.

Design Pragmatic, open, controlled trial with randomisation of practices to structured personal care or routine care; analysis after 6 years.

Setting 311 Danish practices with 474 general practitioners (243 in intervention group and 231 in comparison group).

Participants 874 (90.1%) of 970 patients aged ≥ 40 years who had diabetes diagnosed in 1989-91 and survived until six year follow up.

Intervention Regular follow up and individualised goal setting supported by prompting of doctors, clinical guidelines, feedback, and continuing medical education.

Main outcome measures Predefined clinical non-fatal outcomes, overall mortality, risk factors, and weight.

Results Predefined non-fatal outcomes and mortality were the same in both groups. The following risk factor levels were lower for intervention patients than for comparison patients (median values): fasting plasma glucose concentration (7.9 v 8.7 mmol/l, $P=0.0007$), glycated haemoglobin (8.5% v 9.0%, $P<0.0001$; reference range 5.4-7.4%), systolic blood pressure (145 v 150 mm Hg, $P=0.0004$), and cholesterol concentration (6.0 v 6.1 mmol/l, $P=0.029$, adjusted for baseline concentration). Both groups had lost weight since diagnosis (2.6 v 2.0 kg). Metformin was the only drug used more frequently in the intervention group (24% (110/459) v 15% (61/415)). Intervention doctors arranged more follow up consultations, referred fewer patients to diabetes clinics, and set more optimistic goals.

Conclusions In primary care, individualised goals with educational and surveillance support may for at least six years bring risk factors of patients with type 2 diabetes to a level that has been shown to reduce diabetic complications but without weight gain.

Introduction

Efforts to control hyperglycaemia,¹ hypertension,^{2,3} and dyslipidaemia⁴ may postpone the development of complications in patients with type 2 diabetes.⁵

However, it is not known whether these results can be implemented over a long period in general practice. General practitioners often do not follow international recommendations,^{6,7} and the quality of care is not satisfactory even when clinical guidelines are provided.^{8,9} A combination of interventions, including prompting, may be needed to change general practitioners' behaviour and improve quality of care.¹⁰⁻¹³

We report the final results of a six year study from general practice examining the effect of structured personal care compared with routine care on overall mortality and on risk factors for and incidence of clinical complications in newly diagnosed diabetic patients aged 40 years or older. Structured care included regular follow up and setting of individualised goals for important risk factors, supported by prompting of doctors, feedback on individual patients, short clinical guidelines, and a brief training programme for general practitioners.

Participants and methods

Recruitment of general practitioners

We invited a random sample of two thirds of Danish general practices, excluding singlehanded practices with a doctor aged ≥ 60 years, to participate in the study. Practices were stratified according to number of partners and spelling of practice address and then allocated by random numbers to structured care or routine care. One hundred and forty seven patients entered the study after recruitment when patients changed doctor.

Recruitment of patients

We included all patients aged 40 or older with newly diagnosed diabetes between 1 March 1989 and 28 February 1991. The exclusion criteria were life threatening somatic disease, severe mental illness, unwillingness to participate, and lack of confirmation of diagnosis by a single non-fasting whole blood or plasma glucose concentration $\geq 7.0/8.0$ mmol/l at a major laboratory. All participants gave informed consent, and the protocol was approved by the ethics committee of Copenhagen and Frederiksberg.

Comparison group: routine care

In Denmark, routine care of patients with type 2 diabetes is usually given by general practitioners in ordinary consultations and not in disease management sessions run by nurses. Doctors in the comparison

group were free to choose any treatment and change it over time. During the study period, the study coordinator (NdFO) sent 51 personal letters to doctors in the intervention group and 32 to doctors in the comparison group about study progress and preliminary results.

Intervention group: structured care

Prompted by questionnaires sent one month before the next expected consultation, general practitioners were asked to see patients every three months and screen them annually for diabetic complications. The general practitioner defined with the patient the best possible goals for blood glucose concentration, glycated haemoglobin, diastolic blood pressure, and lipids within three predefined categories (table 1). At each quarterly consultation, the general practitioner was asked to compare the achievements with the goal and consider changing either goal or treatment accordingly. General practitioners were prompted to help overweight patients agree on a small, realistic weight reduction and to follow up on this.

The doctors received annual descriptive feedback reports on individual patients. They comprised the last six measurements of risk factors, complications, current treatment goal, and pharmacological treatment, and a reminder about the role of microalbuminuria as a risk marker for cardiovascular disease.

The general practitioners were given clinical guidelines supported by an annual half day seminar. They were also given four leaflets to hand out to patients. The doctors were not obliged to follow the guidelines concerning diet and drug treatment (box). Generally, the importance of diet was stressed, and doctors were recommended to postpone, if possible, the start of antidiabetic drugs until at least three months after diagnosis to observe the effect of weight loss.

Assessments

Predefined primary outcomes were overall mortality and incidences of diabetic retinopathy, urinary albumin concentration ≥ 15 mg/L, myocardial infarction, and stroke. Secondary outcomes were incidence of peripheral neuropathy, angina pectoris, intermittent claudication, and amputation. Tertiary outcomes were levels of risk factors included in patients' goals.

The doctors assessed body height and weight; blood pressure and heart rate; sense of touch of cotton wool and pin prick on both feet; presence of patellar reflexes; drug treatment; history of myocardial infarction and stroke causing hospital admission; amputation of leg or part before or at the time of diagnosis of diabetes; familiarity with the patient; severe hypoglycaemic events; and doctors' background variables. Primary care ophthalmologists recorded the results of funduscopy. Hypertension was defined as systolic/diastolic blood pressure $\geq 160/90$ mm Hg or the use of antihypertensive or diuretic drugs, or any combination of these. Peripheral neuropathy was defined as lack of a sense of touch of cotton wool or pin prick on at least one foot or absent patellar reflex on at least one knee, or any combination of these.

In questionnaires, patients reported whether they lived alone, education, (former) occupation, smoking habits,¹⁴ leisure time physical activity, angina pectoris,¹⁴ intermittent claudication,¹⁴ global self rated health, change of habits, food habits, symptoms of diabetes, and home glucose monitoring. Blood and urine chemistry were analysed centrally.

Table 1 Treatment goals for intervention group

	Good control	Acceptable control	Poor control
Fasting blood glucose (mmol/l)*	≤ 7.0	≤ 8.0	> 8.0
Non-fasting blood glucose (mmol/l)*	≤ 9.0	≤ 11.0	> 11.0
Glycated haemoglobin (%)†	≤ 7.0	≤ 8.5	> 8.5
Diastolic blood pressure (mm Hg)	≤ 90	≤ 100	> 100
Total cholesterol (mmol/l)	≤ 6.0	≤ 7.0	> 7.0
Fasting triglyceride (mmol/l)	≤ 2.0	≤ 5.0	> 5.0

*Capillary whole blood glucose. †Reference range 5.4-7.4%.

Instructions for general practitioners: The aim is normalisation of blood glucose, blood pressure, lipids, and possibly weight. For some patients, it will be impossible or even inappropriate to try to achieve the ideal goal, but prolonged symptoms of hyperglycaemia or hypoglycaemia must not be accepted for any patient. From an overall therapeutic point of view, the general practitioner chooses to aim at the treatment goals in one of the three categories. The choice of category is primarily based on glycated haemoglobin. Good control (normalisation of metabolism) is particularly relevant in young and middle aged patients and in well motivated older patients. Acceptable control applies to some older patients and patients who are difficult to treat or motivate. Poor control (freedom from symptoms) is intended for use when treatment has shown that any other goal is beyond reach.

The day of death was taken from the death certificate. Data on hospital admissions since diagnosis were obtained from the national hospital discharge registry.

Statistical analysis and sample size

We estimated that we needed between 100 and 1200 patients in each group to detect a 40% difference over 10 years between the groups in the four non-fatal outcomes with 80% power and 95% confidence. Analysis was by intention to treat. Quoted P values are not adjusted for multiple comparisons. Since there are five primary outcome variables we used the Bonferroni method and accepted $P < 0.01$ as significant. All other outcomes were interpreted at the 5% level, but only to show tendencies. We compared intervention and comparison groups at follow up using a Wald test for binary and continuous variables. We used generalised estimating equations methods to account for clustering at doctor level. Similarly, we used logistic regression analysis with non-fatal outcomes as responses to adjust for allocation of treatment group, age, sex, occupation, smoking habits, and time from diagnosis to measurement of outcome. We used a generalised linear mixed model (restricted maximum likelihood methods) with the predefined outcomes and explanatory variables as

Summary of treatment guidelines for general practitioners

Diet

Increase complex carbohydrate to at least 50% of the diet, and in particular increase water soluble fibre
Reduce fat content to maximum of 30%
Reduce alcohol intake
Eat 5-6 meals a day
Increase physical exercise

Smoking

Advise patients to cut down or stop

Persistent hyperglycaemia

Metformin for overweight patients
Glipizide or glibenclamide for patients with normal weight
Tolbutamide for patients > 70 years
If goal for blood glucose is not met, metformin should be combined with a sulphonylurea before starting insulin

Hypertension

Angiotensin converting enzyme inhibitors or β blockers for most patients
Furosemide (frusemide) for patients with heart failure
Thiazides for patients > 70 years

Hyperlipidaemia

Lipid lowering drugs for diet resistant hyperlipidaemia

fixed effects and doctor identification as random effect to model the clustering. The time from diabetes diagnosis to death was taken into account by using a Cox regression model with no random effects.

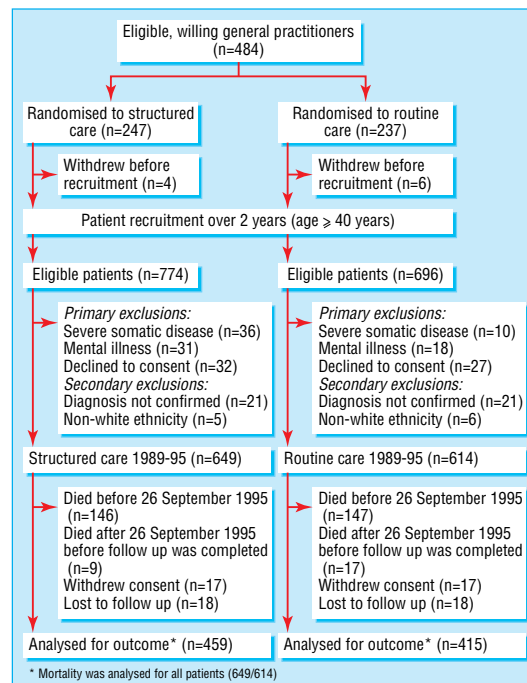
Results

Of 1902 doctors, 484 (25.4%) volunteered (figure). When the study started, the general practitioners in the

Table 2 Baseline characteristics of patients. Values are medians (interquartile ranges) unless stated otherwise

Characteristic	No of respondents (structured/routine care)	Structured care	Routine care
Sociodemographic			
No (%) men	649/614	340 (52.4)	326 (53.1)
Age (years)	649/614	65.5 (55.3-74.0)	65.3 (56.3-73.5)
No (%) live alone	634/600	211 (33.3)	197 (32.8)
No (%) basic school education only	621/583	491 (79.1)	453 (77.7)
(Former) occupation (No (%))	631/596		
Self employed		153 (24.2)	95 (15.9)
Salaried employee		158 (25.0)	186 (31.2)
Worker		246 (39.0)	231 (38.8)
Housewife and other		74 (11.7)	84 (14.1)
Doctor's familiarity with patient (No (%))	648/614		
Thorough		306 (47.2)	311 (50.7)
Moderate		251 (38.7)	229 (37.3)
Poor		91 (14.0)	74 (12.0)
Clinical			
Body mass index (kg/m ²)	647/614	29.4 (26.2-33.0)	28.8 (26.0-32.3)
Body weight (kg)	647/614	81.5 (71.3-94.3)	82.1 (72.0-92.2)
No (%) with hypertension	649/614	487 (75.0)	456 (74.3)
Systolic blood pressure (mm Hg)	649/614	150 (130-164)	148 (130-160)
Diastolic blood pressure (mm Hg)	649/614	85 (80-90)	85 (80-90)
No (%) with diabetic retinopathy	577/559	29 (5.0)	25 (4.5)
No (%) with peripheral neuropathy	645/610	121 (18.8)	120 (19.7)
Resting heart rate (beats/min)	647/613	76 (68-84)	76 (68-84)
No (%) with known cardiovascular disorders:			
History of myocardial infarction	649/613	43 (6.6)	47 (7.7)
Angina pectoris	633/596	74 (11.7)	71 (11.9)
History of stroke	649/614	23 (3.5)	26 (4.2)
Intermittent claudication	634/598	25 (3.9)	20 (3.3)
Amputation	649/614	2 (0.3)	4 (0.7)
Biochemical			
Diagnostic fasting glucose (mmol/l)	649/614	13.8 (10.7-17.0)	13.7 (10.7-17.0)
Glycated haemoglobin (%) [*]	534/506	10.2 (8.6-11.6)	10.2 (8.7-11.9)
Total cholesterol (mmol/l)	628/604	6.2 (5.4-7.1)	6.2 (5.5-7.2)
Fasting triglyceride (mmol/l)	625/604	2.03 (1.44-2.91)	1.98 (1.39-2.95)
Urinary albumin (mg/l)	615/589	11.7 (6.0-32.5)	11.8 (5.7-27.5)
Serum creatinine (µmol/l)	628/605	90 (81-101)	88 (79-100)
Behavioural			
No (%) of smokers	633/598		
Never		210 (33.2)	167 (27.9)
Former		198 (31.3)	225 (37.6)
Current		225 (35.5)	206 (34.5)
Tobacco consumption (g/day) [†]	394/400	17.7 (10.0-23.0)	15.7 (10.0-22.0)
Activity (No (%))	632/598		
Low		182 (28.8)	159 (26.6)
Moderate		405 (64.1)	403 (67.4)
High		45 (7.1)	36 (6.0)
Self rated health (No (%))	635/600		
Very good		71 (11.2)	75 (12.5)
Good		219 (34.5)	195 (32.5)
Average		286 (45.0)	267 (44.5)
Poor or very poor		59 (9.3)	63 (10.5)

^{*}Measured within 45 days of diabetes diagnosis. With a time limit of 365 days, glycated haemoglobin is 9.6% (8.1-11.5%) / 9.7% (8.2-11.5%), n=634/604, P=0.40. Reference range 5.4-7.4%.
[†]Former and current smokers together.



Flow of participants through trial

intervention and comparison groups had similar characteristics (see *BMJ's* website for details).

In all, 1316 (85.9%, range 0-12 per doctor) of 1470 eligible newly diagnosed diabetic patients were considered for this analysis (figure). At least 633 (97.5%) of the 649 patients in the intervention group were considered to have type 2 diabetes. The two groups did not differ in total number of patients included ($P=0.33$, χ^2 test) or inclusion activity over time ($P=0.32$, log rank test). Of 39 baseline variables, only occupation ($P=0.01$, χ^2 test) and smoking habits ($P=0.039$) differed between the two groups (table 2). The numbers completing the final follow up examination were similar in the two groups (459 v 415, $P=0.21$, χ^2 test).

Process of treatment

In the intervention group, the proportion of patients who had an annual clinical examination fell to 79% (327/412) over four years, and attendance at three monthly consultations was even less, despite prompting. The proportion of patients aiming at "good control" fell from 68% (401/587) to 63% (218/348) over four years.

Metformin was more widely used in the intervention group than the comparison group, the only group difference observed (see *BMJ's* website for details). The dose of the drugs was similar in both groups, except for in the eight intervention patients and 12 comparison patients receiving a combination of insulins, where the dose in the intervention group was lower.

Intervention doctors used their patients' participation in the study during consultations with patients more than comparison doctors (see *BMJ's* website for details). Intervention doctors set more optimistic goals for blood glucose concentration ($P=0.0003$, Wilcoxon test) and were less likely to regard their patients' motivation as very good than comparison doctors, but the doctors in the two groups were equally satisfied with their achievements.

Outcomes

When multiple outcomes were taken into account with Bonferroni's adjustment, we found no differences in the predefined primary and secondary outcomes (table 3).

Median glycated haemoglobin fraction was 8.5% in the intervention group, which is 1.1% higher than the upper limit of the reference range (5.4–7.4%) and 0.5% lower than in the comparison group (table 4). The difference of 0.5% corresponds to about 0.8 mmol/l in fasting plasma glucose concentration (table 4). The group differences for median systolic and diastolic blood pressures were 5 mm Hg and 4 mm Hg. Adjustment for baseline level of the outcome, duration of diabetes, age, sex, occupation, and smoking habits in linear regression analyses confirmed the treatment group difference for the logarithm of glycated haemoglobin (difference (log %) -0.056 , 95% confidence interval -0.081 to -0.031 ; $P < 0.0001$), systolic blood pressure (-5.0 mm Hg, -7.6 to -2.4 mm Hg; $P = 0.0002$), and cholesterol concentration (-0.15 mmol/l, -0.29 to -0.02 mmol/l; $P = 0.029$), but not for weight (-0.83 kg, -1.75 to 0.09 kg; $P = 0.076$), diastolic blood pressure (-0.6 mm Hg, -1.9 to 0.7 mm Hg; $P = 0.35$), logarithm of triglyceride concentration (-0.05 log mmol/l, -0.12 to 0.02 log mmol/l; $P = 0.19$), or logarithm of serum creatinine concentration (-0.004 log $\mu\text{mol/l}$, -0.033 to 0.025 log $\mu\text{mol/l}$; $P = 0.79$). Intracluster correlation coefficients varied from -0.021 to 0.054 . Compared with weight at diagnosis, the weight at follow up was on average 2.6 kg lower in the intervention group and 2.0 kg lower in the comparison group.

The patients give similar behavioural reports in both groups, but the intervention seems to have decreased referrals to diabetes clinics and increased the number of consultations (table 4). Hypoglycaemic episodes were suspected in 23% (12/53) of intervention and 11% (6/57) of comparison patients receiving insulin.

Discussion

This long term randomised trial in primary care shows that a multifaceted intervention directed at general practitioners moderates risk factors of patients with newly diagnosed type 2 diabetes. The interventions included regular follow up and individualised goals for patients supported by prompting of doctors, clinical guidelines, feedback, and continuing medical education. We achieved the same level of risk factors as recent large intervention studies from secondary care without the expected adverse weight gain.^{1 2 5}

The randomisation of practices was successful both on doctor and patient level, and follow up was completed for 90% of surviving patients. The list system with a well defined background population in each practice, the few exclusions, the unchanged inclusion activity over time irrespective of treatment allocation, and doctors' self reports suggest that our patients are likely to be representative of the general population of newly diagnosed diabetic people. This is an advantage over intervention studies in secondary care, which often use selected study populations.¹

Predefined outcomes

In retrospect, our study was underpowered to detect differences in the primary outcomes in an intention to

Table 3 Outcomes at end of study.* Values are numbers (%) of group (mortality) or numbers (%) who completed follow up examination and did not have the outcome at baseline (all other outcomes)

	No (%) in structured care group	No (%) in routine care group	P value†
Primary outcomes:			
Overall mortality	216/649 (33.3)	208/614 (33.9)	0.82
Diabetic retinopathy	43/359 (12.0)	45/330 (13.6)	0.55
Urinary albumin ≥ 15 mg/l	56/249 (22.5)	72/234 (30.8)	0.04
Myocardial infarction	15/437 (3.4)	18/393 (4.6)	0.40
Stroke	18/446 (4.0)	16/405 (4.0)	0.95
Secondary outcomes:			
Peripheral neuropathy	69/375 (18.4)	69/329 (21.0)	0.41
Angina pectoris	22/371 (5.9)	23/346 (6.7)	0.68
Intermittent claudication	13/382 (3.4)	13/374 (3.5)	0.96
Amputation	2/459 (0.44)	4/414 (0.97)	0.35

*Median follow up period for structured care group was 7.41 years for mortality and 5.75 years for other outcomes; median follow up for routine care group was 7.32 years and 5.86 years, respectively.

†Wald test. As there are five outcomes we accepted $P < 0.01$ as significant.

treat analysis after only six years.^{1 2} Furthermore, some outcome measures lacked precision because we kept the demands on practitioners and patients to a minimum to prevent attrition.¹⁵

Risk factors

After almost six years of intervention, the glycaemic control in the intervention group was similar to that achieved in the intervention arms of the Steno type 2 study⁵ and UK prospective diabetes study at the same point.¹ The result is put into perspective by the relatively high median plasma glucose concentration at presentation in our study (13.8 mmol/l) compared with the UK prospective diabetes study (11.3 mmol/l), primarily reflecting the low diagnostic limit in that study.

The glycated haemoglobin fraction in our routine care group, however, was only 0.5% higher than in the structured care group. This reflects the fact that comparison doctors were supposed to "do their best," and were not under the constraints imposed on doctors treating the comparison group in the UK prospective diabetes study.¹ The doctors' reports on their use of study participation and their patients' attitude to it indicate a beneficial effect of study participation in itself. This is highest in the intervention group but also present in the comparison group. The many initiatives taken in Denmark to improve diabetes treatment in primary care may also have contributed.^{16–18}

The favourable weight course, especially in the intervention group, might be ascribed to doctors being taught to await the effect of diet, exercise, and weight loss before starting antidiabetic drugs. This contrast with the strategy in UK prospective diabetes study¹ and Steno type 2 study,⁵ which used stepwise increase of drugs to reach predefined treatment goals. Our individually agreed small, realistic weight losses may have prevented doctors and patients from losing focus on the individual goals for risk factors, in contrast to other approaches to personal care.¹⁹

The average difference between treatment groups in blood pressures was larger than in Steno type 2 study, but smaller than in the UK prospective diabetes study subgroup of hypertensive patients.

Despite reduced glycosuria, the symptom burden as well as a simple measure of self rated health was the same in both groups as in the UK prospective diabetes study.²⁰ Our focus on individualised treatment there-

Table 4 Clinical, biochemical, behavioural, and process variables at end of study. Values are medians (interquartile ranges) unless stated otherwise

	No of patients (structured/ routine care)	Structured care	Routine care	P value*
Clinical				
Body weight (kg)	448/404	79.9 (69.5-90.4)	80.5 (70.0-92.0)	0.72
No (%) with hypertension	455/409	333 (73)	307 (75)	0.56
Systolic blood pressure (mm Hg)	455/409	145 (130-160)	150 (140-165)	0.0004
Diastolic blood pressure (mm Hg)	455/409	80 (78-90)	84 (78-90)	0.40
Resting heart rate (beats/min)	452/404	72 (68-80)	76 (68-80)	0.43
Biochemical				
Fasting plasma glucose (mmol/l)†	350/296	7.9 (6.5-10.6)	8.7 (7.2-11.6)	0.0007
Glycated haemoglobin (%)‡	450/408	8.5 (7.7-9.5)	9.0 (8.0-10.4)	<0.0001
Total cholesterol (mmol/l)	449/408	6.0 (5.2-6.8)	6.1 (5.4-6.9)	0.12
Fasting triglyceride (mmol/l)	418/350	1.78 (1.25-2.52)	1.89 (1.27-2.75)	0.32
Serum creatinine (µmol/l)	449/408	89 (81-103)	91 (80-105)	0.84
No (%) with glycosuria	445/400	100 (22)	148 (37)	<0.0001
Behavioural (No (%) of patients)				
Has altered habits	417/391	344 (82)	315 (81)	0.48
Smoking	419/390			
Never		147 (35)	124 (32)	0.32
Former		138 (33)	151 (39)	0.10
Current		134 (32)	115 (29)	0.45
Activity	415/392			
Low		122 (29)	122 (31)	0.62
Moderate		258 (62)	239 (61)	0.75
High		35 (8)	31 (8)	0.78
Food habits	416/393			
Diet with certain amounts of selected foodstuffs		140 (34)	121 (31)	0.59
Full diet without sugar		213 (51)	207 (53)	0.67
Diet as non-diabetic subjects		63 (15)	65 (17)	0.36
Performs home blood or urine glucose monitoring	416/388	117 (28)	114 (29)	0.73
Self rated health	421/394			
Very good		68 (16)	83 (21)	0.087
Good		176 (42)	150 (38)	0.29
Average		153 (36)	147 (37)	0.77
Poor or very poor		24 (6)	14 (4)	0.15
Process of care				
No of consultations/year	459/414	6 (5-10)	6 (4-9)	0.002
No of diabetes related consultations/year	459/414	4 (3-6)	4 (2-6)	<0.0001
No (%) ever treated at diabetes clinic	459/415	79 (17)	106 (26)	0.009
No of hospital admissions since diagnosis	459/415	1 (0-3)	1 (0-3)	0.79
Total length of stay in hospital (days)	281/256	16 (7-39)	19 (8-45)	0.066
No (%) with severe hypoglycaemia since diagnosis	457/413	17 (4)	15 (4)	0.94
No (%) with symptoms of diabetes in past two weeks	419/393	194 (46)	193 (49)	0.42

*Wald test.

†Including only results from samples analysed one day after sampling, or less.

‡Reference range 5.4-7.4%.

fore did not affect wellbeing measurably, although wellbeing has been reported to improve in patient centred diabetes care.¹⁹

What caused the reduction in risk factors?

Our flexible approach to the intervention may have maximised not only doctors' ability to participate but also the ultimate generalisability of results. The approach is feasible to implement within the health service²¹ and the patient sample was non-selective. In complex interventions the effect cannot be ascribed to single elements, although the continuing medical education is probably a core element.¹²⁻¹³ The fact that we used many ways to change doctors' behaviour may be the reason for success.¹⁰⁻¹¹

The intervention apparently did not affect patient behaviour, except that more followed a three monthly follow up scheme, but this could be because of limitations in our measures. Intervention doctors, however, became more focused on lowering risk factors

through setting goals, which perhaps prevented doctors from losing professional autonomy¹⁵⁻²² and involved patients in decision making.¹⁹⁻²³ The psychological effect of the labelling of care explicitly as good, acceptable, and poor must not be underestimated either.²⁴ Although normoglycaemia was rarely achieved in any of the groups, this was the goal for most intervention patients throughout the study. Contrary to study recommendations, the referral rate of intervention patients to diabetes clinics was low. This could be because doctors were empowered by structuring care²⁵ or because of patients' improved diabetes status.²⁶

The only major difference in drug treatment between groups was that metformin was used more in the intervention group, especially among obese patients, and this may have contributed to the lower glycated haemoglobin fraction.²⁷ Doctors' reports on their patients' antihypertensive treatment were similar in both groups. Therefore, the effect of the intervention

on risk factors may also be partly explained by better compliance with treatment,²⁸ which has been shown to be poor in type 2 diabetic patients.²⁹ The prevalence of severe hypoglycaemia did not differ between groups and was similar to that in other trials.¹⁻⁵ The tendency among those receiving insulin towards more hypoglycaemic episodes in the intervention group, unrelated to dose, supports the compliance hypothesis mentioned above.

Conclusion

We have shown that even in a group of motivated, volunteering general practitioners that were already supplying acceptable basic patient care, a multifaceted, individualised disease management strategy focusing on individualised goals and educational and surveillance support can provide extra benefit for patients with type 2 diabetes patients for at least six years. The flexible approach to the intervention and the population based patient sample suggest that our model for structured personal care could be applied at population level. Use of the model may reduce risk factors to a level that has been shown to have a beneficial effect on the development of diabetic complications without adverse weight gain.

We thank the patients, general practitioners, and ophthalmologists who volunteered to take part in this study. We thank Niels Keiding for statistical advice, Carl Erik Mogensen, Niels Vesti Nielsen, and Dorte Gannik for advice on estimation of renal involvement, diabetic retinopathy, and patient attitudes and behaviour and Klaus Barfoed, Inge Bihlet, Ulla Eithz, Karen Faurfelt, Jørgen Garbøl, Jan Erik Henriksen, Poul Erik Gaarde Madsen, Jens Olesen, and Birthe Palmvig for their contributions to the seminars. We acknowledge the help of Jørgen Bo Nielsen, Lars C Larsen, Charlotte Hindsberger, Lars Jørgen Hansen, Volkert Siersma, and Maeve Drewsen and the expert technical assistance of Merete Møller, Elin Bang, Inge Bihlet, Ulla Johannesen, Klaus Tønning Sørensen, Christina Hundrup, Nann Agerlin Hansen, Birgitte Pedersen, Jesper Løken, Karsten Sørensen, and Lise Bergsøe.

Funding: Danish Medical Research Council, Danish Research Foundation for General Practice, Health Insurance Foundation, Danish Ministry of Health, Novo Nordisk Farmaka Denmark, Pharmacy Foundation, Foundation for General Practice in Copenhagen, Frederiksberg, Tårnby og Dragør, Dr Sofus Carl Emil Friis and his wife Olga Doris Friis Trust, Danish Medical Association Research Fund, Velux Foundation, Rockwool Foundation, Novo Nordisk, Danish Diabetes Association, Oda og Hans Svenningsen Foundation, A P Møller Foundation for Advancement of Medical Science, Novo Nordisk Foundation, Captain Axel Viggo Mørch and his wife's Trust, Danish Eye Health Society, Mogens and Jenny Vissing's Trust, and Bernhard and Marie Klein's Trust.

Competing interests: None declared.

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What is already known on this topic

Evidence is increasing that control of hyperglycaemia, hypertension, and dyslipidaemia may postpone the development of diabetic complications in patients with type 2 diabetes

Maintaining good control over a long period can be difficult

What this study adds

Structured individualised personal care with educational and surveillance support for general practitioners reduced levels of risk factors in type 2 diabetic patients after six years

Risk factors were reduced to a level that has been shown to have a beneficial effect on diabetic complications

Participants also showed modest weight loss

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