DIABETES/METABOLISM RESEARCH AND REVIEWS
Diabetes Metab Res Rev 2011; **27:** 383–391.
Published online in Wiley Online Library (wileyonlinelibrary.com) **DOI:** 10.1002/dmrr.1186

RESEARCH ARTICLE

Medical care of type 2 diabetes in German Disease Management Programmes: a population-based evaluation

Reneé G. Stark[1]*
Michaela V. Schunk[1]
Christine Meisinger[2]
Wolfgang Rathmann[3]
Reiner Leidl[1,4]
Rolf Holle[1] for the KORA Study Group[†]

[1]*Helmholtz Zentrum München, Institute for Health Economics and Healthcare Management, Neuherberg, Germany*
[2]*Helmholtz Zentrum München, Institute of Epidemiology, Neuherberg, Germany*
[3]*German Diabetes Center, Leibniz Center for Diabetes Research, Institute of Biometrics and Epidemiology, Heinrich Heine University, Düsseldorf, Germany*
[4]*Department of Health Economics and Healthcare Management, Munich School of Management, University of Munich, Munich, Germany*

*Correspondence to:
Reneé G. Stark,
Helmholtz Zentrum München,
Institute for Health Economics and Healthcare Management,
Ingolstaedter Landstrasse 1,
Neuherberg D-85764,
Germany
E-mail:
r.stark@helmholtz-muenchen.de

[†]The KORA study group consists of H.-E. Wichmann (speaker), R. Holle, J. John, T. Illig, C. Meisinger, A. Peters and their coworkers, who are responsible for the design and conduct of the KORA studies.

Received: 7 June 2010
Revised: 20 December 2010
Accepted: 27 January 2011

Abstract

Objective Type 2 diabetes disease management programmes (DDMPs) are offered by German social health insurance to promote healthcare consistent with evidence-based medical guidelines. The aim of this study was to compare healthcare quality and medical endpoints between diabetes management programme participants and patients receiving usual care designated as controls.

Methods All patients with type 2 diabetes (age range: 36–81) in a cross-sectional survey of a cohort study, performed by the Cooperative Health Research in the Region of Augsburg, received a self-administered questionnaire regarding their diabetes care. Physical examination and laboratory tests were also performed. The analysis only included patients with social health insurance and whose participation status in a diabetes disease management program was validated by the primary physician ($n = 166$). Regression analyses, adjusting for age, sex, education, diabetes duration, baseline waist circumference and clustering regarding primary physician were conducted.

Results Evaluation of healthcare processes showed that those in diabetes disease management programmes ($n = 89$) reported medical examination of eyes and feet and medical advice regarding diet [odds ratio (OR): 2.39] and physical activity (OR: 2.87) more frequently, received anti-diabetic medications (OR: 3.77) and diabetes education more often (OR: 2.66) than controls. Both groups had satisfactory HbA_{1c} control but poor low-density lipoprotein cholesterol control. Blood pressure goals (<140/90 mmHg) were achieved more frequently by patients in diabetes disease management programmes (OR: 2.21).

Conclusions German diabetes disease management programmes are associated with improved healthcare processes and blood pressure control. Low-density lipoprotein cholesterol control must be improved for all patients with diabetes. Further research will be required to assess the long-term effects of this diabetes disease management programme. Copyright © 2011 John Wiley & Sons, Ltd.

Keywords type 2 diabetes; disease management; medical care

Introduction

Patients with type 2 diabetes require complex medical care. Type 2 diabetes disease management programmes (DDMPs) were introduced by German social health insurance (SHI) companies (insuring 90% of the population) to improve the process and quality of medical care. As regulations stipulate most of the components of DDMPs, the programmes are relatively similar although each health insurance company offers its own DDMP. Regulations define eligible patients (factors required for the diagnosis) and systematic and regular medical follow-up. They also specify treatment goals, baseline diabetes therapy, treatment goals for common concomitant diseases (e.g. hypertension) and goals for the prevention and treatment of

diabetes complications. Education of patients and healthcare providers, coordination of complex medical care such as patient referrals to qualified diabetologists and ophthalmologists, and support measures such as reminders for patients and physicians and structured feedback to physicians, based on their patient documentation are also stipulated in the regulations. In Bavaria, where the study was performed, the major health insurance companies have signed the same contract with the Bavarian association of physicians licenced with statutory insurance, which stipulates the responsibilities of the physicians. Programmes of insurance companies will differ in the information brochures that are provided to patients, other support measures for patients (e.g. referral to a dietician through the health insurance company) and feedback to physicians. The importance of the patient's role in the care process [1,2] is also reflected in the DDMPs, as patients must consent to enrolment and agree to actively participate in their care and comply with program requirements [3]. Various outcomes (such as medical outcomes, quality of life and costs of healthcare) of DDMP participants (DDMPps) must be evaluated according to German regulations [3,4], but no controls need to be included in this longitudinal evaluation. Comparison of patients enrolled in DDMPs with patients receiving usual diabetes care regarding healthcare processes (e.g. medical follow-ups and patient education) and medical outcomes [5] would help assess the effect of DDMPs on diabetes care.

In addition to examining the effect of DDMPs on individual patients, their overall effect on diabetes care and on individual patient risk for cardiovascular disease (CVD) can indicate their usefulness. The 2009 Diabetes Recognition Programme (DRP) [6] in the United States combines assessment criteria of the Diabetes Quality Improvement Programme [7] with the results of ongoing research so that the care of patients with type 2 diabetes can be compared between physicians and healthcare settings. The DRP criteria assess not only the therapeutic goals reached but also the percentage of patients not reaching less stringent goals, thus also accounting for individualized therapeutic goals [8]. As the criteria are based on internationally accepted research and standards of care [5], they are also useful in evaluating diabetes care in countries outside of the United States. Reduction of patient risk for macroangiopathy, CVD and stroke is also a goal of DDMPs. Various accepted tools are available to assess this risk. The United Kingdom Prospective Diabetes Study risk engine [9–11] calculates CVD risk specifically for diabetic patients.

Although DDMPs have been offered by German SHI since 2002, previous analyses of DDMPs have only examined SHI data [12] or surveyed patients registered with a specific SHI [13]. Using population-based studies, 'real-life' care of DDMPps can be compared with that of patients with diabetes not participating in DDMP (controls) and parameters not available in insurance data can be collected and examined. Furthermore, results are not limited to specific SHI companies. The aim of this study is to compare the care of DDMPps and controls regarding variables reflecting the healthcare processes (medical investigations and follow-up, diabetes education and patient self-management) and medical outcomes (physical examination and laboratory) in a population-based study using both national [3,4] and international standards [5,6].

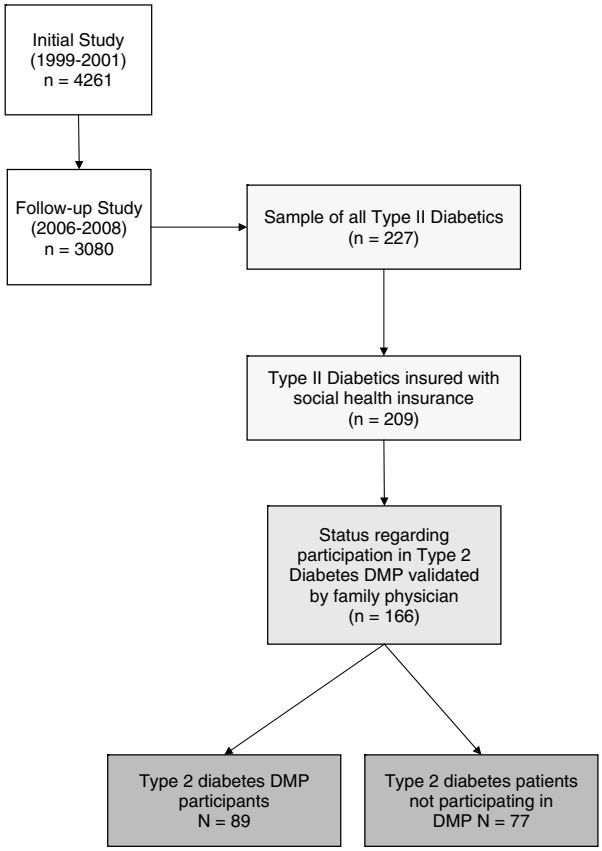

Figure 1. Study design and patient selection

Methods

Study design and subjects

As part of the Cooperative Health Research in the Region of Augsburg (KORA) [14,15], a cohort sample was drawn from the population aged 25 to 74 years with German nationality. A two-stage procedure was used, where first Augsburg city and 16 communities from the adjacent counties were selected by cluster sampling and then stratified random sampling was performed within each community. Figure 1 shows the study design. The initial cross-sectional survey (KORA survey S4, 4261 participants) was performed from 1999 to 2001 and a follow-up survey of the same cohort was performed between October 2006 and May 2008 (KORA F4 study, 3080 participants). Both studies were approved by the Ethics Committee of the Bavarian Medical Association and all study participants provided written informed consent. In the study centre, subjects were interviewed regarding

DOI: 10.1002/dmrr

Table 1. Comparison of baseline characteristics (in 2001) of patients with type 2 diabetes in 2008, according to disease management programme enrolment status

	Controls ($n = 77$)[a]	Disease management programme participants ($n = 89$)[a]	p-Value*
Demographics and characteristics in 2008			
Male (%)	55.8	55.1	0.9189
Age (years)	68.6 (9.9)	67.5 (8.2)	0.1673
Education (%, secondary general school)	74.0	78.7	0.4833
Duration of diabetes (years)	8.1 (9.1)	8.9 (6.8)	**0.0246**
Complications of diabetes[b] (%)	57.1	47.2	0.2007
Severe diabetes complications[c] (%)	18.2	13.5	0.4062
Less severe diabetes complications[d] (%)	50.7	42.7	0.3055
Average number of chronic diseases according to medications taken[f]	3.1 (1.98)	3.6 (1.79)	0.1614
Values at examination in 2001			
Presence of diabetes (%)	29.9	43.8	0.0639
Oral anti-diabetic therapy (%)	20.8	30.3	0.1610
Insulin therapy (%)	6.5	9.0	0.5507
Complications of diabetes[b] (%)	24.7	23.6	0.8711
Severe diabetes complications[c] (%)	9.1	7.9	0.7769
Less severe diabetes complications[d] (%)	16.9	19.1	0.7111
Smoker[e] (%)	11.7	21.4	0.0974
Systolic blood pressure (mmHg)	141.8 (20.9)	142.3 (19.9)	0.8381
Diastolic blood pressure (mmHg)	83.4 (11.4)	83.4 (10.9)	0.6839
Anti-hypertensive therapy (%)	48.1	50.6	0.7470
Waist circumference (cm)	101.3 (9.4)	104.8 (10.8)	**0.0221**
Body mass index (kg/m^2)	30.5 (4.5)	32.1 (5.0)	**0.0161**
HbA_{1c} (%)	6.4 (1.34)	6.5 (1.12)	0.1976
High-density lipoprotein (mg/dL)	50.9 (12.6)	48.8 (11.9)	0.1139
Low-density lipoprotein (mg/dL)	150.4 (44.6)	137.6 (37.7)	0.0972
Creatinine (mg/dL)	0.88 (0.19)	0.84 (0.19)	0.1317

[a]Values are shown in percentage or mean and standard deviation.
[b]Patient report of any of the following complications associated with diabetes: hospitalized for myocardial infarct, hospitalized for stroke, blindness with report of retinopathy, amputation, retinopathy, proteinuria, neuropathy and peripheral vascular disease.
[c]Patient report of any of the following severe complications associated with diabetes: hospitalized for myocardial infarct, hospitalized for stroke, blindness with report of retinopathy and amputation.
[d]Patient report of any of the following less severe complications associated with diabetes: retinopathy, proteinuria, neuropathy and peripheral vascular disease.
[e]Regular and occasional smokers.
[f]Number of comorbidities calculated according to the Pharmacy-based Cost Group model [16].
*p-Value is based on a Wilcoxon test for continuous variables or a chi-squared test for categorical variables, differences significant at $p < 0.05$ level are shown in bold.

demographic and disease-related parameters and medications taken within the last week and anthropometric [blood pressure (BP), weight and height] and laboratory examinations were performed.

This study only evaluated subjects with type 2 diabetes ($n = 227$), which were those subjects who stated that they had a clinical diagnosis of diabetes or who reported anti-diabetic medications among their medications taken in the last 7 days. In case of doubt, the family physician was questioned. These subjects were asked to fill in a self-administered questionnaire regarding their experience with diabetes, the course of their treatment, their self-management and whether they were enrolled in a DDMP. The analysis only included subjects insured with SHI ($n = 209$) as DDMPs were only offered by these companies. Another 43 subjects were excluded from the analysis because of missing validation data (no physician reply: $n = 30$; DDMP status missing: 4; start date of DDMP missing: 9). Patients for whom the physician validated a DDMP registration date before the KORA examination date were considered to be DDMPps ($n = 89$) and patients for whom the physician validated that they did not participate in DDMP or the DDMP registration date was after the KORA examination date were considered as controls ($n = 77$).

Evaluation of diabetes care

Comparisons between DDMPps and controls were based on parameters that reflect statutory requirements [3] and published guidelines [5]. Quality of medical care was evaluated on the basis of patient reports regarding medical recommendations (physical activity and diet) and examinations (BP, feet, eyes, proteinuria, HbA_{1c} and cholesterol) over the last 12 months. Evaluation of patient self-management included participation in diabetes education, filling in a diabetes diary and self-checks of feet, blood glucose, BP, weight at least weekly over the last

DOI: 10.1002/dmrr

6 months. Differences in pharmacological therapy were assessed on the basis of reported medications taken in the last 7 days. Pharmacological therapy was also used to calculate the number of patient comorbidities based on the Pharmacy-based Cost Group model [16]. Medical outcomes [BP, body mass index (BMI), waist circumference, HbA_{1c}, low-density lipoprotein (LDL) cholesterol, high-density lipoprotein (HDL) cholesterol and creatinine] and lifestyle habits (sports and smoking) were evaluated regarding the achievement of therapeutic goals [5], differences in parameter means between the groups and differences in changes in parameter values (compared to the baseline study) between the groups. To evaluate overall care between DDMPps and controls, the 2009 DRP performance criteria [6] regarding HbA_{1c}, BP, LDL, smoking and eye, foot and nephropathy examinations were compared between DDMPps and controls in a *post hoc* analysis.

Statistical analysis

Data evaluation was performed with SAS 9.1 (SAS Institute, Cary, NC). Baseline characteristics (Table 1) were compared between the two groups using a Wilcoxon test for continuous variables or a chi-squared test for categorical variables. Categorical outcomes were examined with logistic regression and continuous outcomes with a generalized linear model. Regression analyses were adjusted for age, sex, education, diabetes duration, waist circumference (significantly different in 2001, see Table 1) and clustering of care by the primary physician using mixed models. Differences in categorical values are reported as odds ratios with the 95% confidence interval, and differences in continuous values are reported as mean differences between the groups with the 95% confidence interval.

Results

Of 166 subjects who had validated data on DDMP participation, 89 (54%) were DDMPps. Subjects were cared for by 115 different physicians, so that each physician had a mean of 1.4 patients included in this study. Characteristics of analysed patients including parameters in the initial study performed in 2001 are shown in Table 1. Average DDMP enrolment was 27 months according to the validation. Patient self-reports of DDMP status were correct for 44 of 89 DDMPps and 56 of 77 controls, but only 2 of 2000 offered programmes were named as examples. Although mean diabetes duration was similar between the groups, median diabetes duration was 8 years (interquartile range: 4–12) for DDMPps and 4 years (interquartile range: 1–10) for controls. The number of patients reporting severe diabetes complications, less severe diabetes complications and any diabetes complication were similar between the groups. DDMPps and controls also had a similar average number of chronic diseases (see Table 1). However, in 2001, more DDMPps smoked and more were overweight with a higher BMI and waist circumference.

Process parameters

DDMPs were associated with positive changes in healthcare processes (see Table 2). DDMPps reported medical advice regarding diet and physical activity and medical examination of eyes and feet more frequently over the previous year than did controls. Surprisingly, patients reported laboratory testing of cholesterol more frequently than the performance of HbA_{1c} tests. DDMPps also reported the intake of anti-diabetic (especially oral anti-diabetic patients either alone or in combination with insulin) and anti-hypertensive medications more often. In both groups, these two medication groups were taken twice as frequently as platelet aggregation inhibitors and lipid-lowering medications.

DDMPps more frequently reported attendance of diabetes education classes, self-measurement of BP (see Table 2), keeping a diabetes diary and self-examination of blood glucose than did controls. The significance of DDMP participation did not change even when the analysis of process parameters was also adjusted for present insulin use. In this case, DDMPps were more likely to keep a diabetes diary ($p = 0.048$).

Outcome parameters

Analysis of the achievement of therapeutic goals (Table 3) showed that BP goals (<140/90 mmHg) were achieved more frequently by DDMPps than by controls ($p = 0.037$), whereas both groups achieved a HbA_{1c} goal of <7.0% equally well. Evaluation of mean and mean change of parameter values showed no significant differences between controls and DDMPps regarding the mean systolic and diastolic BP, LDL cholesterol or creatinine. The groups did not differ regarding mean HbA_{1c} in this study, but the variance of HbA_{1c} was lower in the DDMPps (F-test: $p = 0.0073$). Furthermore, of patients with an $HbA_{1c} > 7\%$, only 4% of DDMPps (1 of 28) received no anti-hyperglycaemic medication, whereas this was true for 38% of controls (10 of 26). This difference remained significant ($p = 0.0129$) after adjustment for diabetes duration. HDL cholesterol increased from baseline significantly more in DDMPps than in controls.

Lifestyle parameters

Of 19 DDMPps who smoked during the baseline survey (2001), 12 (63%) stopped smoking, whereas only 2 of 7 (29%) controls had stopped smoking. Examination of regular leisure time exercise for more than 2 h/week showed that more controls (20.8%) than DDMPps (10.1%) reported this amount of exercise (adjusted p-value: 0.073). Compared with controls, DDMPps had a larger waist circumference and a higher BMI but changes in BMI and waist circumference from baseline were not significantly different.

DOI: 10.1002/dmrr

Table 2. Patient-reported medical management and self-management of diabetes according to disease management programme participation (in 2008)

	Controls (%; $n = 77$)	Disease management programme participants (%; $n = 89$)	Odds ratio (95% confidence interval)[a]	p-Value
Medical advice[b,c]				
Physical activity (%)	43.8	68.6	**2.87 (1.40 to 5.86)**	**0.0050**
Diet (%)	45.8	69.7	**2.39 (1.19 to 4.81)**	**0.0160**
Medical examination[b,c]				
Eyes (%)	58.9	82.8	**3.28 (1.43 to 7.55)**	**0.0062**
Feet (%)	38.4	67.4	**3.25 (1.59 to 6.65)**	**0.0018**
Blood pressure (%)	94.5	96.6	1.43 (0.28 to 7.22)	0.6569
HbA_{1c} (%)	44.4	58.6	1.80 (0.84 to 3.84)	0.1271
Cholesterol (%)	84.7	97.7	**6.01 (1.11 to 32.57)**	**0.0380**
Proteinuria (%)	69.9	78.2	1.37 (0.62 to 2.99)	0.4280
Medications prescribed[d]				
Anti-diabetic therapy (%)	57.1	85.4	**3.77 (1.64 to 8.65)**	**0.0024**
Oral anti-diabetic therapy only (%)	37.7	65.2	–	–
Insulin only (%)	14.3	6.7	–	–
Oral anti-diabetic therapy + insulin (%)	5.3	13.5	–	–
Anti-hypertensives (%)	70.1	82.0	1.97 (0.86 to 4.53)	0.1083
Lipid-lowering medications (%)	32.5	40.5	1.65 (0.76 to 3.57)	0.1966
Platelet aggregation inhibitors (%)	29.9	40.5	1.76 (0.85 to 3.61)	0.1235
Diabetes education[c,e]	39.1	62.8	**2.66 (1.27 to 5.56)**	**0.0107**
Diabetes diary (%)[c]	20.6	34.9	1.99 (0.91 to 4.35)	0.0830
Self-management[c,f]				
Feet (%)	50.8	57.0	1.31 (0.65 to 2.64)	0.4445
Blood glucose (%)	42.4	54.7	1.39 (0.63 to 3.07)	0.4020
Weight (%)	48.5	57.0	1.45 (0.71 to 2.95)	0.3004
Blood pressure (%)	43.1	60.5	**2.20 (1.09 to 4.44)**	**0.0292**

[a]Odds ratio compares reports of disease management programme enrolees *versus* non-enrolees regarding whether consultations/examinations were performed. Values in bold type represent p values <0.05. Odds ratio was adjusted by logistic regression for age, sex, education (secondary general *versus* other secondary education), diabetes duration, waist circumference at baseline and clustering regarding family physician.
[b]In the last 12 months.
[c]Missing values for medical advice and examination: controls, 4–5 and disease management programme, 2–3; and for diabetes education, diary and self-management: controls, 8–12 and disease management programme, 3.
[d]On the basis of patient reports of medications taken in the last week.
[e]At any time in the past.
[f]Patient-reported self-examination or self-measurement at least weekly in the last 6 months.

Evaluation of overall care

Comparison of overall care according to the performance criteria of the 2009 DRP is shown in Table 4. Although the care of controls fulfilled 6 of 11 criteria and would have scored 50 of 100 possible points, the care of DDMPps fulfilled 8 of 11 criteria and scored 75 points. Medical care differed between the groups in that >35% of controls had a BP ≥140/90 mmHg and <60% of controls had an eye examination. Both groups did not fulfil the criteria that ≤37% of patients had an LDL ≥130 mg/dL, that ≥36% of patients had an LDL <100 mg/dL and that ≥80% of patients had a foot examination.

Discussion

DDMPs were introduced to improve the medical care of patients with diabetes. This analysis compared healthcare processes and outcomes of medical care between DDMPps and controls based on patient reports and ancillary examinations. We found that appropriate healthcare processes were reported more frequently by DDMPps than by controls. Furthermore, although the DDMPps examined in this study had a higher median diabetes duration and were more obese than controls, they reached therapeutic goals for BP significantly more frequently and other therapeutic goals as frequently as controls. Evaluation of overall care, even according to foreign (American) standards [6], was better in DDMPs.

The population-based approach of this study provides two comparable groups of patients with type 2 diabetes who are eligible to participate in DDMPs. Very ill patients did not participate in either group as a study centre visit was required [17]. In comparison, controls in health insurance data may be very ill, as they utilize healthcare facilities but may be less likely to enrol in DDMPs because of severe illness or prolonged hospitalization. In our study, we showed that the groups were similar

DOI: 10.1002/dmrr

Table 3. Measured medical outcomes in 2008 including therapeutic goals, mean values and changes in mean values from 2001 according to disease management programme participation

	Controls ($n = 77$)[a]	Disease management programme participants ($n = 89$)[a]	Adjusted comparison of controls with disease management programme participants (95% confidence interval)[b]	*p*-Value
Patients achieving therapeutic goals (%)[c]			Odds ratio[b]	
HbA_{1c} value <7.0%	64.5	63.6	1.14 (0.56 to 2.33)	0.7127
BP <140/90 mmHg	63.6	79.8	**2.21 (1.05 to 4.64)**	**0.0371**
Low-density lipoprotein cholesterol <100 mg/dL	27.6	16.9	0.45 (0.19 to 1.07)	0.0694
High-density lipoprotein cholesterol (men: ≥40 mg/dL and women: ≥50 mg/dL)	63.2	70.8	1.59 (0.75 to 3.36)	0.2231
Body mass index <30 kg/m^2	50.0	39.3	1.14 (0.44 to 2.99)	0.7856
Waist circumference (men: <102 cm; women: <88 cm)	27.4	19.1	1.61 (0.46 to 5.71)	0.4499
Mean patient values			Mean differences[d]	
HbA_{1c} (%)	6.76 (1.23)	6.85 (0.91)	−0.02 (−0.35 to 0.32)	0.9140
Systolic BP (mmHg)	136.0 (19.5)	131.1 (19.0)	4.2 (−1.8 to 10.3)	0.1684
Diastolic BP (mmHg)	75.3 (10.7)	73.1 (9.0)	2.2 (−1.0 to 5.3)	0.1685
High-density lipoprotein cholesterol (mg/dL)	48.4 (11.1)	50.3 (10.9)	−2.6 (−6.0 to 0.8)	0.1320
Low-density lipoprotein cholesterol (mg/dL)	128.9 (39.0)	124.3 (32.0)	4.0 (−6.8 to 14.7)	0.4628
Body mass index (kg/m^2)	30.5 (4.9)	32.0 (5.4)	0.2 (−0.8 to 1.3)	0.6400
Waist circumference (cm)[f]	103.5 (10.4)	107.1 (12.3)	0.2 (−2.0 to 2.4)	0.8430
Creatinine (mg/dL)	1.05 (0.67)	0.98 (0.27)	0.07 (−0.08 to 0.23)	0.3541
Change in mean values[e]				
HbA_{1c} (%)	0.33 (1.4)	0.34 (1.2)	−0.05 (−0.37 to 0.28)	0.7667
Systolic BP (mmHg)	−6.5 (20.4)	−11.3 (20.3)	4.1 (−1.3 to 9.5)	0.1349
Diastolic BP (mmHg)	−8.4 (10.6)	−10.3 (11.1)	1.7 (−1.0 to 4.5)	0.2072
High-density lipoprotein cholesterol (mg/dL)	−2.6 (8.5)	1.4 (8.7)	**−3.5 (− 5.9 to − 1.1)**	**0.0053**
Low-density lipoprotein cholesterol (mg/dL)	−23.0 (45.3)	−13.4 (35.2)	−0.9 (−10.8 to 9.0)	0.8573
Body mass index (kg/m^2)	0.05 (2.41)	−0.13 (2.39)	0.1 (−0.7 to 0.9)	0.7097
Waist circumference (cm)[f]	2.6 (7.0)	2.4 (6.3)	0.2 (−2.0 to 2.4)	0.8430
Creatinine (mg/dL)	0.17 (0.61)	0.16 (0.20)	−0.02 (−0.12 to 0.07)	0.6124

BP, blood pressure.

[a]Values are shown in percentage or mean and standard deviation and are from 2008 unless indicated otherwise.

[b]Odds ratio compares achievement of therapeutic goals between disease management programme participants and controls adjusted by logistic regression for age, sex, education (secondary general *versus* other secondary education), diabetes duration, waist circumference at baseline and clustering regarding family physician. Values in bold type represent *p* values <0.05.

[c]Missing values for controls: body mass index, 5; waist circumference, 4; blood pressure, 1; otherwise, 0; and for disease management programme: HbA_{1c}, 1; otherwise, 0.

[d]Mean differences of outcome parameters between controls and disease management programme participants adjusted by generalized linear model regression for age, sex, education (secondary general *versus* other secondary education), diabetes duration, waist circumference at baseline and clustering regarding family physician. Significant differences at $p < 0.05$ are displayed in bold type.

[e]Change in parameter between 2008 and initial measurement in 2001.

[f]Adjusted differences in the change of waist circumference do not differ from adjusted differences in mean patient values as baseline value is used to adjust both values.

Table 4. Comparison of diabetes recognition programme criteria and overall care of patients with type 2 diabetes according to disease management programme enrolment status

	Patients required to fulfil criteria (%)	Controls ($n = 77$)[a]	Disease management programme participants ($n = 89$)[a]
$HbA_{1c} > 9\%$	≤15	2.6	1.1
$HbA_{1c} < 8\%$	60	84.2	90.9
$HbA_{1c} < 7\%$	40	64.5	63.6
Blood pressure ≥140/90 mmHg	≤35	36.4	20.2
Blood pressure <130/80 mmHg	25	39.0	48.3
Low-density lipoprotein cholesterol ≥130 mg/dL	≤37	40.8	40.5
Low-density lipoprotein cholesterol <100 mg/dL	36	27.6	16.9
Eye examination	60	58.9	82.8
Foot examination	80	38.4	67.4
Non-smokers	80	89.6	92.1
Nephropathy assessment	80	85.7	89.9
Number of criteria fulfilled (of 11)	–	54.5	72.7
Number of recognition points (of 100)	–	50.0	75.0

[a]Values are shown in percentage.

regarding severe diabetes complications, less severe diabetes complications and the total number of comorbidities (as determined by their medications). The diagnosis of diabetes is also relatively certain, even in patients with fairly new disease (before pharmacotherapy), because it is based on self-reported disease, medications and validation by the family physician for questionable cases. As DDMP names vary considerably between SHI companies and may not reveal the disease management aspect, validation of DDMP participation by the family physician also strengthens study results given that patient reports alone have a low sensitivity [18].

The study results are limited by the small number of patients. This is because of a prevalence of patients with diabetes which ranges between 6 and 8% [19], the exclusion of patients with type 1 diabetes and those privately insured and missing data regarding DDMP status. In a study including 166 patients, one can expect to recognize differences between the groups that are larger than half a standard deviation with a power of 0.9, which is equivalent to a moderate effect size. Thus, for HbA_{1c} we would have required a difference of at least 0.5% between the groups to identify a significant difference. Subgroup analyses with fewer patients reduce the power to recognize differences. Furthermore, as the subjects were only selected from one region, their healthcare habits may only be representative of this region. Structural inequality may exist between patient groups in non-randomized comparative studies. We have attempted to account for baseline group differences by adjusting for confounders, which could have an effect on medical care processes and outcomes. Both groups were similar regarding age, gender ratio and education, although higher levels of education have been associated with an increased willingness to participate in DDMPs [20]. Significant differences existed between the groups regarding obesity in the baseline S4 study and median diabetes duration. Adjustment for baseline waist circumference and diabetes duration attempted to account for these differences but the effect that these parameters can have on the ability of reaching therapeutic goals must be kept in mind.

The parameters of process quality indicate that DDMPs are associated with improved healthcare processes organized by physicians. Primary care processes (e.g. foot examination and anti-diabetic prescriptions) and the coordination of specialized care (eye examinations and diabetes education) were reported more often by DDMPps. Although patient reports regarding process measures may be biased by the lack of standardized questionnaires (diet and exercise) and by underreporting because of a lack of knowledge regarding which tests were performed (e.g. tests for proteinuria), similar process changes for DDMPs have been reported on the basis of German SHI data [12], which reflect reimbursement for medical services and for other disease management programmes [21]. To ensure that medical treatment processes (medical advice and medical examination) did not differ between the groups because of differences in the requirement for intensive treatment, we also compared subjects with a diabetes duration ≥4 years ($n = 109$) with a chi-squared test. We found the same significant differences ($p < 0.05$) between the groups regarding medical advice and medical examinations, except that patient-reported medical examination of cholesterol differed only at a p value of 0.0989. DDMPps have also reported a higher level of satisfaction with physician coordination and care than controls [13]. Increased physician reimbursement for the care of DDMPps may have been an important incentive to enrol patients and to adhere to DDMP guidelines [22].

Examination of medical outcomes and therapeutic goals showed that a BP below 140/90 mmHg was measured more frequently in DDMPps than in controls, a goal associated with a lower risk of CVD [23]. HbA_{1c} goals were achieved by both groups equally, but the variance of HbA_{1c} was lower in the DDMP group. This may be the result of

DOI: 10.1002/dmrr

regular follow-up of the DDMP group, leading to earlier treatment of hyperglycaemia. Of subjects with an elevated HbA_{1c}, more DDMPps than controls were receiving antidiabetic medications. As all laboratory parameters were measured in the same laboratory with very good reproducibility, it is unlikely that significant between-group differences were not measured. However, in this study, we could not evaluate whether the groups differed in reaching individualized HbA_{1c} goals. Furthermore, the United Kingdom Prospective Diabetes Study showed that even with intensive treatment starting directly at the onset of diabetes, HbA_{1c} increases over time [24]. Thus, due to the higher median diabetes duration, the DDMP group will have more difficulties achieving a better HbA_{1c} compared to controls. Another study of DDMPps [25] showed that average HbA_{1c} levels improved in a 3-year follow-up cohort and that the proportion with a $HbA_{1c} > 7.5\%$ and a BP >140/90 mmHg decreased over 3 years from 16.3 to 9.8%. Our DDMPps were more obese than controls. The Steno 2 study showed that intensive therapy for patients with similar BMI and waist circumference values decreased HbA_{1c} values, BP, cholesterol and triglyceride levels, which significantly reduced the risk of CVD [26,27]. Although our DDMPps exercised less than controls, the groups had similar HDL levels and HDL improved more in DDMPps than in controls. This could be partly because of dietary advice for DDMPps regarding alcohol consumption with subsequent effects on triglyceride and HDL levels. Compared with usual DDMPps, our study may select for healthier or more motivated patients, as is suggested by the high rate of DDMPps who stop smoking. However, the motivation level of controls is also high, as they report a higher level of exercise and a higher proportion were non-smokers at baseline. Programmes to improve diabetes care have also been introduced in other countries [7,28,29] and have been shown in studies to significantly improve systolic BP, HbA_{1c} and LDL [30].

The 2009 DRP performance criteria, evaluating medical processes and outcomes, support that medical care of DDMPps was better than for controls, but show that the regulation of LDL cholesterol and the performance of foot examinations was poor in both groups. Lipid control is an important factor in reducing CVD risk in patients with type 2 diabetes [27]. A meta-analysis of statin studies in patients with diabetes showed a 21% proportional reduction in major vascular events per mmol/L reduction in LDL cholesterol [31]. Calculation of individual 10-year risk for CVD according to the United Kingdom Prospective Diabetes Study risk engine [9–11] showed that in subjects without a history of myocardial infarct or stroke (DDMP: 76 and controls: 64), mean CVD risk (DDMP: $23 \pm 12\%$ and controls: $25 \pm 17\%$) and mean fatal CVD risk (DDMP: $17 \pm 11\%$ and controls: $19 \pm 16\%$) were similar between the groups. Specific LDL cholesterol goals in DDMP could be an important contribution to long-term reductions in CVD risk, especially as 49% of DDMPps had a calculated CVD risk greater than 20%. Compared with DRP performance criteria, German DDMP benchmarks of care reflect regulations regarding the evaluation of parameter changes of DDMPps [32] and require individual goals for HbA_{1c}. As we had no access to these values, achievement of HbA_{1c} goals and their appropriateness could not be evaluated in this study.

The improvements in healthcare processes which are associated with DDMP participation provide the necessary prerequisites for improvements in outcomes. The existence of long-term effects must be evaluated in a follow-up examination. A systematic review of various DDMPs found that programmes significantly improve screening for retinopathy and foot lesions but only modestly improve glycaemic control (glycated haemoglobin by 0.5%). Even this small improvement in glycaemic control was postulated to reduce microvascular complications by 15% [21].

This study provides insights regarding differences in diabetes care associated with the introduction of nationwide DDMPs. The results indicate that drug therapy, medical advice and follow-up have improved for DDMPps. Although our DDMPps had a higher median diabetes duration and were more obese than controls, they reached therapeutic goals at least as frequently as controls. Evaluation of overall care according to international standards was better in DDMPs. However, this study also shows that some aspects of medical management, e.g. regarding LDL cholesterol and foot examinations, must be improved for all patients with type 2 diabetes in Germany. Further research regarding long-term microvascular and macrovascular effects of DDMPs and the optimization of patient participation and of medical care of less compliant patients is required.

Acknowledgements

The KORA research platform (KORA) was initiated and financed by the Helmholtz Zentrum München – German Research Center for Environmental Health, which is funded by the German Federal Ministry of Education and Research and by the State of Bavaria. The patient survey regarding diabetes was part of the project 'Health Economic Aspects of Diabetes Mellitus Type 2 in longitudinal and cross-sectional studies' funded by the Federal Association of Statutory Regional Health Funds (AOK Bundesverband). This study was also supported in part by a grant from the German Federal Ministry of Education and Research (BMBF) to the German Center for Diabetes Research (DZD e.V.).

Conflict of interest

The authors have no conflicts of interest.

DOI: 10.1002/dmrr

References

1. Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness. *JAMA* 2002; **288:** 1775–1779.
2. Glasgow RE, Wagner EH, Schaefer J, Mahoney LD, Reid RJ, Greene SM. Development and validation of the Patient Assessment of Chronic Illness Care (PACIC). *Med Care* 2005; **43:** 436–444.
3. Legal stipulations regarding disease management programs. 2009; http://www.aok-gesundheitspartner.de/inc_ges/download/dl.php/bundesverband/dmp/imperia/md/content/gesundheitspartner/bund/dmp/gesetzlichegrundlagen/dmp_gesetl_20rsav_aendverord.pdf [11 November 2009].
4. Evaluation criteria stipulated by the federal social insurance authority. 2009; http://www.bundesversicherungsamt.de/cln_162/nn_1046154/DE/DMP/Downloads/Downloads__Evaluation__gesamt,templateId=raw,property=publicationFile.pdf/Downloads_Evaluation_gesamt.pdf [4 December 2009].
5. American Diabetes Association. Standards of medical care in diabetes-2009. *Diabetes Care* 2009; **32**(Suppl. 1): S13–S61.
6. Performance criteria of the 2009 Diabetes Recognition Program. 2009; http://www.ncqa.org/tabid/139/Default.aspx [3 December 2009].
7. Fleming BB, Greenfield S, Engelgau MM, Pogach LM, Clauser SB, Parrott MA. The Diabetes Quality Improvement Project: moving science into health policy to gain an edge on the diabetes epidemic. *Diabetes Care* 2001; **24:** 1815–1820.
8. Changes to the Diabetes Recognition Program – frequently asked questions. 2010; http://www.ncqa.org/tabid/1023/Default.aspx [15 November 2010].
9. UKPDS risk engine. 2010; http://www.dtu.ox.ac.uk/index.php?maindoc=/riskengine/ [19 March 2010].
10. Kothari V, Stevens RJ, Adler AI, *et al*. UKPDS 60: risk of stroke in type 2 diabetes estimated by the UK Prospective Diabetes Study risk engine. *Stroke* 2002; **33:** 1776–1781.
11. Stevens RJ, Kothari V, Adler AI, Stratton IM. The UKPDS risk engine: a model for the risk of coronary heart disease in Type II diabetes (UKPDS 56). *Clin Sci (Lond)* 2001; **101:** 671–679.
12. Ullrich W, Marschall U, Graf C. Versorgungsmerkmale des diabetes mellitus in Disease-Management-Programmen. *Diabetes, Stoffwechsel Herz* 2007; **16:** 407–414.
13. Szecsenyi J, Rosemann T, Joos S, Peters-Klimm F, Miksch A. German diabetes disease management programs are appropriate for restructuring care according to the chronic care model: an evaluation with the patient assessment of chronic illness care instrument. *Diabetes Care* 2008; **31:** 1150–1154.
14. Holle R, Happich M, Lowel H, Wichmann HE. KORA – a research platform for population based health research. *Gesundheitswesen* 2005; **67**(Suppl. 1): S19–S25.
15. Information regarding the KORA Study Platform. 2010; http://www.helmholtz-muenchen.de/en/kora-en/information-for-scientists/study-types/index.html [15 November 2010].
16. Lamers LM, van Vliet RC. The Pharmacy-based Cost Group model: validating and adjusting the classification of medications for chronic conditions to the Dutch situation. *Health Policy* 2004; **68:** 113–121.
17. Holle R, Hochadel M, Reitmeir P, Meisinger C, Wichmann HE. Prolonged recruitment efforts in health surveys: effects on response, costs, and potential bias. *Epidemiology* 2006; **17:** 639–643.
18. Stark R, Schunk M, Leidl R, Meisinger C, Holle R. Process evaluation of disease management programs for type 2 diabetes based on a representative population in the area of Augsburg (KORA). *Betriebswirtschaftliche Forsch Praxis* 2009; **3:** 283–301.
19. Rathmann W, Haastert B, Icks A, *et al*. High prevalence of undiagnosed diabetes mellitus in Southern Germany: target populations for efficient screening. The KORA survey 2000. *Diabetologia* 2003; **46:** 182–189.
20. Dunkelberg S, Zingel D, Noack A, van den Bussche H, Kaduszkiewicz H. Which patients are (not) included in the DMP diabetes programme? *Gesundheitswesen* 2006; **68:** 289–293.
21. Knight K, Badamgarav E, Henning JM, *et al*. A systematic review of diabetes disease management programs. *Am J Manag Care* 2005; **11:** 242–250.
22. Shortell SM, Gillies R, Siddique J, *et al*. Improving chronic illness care: a longitudinal cohort analysis of large physician organizations. *Med Care* 2009; **47:** 932–939.
23. Cushman WC, Evans GW, Byington RP, *et al*. Effects of intensive blood-pressure control in type 2 diabetes mellitus. *N Engl J Med.* 2010; **362:** 1575–1585.
24. UK Prospective Diabetes Study (UKPDS) Group. 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. *Lancet* 1998; **352:** 837–853.
25. Rothe U, Muller G, Schwarz PE, *et al*. Evaluation of a diabetes management system based on practice guidelines, integrated care, and continuous quality management in a Federal State of Germany: a population-based approach to health care research. *Diabetes Care* 2008; **31:** 863–868.
26. Gaede P, Vedel P, Larsen N, Jensen GV, Parving HH, Pedersen O. Multifactorial intervention and cardiovascular disease in patients with type 2 diabetes. *N Engl J Med* 2003; **348:** 383–393.
27. Gaede P, Lund-Andersen H, Parving HH, Pedersen O. Effect of a multifactorial intervention on mortality in type 2 diabetes. *N Engl J Med* 2008; **358:** 580–591.
28. Ahmann AJ. Guidelines and performance measures for diabetes. *Am J Manag Care* 2007; **13**(Suppl. 2): S41–S46.
29. Goderis G, Borgermans L, Grol R, *et al*. Start improving the quality of care for people with type 2 diabetes through a general practice support program: a cluster randomized trial. *Diabetes Res Clin Pract* 2010; **88:** 56–64.
30. Peterson KA, Radosevich DM, O'Connor PJ, *et al*. Improving diabetes care in practice: findings from the TRANSLATE trial. *Diabetes Care* 2008; **31:** 2238–2243.
31. Kearney PM, Blackwell L, Collins R, *et al*. Efficacy of cholesterol-lowering therapy in 18,686 people with diabetes in 14 randomised trials of statins: a meta-analysis. *Lancet* 2008; **371:** 117–125.
32. Quality assurance indicators for disease management programs. 2009; http://www.aok-gesundheitspartner.de/imperia/md/content/gesundheitspartner/bayern/arztundpraxis/dmp/vertragliche_gesetzliche_grundlagen/internistische_diagnosen/kvb-plattformvertrag/anl_02e_dm2_qs_090325.pdf [4 December 2009].