Implementation of the Chronic Care Model in Small Medical Practices Improves Cardiovascular Risk but Not Glycemic Control

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OBJECTIVE

To test whether the implementation of elements of the Chronic Care Model (CCM) via a specially trained practice nurse leads to an improved cardiovascular risk profile among type 2 diabetes patients.

RESEARCH DESIGN AND METHODS

This cluster randomized controlled trial with primary care physicians as the unit of randomization was conducted in the German part of Switzerland. Three hundred twenty-six type 2 diabetes patients (age >18 years; at least one glycosylated hemoglobin [HbA_{1c}] level of ≥7.0% [53 mmol/mol] in the preceding year) from 30 primary care practices participated. The intervention included implementation of CCM elements and involvement of practice nurses in the care of type 2 diabetes patients. Primary outcome was HbA_{1c} levels. The secondary outcomes were blood pressure (BP), LDL cholesterol, accordance with CCM (assessed by Patient Assessment of Chronic Illness Care [PACIC] questionnaire), and quality of life (assessed by the 36-item short-form health survey [SF-36]).

RESULTS

After 1 year, HbA_{1c} levels decreased significantly in both groups with no significant difference between groups (−0.05% [−0.60 mmol/mol]; $P = 0.708$). Among intervention group patients, systolic BP (−3.63; $P = 0.050$), diastolic BP (−4.01; $P < 0.001$), LDL cholesterol (−0.21; $P = 0.033$), and PACIC subscores ($P < 0.001$ to 0.048) significantly improved compared with control group patients. No differences between groups were shown in the SF-36 subscales.

CONCLUSIONS

A chronic care approach according to the CCM and involving practice nurses in diabetes care improved the cardiovascular risk profile and is experienced by patients as a better structured care. Our study showed that care according to the CCM can be implemented even in small primary care practices, which still represent the usual structure in most European health care systems.

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Chronic diseases and multiple morbidities have shown an increasing prevalence in most industrialized countries, including Switzerland (1). Among these chronic diseases, diabetes is one of the most prevalent ones (2). The Chronic Care Model (CCM) has been developed as an evidence-based approach for the care of chronically ill patients. A central element of the CCM is the team-centered care approach, which facilitates and produces effective interactions between proactive primary care practice teams, and empowers patients with the aim to improve processes and outcomes in patients with chronic illnesses (3,4).

In contrast to the United States, experiences in European countries with the CCM approach are rare. Many European health care systems, for example in Germany, Austria, Switzerland, France, Italy, and Spain, are physician-centered and do not involve practice nurses or other nonphysician professions in care. Advocates for health care among the politicians in these countries are very interested in team-based approaches, especially in the care of chronically ill patients, since, on the one hand, the number of these patients is increasing and, on the other hand, a shortage of primary care physicians (PCPs) exists in most of these countries (5).

Regarding the care for diabetes patients, the optimal cardiovascular risk profile is one of the most important targets for health expectancy and quality of life (6). The aim of this study was to investigate whether a team-based approach according to the CCM, which included the involvement of a practice nurse in the care for type 2 diabetes patients results in an improved cardiovascular risk profile after 1 year, namely, glycosylated hemoglobin (HbA_{1c}), blood pressure (BP), and LDL cholesterol. Additionally, we examined whether the intervention resulted in an improved quality of life for the patients and improved patients' perspective of the provided care.

RESEARCH DESIGN AND METHODS

This study was a cluster randomized controlled trial with PCPs as the unit of randomization. Detailed information about design and methods (7) and the baseline characteristics of the study patients (8) was published previously. The study protocol has been approved by the ethics committee of the Kanton of Zurich and received an unrestricted positive vote on 25 January 2010.

Recruitment of Participants

Eligible criteria for PCPs were that they participated in routine primary care of unselected patients. If they were working in a non–single-handed practice, it was required that patients were clearly allocated to individual PCPs. About 800 randomly selected PCPs from the eastern part of Switzerland were invited to an information meeting on the study. Additionally, the project was presented in several quality-circle meetings in the PCPs' networks.

Eligible patients were identified through the PCP registry, based on laboratory results, and received an invitation letter by the PCPs with information about the study. Patients were included in consecutive order of attendance in the practice, regardless of the reason for the encounter. The inclusion criteria were adulthood (age $>$18 years), diagnosis of type 2 diabetes according to international diagnostic criteria (9), and at least one HbA_{1c} level of $\geq$7.0% (53 mmol/mol) measured within the preceding year. The latter criterion was formulated because the aim of the study was to reduce HbA_{1c} values by 0.5%, considering the current recommendations in guidelines (HbA_{1c} 6.5% [48 mmol/mol]) at study onset (10). Exclusion criteria were insufficient language skills to read and understand informed consent, patient information, and questionnaires; practice contact for emergencies only (i.e., no continuous patient-doctor relationship); and a life expectancy of $<$6 months.

Intervention

The intervention aimed at providing team care according to the CCM. To perform CCM-based care, a team approach involving the practice nurse is required. Usual care in Switzerland is focused on the PCP and the PCP-patient relationship, based on good clinical practice. As in most European countries, practice nurses in Switzerland are currently only marginally involved in the care for patients, and their education is less focused on medical issues, addressing mainly administrative matters. We established the intervention based on the results of a qualitative prestudy concerning the implementation of CCM elements, the involvement of practice nurses (11), and preliminary results of a systematic review conducted by our research group assessing effective interventions in primary care to improve care for diabetes patients (12).

Intervention on Cluster Level (Provider of Health Care)

Practice nurses of the intervention group were trained right after randomization in a 6-day educational course "Treatment of long term patients—module diabetes," organized by the union of Swiss practice nurses (13). The course provided medical knowledge for the treatment of diabetes patients and general communication skills, and it empowered practice nurses for their role in a team providing structured care for chronically ill patients. The practice nurses also learned how to perform visits and follow-up consultations by means of a monitoring tool developed for the study (described below) (14).

In addition, PCPs and practice nurses from the intervention group participated in two 4-h interactive workshops. The first workshop was scheduled right after randomization and addressed the implementation of the team approach in practice and evidenced-based therapy of diabetes. The second workshop took place after 6 study months, and covered professional exchange between practice nurses and PCPs regarding implementation experience and management of cardiovascular risk factors.

Intervention on Practice Level (Patients)

The intervention on the practice level maintained that practice nurses be involved in the care of type 2 diabetes patients. Practice nurses planned independent consultations with patients. The monitoring tool guided them through the consultations, and provided the opportunity to record relevant parameters and assistance for self-management support in order to help the patient in selecting

appropriate, concrete behavioral goals, in developing plans for reaching those goals, and in evaluating the progress and adequacy of those plans. The monitoring tool addressed clinical parameters (e.g., HbA_{1c}, BP, and LDL cholesterol levels), examinations (e.g., food control, neurological tests, and eye examinations), adherence to prescribed drugs, self-care goals, and other recommendations. The clinical aim of the tool was to ensure that treatment recommendations were followed. The assessed parameters were classified regarding their clinical urgency and importance into a traffic light scheme (green, amber, and red), and the practice nurses forwarded the tool to the PCPs. So the PCPs obtained an immediate overview on the current situation of the patients. We recommended practice nurse consultations every 4 months, but frequency could be adapted according to the clinical situation of the patient (14).

Overall, the intervention included the implementation of the following CCM elements: organization of health care and delivery system design (with involvement of the practice nurse); clinical information systems (using the CARAT [Chronic Care for Diabetes] study monitoring tool); decision support (with guideline-based instructions on the tool, and requiring the availability of a diabetes specialist at University Hospital Zurich); and self-management support (provided by the practice nurse). More detailed information is provided in the study protocol (7).

Outcome Measures

The primary study outcome was the HbA_{1c} level. Secondary clinical outcomes were the cardiovascular risk factors systolic and diastolic BP and LDL cholesterol level. Clinical parameters were assessed by the practice team using point-of-care laboratory analysis and/or analysis by external laboratories. Patient-reported secondary outcomes were accordance with the CCM from patients' perspective measured by the Patient Assessment of Chronic Illness Care questionnaire (PACIC) (15,16) and the generic health-related quality of life assessed by the SF-36 (17).

Sample Size

We aimed at inducing a reduction of 0.5% in the HbA_{1c} level for the intervention group patients. Since no epidemiological data regarding HbA_{1c} level from the Swiss primary care setting was available at the time of study protocol development, we assumed, based on previous German data (18) and on our inclusion criteria ($HbA_{1c} \geq 7.0\%$ [53 mmol/mol]), a mean HbA_{1c} of 7.7% (61 mmol/mol) at baseline assessment time. In accordance with data from the DIG (Diabetes in Germany) study (19) and the ACCORD (Action to Control Cardiovascular Risk in Diabetes) trial (20), we assumed an SD of 1.2% (13 mmol/mol) and, based on our previous studies and on data available from the website of the University of Aberdeen (21), an intraclass correlation coefficient (ICC) of 0.04 for the primary outcome HbA_{1c}. We aimed at 80% power; the significance level was set to 0.05. We performed the sample size calculation with the Cluster Randomization Sample Size Calculator, version 1.02, of the University of Aberdeen. Based on our assumptions and definitions, the sample size calculation resulted in the inclusion of 12 patients and 11 practices in each arm. Considering a higher drop-out rate in cluster randomized trials since the dropout of one cluster leads to the loss of all patients in a cluster, we assumed a drop-out rate of 20%, resulting in 14 practices in each arm and 28 practices, including 12 patients, in total (22–24).

Randomization

The PCPs who agreed to participate in the study were alphabetically ordered by their family names in a list with numbers from 1 to 30. An independent research assistant, who was not involved in the study and was blind to the identity of the PCPs, randomly allocated by statistical computer software SPSS (version 18.0) 15 letters A and 15 letters B to numbers 1–30 and to the corresponding PCPs, respectively. The assignment of the letters A and B to either the intervention or control group was randomly conducted by a second research assistant who drew blinded a ticket with the letters A or B and a ticket with the group allocation intervention or control group from an envelope.

We informed all PCPs about the group allocation after the inclusion of patients and baseline assessments to minimize selection bias. We did not constrain cluster randomization by any stratification.

Statistical Methods

Baseline characteristics of PCPs and patients according to intervention and control group are presented as the means and SDs for continuous variables, and frequencies and percentages for categorical data.

Analyses were conducted by intention-to-treat. Missing follow-up data of patients who dropped out were substituted by baseline assessment data (last observation carried forward). For the primary outcome, HbA_{1c} level and clinical outcomes systolic BP, diastolic BP, LDL cholesterol level, and SF-36 results, we analyzed the mean (95% CI) differences in changes over time between groups using *t* tests for independent samples. ICCs were calculated for the primary and clinical secondary outcomes to assess a potential clustering effect. To assess the independent effect of the treatment group, we additionally conducted multilevel regression analyses with the PCP as the cluster level considering the changes over time in the primary and clinical secondary outcomes as predictor variables, and potentially confounding variables as determinants (patient's sex and age, smoking status, BMI, number of comorbidities, number of visits during the study year, total number of drugs, treatment of correspondent medication [antidiabetic therapy for HbA_{1c}, antihypertensive therapy for BP, lipid-lowering therapy for LDL cholesterol], and changes in correspondent medication during the study year). Mean differences over time of the PACIC subscales were calculated using the nonparametric Mann-Whitney *U* test, since the PACIC subscales are ordinally scaled and the scores were not normal distributed. The significance level was set at 0.05. Statistical analyses were performed using Stata version 12.0 (StataCorp, 2010).

RESULTS

A total of 30 PCPs from the German-speaking part of Switzerland who

recruited 326 type 2 diabetes patients participated in the study. Recruitment of PCPs took place between November 2009 and February 2010, and the recruitment of patients and baseline assessment took place between January and April 2010. PCPs were informed about their allocated group after they finished patient inclusion. The intervention ran from April 2010 until May 2011, and follow-up assessments were conducted 1 year after baseline assessments. Figure 1 shows the flow of PCPs and patients through the study. In total, 23 patients (7%) were lost to follow-up.

PCP and patient demographic and clinical characteristics are presented in Table 1. PCPs from both groups were comparable, except that more control group than intervention group PCPs worked in single-handed practices.

Table 2 shows the primary, secondary, and additional clinical outcomes. At baseline, intervention group patients had a mean HbA_{1c} level of 7.8% (62 mmol/mol), a mean systolic BP of 140 mmHg, a mean diastolic BP of 83 mmHg, and a mean LDL cholesterol level of 2.8 mmol/L. For control group patients, the mean HbA_{1c} level was 7.6% (59 mmol/mol), mean systolic BP was 138 mmHg, mean diastolic BP was 79 mmHg, and mean LDL cholesterol level 2.5 mmol/L. At follow-up, the intervention and control groups did not differ significantly in the mean change over time of the primary outcome HbA_{1c} level, but the HbA_{1c} level improved significantly in both groups, as follows: −0.27% (−3.4 mmol/mol; $P = 0.033$) in the intervention; and −0.22% (−2.9 mmol/mol; $P = 0.002$) in the control group. Statistically significant differences could be observed in the mean changes over time between the intervention and control groups for the secondary clinical outcomes systolic BP, diastolic BP, and LDL cholesterol level. In detail, the systolic BP, diastolic BP, and LDL cholesterol level of the intervention group patients improved over time, whereas the corresponding levels of the control group patients remained approximately the same. There was no evidence for a statistically significant clustering effect. Estimated effects based on multilevel regression analyses were of the same magnitude; however, changes in LDL cholesterol levels no longer reached the level of significance (Supplementary Table 1).

Descriptive results with regard to health care utilization, further clinical outcomes, and medications are presented comprehensively in Supplementary Table 2. Briefly, the mean number of visits to general practices during the last year increased in both groups (from 8.3 to 9.6 in the intervention group; from 7.9 to 8.4 in the control group). However, the mean difference in change between groups was not statistically significant (1.07; $P = 0.155$). In terms of changes in medications (categorized as change/no change) from baseline to follow-up, no significant differences could be detected regarding antidiabetic therapy ($\chi^2 = 0.03$, $P = 0.862$), antihypertensive therapy ($\chi^2 = 2.63$, $P = 0.105$), and lipid-lowering therapy ($\chi^2 = 0.57$, $P = 0.449$).

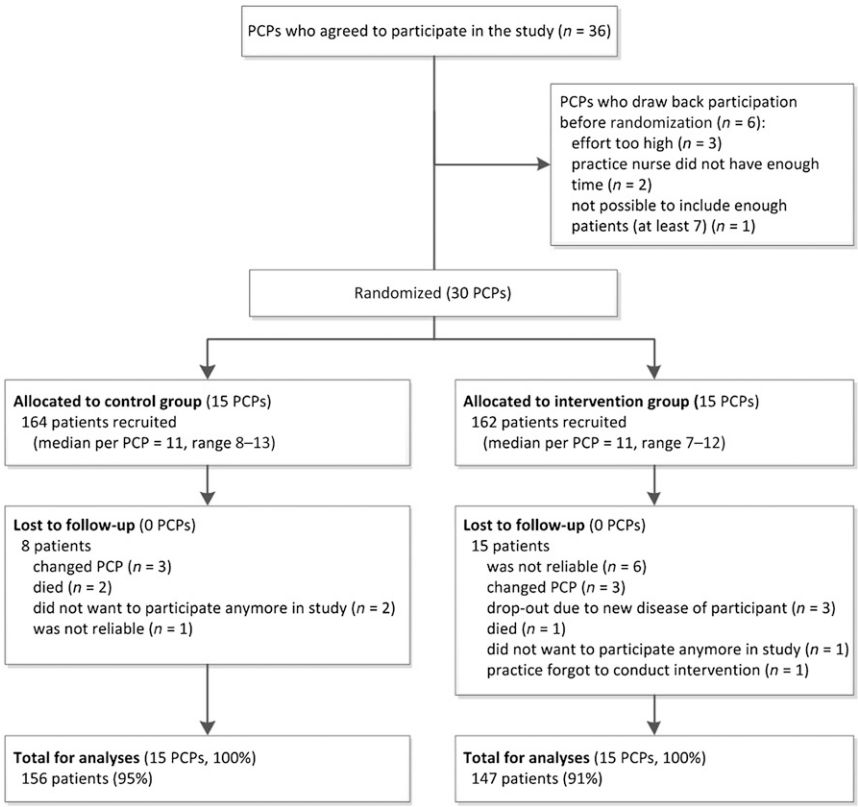

Figure 1—Flow diagram of recruitment and follow-up of PCPs and patients.

Table 1—Baseline characteristics of intervention and control group at cluster (PCPs) and individual (type 2 diabetes patients) levels

Characteristics	Intervention group (*n* = 162)	Control group (*n* = 164)
PCP factors at baseline		
PCPs, *n*	15	15
Age, mean (SD), years	50.0 (6.9)	51.5 (7.6)
Men	13 (87)	14 (93)
Organization of PCPs' practices		
Single-handed practice	3 (20)	7 (47)
Group practice (>1 PCP)	12 (80)	8 (53)
Member of a PCP network	10 (67)	7 (47)
Patient factors at baseline		
Age, mean (SD), years	65.7 (10.4)	68.3 (10.6)
Men	88 (54)	99 (60)
Living together with partner/family (*n* = 314)	125 (79)	121 (78)
Education, mean (SD), years (*n* = 312)	11.6 (3.2)	11.7 (3.1)
Smoking (patient reported)		
Current smoker	22 (14)	14 (9)
Former smoker	63 (39)	66 (40)
Never smoker	73 (45)	76 (46)
Missing	4 (2)	8 (5)
BMI, mean (SD)	30.5 (5.3)	30.7 (5.9)
Antidiabetic therapy		
None	4 (2)	8 (5)
Only oral	108 (67)	100 (61)
Only insulin	11 (7)	15 (9)
Combined (insulin and oral)	36 (22)	41 (25)
Missing	3 (2)	—
Diabetes duration, mean (SD), years (*n* = 322)	9.5 (7.4)	10.3 (7.8)
No comorbidities, mean (SD)	2.5 (1.6)	2.9 (1.5)
No drugs, mean (SD) (*n* = 321)	4.6 (2.2)	4.9 (2.0)
No consultations in last year, mean (SD) (*n* = 325)	8.3 (6.8)	7.9 (5.2)
PHQ-9 summary score, mean (SD) (*n* = 302)	5.1 (4.7)	5.3 (4.8)
Compliance (assessed by PCPs)		
Very good	47 (29)	62 (38)
Rather good	80 (50)	69 (42)
Rather and very bad	33 (20)	33 (20)
Missing	2 (1)	—

Values are numbers (percentages), unless stated otherwise. PHQ-9, Patient Health Questionnaire short form.

Regarding the patient-reported secondary outcomes, we found statistically significant differences in changes over time between intervention and control group patients in all PACIC subscales and in the PACIC summary score, showing improved levels for intervention group patients and mostly unchanged scores for control group patients at follow-up (Table 3). For all scores of the SF-36 subscales, we did not find statistically significant differences in changes between the two groups over time.

CONCLUSIONS

In our study, a chronic care approach performed according to the CCM and involving the practice nurse in diabetes care improved the cardiovascular risk profile of patients with type 2 diabetes. Patients experienced the changes in the care provided as having a better structure, which is reflected in the increased PACIC scores. Furthermore, our results showed that CCM care can be implemented even in inexperienced small primary care practices, which still represent the most common situation in many European health care systems.

After 1 year of intervention, the primary outcome HbA_{1c} level slightly improved in both groups of our study without showing a significant difference between the intervention and control groups. Several reasons might account for that. First of all, the PCPs could not be blinded; they knew that they had participated in a diabetes trial that might also have increased the attention toward the HbA_{1c} level in the control group. Furthermore, the HbA_{1c} levels were already quite good in most patients at baseline, especially when taking into account that the recommendations for HbA_{1c} target levels changed during the study period. Current guidelines recommend less strict targets, especially for older patients, a group that constituted most of the patients in our sample (6,10). Additionally, most of the patients in our sample had multiple morbidities, which also might have kept PCPs away from very rigorous HbA_{1c} target levels. Overall, it can be concluded that the HbA_{1c} level was satisfactory in most patients, and only a small amount of room remained for improvement without increasing the risk of hypoglycemia for many of these old patients with multiple morbidities (20,25). Interestingly, on the one hand, previous studies found similar results with no significant difference in HbA_{1c} decrease between the two groups (26), and on the other hand also a decline in HbA_{1c} levels only in the CCM group (27) after the implementation of CCM elements.

Our hypothesis that the nonsignificance of the HbA_{1c} level was caused by the study participation effect is supported by the finding that BP, which was not mentioned as being a primary study aim, improved significantly only in the intervention group. PCPs and practice nurses from the intervention group were sensitized to the management of cardiovascular risk factors, which was a topic in the educational courses and workshops. Furthermore, the intervention-monitoring tool guided the practice nurse through a systematic monitoring of the BP. Nevertheless, the mean BP values at the end of the study period indicate that there is still room for improvement, at least for the mean systolic BP, which did not fulfill current recommendations (6) and was slightly higher compared with other samples (28,29). The same effect occurred in the LDL cholesterol levels. LDL cholesterol level was also defined as a treatment aim in the intervention-monitoring tool

Table 2—Primary outcome, clinical secondary outcomes, and additional characteristics at baseline and follow-up in type 2 diabetes patients per allocated group

Outcomes	Participants, *n* (baseline/follow-up)		Outcome at baseline		Outcome at follow-up		ICC	Difference in change between groups, mean (95% CI)*	*P* value†
	Intervention	Control	Intervention	Control	Intervention	Control			
Primary outcome									
HbA_{1c} (%)	162/147	164/156	7.8 (1.5)	7.6 (1.1)	7.6 (1.2)	7.3 (1.0)	<0.001	−0.05 (−0.34 to 0.23)	0.708
HbA_{1c} (mmol/mol)	162/147	164/156	62 (16)	59 (12)	59 (13)	56 (10)	<0.001	−0.60 (−3.72 to 2.52)	0.707
Secondary outcomes									
Systolic BP (mmHg)	162/145	164/155	140.3 (18.4)	137.8 (16.8)	136.4 (17.5)	137.5 (16.9)	0.019	−3.63 (−7.26 to 0.00)	0.050
Diastolic BP (mmHg)	162/144	164/155	83.1 (10.4)	78.7 (10.2)	79.6 (9.9)	79.2 (11.2)	<0.001	−4.01 (−6.23 to −1.78)	<0.001
LDL cholesterol (mmol/L)	159/146	164/154	2.8 (1.1)	2.5 (1.1)	2.7 (1.0)	2.6 (1.0)	0.040	−0.21 (−0.39 to −0.02)	0.033
Additional characteristics									
BMI (kg/m^2)	162/146	164/154	30.5 (5.3)	30.7 (5.9)	30.0 (4.9)	30.8 (5.8)		−0.24 (−0.62 to 0.14)	0.213
HDL cholesterol (mmol/L)	161/147	164/156	1.2 (0.3)	1.3 (0.4)	1.2 (0.3)	1.3 (0.5)		−0.05 (−0.13 to 0.02)	0.182
Total cholesterol (mmol/L)	162/147	163/156	5.0 (1.2)	4.7 (1.1)	4.9 (1.1)	4.7 (1.1)		−0.08 (−0.28 to 0.13)	0.469
Waist/hip ratio									
Male‡	87/79	91/84	1.02 (0.08)	1.01 (0.07)	1.01 (0.06)	1.00 (0.06)		0.01 (−0.01 to 0.03)	0.372
Female‡	74/66	62/60	0.92 (0.06)	0.93 (0.09)	0.92 (0.06)	0.94 (0.11)		−0.01 (−0.03 to 0.02)	0.521
Capillary fasting blood glucose (mmol/L)	162/145	164/154	8.4 (2.5)	7.7 (2.2)	7.9 (2.0)	7.3 (1.9)		−0.14 (−0.69 to 0.41)	0.612

Values are mean (SD), unless otherwise stated. *Value interpretable in relation to intervention group: a negative value indicates greater negative change, and a positive value greater positive change in the intervention group compared with control subjects. †*t* test for independent samples. ‡Waist circumference (cm)/hip circumference (cm).

and was discussed as an important target in the interactive workshop for PCPs and practice nurses. Our data showed some medical treatment intensification regarding LDL cholesterol level as well as BP, but whether the improvements are due to the intensification or caused by an increased adherence by the patients can finally not be determined.

Interestingly, according to the improvements in BP and LDL cholesterol levels, patients' experiences of provided care also changed. All PACIC subscales showed significantly higher scores over time in the intervention group. Obviously, patients experienced the changes or the differences in provided care that are associated with the CCM. This effect was not observed for control group patients, despite the improvement in their HbA_{1c} levels over time.

We could not observe significant changes over time for generic health-related quality of life (HRQL), which was assessed by the SF-36. The SF-36 is probably the most common HRQL instrument, but it is not very specific. Although the intervention resulted in improvements in clinical parameters and perception of the provided care, patients' general HRQL status was not affected. This finding emphasizes the importance of disease-specific HRQL assessments to detect the concrete changes of intervention. However, the scores of the eight SF-36 domains remained remarkably constant over time in both the intervention and control groups. This result supports the high test-retest reliability of the instrument in general.

Improving diabetes care is obviously a challenging goal, which may not be achieved by simple approaches targeting single aims only. A recent study (30) with similar methodology assessed, for instance, the effect of peer support for patients with type 2 diabetes but could not show significant differences between groups in the improvement of the cardiovascular risk factors. In another study (31), patients with newly diagnosed type 2 diabetes received a 6-h structured group educational intervention, but no significant differences in the change in

Table 3—Patient-reported secondary outcome PACIC: scores at baseline and follow-up in type 2 diabetes patients per allocated group

	Participants at baseline/follow-up, *n*		Outcome at baseline		Outcome at follow-up		
PACIC	Intervention	Control	Intervention	Control	Intervention	Control	*P* value*
Summary score†	148/129	142/135	3.1 (0.9)	3.2 (0.8)	3.3 (0.8)	3.2 (1.0)	0.001
Patient activation	153/135	153/139	3.8 (1.1)	3.9 (1.2)	3.9 (1.1)	3.9 (1.2)	0.032
Delivery system	148/131	147/140	3.8 (0.9)	3.9 (0.8)	3.9 (0.9)	3.7 (0.9)	<0.001
Goal setting	147/131	148/137	2.8 (0.9)	2.9 (1.0)	3.1 (1.0)	2.9 (1.1)	0.003
Problem solving	149/131	146/135	3.1 (1.3)	3.4 (1.2)	3.4 (1.2)	3.4 (1.2)	0.016
Follow-up	146/129	142/137	2.6 (1.0)	2.7 (1.1)	2.7 (1.0)	2.6 (1.2)	0.048

Values are mean (SD), unless otherwise stated. *Nonparametric Mann-Whitney *U* test. †One missing value was allowed and was replaced by the mean value of the remaining items.

HbA_{1c}, BP, or LDL cholesterol level between the control and intervention groups could be shown after 12 months. On the other hand, a recent review (32) assessing the effects of the CCM on diabetes patients in the United States found that the CCM is effective in improving the health of people who have diabetes and are in primary care. The authors emphasized in their review that no single component of the CCM was found to be crucial for improved outcomes; incorporating multiple components together in the same intervention can help facilitate better CCM implementation (32). Shojania et al. (33) concluded in 2004 that multifaceted interventions to improve the quality of diabetes care have a greater chance of success than single-faceted interventions; this finding has been confirmed by several other reviews addressing diabetes care but also other chronic diseases (34,35). The CCM obviously represents such a multifaceted intervention, but, surprisingly, many trials do not reflect its core elements (12).

A strength of this trial is that it is a study within a real-life setting, reflecting the situation as it occurs in most European countries, with small inexperienced practices, regarding such approaches and a nonexistent culture of involving practice nurses in the care. Therefore, our results are not only important regarding the disease-specific outcomes; they also prove that the CCM approach can be implemented with acceptable effort in daily primary care. The CCM has shown positive effects in several chronic diseases including diabetes (26,27,36–38), but evidence regarding implementation in small, often single-handed primary care practices, which is the most common type of practice in many European countries, is still rare (39).

This is a pragmatic cluster randomized controlled trial. Some limitations should be acknowledged. First of all, due to the study design, it was not possible to blind PCPs and practice nurses to group allocation, which might have influenced the results or might have led to a more pronounced effect of the intervention. Second, we scheduled follow-up assessments 1 year after baseline assessments and the onset of the implementation of the intervention, respectively. We first planned follow-up assessments after 2 study years to obtain a longer implementation period as the basis of our analyses. But many PCPs who were allocated to the control group also wanted to implement the team approach after the end of the study, so we could not let them wait for another year. Finally, cluster effects might influence such trials. We have adjusted our power calculation to this but also calculated the ICC of the clinical variables. However, it has to be mentioned that a small cluster effect occurred only regarding the LDL cholesterol level; interestingly, HbA_{1c} and BP levels showed no clustering at all.

A chronic care approach conducted according to the CCM and involving practice nurses in diabetes care improved the cardiovascular risk profile and was experienced by patients as a better structured form of care. Our study showed that care according to the CCM can be implemented even in small primary care practices, which still represent the usual structure for care in most European health care systems.

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statistical input, and contributed to the interpretation of the data. T.R. contributed to the conception and design of the study, provided clinical input, developed the traffic light scheme, organized the recruitment of primary care physicians, organized and conducted the interactive workshops with the primary care physicians and practice nurses, conducted statistical analyses, and contributed to the interpretation of the data. All authors contributed to successive drafts of the manuscript, and read and approved the final version of the manuscript. A.F. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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