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

Short running title: The CARAT-study

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ABSTRACT

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 unit of randomization was conducted in the German part of Switzerland. 326 type 2 diabetes patients (age >18 years, at least one HbA1c level of ≥7.0% [53 mmol/mol] in 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 glycosylated hemoglobin (HbA1c) levels. The secondary outcomes were blood pressure (BP), LDL-cholesterol, accordance to CCM (assessed by PACIC) and quality of life (assessed by SF-36).

RESULTS – After 1 year HbA1c 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<0.001), diastolic BP (-4.01; p=0.050), LDL-cholesterol (-0.21; p=0.033) and PACIC subscores (p<0.001 to p=0.048) significantly improved compared to 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.

TRIAL REGISTRATION: Current controlled trials: ISRCTN05947538

Chronic diseases and multimorbidity show an increasing prevalence in most industrialized countries, also in Switzerland (1). Among these chronic diseases, diabetes is one of the most prevalent ones (2). The Chronic Care Model (CCM) has been developed as 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 empowered patients with the aim to improve processes and outcomes in 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, as for example in Germany, Austria, Switzerland, France, Italy and Spain are physician centered and do not involve practice nurses or other non-physician professions in care. Health politicians in these countries are very interested in team based approaches, especially in the care for chronically ills, 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 if 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 one year, namely glycosylated hemoglobin (HbA1c), blood pressure (BP) and LDL-cholesterol. Additionally, we examined if the intervention resulted in an improved quality of life of 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 unit of randomization. Detailed information about design and methods (7) and the patients' baseline characteristics

(8) of the study was published previously. The study protocol has been approved by the ethics committee of the Kanton Zurich and received an unrestricted positive vote on 25.01.2010.

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 PCPs' networks.

Eligible patients were identified through the PCPs 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 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 HbA1c level of ≥7.0% (53 mmol/mol) measured within the preceding year. The latter criterion was formulated because the aim of the study was to reduce HbA1c values by 0.5% points considering the current recommendations in guidelines (HbA1c = 6.5% [48 mmol/mol]) at study onset (10).

Exclusion criteria were insufficient language skills to read and understand informed consent, patient information and the questionnaires, practice contact for emergencies only (i.e. no continuous patient-doctor relationship) and a life expectancy less than six 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. Like 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 but addresses mainly administrative matters. We established the intervention based on the results of a qualitative pre-study concerning the implementation of CCM elements and the involvement of practice nurses (11) and on 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 days 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, general communication skills and it empowered practice nurses for their role in a team providing structured care for chronically ills. 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-hours 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 part 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 practice level contained that practice nurses were involved in the care of type 2 diabetes patients. Practice nurses planned independent consultations with patients. The monitoring tool guided them through the consultations, provided the opportunity to record relevant parameters and assistance for self-management support in order to reinforce 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. HbA1c, BP, LDL-cholesterol), examinations (e.g. food control, neurological tests, eye examination), 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, 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 CCM elements organization of health care and delivery system design (involvement of practice nurse), clinical information systems (use of CARAT-monitoring tool), decision support (guideline based instructions on the tool, availability of diabetes specialist at the 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 HbA1c level. Secondary clinical outcomes were the cardiovascular risk factors systolic and diastolic BP and LDL-cholesterol. Clinical parameters were assessed by the practice team using point-of-care laboratory analysis and/or external laboratories. Patient-reported secondary outcomes were accordance to the CCM from patients' perspective measured by the Patient Assessment of Chronic Illness Care questionnaire (PACIC) (15, 16) and generic health-related quality of life assessed by the SF-36 (17).

Sample size

We aimed at inducing a reduction of 0.5% points in the HbA1c for the intervention group patients. Since no epidemiological data regarding HbA1c 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 (HbA1c ≥7.0% [53 mmol/mol]) a mean HbA1c of 7.7% (61 mmol/mol) at baseline assessment time. In accordance to data from the "Diabetes in Germany" (DIG)-study (19) and the ACCORD trial (20) we assumed an SD of 1.2% (13 mmol/mol) and based on our previous studies and on data available at the website of the University of Aberdeen (21) an intraclass correlation coefficient of 0.04 for the primary outcome HbA1c. 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 drop-out 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 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 to 30 and to the corresponding PCPs, respectively. The assignment of the letters A and B to either 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 means and standard deviations (SD) 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 HbA1c and clinical outcomes systolic BP, diastolic BP, LDL-cholesterol and SF-36, we analyzed mean (95% CI) differences in changes over time between groups using t-tests for independent samples. Intraclass correlation coefficients (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 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 HbA1c, antihypertensive therapy for blood pressure, lipid-lowering therapy for LDL-cholesterol], changes of correspondent medication during the study year). Mean differences over time of the PACIC subscales were calculated using the non-parametric Mann Whitney U-test, since the PACIC subscales are ordinal scaled and the scores were not normal distributed. The significance level was set at 0.05. Statistical analyses were performed using Stata 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, recruitment of patients and baseline assessment between January and April 2010. PCPs were informed about their allocated group after they finished patient inclusion. The intervention run from April 2010 until May 2011, and follow-up assessments were conducted one 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 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 HbA1c 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 of 2.8 mmol/l. For control group patients, mean HbA1c was 7.6% (59 mmol/mol), mean systolic BP 138 mmHg, mean diastolic BP 79 mmHg and mean LDL-cholesterol 2.5 mmol/l. At follow-up ,the intervention and control group did not differ significantly in the mean change over time of the primary outcome HbA1c, but the HbA1c improved significantly in both groups; -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 group for the secondary clinical outcomes systolic BP, diastolic BP and LDL-cholesterol. In detail, systolic BP, diastolic BP and LDL-cholesterol of the intervention group patients improved over time, whereas the corresponding levels of the control group patients approximately remained. There was no evidence for a statistically significant clustering effect. Estimated effects based on multilevel regression analyses were of the same magnitude however did not reach significance level anymore for LDL-cholesterol changes (Supplemental Table S1).

Descriptive results with regard to health care utilization, further clinical outcomes and medications are presented comprehensively in Supplemental Table S2. Briefly, the mean number of visits in 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-square=0.03, p=0.862), antihypertensive therapy (chi-square=2.63, p=0.105) and lipid-lowering therapy (chi-square=0.57, p=0.449).

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 the PACIC summary score showing improved levels for intervention group 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 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 provided care as a better structured which is reflected by 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 one year of intervention, the primary outcome HbA1c slightly improved in both groups of our study without showing a significant difference between intervention and control group. Several reasons might account for that. First of all, the PCPs could not be blinded; they knew

that they participated in a diabetes trial which might also have increased the attention towards the HbA1c in the control group. Furthermore, the HbA1c levels were already quite good in most patients at baseline, especially when taken into account that the recommendations for HbA1c targets changed during the study period. Current guidelines recommend less strict targets, especially for older patients, as most of our patients were (6, 10). Additionally, most of the patients in our sample were multimorbid which also might have kept PCPs away from very rigorous HbA1c targets. Overall, it can be concluded that the HbA1c was satisfactory in most patients, and only small room remained for improvement without increasing the risk of hypoglycemia for many of these old and multimorbid patients (25, 26). Interestingly, previous studies found on the one hand similar results with no significant difference of HbA1c decrease between the two groups (27) and on the other hand also a decline in HbA1c in the CCM group only (28) after the implementation of CCM elements.

Our hypothesis that the non-significance in the HbA1c was caused by the study-participating effect is supported by the finding that blood pressure, 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 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 which was slightly higher compared to other samples (29, 30). The same effect occurred in the LDL-cholesterol levels. Also LDL-cholesterol was defined as a treatment aim in the intervention monitoring tool 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 as well as regarding 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, 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 which are associated with the CCM. This effect was not observed for control group patients, despite the improvement of their HbA1c 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 of clinical parameters and perception of the provided care, patients' general HRQL was not affected. This finding emphasizes the importance of disease specific HRQL assessments to detect concrete changes of intervention. However, the scores of the eight SF-36 domains remained remarkably constant over time in both groups, the intervention and control group. This result supports the high test-retest reliability of the instrument in general.

Improving diabetes care is obviously a challenging aim which may not be achieved by simple approaches targeting at single aims only. A recent study 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 (31). In another study, newly diagnosed type 2 diabetes patients received a 6 hours structured group educational intervention, but no significant differences in change in HbA1c, BD or LDL-cholesterol between control and intervention group could be shown after 12 months neither (32). On the other hand, a recent review assessing the effects of the CCM on diabetes patients in the United States found that CCM is effective in improving the health of people who have diabetes 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 (33). Shojiana et al. concluded in 2004 that multifaceted interventions to improve the quality of diabetes care have a greater chance of success than single-faceted interventions (34); this finding has been confirmed by several other reviews, addressing diabetes care but also other chronic diseases (35, 36). 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 non-existing 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 (27, 28, 37-39) but evidence regarding implementation in small, often single handed primary care practices as the most common type of practice in many European countries is still rare (40).

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 one year after baseline assessments and the onset of the implementation of the intervention, respectively. We first planned follow-up assessments after two study years to obtain a longer implementation period as 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 intraclass correlation coefficient (ICC) of the clinical variables. However, it has to be mentioned that a small cluster

effect only occurred regarding the LDL-cholesterol, interestingly, HbA1c and BP showed no clustering at all.

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.

Author Contributions

A.F., O.S., C.C., U.H. and T.R. contributed to conception and design of the study. A.F., C.C. and J.R. organized data collection and data management. C.C., T.R. and O.S. provided clinical input and developed the traffic light scheme. A.F. and T.R. organized recruitment of primary care physicians. T.R., A.F., C.C. and J.R. organized and conducted the interactive workshops with the primary care physicians and practice nurses. A.F., O.S. and T.R. conducted statistical analyses, statistical input was provided by U.H. T.R., A.F., O.S., C.C. and U.H. contributed to the interpretation of the data. A.F. wrote the first draft of the paper and all authors contributed to successive drafts 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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No potential conflicts of interest relevant to this article were reported.

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

	Intervention group (n=162)	Control group (n=164)
PCP factors at baseline		
No of PCPs	15	15
Mean (SD) age (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		
Mean (SD) age (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)
Mean (SD) years of education (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)
Mean (SD) BMI	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)	-
Mean (SD) diabetes duration (years) (n=322)	9.5 (7.4)	10.3 (7.8)
Mean (SD) no comorbidities	2.5 (1.6)	2.9 (1.5)
Mean (SD) no of drugs (n=321)	4.6 (2.2)	4.9 (2.0)
Mean (SD) no consultations last year (n=325)	8.3 (6.8)	7.9 (5.2)
Mean (SD) PHQ summary score (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

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

	No of participants (baseline/follow-up)		Mean (SD) outcome at baseline		Mean (SD) outcome at follow-up		ICC*	Mean difference in change between groups (95% CI†)	P value‡
	Intervention	Control	Intervention	Control	Intervention	Control			
Primary outcome									
HbA1c (%)	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
HbA1c (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 blood pressure (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 blood pressure (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
Waist hip ratio, 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
Fasting blood sugar (capillary; 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

*ICC = intraclass correlation coefficient. †Value interpretable in relation to intervention group: Negative value indicates greater negative change and positive value greater positive change in intervention group compared to controls. ‡T-test for independent samples. ‖Waist circumference (cm)/hip circumference (cm).

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

	No of participants (baseline/follow-up)		Mean (SD) outcome at baseline		Mean (SD) outcome at follow-up		P value*
	Intervention	Control	Intervention	Control	Intervention	Control	
PACIC							
PACIC: Summary score†)	148/129	142/135	3.1 (0.9)	3.2 (0.8)	3.3 (0.8)	3.2 (1.0)	0.001
PACIC: Patient activation	153/135	153/139	3.8 (1.1)	3.9 (1.2)	3.9 (1.1)	3.9 (1.2)	0.032
PACIC Delivery system	148/131	147/140	3.8 (0.9)	3.9 (0.8)	3.9 (0.9)	3.7 (0.9)	<0.001
PACIC Goal setting	147/131	148/137	2.8 (0.9)	2.9 (1.0)	3.1 (1.0)	2.9 (1.1)	0.003
PACIC Problem solving	149/131	146/135	3.1 (1.3)	3.4 (1.2)	3.4 (1.2)	3.4 (1.2)	0.016
PACIC Follow-up	146/129	142/137	2.6 (1.0)	2.7 (1.1)	2.7 (1.0)	2.6 (1.2)	0.048

*Non-parametric Mann Whitney U-test. †For PACIC summary score: 1 missing allowed and replaced by mean value of remaining items.

Figure legend

Figure 1: Flow diagram of recruitment and follow-up of primary care physicians and patients

Supplemental Table S1: Multilevel regression analyses to assess the independent effect of the intervention on primary and secondary clinical outcomes

Outcome*	Adjusted difference in change between groups†	p-value
HbA1c‡	-0.11 (95% CI -0.42 to 0.21)	0.511
Systolic blood pressure§	-4.29 (95% CI -8.19 to -0.39)	0.031
Diastolic blood pressure§	-3.58 (95% CI -5.96 to -1.19)	0.003
LDL-cholesterol‖	-0.18 (95% CI -0.42 to 0.05)	0.130

*Difference from baseline to follow-up. †Coefficient for treatment group; negative value indicates greater negative change and positive value greater positive change in intervention group compared to controls. ‡Multivariate controlled for: PCP as cluster level, patient's sex, patient's age, smoking status, BMI, number of comorbidities, number of visits during study year, total number of drugs, antidiabetic therapy, and change of antidiabetic therapy. §Multivariate controlled for PCP as cluster level, patient's sex, patient's age, smoking status, BMI, number of comorbidities, number of visits during study year, total number of drugs, antihypertensive therapy, and change of antihypertensive therapy. ‖Multivariate controlled for PCP as cluster level, patient's sex, patient's age, smoking status, BMI, number of comorbidities, number of visits during study year, total number of drugs, lipid-lowering therapy, and change of lipid-lowering therapy.

Supplemental Table S2: Characteristics of health care utilization during the year of intervention, other patient's outcomes and medication at baseline and follow-up in type 2 diabetes patients per allocated group

	No of participants (baseline/follow-up)		N (%) outcome at baseline		N (%) outcome at follow-up	
	Intervention	Control	Intervention	Control	Intervention	Control
Health care utilization						
Hospitalizations due to hypoglycemic episodes*	n/a/115	n/a/142			1 (1)	1 (1)
Hospitalizations due to hyperglycemic episodes*	n/a/115	n/a/142			0 (0.0)	3 (2)
Hospitalizations due to cardiovascular episodes*	n/a/114	n/a/142			8 (7)	6 (4)
Hospitalizations due to other reasons*	n/a/114	n/a/142			7 (6)	12 (8)
Other patient's outcomes						
Number of visits in general practice† (m, SD)	162/143	163/153	8.3 (6.6)	7.9 (5.1)	9.6 (5.6)	8.4 (5.9)
Compliance (m, SD)‡	160/145	164/156	1.91 (0.70)	1.84 (0.77)	1.94 (0.79)	1.83 (0.8)
Severe hypoglycemia (≥1 episodes)†§ (m, SD)	162/146	164/156	13 (8.0)	19 (11.6)	12 (8.2)	8 (5.1)
Foot status (pathological)‖	161/145	164/155	30 (18.6)	22 (13.4)	26 (17.9)	28 (18.1)
Peripheral pulse status (pathological)¶	162/144	164/156	50 (30.9)	47 (28.7)	40 (27.8)	52 (33.3)
Monofilament test (pathological)#	161/144	151/155	17 (10.6)	25 (16.6)	22 (15.3)	31 (20.0)
Annual eye exam† pathological non-pathological not conducted	162/144	161/155	 15 (9.3) 104 (64.2) 43 (26.5)	 13 (8.1) 90 (55.9) 58 (36.0)	 15 (10.4) 110 (76.4) 19 (13.2)	 11 (7.1) 88 (56.8) 56 (36.1)
Medication						
Any antidiabetic therapy	159/147	164/154	155 (97.5)	157 (95.7)	143 (97.3)	146 (94.8)
Oral alone**	159/147	164/154	108 (67.9)	100 (61.0)	97 (66.0)	91 (59.1)
Insulin alone**	159/147	164/154	11 (6.9)	15 (9.1)	11 (7.5)	14 (9.1)
Combined (insulin and oral) **	159/147	164/154	36 (22.6)	41 (25.0)	35 (23.8)	41 (26.6)
Specific antidiabetic therapies						
Insulin**	159/147	164/154	47 (29.6)	56 (34.1)	46 (31.3)	55 (35.7)
Metformin/Biguanid	159/147	164/154	132 (83.0)	122 (74.4)	124 (84.4)	116 (75.3)
Sulfonylurea	159/147	164/153	67 (42.1)	69 (42.1)	65 (44.2)	55 (35.9)
Gliptine (DPP-III)	159/147	164/154	20 (12.6)	24 (14.6)	26 (17.7)	31 (20.1)

	No of participants (baseline/follow-up)		N (%) outcome at baseline		N (%) outcome at follow-up	
	Intervention	Control	Intervention	Control	Intervention	Control
Glitazone	159/147	164/154	8 (5.0)	11 (6.7)	4 (2.7)	14 (9.1)
Glinide	159/147	164/154	7 (4.4)	3 (1.8)	3 (2.0)	3 (1.9)
Incretin mimetic	159/146	164/154	3 (1.9)	3 (1.8)	2 (1.4)	0 (0)
α-Glucosidase inhibitor	158/147	164/154	4 (2.5)	0 (0)	3 (2.0)	0 (0)
*Any antihypertensive therapy***	159/147	164/154	117 (73.6)	129 (78.7)	113 (76.9)	129 (83.8)
Diuretics	159/147	164/153	72 (45.3)	88 (53.7)	79 (53.7)	91 (59.5)
Inhibitor of the angiotensin converting enzyme (ACE-I)	159/147	164/153	80 (50.3)	76 (46.3)	69 (46.9)	62 (40.5)
Beta-blocker	159/147	164/154	46 (28.9)	55 (33.5)	45 (30.6)	53 (34.4)
Angiotensin II inhibitor (ARB)	159/147	164/153	25 (15.7)	45 (27.4)	35 (23.8)	53 (34.6)
Calcium antagonists	159/147	164/154	33 (20.8)	31 (18.9)	37 (25.2)	34 (22.1)
other antihypertensive agents	159/147	164/154	2 (1.3)	2 (1.2)	8 (5.4)	14 (9.1)
*Any lipid-lowering therapy***	159/147	164/154	80 (50.3)	102 (62.2)	80 (54.4)	96 (62.3)
Statin	159/147	164/154	79 (49.7)	101 (61.6)	78 (53.1)	94 (61.0)
other lipid-lowering therapy	159/147	164/154	5 (3.1)	3 (1.8)	4 (2.7)	3 (1.9)
*Any antiplatelet therapy***	159/147	164/154	78 (49.1)	101 (61.6)	81 (55.1)	98 (63.6)
Aspirin	159/147	164/154	70 (44.0)	88 (53.7)	71 (48.3)	85 (55.2)
Phenprocoumon	159/146	164/154	10 (6.3)	11 (6.7)	9 (6.2)	13 (8.4)
Clopidogrel	159/147	164/154	9 (5.7)	8 (4.9)	8 (5.4)	5 (3.2)
Any antidepressants	159/147	164/154	22 (13.8)	15 (9.1)	26 (17.7)	24 (15.6)
Number of drugs total (m, SD)	157/145	164/150	4.6 (2.2)	4.9 (2.2)	5.1 (2.2)	5.3 (2.0)

*At least 1 hospitalization within the last 12 months. †Within the last 12 months. ‡Compliance assessed by GP: 1=very good, 2=rather good, 3=rather bad, 4=very bad. §Clinical symptoms and/or hospitalizations/need for action. ‖Pathological if either osteoarthropathy, mycosis or ulcerations. ¶Pathological if 1 of 4 arteries non-palpable (A. tibialis posterior, a. dorsalis pedis), bilateral. #According to Semmes-Weinstein. **1 or more drugs possible.