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ORIGINAL ARTICLE

No selection, but higher satisfaction of people participating in the disease management programme diabetes type 2 in Germany

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Abstract

Aims We analysed metabolic control, complications and satisfaction in people with and without DMP participation.

Methods We retrospectively analysed the German data of the GUIDANCE study. The general practices included ($n = 38$) were selected from the physicians' register of the Thuringian Association of Statutory Health Insurance Physicians. Half of the practices ($n = 19$) participated in the DMP "Diabetes mellitus type 2".

Results Nine hundred and fifty-nine people were included in the analysis. Of these, 541 (56.4%) were enrolled in the DMP and 418 (43.6%) not. There was no difference between the two groups (DMP vs. no DMP) regarding age (67.8 vs. 67.6y), gender (female 50.6 vs. 52.2%), diabetes duration (9.8 vs. 9.5y), BMI (31.3 vs. 30.7 kg/m^2), HbA1c (7.2 vs. 7.2%), systolic blood pressure (139 vs. 140 mm Hg) or antihypertensive drug (89.5 vs. 88.8%). More DMP participants had regular screening of diabetic late complications: retinopathy 84.7 versus 69.9% ($p < 0.001$); polyneuropathy 93.0 versus 52.6% ($p < 0.001$). Chronic kidney disease was more frequent in DMP participants (15.0 vs. 9.3%, $p = 0.005$). Treatment satisfaction was higher in participants enrolled in the DMP (31.1 vs. 30.0; $p = 0.002$).

Conclusions DMP participants do not exhibit positive selection. Process quality and treatment satisfaction are higher in DMP participants.

Keywords Disease management programme · Type 2 diabetes · Treatment satisfaction

Abbreviations

BMI	Body mass index
HbA1c	Glycated haemoglobin
DMP	Disease management programme
DTSQ	Diabetes Treatment Satisfaction Questionnaire

Introduction

The care of chronically ill patients is a core issue of health policy, both in Germany and in other countries. The basis is a uniform quality of care and the management of the costs [1].

The disease management programme (DMP) "Diabetes mellitus" was introduced in Germany in 2002 with the aim of improving the treatment and processing quality. Hereby, late complications should be reduced by structured and continuous diabetes care. The four core elements of the DMP are as follows: (1) integrated practice guidelines, (2) integrated care structures, (3) integrated quality management and (4) patient education programmes [2].

The number of people participating in the DMP is rising. In the German state of North Rhine-Westphalia, the number of enrolled patients has doubled from 253.351 in 2005 to 528.064 individuals in 2015 [3, 4]. The evaluations of type 2 diabetes data indicate positive results. People enrolled in the DMP were more likely to receive structured, patient-oriented medicine; a higher percentage received medication against hyperglycaemia, hypertension and hypercholesterolaemia, had improved HbA1c and blood pressure and had more frequent foot examinations and screenings for retinopathy [5–8]. Furthermore, people enrolled in the DMP had at least a survival benefit [9].

Additionally, doubts were cast whether the DMP is actually beneficial considering the lack of randomised controlled

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trials. However, it would be unethical to do such trials which withhold from people with diabetes mellitus elements of treatment after implementation of the DMP as a medical standard throughout the country. Thus, the lack of an adequate control group remains the most common criticism of the results of the DMP. A selection bias through the enrolment of healthier patients with higher social status is repeatedly discussed.

The aim of this retrospective, observational analysis was to compare German participants of the GUIDANCE study with and without DMP participation, regarding metabolic control, late complications and process parameters.

Research design and methods

The GUIDANCE study is a retrospective, cross-sectional study on the level of ambulatory care based on records of 7.597 people with type 2 diabetes in France, Belgium, Italy, the Netherlands, Sweden, UK, Ireland and Germany. Methods and main results of the GUIDANCE Study were published previously [10].

The GUIDANCE Study included adult people with type 2 diabetes in primary and secondary ambulatory care. The main exclusion criteria were as follows: patients with other types of diabetes; patients not usually managed at the recruiting site; severe physical or mental health conditions; pregnancy and inability or unwillingness to provide written consent. The data were collected from March 2009 to December 2010. The responsible Ethics Committee had given approval. All participants signed informed consent.

We analysed the German cohort of the GUIDANCE data with 959 individuals from 38 practices in Thuringia. The general practices were selected from the physicians' register of the Thuringian Association of Statutory Health Insurance Physicians in a kind of quasi-randomisation. It means that per district a physician was recruited in a blinded manner. If the physician objected to participating in the study, another physician from the same district was recruited and so on. Altogether we invited 186 physicians and 38 were enrolled. The participating physicians were asked to fill out a questionnaire, and the data were collected. Half of the 38 practices ($n = 19$, 50%) participated in the DMP "Diabetes mellitus type 2".

Data of study participants were collected from the medical records. Potential patients were recruited by their physicians/nurses.

Each participating practice provided details of their HbA1c method and the normal range of people without diabetes. The HbA1c values of the participants were adjusted to the mean normal value of healthy people of the Diabetes Control and Complications Trial (DCCT (5.05%, 32 mmol/mol) [11, 12].

Heart disease was defined as the presence of coronary heart disease or heart failure.

People were asked if they were satisfied with their HbA1c. Satisfaction with the diabetes treatment was evaluated with the "Diabetes Treatment Satisfaction Questionnaire Status" (DTSQs) (range 0–36) [13]. Higher scores indicate greater satisfaction with treatment. The generic health status was measured with the EQ5-D visual scale (range 0–100), and higher scores indicate higher generic health status [14].

Statistical analysis

The characteristics of the participants were described by mean and standard deviation for continuous variables, absolute and relative frequency for categorical variables. Intergroup differences were examined subject to the type of scale using either Fisher's test or t test. A p value < 0.05 was considered statistically significant. Statistical analysis was performed with IBM SPSS Statistics 22 (IBM Corp., Armonk. NY).

Results

Nine hundred and fifty-nine people from 38 practices in Thuringia, Germany (mean age 67.7y, diabetes duration 9.7y, HbA1c 7.2% (55 mmol/moll)), were included. Of those, 541 (56.4%) individuals participated in the DMP and 418 (43.6%) did not. 87.5% ($n = 839$) were retrieved from primary and 12.5% ($n = 120$) from secondary (specialist) care level. All people from secondary care participated in the DMP. On average, 25 people (2–94) from each practice were enrolled.

No differences existed between DMP versus no DMP participants regarding age, gender, diabetes duration, HbA1c, body mass index (BMI) as well as systolic blood pressure and number of people receiving antihypertensive treatment (Table 1).

More DMP participants were treated with statins (45.3 vs. 38.0%; $p = 0.017$) and insulin (41.6 vs. 33.3%; $p = 0.009$). On the contrary, no DMP participants had more often oral antidiabetic drug therapy with Metformin (57.4 vs. 50.3%; $p = 0.031$).

28.3% of all study participants had at least one diabetes-related late complication of the eyes, kidney or foot. Diabetic late complications occurred more frequently in DMP participants with 33.5 vs. 21.5% with at least one complication ($p < 0.001$). In detail: neuropathy 24.8 vs. 12.2% ($p < 0.001$), chronic kidney disease 15.0 vs. 9.3% ($p = 0.005$) as well as foot ulcers (3.9 vs. 1.0%; $p = 0.004$).

There was no difference regarding the prevalence of retinopathy (11.1 vs. 7.7%, $p = 0.078$), blindness (0.6 vs. 1.0%, $p = 0.477$), lower limb amputation (1.7 vs. 1.0%,

Table 1 Comparison of people with and without participation in the DMP

Characteristic	DMP ($n = 541$)	No DMP ($n = 418$)	p value
Age (y)	67.8 ± 9.7	67.6 ± 10.3	0.746
Female n (%)	274 (50.6)	218 (52.2)	0.692
Diabetes duration (y)	9.8 ± 6.9	9.5 ± 7.6	0.506
HbA1c (%) (mmol/mol)	7.17 ± 1.0 (54.9 ± 12.6)	7.15 ± 1.2 (54.7 ± 10.4)	0.810
BMI (kg/m^2)	31.3 ± 5.5	30.7 ± 5.4	0.193
Systolic blood pressure (mm Hg)	139.1 ± 14.6	140.3 ± 16.3	0.215
Diastolic blood pressure (mm Hg)	82.4 ± 8.6	80.8 ± 8.8	0.007
Late complications			
Retinopathy n (%)	60 (11.1)	32 (7.7)	0.078
Blindness n (%)	3 (0.6)	4 (1.0)	0.477
Neuropathy n (%)	134 (24.8)	51 (12.2)	< 0.001
Foot ulcera n (%)	21 (3.9)	4 (1.0)	0.004
Amputation n (%)	9 (1.7)	4 (1.0)	0.410
Albuminuria n (%)	40 (13.5)	73 (9.6)	0.131
Chronic kidney disease n (%)	81 (15.0)	39 (9.3)	0.010
Serum creatinine (µmol/l)	88.7 ± 42.0	80.7 ± 18.6	0.010
Antihyperglycaemic medication n (%)	481 (88.9)	381 (91.1)	0.001
Antihypertensive agents n (%)	484 (89.5)	371 (88.8)	0.922
Statin n (%)	245 (45.3)	159 (38.0)	0.017
Treatment Satisfaction DTSQ (score 0–36)	31.1 ± 4.7	30.0 ± 5.4	0.002
Satisfaction with HbA1c n (%)	295 (54.7)	189 (45.0)	< 0.001
EQ5-D visual scale	69.6 (± 17.5)	69.6 (± 16.0)	0.960

$p = 0.410$) and heart disease (34.4 vs. 36.1%; $p = 0.586$) between DMP and no DMP participants.

The people who enrolled in the DMP had a slightly higher treatment satisfaction (31.1 vs. 30.0; $p = 0.02$) and were more satisfied with their own HbA1c value (54.7 vs. 45.0%; $p < 0.001$). A larger proportion of people in the DMP were satisfied with an HbA1c value > 7% (53 mmol/mol) than people not enrolled in the DMP (28.7 vs. 21.4%; $p = 0.047$) and vice versa a smaller proportion dissatisfied with an HbA1c ≤ 7% (53 mmol/mol) (15.8 vs. 24.6%; $p = 0.04$). More DMP participants took part in a stop-smoking programme if necessary (1.9 vs. 0.5%, $p = 0.009$) and were aware of diabetes guidelines or recommendations (61.9 vs. 38.1%; $p < 0.001$). No differences were seen in the generic health status (69.6 vs. 69.6; $p = 0.960$).

Screening for polyneuropathy (93.0 vs. 52.6%; $p < 0.001$), foot pulse (95.2 vs. 64.4%; $p < 0.001$), albuminuria (32.7vs. 18.4%, $p < 0.001$) and retinopathy (84.7 vs. 69.9%; $p < 0.001$) was performed more frequently in DMP participants, and more DMP participants took part in a diabetes treatment and education programme (73.3 vs. 55.7%; $p < 0.001$) (Table 2).

Discussion

The DMP for people with type 2 diabetes introduced in Germany in 2002 was often criticised for being a positive selection and the register and its results thus not being representative of the average German diabetes patient [2, 4]. Our results clearly demonstrate that patient characteristics of

Table 2 Comparison of people with and without participation in the DMP regarding process quality

Process quality	DMP ($n = 541$)	No DMP ($n = 418$)	p value
Screening of polyneuropathy n (%)	503 (93.0)	220 (52.6)	< 0.001
Screening of foot pulse n (%)	515 (95.2)	269 (64.4)	< 0.001
Screening for retinopathy n (%)	458 (84.7)	291 (69.9)	< 0.001
Screening of albuminuria n (%)	177 (32.7)	77 (18.4)	< 0.001
Participation in a diabetes education programme n (%)	395 (73.3)	233 (55.7)	< 0.001

DMP and non-DMP members were similar for age, diabetes duration and HbA1c. Hence, the postulation that predominantly healthier patients are enrolled in the DMP cannot be confirmed.

The prevalence of 33.5% of diabetes late complications is comparable to health insurance data from Germany with a prevalence of 33.9% [15]. However, our data also showed that the screenings for late complications are significantly more frequent in DMP participants. This could be one reason for the higher prevalence of complications. This assumption is supported by the data of Ullrich et al. [8] according to which non-DMP participants are treated more frequently for advanced complications in the hospital. Particularly noteworthy is the difference in the sum of minor and major amputations between DMP and non-DMP participants in the study by Ullrich et al. Furthermore, 12.5% of the people were enrolled from secondary care level and all enrolled in the DMP. It is known that the patients from secondary care level have more diabetes-related complications [16]. The physicians receive remuneration for each patient in the DMP, and as a prerequisite for this remuneration, they provide data. This could be an important reason for the better process quality and documentation.

Although people enrolled in the DMP had more diabetes-related complications, treatment satisfaction was higher (31 vs. 30 points). A possible reason could be that DMP participants reported a better patient-centred, structured and collaborative care compared to patients who did not participate in the DMP [5]. This is also reflected in our data taking into account the higher rate of screenings for late complications and the higher participation in patient education programmes.

Mean HbA1c in both groups was comparable and mostly on target, but people enrolled in the DMP were more satisfied with their HbA1c, even with an HbA1c value above 7% (53 mmol/l). This finding was also reported in the study by Elkeles et al. [7]. It is well known that social background is tightly linked to health status and outcome parameters [17]. In this study, only a marginal difference in the education level in favour of the DMP participants was present (49 vs. 45% have a higher school education) which is unlikely to explain the differences in satisfaction and health status. Graf et al. [18] showed in their study that DMP participants were more frequently involved in decisions concerning therapies and treatment targets. Less attention, communication and explanation from the physician could contribute to this finding. With regard to the problem of overtreatment, the patient-centred approach of the disease management programmes in combination with evidence-based treatment paths might reduce the extent of overtreatment.

These results reflect the efficiency of the disease management programme to implement guideline-based care and cost management. In a propensity score-matched survival time analysis of Drabik et al., this effect is shown with a longer survival time with lower costs for the health care system in DMP participants [19].

Our analysis has some limitations. Selection bias cannot be excluded. People had to give their consent. Therefore, it is possible that those with more severe health problems or very bad metabolic control were less likely to give their consent. It is also possible that predominantly primary care physicians with a special interest in diabetes agreed to take part in the study, which may not be representative of the average physician. Furthermore, it is possible that some patients who were treated by physicians who did not participate in the DMP are nevertheless enrolled in the DMP by other physicians, e.g. specialist. However, this is not very likely, as the majority of patients are treated exclusively by the primary care physician. On the other hand, patients who were treated by physicians who participate in the DMP are not enrolled in the DMP, because patients gave not their agreement. Another limitation is that only Thuringia practices were enrolled. A strength of our trial is the large number of patients and the very detailed, complete dataset.

Conclusions

In this retrospective analysis, comparing people with diabetes type 2 enrolled and not enrolled in a DMP and treated in the same area, no selection bias was found with respect to healthier persons in the disease management programme. The more frequent participation in patient education and training programmes, the regular and structured physician contacts and screening examinations, as well as a greater knowledge of the disease leads to a higher satisfaction of persons enrolled in the disease management programme. The guideline-based care, the patient-centred approach and the informed, shared decision-making should not, however, be reserved exclusively for DMP participants.

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Authors' contributions CK had the research idea and wrote the manuscript. NM researched data. NK, CKl, UAM and NM reviewed/edited the manuscript and contributed to the discussion.

Compliance with ethical standards

Conflict of interest No potential conflict of interest relevant to this article was reported.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the insti-

tutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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