'Knowing what matters in diabetes: healthier below 7': results of the campaign's first 10 years (part 1): participants with known type 2 diabetes

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Introduction During the 'Knowing what matters in diabetes: healthier below 7' diabetes campaign, more than 30 000 randomly participating individuals underwent an occasional, voluntary diabetes risk check between 2005 and 2014.

Methods This campaign aimed to inform individuals in Germany about diabetes mellitus and its complications, the established risk factors for development of type 2 diabetes (T2D), their prevalence and management in the real-life population, the quality of risk factor control and actual disease management in participants with a history of established diabetes mellitus [people with diabetes (PWD)]. Besides demographic characteristics (e.g. sex, age) and anamnestic information (antihypertensive treatment, history of elevated plasma glucose levels, genetic disposition), risk factor assessment included BMI, waist circumference, and lifestyle (physical activity, nutritional habits). The requested information was complemented by direct measurements of blood pressure (BP) (routine), plasma glucose, and HbA_{1c} (voluntary). Between 2005 and 2014, more than 31 000 individuals participated in 45 single campaigns in numerous German cities. Here, we report on the results of the subgroup of participants with known diabetes mellitus.

Results Among the 26 522 individuals with a completed questionnaire participating in the years 2006–2014, 21 055 participants (79.4%) did not have a history of diabetes and 5098 individuals (19.2%) reported being diagnosed with T2D, 369 (1.4%) with type 1 diabetes. The proportion of participants with T2D increased markedly over the years from 13.3 (2006) to 21.7% (2014). The age group older than 64 years was the largest within this subgroup (67.3%), 48.4% men and 51.6% women. The prevalence of overweight or obesity was found in 78% and 69.2% of the PWD. More than 40% of individuals with T2D had no regular physical exercise and more than 15% had unfavorable nutritional habits. In all, 69.9% of participants with T2D had elevated BP as assessed during the campaign or reported

Introduction

The prevalence and incidence of type 2 diabetes (T2D) are increasing steadily worldwide. With approximately six

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treatment with antihypertensive drugs at any time. On average, almost half of PWD (46.3%) had an HbA_{1c} above 7.0%; a significant trend toward higher values over the 10-year period was observed.

Conclusion The analysis of PWD participating in the 'Knowing what matters in diabetes: healthier below 7' campaign showed that despite huge efforts in the past, important aspects for progression and complications of T2D mellitus are still not well controlled. This includes lifestyle habits as well as pharmaceutical treatment. Although the participants in this study cannot be considered a representative sample of the German population and occasional measurements without standardization further limit firm conclusions, the BP, plasma glucose, and HbA_{1c} results indicate that a major proportion of PWD have insufficient metabolic and BP control. The marked increase in the proportion of T2D among all participants over time is consistent with the increasing prevalence of T2D mellitus found in many other countries worldwide in the recent decades. Our findings underline the importance of an optimized therapy for further improvement of disease management in those already diagnosed with this common chronic, progressive disease. Cardiovasc Endocrinol 5:14-20 Copyright © 2016 Wolters Kluwer Health, Inc. All rights reserved.

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million individuals diagnosed with T2D [1], Germany is among the countries with the highest prevalence of diabetes in Europe [2], not considering the probably significant number of individuals still undiagnosed.

The primary aim in the treatment of patients with manifest diabetes is to reduce disease-associated complications including macrovascular (coronary heart disease,

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myocardial infarction, stroke, peripheral occlusive disease) and microvascular disease (retinopathy, nephropathy) as well as neuropathy, diabetic foot syndrome, and in general quality of life. Early diagnosis of diabetes, lifestyle changes, and efficient, individualized therapies initiated early in the course of the disease can prevent subsequent complications that make diabetes one of the most expensive chronic diseases in Germany [3].

There is an ongoing scientific discussion on the targets of glycemic control (fasting or postprandial glucose or HbA_{1c}) and the optimal strategy for glycemia control in individuals with diabetes. Although an individual approach should be followed, there is a relatively broad consensus to recommend an HbA_{1c} below 7.0% (53 mmol/ml) for the prevention of diabetes-associated complications.

The guidelines of the American Diabetes Association recommend an HbA_{1c} below 7.0% to reduce microvascular complications [4]. A consensus paper of European Association for the Study of Diabetes and American Diabetes Association calls upon an individual approach, metabolic control, and individualized treatment taking into account patient age, duration of disease, comorbidities, and life expectancy [5]. Besides the promotion of prevention and early detection of diabetes, health care systems still strive to improve disease management.

Furthermore, the recommendations include an improvement of blood pressure (BP) and lipid management as these interventions have proven to be very efficient in reducing cardiovascular risk [6].

Background of the campaign

In 2005, the campaign 'To know what counts in diabetes: stay healthy below 7' was initiated to contribute toward activities addressing unresolved problems in diabetes. Carried out with many different partner organizations, the campaign aimed at raising awareness about the problem, to identify those at high risk, and to inform those who are already affected by T2D about the different aspects of risk factor management and measures to optimize their disease management.

More than 31 000 individuals have participated voluntarily since the start of the campaign by completing standardized questionnaires and undergoing specific investigations as described in the methodology section.

This paper summarizes the findings of risk factor management in patients who already had a diagnosis of T2D (because of the low number, individuals with type 1 diabetes are not considered). Data analysis included detection of possible trends over time.

Methodology

Between 2005 and 2014, during the 'Knowing what matters in diabetes: healthier below 7' campaign, 45 single campaigns were organized in shopping centers in several German cities. During these action days, center visitors were offered information on the metabolic disorder diabetes and had the opportunity to have their own individual diabetes risk determined by experts. Participants reporting to have diabetes (type 1 or 2) were offered to have their metabolic status checked including measurements of plasma glucose and HbA_{1c} as an indicator for long-term metabolic control and quality of treatment.

The following data were collected from all participants using the modified FINDRISK questionnaire developed by Lindström and colleagues [7,8].

- (1) Sex (male, female).
- (2) Weight (kg).
- (3) Height (cm).
- (4) Age (<45, 45–54, 55–64 and >64 years).
- (5) BMI ($< 25 \text{ kg/m}^2 = \text{normal range}, 25-30 \text{ kg/m}^2 = \text{overweight}$ and $> 30 \text{ kg/m}^2 = \text{obesity}$) classified according to the WHO criteria [9].
- (6) Waist circumference (<94, 94–102 and >102 cm for men and <80, 80–88, and >88 cm for women).
- (7) Familial diabetes risk (diabetes in first-degree relative/second-degree relative; yes/no).
- (8) Physical activity (≥30 min on most days a week; yes/ no).
- (9) Nutritional habits (daily consumption of vegetables, fruits, or whole grain bread; yes/no).
- (10) History of diabetes (type 1, type 2, no history).
- (11) Elevated plasma glucose level at any time in the past (yes/no).
- (12) History of antihypertensive drug therapy (yes/no).
- (13) Systolic and diastolic BP (mmHg) classified according to the ESH/ESC Guideline or management of arterial hypertension [10]. Hypertension was diagnosed when antihypertensive medication was taken or when random BP was more than 140/85 mmHg.

Participants could also have their plasma glucose levels checked voluntarily. Participants already diagnosed with T2D (as well as those without a known history of diabetes, but a moderate or a high diabetes risk score in the FINDRISK \geq 15) were proposed to have their HbA_{1c} value determined as one of the most important diagnostic criteria, with a value over 7.0% indicating poorly controlled diabetes (or a high probability of diabetes in nondiabetic participants).

In this paper, only the data collected from participants with known T2D are presented.

Biometric evaluation

All data collected between 2005 and 2014 were checked for completeness and plausibility. Implausible data were excluded from the statistical analysis. Missing data were not replaced.

For data analysis, descriptive methods were used. For quantitative parameters, the following statistical features were determined: mean, standard deviation, median, 25th and 75th percentiles, minimum and maximum values, 95% confidence intervals as well as the *P* values. For qualitative parameters, the absolute and relative frequencies were calculated and the results were presented as histograms or stack diagrams.

On the basis of the year of collection, the data were categorized into 10 annual slices (2005–2014).

The statistical procedures and the resulting P values were used exclusively for exploratory description of the results, without having any confirmatory nature.

The level of significance was generally set to 0.05 with α adjustment according to Bonferroni.

The results of all 10 single years have been examined, thus enabling the detection of changes and trends in patient characteristics as well as frequency and severity of risk factors and final outcomes over time.

As the questionnaire used in 2005 did not include differentiation between the types of diabetes and offered no possibility to establish whether diabetes was already diagnosed or not, the year 2005 was not included in any table or graph using these separate categories or in the following analysis.

Biometric evaluation was performed using the IBM SPSS Statistics 20 statistical software (IBM, Armonk, New York, USA).

Results

In total, of 45 single campaigns conducted in 25 cities all over Germany, a total of 31 085 questionnaires were collected.

Finally, a total of 26 522 questionnaires were evaluated (2006–2014). Of these 26 522 participants with valid questionnaires in the years 2006–2014, 5098 reported known T2D (19.2%).

Whereas in 2006 13.3% were people with diabetes (PWD), in 2014 21.7% had T2D; thus, the proportion of individuals with T2D has increased markedly over time (Fig. 1).

Age

Participants older than 64 years of age were the largest group of T2D patients, with an average frequency of 67.3% (ranging from 48.8% in 2013 to 71.6% in 2008) during the 10-year period. Only 3.2% of the participants with T2D



Percentage of participants with diabetes over time. DM, diabetes mellitus.

belonged to the youngest age category (<45 years); 7.4% of the participants were between 45 and 54 years of age and 22.1% were between 55 and 64 years of age.

The ratio between the age groups remained constant over the years.

Sex

In all, 51.6% of T2D patients were women and 48.4% were men. The sex ratios remained constant over the years.

BMI

More than one-third (34.4%) of all the T2D participants were obese, 43.6% were overweight, and only 22.5% of the diabetics had a BMI in the normal range (Fig. 2).

The median BMI was 28.1 kg/m², whereas it was 26.0 in the entire population (n = 30 119).

Whereas the proportion of individuals with low BMI $(< 25 \text{ kg/m}^2)$ was significantly higher in the entire population studied than among individuals with T2D, it was the opposite for high BMI $(> 30 \text{ kg/m}^2; \text{ Table 1})$.



Distribution of BMI classes among individuals with type 2 diabetes.

Table 1 BMI classes among all participants and individuals with type 2 diabetes

ВМІ	All participants (%)	T2D (%)	
< 25	35.9	21.9	
25–30	43.6	43.6	
> 30	20.5	34.4	

T2D, type 2 diabetes.

Fig. 3



Relative frequencies of BMI values in patients with type 2 diabetes over time.

In contrast to the entire population studied, there was no trend toward increasing BMI values over time (Fig. 3).

Waist circumference

Waist circumference values were above the critical values (>102 cm in men and >88 cm in women) in 69.2% of T2D without changes over time.

Lifestyle: exercise and nutrition

Almost half (40.7%) of the T2D participants reported that they did not exercise regularly, whereas 16.2% reported that they did not eat fruits, vegetables, and whole grain bread on a daily basis. Similar to nondiabetic participants, a trend toward less favorable nutritional habits was found over the years (P < 0.001).

Diabetes in the family

Overall, 55.9% of T2D participants reported the presence of this disease in first-degree and/or second-degree relatives, whereas this proportion was 39.8% among nondiabetics.

Blood pressure and antihypertensive medications

Compared with 42% of all participants, almost 73% of the participants with T2D reported that they are taking – or have taken at any time in the past – antihypertensive medication; these PWD should be considered known

hypertensives as they were, or had been, treated with antihypertensive medication.

The mean systolic BP in PWD was 149.9 mmHg (n = 4763) and the mean diastolic BP was 85.8 mmHg (n = 4760). No trend toward improvement in BP control over the years was observed.

In all participants, the mean BP was 143.5 mmHg (systolic; n = 29283) and 85.3 mmHg (diastolic; n = 29268), respectively.

When considering the threshold values of 140 mmHg (systolic) and 85/90 mmHg (diastolic) for differentiation of participants with versus without hypertension, 69.9% of participants with T2D had manifest hypertension compared with 57.8% (15 933 out of 27 589) of all participants (Table 2), which is consistent with the proportion defined by intake of antihypertensives.

HbA_{1c}

A total of 4170 HbA_{1c} measurements were performed in PWD (about 82% of participating PWD had their HbA_{1c} measured during the campaign).

Almost half of the participants with already diagnosed T2D had HbA_{1c} values greater than 7.0%, which indicates suboptimal plasma glucose control. Furthermore, one-tenth of these participants had HbA_{1c} values between 8.0 and 9.0% and ~4% had HbA_{1c} values above 9.0% (Table 3). These proportions were comparable in men and women.

Only 54% had their HbA1c at target (<7%).

Over the years, a temporal trend toward higher HbA_{1c} values was observed in T2D patients (P < 0.001; Fig. 4).

Discussion and conclusion

Initiated in 2005, the nationwide campaign 'Knowing what matters in diabetes: healthier below 7' generated considerable interest among the German population.

During the 10-year period (2005–2014), a total of 31 085 individuals participated. For most variables, 26 522 valid questionnaires were collected between 2006 and 2014 including 5098 questionnaires of participants with a history of T2D (21% of the total population) and 369 questionnaires of participants with type 1 diabetes

Table 2	Blood	pressure a	and use	of antih	ypertensive	agents
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	All participants	PWD
Mean RR systolic	143.5	149.9
Mean RR diastolic	85.3	85.8
AHT (%)	42.2	72.9
Individuals with documented increased blood pressure (>140/>85 mmHg) (%)	57.8	69.9

AHT, anti hypertensive treatment; PWD, people with diabetes; RR, hypertension.

Table 3 HbA1c values in individuals with T2D

HbA _{1c} (%)	Individuals	
< 7.0	53.7	
≥ 7.0	46.3	
8.0 to 9.0	10.9	
> 9.0	4.4	

T2D, type 2 diabetes.





Evolution of HbA1c levels over time in T2D. T2D, type 2 diabetes.

(1.4%); in this report, we have only analyzed those with known T2D.

In these 10 years, the proportion of participants with known diabetes mellitus increased markedly from 14.3% in 2006 to 23.4% in 2014. This increase may at least in part be attributed to increasing awareness of the campaign among individuals with known or suspected diabetes, and thus may not reflect a factual increase in the prevalence of diabetes of the same magnitude. However, there are several reports on a similar increase in the prevalence of T2D in the general population including such different countries as Sweden [11], Portugal [12], and Iran [13] and even in children [14]. Consequently, the prevalence of prediabetes was also reported to increase, for example, in the UK from 2003 to 2011 [15].

The results of the 'Knowing what matters in diabetes: healthier below 7' campaign also confirm earlier findings by the Robert Koch-Institute, which show an increasing prevalence of diabetes mellitus in the German adult population between 2003 and 2009 [16]. This increase can at least partially be explained by an increasing prevalence of risk factors such as an unhealthy lifestyle, and consequently the prevalence of overweight and obesity.

Lifestyle risk factors

As expected, a large proportion of PWD showed established risk factors. The prevalence of overweight and obesity was observed in more than three quarters (78%) of the participants, with 44% being overweight and 34% being obese. Also, 69.2% had a waist circumference above 88/102 cm, which, together with plasma glucose, BP, and serum lipids, which have not been investigated in this study, is indicative of metabolic syndrome [17].

Lifestyle management remains suboptimal as 41% of the PWD admitted that they do not exercise on a daily basis; furthermore, about 15% did not follow a diet rich in fiber. Considering that there is usually an underreporting/ reporting bias, the proportion of patients actually adhering to a diet and therapeutic lifestyle change should be expected to be even much lower.

HbA_{1c}

Importantly, desirable glycemic control, as indicated by an actual measured HbA1c, turned out to be suboptimal in almost 50% of the patients as 46.3% had an HbA_{1c} more than or equal to 7.0% and more than 10% had an HbA_{1c} more than or equal to 8.0%, the latter not fulfilling even less stringent criteria for glycemic control [6].

This finding is in accordance with other observations, which indicate that a considerable proportion of patients with diabetes mellitus do not achieve their targets [18]. The recent report of the ARIC (Atherosclerosis Risk in Communities) study, however, indicated somewhat better metabolic control in that population as about 72% had an HbA_{1c} below 7% [19].

Blood pressure control

Furthermore, in many intervention studies [20,21], it was clearly shown that T2D patients benefit from good BP control. Therefore, the guidelines for the management of arterial hypertension [9] set a target less than 140 mmHg for systolic BP of, and less than, 85 mmHg for diastolic BP. In this analysis, only 30% of the participants had adequate BP control. BP management in PWD is often not adequate; many studies indicate suboptimal BP control [22,23]. As an exception, the ARIC population showed BP less than 140/090 mmHg among 73% of PWD [19].

Limitations

However, the limitations of the campaign have to be considered. As the data collection took place in the context of several single campaigns in German cities, there is an evident selection bias: individuals were from geographically restricted regions in the vicinity of campaign sites that cannot be considered representative for the entire German population. Also, participants might represent a positive selection of individuals with known T2D as these might have been more interested in obtaining additional information about their disease and volunteered to participate in the metabolic testing. Certainly, therefore, the data are not

representative for the entire German population and our results are not comparable with the results of populationbased studies, in which the frequency and distribution of diabetes risk factors have been determined [24–26].

However, even if one takes this into account, it is important to note that even in that somewhat 'preselected' group, measures of individual lifestyle and the assessed risk factor management were shown to be suboptimal in most individuals with T2D.

Thus, the results of the present study provide a view on the current risk factor management and treatment quality in already diagnosed T2D in Germany.

Our results show that activities such as the 'Knowing what matters in diabetes: healthier below 7' campaign are necessary and important as they can increase awareness and draw attention to a widespread disease such as diabetes mellitus and its risk management. The campaign showed that those with already diagnosed diabetes have a marked deficit in good cardiometabolic risk factor control; therefore, reminding them of the importance of a good and comprehensive risk management such as good plasma glucose and BP control and, most importantly, improvement of their individual lifestyle could contribute toward better management of diabetes.

The results of this campaign should have implications and consequences for all parties involved in diabetes care: general practitioners, diabetes specialists, and clinicians as well as health insurance companies. Individuals with diabetes should be aware that they benefit from a more comprehensive risk factor management including good glycemic control but also strict BP and lipid management. However, most importantly, a better lifestyle is required.

Overall, with respect to individuals with known T2D, our campaign showed that these individuals often show unsatisfactory risk factor control. It has to be pointed out that these results have been found in a highly developed Western country with a sophisticated medical infrastructure and providing free access to medical care and a multitude of elaborate patient education programs. This is why it is very important that programs such as the 'Knowing what matters in diabetes: healthier below 7' campaign increase public awareness of this disease and its complications, and also the importance of a broad risk factor management.

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Conflicts of interest

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