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‘Knowing what Matters in diabetes: Healthier below 7’: results of the campaign’s first 10 years (part 2), participants without known diabetes history

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Introduction **Type 2 diabetes represents a major problem in many societies. Early detection and, even better, prevention could help to reduce the burden of the disease. Therefore, increased awareness of disorders of glucose metabolism is important. During the campaign ‘Knowing what Matters in diabetes: Healthier below 7’, in the last few years, more than 31 000 shopping mall visitors in Germany were voluntarily checked for their potential diabetes risk.**

Methods **With a modified FINDRISK questionnaire, demographic, anthropometric and anamnestic data relevant for the estimation of the potential diabetes risk were collected. In addition, medical data such as plasma glucose, blood pressure (BP), BMI and waist circumference were obtained. Furthermore, lifestyle habits were documented. Hemoglobin (Hb)A_{1c} was assessed randomly in a subgroup of individuals ($n = 4133$). In total, data from 26 522 valid questionnaires were collected and evaluated over 10 years (2005–2014) from 45 single locations throughout Germany. Results from participants with manifest diabetes have already been published in this journal. Here, we report on the results from participants without a previous history of diabetes mellitus.**

Results **Among the 26 522 participants with a completed questionnaire, 21 055 (79.4%) participants did not have a previous history of diabetes. Characteristic risk factors for diabetes were common in this group. With about 17% being obese and 40% being overweight, more than half of these individuals were thus beyond the normal BMI range. In addition, waist circumference exceeded common thresholds in 44% of the participants. As expected, many of them followed an unhealthy lifestyle as 35% reported no regular physical activity and 20% reported an unhealthy diet. The mean BP was 141/85 mmHg. More than half (51%) half of the patients in the nondiabetic group had a systolic BP above 140 mmHg, but only one-third (35%) reported concomitant treatment with antihypertensives. In the questionnaire, 14% of the participants had a FINDRISK sum score of 15 points and above, indicating a moderate or high risk of potentially developing type 2 diabetes within 10 years. Surprisingly, in the subgroup with HbA_{1c} measurements ($n = 4133$), 18.5% of the participants without a diagnosis or a history of diabetes were found to have an HbA_{1c} value of at least 6.5% indicating manifest, previously undetected type 2 diabetes.**

Conclusion **The data collected in individuals without a known history of diabetes indicate a considerable prevalence of typical risk factors associated with diabetes. In addition, the data confirmed that screening of apparently healthy individuals consistently shows a significant proportion of individuals with previously undetected type 2 diabetes which, in the subgroup, was surprisingly high. As there is convincing evidence for the beneficial effect of relatively simple lifestyle interventions such as an increase of physical activity and avoidance of unfavourable diets, and weight reduction, campaigns such as ‘Knowing what Matters in diabetes: Healthier below 7’ can be an appropriate option to encourage primary prevention among the sedentary population as well as a suitable tool for early disease recognition. Therefore, campaigns such as this should be intensified and options for early preventive intervention should be offered to reduce long-term disease burden and healthcare costs.** ***Cardiovasc Endocrinol*** **6:48–54 Copyright © The Author(s). Published by Wolters Kluwer Health, Inc.**

Cardiovascular Endocrinology 2017, **6**:48–54

Keywords: diabetes mellitus, hypertension, primary prevention, risk factors, screening, type 2 diabetes

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Received 15 September 2016 **Accepted** 16 November 2016

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DOI: 10.1097/XCE.0000000000000109

Introduction

Type 2 diabetes is a steadily increasing problem for healthcare systems worldwide and Germany is one of the most severely affected countries in Europe [1,2]. As

many patients live with undiagnosed diabetes, the high incidence and prevalence figures still underestimate the problem.

Early diagnosis and changes in lifestyle supplemented by individually tailored antidiabetic treatment can prevent or at least delay microvascular and macrovascular complications in manifest diabetes [3].

There is consensus that primary prevention is even more important to reduce the incidence, the associated disease burden and healthcare costs of this chronic progressive disease in the future [4]. Theoretically, this should be relatively easy to achieve. As the most important risk factors for the development of diabetes have been well known for decades, almost all of them can be influenced or modified and thus support the decrease of the individual diabetes risk [5,6].

It is well known that physical inactivity and less favourable nutritional habits are the main drivers of weight gain and obesity concurrently promoting the development of impaired glucose tolerance, insulin resistance and finally type 2 diabetes mellitus. In Germany, more than half of the adult population is considered overweight and approximately one-quarter is already obese [7]. Meanwhile, this disease is also increasingly being diagnosed in children and adolescents [8].

A family history of diabetes, hypertension and several other modifiable risk factors also contribute towards the development of impaired glucose metabolism and permanent hyperglycemia [9].

Background of the campaign

In 2005, the campaign 'Knowing what Matters in diabetes: Healthier below 7' was initiated to raise awareness of the disease, to identify individuals with a potential risk of developing diabetes and to inform those who are already affected about an optimized diabetes management; therefore, the term 'below 7' refers to the hemoglobin (Hb)A_{1c}-target for those with a history of diabetes.

Everyone was invited to participate in the shopping mall activities – irrespective of known/unknown diabetes diagnosis, age, sex, BMI or other individual characteristics, and no selection process was applied. Thus, the participants of the campaign represent a random sample of the general population.

By the end of 2014, more than 31 000 individuals had participated voluntarily by completing standardized questionnaires and had undergone examinations with respect to key metabolic parameters and other diabetes risk factors. The results from 5098 participants who already had a manifest diagnosis of type 2 diabetes have been published earlier [1].

Methodology

Methods applied during the campaign have been described in detail elsewhere [1]. In brief, 45 single campaigns have been conducted in German shopping malls between 2005 and 2014 offering voluntary participation to visitors. This included the completion of a modified FINDRISK questionnaire with eight items [10] and additionally blood pressure (BP) and blood glucose measurement and optionally the determination of HbA_{1c}.

In addition to the results published for participants with manifest type 2 diabetes [1], this paper presents the data collected from participants without a previous history of diabetes.

Weight and height were documented as indicated by participants. BP was measured in the right arm in the sitting position after an obligatory 5 minutes rest. Waist circumference was measured with an appropriate tape according to official recommendations [11]. HbA_{1c} was measured using the Progen/Alere A_{1c}-test kit (Alere Technologies GmbH, Jena, Germany) as described previously [1]. A modified version of Lindstroem's FINDRISK questionnaire [10] was used.

Biometric evaluation

After checking for completeness and plausibility, unlikely data were excluded from the statistical analysis. Missing data were not replaced. Because of missing items on history and type of diabetes in the 2005 questionnaire, this year was considered a feasibility period and therefore excluded from respective analyses.

As the investigation followed an exploratory approach, only descriptive statistical methods were used for data analysis. To detect trends during the 10-year observation period, the results of the campaign were examined year by year. The level of significance was generally set to 0.05, with α adjustment according to Bonferroni.

The biometric evaluation was performed using the 'IBM SPSS Statistics 20' statistical software (IBM Corporation, Armonk, New York, USA). Further details on statistics can be found in [1].

Results

In total, from 45 single campaigns conducted in 25 German cities, 31 085 questionnaires were collected and consequently 26 522 complete questionnaires were evaluated (2006–2014). Of these 26 522 participants, the majority of 21 055 (79.4%) attendants reported no history nor a previous diagnosis of type 1 or type 2 diabetes mellitus. The proportion of participants without known diabetes varied between 73.4% (2011) and 88.0% (2013).

Age

Age was documented in 21 035 participants without a previous history of diabetes. The majority (40%) of the individuals were older than 64 years of age, 21.7% were

between 55 and 64 years of age and 38.4% were younger than 55 years of age.

Sex

In total, 62.5% of nondiabetic participants were women and 37.5% were men. This represented a significant difference between the sexes without any trend over time.

Diabetes in family history

Almost 40% of the participants without manifest diabetes reported manifest diabetes in first-degree and/or second-degree relatives.

BMI

The mean BMI was 26.1 kg/m^2 and the median BMI was 25.6 kg/m^2. About 16.5% of all nondiabetic participants, that is, one out of six individuals, were obese, nearly 40% were overweight and less than half of the individuals (43.7%) had a BMI in the normal range (Fig. 1).

Compared with the group of patients with diabetes, the BMI was lower in the nondiabetic group with a markedly lower rate of obesity (Table 1).

In all the participants, there was no trend towards an increase in BMI values over time (Fig. 2).

Waist circumference

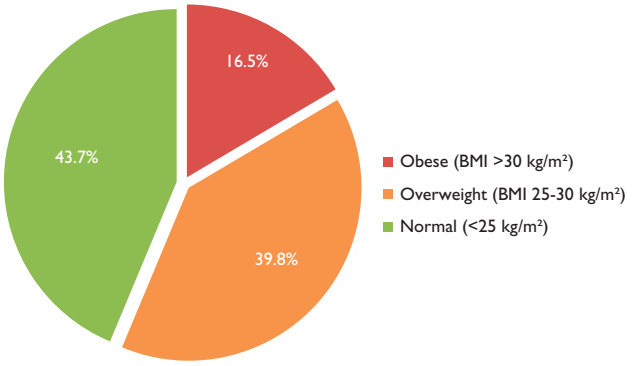
Waist circumference values were above the critical values (>102 cm in men and > 88 cm in women) in 44.0% of the nondiabetic participants. No trend over time could be detected (Fig. 3).

Lifestyle

Exercise

More than a third (34.9%) of the participants without diabetes reported a lack of physical activity, meaning that they did not exercise regularly. However, in this group,

Fig. 1

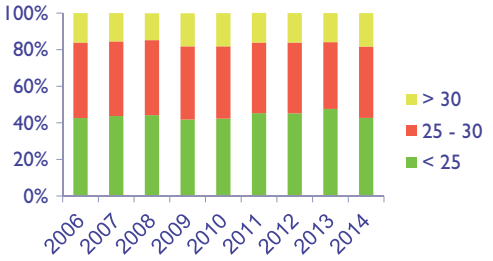


Distribution of BMI classes (%) among participants without a history of diabetes.

Table 1 BMI classes among all participants and those with and without known diabetes

BMI (calculated)	All participants [*n* (%)]	Nondiabetics [*n* (%)]	Type 2 diabetes [*n* (%)]
< 25	10 130 (39.4)	9037 (43.7)	1093 (21.9)
25–30	10 416 (43.6)	8241 (39.8)	2175 (43.6)
> 30	5141 (20.0)	3424 (16.5)	1717 (34.4)

Fig. 2



Relative frequencies of BMI values in participants without diabetes over time.

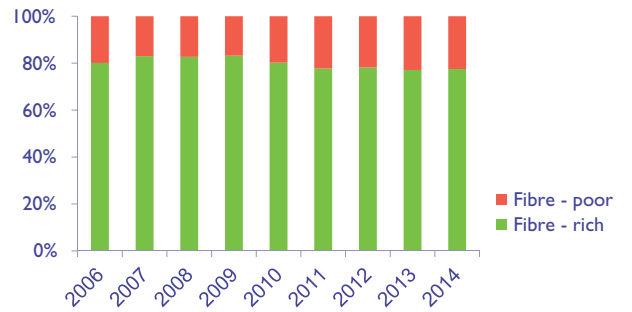
Fig. 3

Development of waist circumference in participants without diabetes over time.

Fig. 4

Proportion of participants with and without physical activity/exercise over time.

Fig. 5



Proportion of nondiabetic participants with and without a healthy/fibre-rich diet over time.

there was a temporal trend towards more physical activity over the 10 years of the campaign ($P < 0.001$; Fig. 4).

Nutrition

On average, 20% of nondiabetic participants reported less favourable nutritional habits, that is, no daily consumption of fruits, vegetables and whole-grain bread. A trend towards less favourable nutritional habits was found over the years ($P < 0.001$; Fig. 5).

BP and concomitant antihypertensive therapy

The mean systolic BP in the nondiabetic group was 141.4 mmHg and the mean diastolic BP was 85.2 mmHg, with a trend towards slightly lower systolic ($P < 0.01$) and higher diastolic ($P < 0.001$) BP values over the 10 years (data not shown). Patients with diabetes had a significantly higher systolic BP (Table 2).

Antihypertensive treatment was more frequent in the patients with diabetes (Table 3); however, at least 35% of those without known diabetes reported previous and/or current use of antihypertensives. Thus, about one-third of the nondiabetic participants must have had hypertension as they took antihypertensive medication.

However, systolic BP above 140 mmHg was found in more than half of the individuals in the nondiabetic group (51%), whereas among patients with diabetes, this was even higher (67%) – despite more antihypertensive medication (Table 3).

Table 2 Blood pressure values of participants with or without diabetes

	Nondiabetic participants		Type 2 diabetic participants	
Blood pressure (mmHg)	Systolic	Diastolic	Systolic	Diastolic
$N = 25\,050$	20 287	20 276	4763	4760
Mean	141.4	85.2	149.9	85.8
SD	21.5	11.8	22.2	12.5

Good BP control, as defined by less than 140/ < 90 mmHg, was found in 43% of the nondiabetic individuals and only 29% of the diabetic patients. As elevated BP is also one of the important predictors of type 2 diabetes, this furthers indicates the higher risk for DM2 in this nondiabetic population.

FINDRISK questionnaire

According to Lindström *et al.* [10], the FINDRISK sum score can take values between 0 (no risk at all) and 23 (considerable risk) (Table 4).

In total, about half of the nondiabetic participants had a low potential risk, 37% had a slightly increased risk, 14.3% showed a moderately increased risk and only 1.3% showed a very high risk of potentially developing type 2 diabetes within 10 years.

HbA_{1c} (in a random subgroup)

A total of 4133 HbA_{1c}, measurements were performed in individuals without previous diabetes, meaning that, randomly, about 20% of this group had their HbA_{1c} measured during the campaign.

The median HbA_{1c} value in the group of nondiabetics was 5.9% and thus significantly lower ($P < 0.001$) compared with 6.9% in participants with manifest type 2 diabetes ($n = 4170$). In contrast to patients with type 2 diabetes, no trend towards higher HbA_{1c} values over time was observed in nondiabetics.

In this subgroup, with randomly measured HbA_{1c}, surprisingly, a considerable proportion of individuals had an HbA_{1c} of at least 6.5%, which is – according to ADA [12] – equivalent to the diagnosis of type 2 diabetes, and another 24% showed an HbA_{1c} between 6.0 and 6.5%, which indicates a substantial risk (Table 5 and [12]).

Discussion

This study found a very high prevalence of risk factors for developing type 2 diabetes in a large group of nondiabetic participants of the campaign 'Knowing what Matters in diabetes: Healthier below 7' (Table 6). In the last 10 years, 21 055 individuals without a history of type 2 diabetes participated in a risk screening. In this group, a high proportion had a family history of diabetes, was overweight or obese and had an unhealthy lifestyle. Furthermore, hypertension was highly prevalent (and often uncontrolled); the FINDRISK questionnaire identified 16% with a substantial 10-year risk of diabetes and, even more surprisingly, in those in whom HbA_{1c} was tested, we found that almost 20% of the individuals had an HbA_{1c} of at least 6.5%, which means that a relevant proportion (1 out of 5) already had a diagnosed type 2 diabetes (Fig. 6).

Thus, in this nondiabetic group, we found a high proportion of participants with several risk factors for the development of diabetes (Table 6: almost 40% of the

Table 3 Concomitant medication and blood pressure in diabetic and nondiabetic participants

	All participants [*n* (%)]		Nondiabetic participants [*n* (%)]		Type 2 diabetic participants [*n* (%)]	
	Yes	No	Yes	No	Yes	No
On antihypertensive treatment	11 069 (42.5)	14 996 (57.5)	7393 (35.2)	13 631 (64.8)	3676 (72.9)	1365 (27.1)
Proportion with > 140/ > 90 mmHg	7062 (41.1)	10 103 (58.9)	5503 (27.1)	8727 (43.09)	1559 (32.8)	1376 (28.9)

Table 4 Allocation of nondiabetic participants to Findrisk classes

Findrisk sum score (modified according to [6]	Potential risk of developing type 2 diabetes within 10 years	Participants [*n* (%)]
< 10	Low (1%)	9965 (47.4)
10–14	Slightly elevated (4%)	7795 (37.0)
15–19	Moderately elevated (16%)	3.005 (14.3)
> 20	Very high (50%)	281 (1.3)

Table 5 Categories of increased risk for diabetes (prediabetes or impaired glucose metabolism)

Test	Term	Mg/dl	Mmol/l
Fasting glucose[a]	Impaired fasting glucose	100–125	5.6–6.9
2 h PG in the 75 g OGTT[a]	Impaired glucose tolerance	140–199	7.8–11.0
HbA_{1c}[a]	[a]	5.7–6.5%	39–46 mmol/mol

According to ADA [12].
HbA_{1c}, hemoglobin A_{1c}; OGTT, oral glucose tolerance test; PG, plasma glucose.
[a]For all three tests, the risk is continuous, extending below the lower limit of the range and becoming disproportionately greater at the higher end of the range.

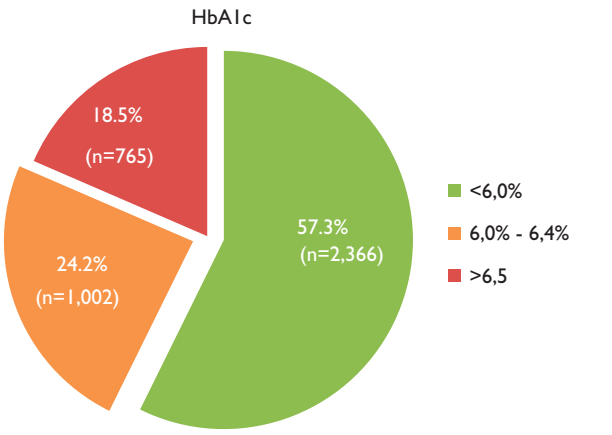
Table 6 Prevalence of risk factors in the nondiabetic population

Types of risk factor	Prevalence (%)
Overweight and obesity	56.3
Increased waist circumference	44.0
Hypertension (>140/ > 90 mmHg)	27.1
Systolic blood pressure (>140 mmHg)	51.1
On antihypertensive treatment	35.0
Positive family history for DM	40.0
Lack of exercise	34.9
Unfavourable diet	20.0
Moderately or highly elevated FINDRISK sum score	15.6
$HbA_{1c} \geq 6.5\%$ (newly diagnosed diabetes)	18.5

DM, diabetes mellitus; HbA_{1c}, hemoglobin A_{1c}.

participants reported the presence of diabetes in first-degree or second-degree relatives, which was a lower percentage than in the group of patients with manifest type 2 diabetes mellitus (56%) [1]. Overweight and obesity were highly prevalent, and yet not as high as in individuals with known diabetes. The waist circumference was above the critical values in 44% of the participants. An unhealthy lifestyle with a lack of physical activity was reported by 35% of the participants and less favourable nutritional habits were reported by 20%. Furthermore, hypertension was highly prevalent in the nondiabetic population, as indicated by the use of antihypertensives (35%) and the BP; 51% had a systolic BP more than 140 mmHg.

Fig. 6



HbA_{1c} values in the nondiabetic population. HbA_{1c}, hemoglobin A_{1c}.

Furthermore, in the subgroup with HbA_{1c} testing, not only did 18.5% already have manifest diabetes, another 24.2% had an HbA_{1c} between 6.0 and 6.4%, indicating an increased risk of diabetes [12]. Hence, these nondiabetic participants represent a high-risk group (Table 5).

Lifestyle modification needed

As BMI and body fat distribution are established risk factors for the development of type 2 diabetes, primary prevention has to target the main causes of overweight and obesity, mainly unfavourable nutritional habits and lack of physical activity. Therefore, it is alarming that among the participants without manifest diabetes, many more than half of them were overweight or obese and also nearly half of them had a waist circumference above the common threshold values that may indicate a metabolic disorder. As waist circumference is also directly associated with the amount of visceral fat, it is also closely linked to the pathophysiology of diabetes [13].

The risk of developing type 2 diabetes is further increased by a genetic disposition as about 40% of these individuals reported the prevalence of diabetes in close relatives.

As one out of three participants reported a lack of physical activity and one out of five participants had an unhealthy diet, lifestyle factors will contribute considerably towards the increasing incidence of diabetes in

Germany within the next few years. Taking into account the reporting bias, the lifestyle-associated risk in the general population is certainly much higher than reported here.

BP control – a lot of room for improvement and a risk predictor for diabetes

The mean measured systolic BP in the nondiabetic group was 141 mmHg and the mean diastolic BP was 85 mmHg with a trend towards slightly lower systolic ($P < 0.01$) and higher diastolic ($P < 0.001$) BP values over the 10 years; 35% of the participants were on antihypertensives, but 51% of the individuals in the entire group had systolic BP above 140 mmHg and altogether a considerable proportion had uncontrolled hypertension ($\geq 140/\geq 90$ mmHg). Increased BP is not only a risk factor for cardiovascular disease but also another risk factor for the development of type 2 diabetes. Compared with individuals with diabetes, however, the prevalence of hypertension and uncontrolled BP was lower (Table 3).

Early detection and intervention matters

Numerous publications have clearly shown that prevention programmes aimed at a healthier diet and an increased physical activity can have a considerable beneficial effect on risk factors and diabetes incidence. Improvements in body weight, diet and exercise capacity can easily be achieved with modest efforts [14]. However, more intensive lifestyle interventions and, in particular, a weight loss of at least 5% maintained over a longer period of time had a more pronounced effect in European clinical trials [15,16]. Consequently, such improvements were associated with a markedly reduced incidence of diabetes over an observational period of one to several years [15–18], with lifestyle interventions being clearly superior to metformin and also improving associated cardiovascular risk factors such as hypertension and dyslipidaemia [17].

A recent systematic review evaluating 53 clinical studies with 66 intervention programmes in individuals at increased risk for type 2 diabetes confirmed that the recommendation of an increase in physical activity together with a healthier diet decreased body weight and fasting blood glucose levels, reduced the incidence of type 2 diabetes (relative risk reduction: 0.59) and improved other cardiometabolic risk factors [19]. Risk factor control for diabetes prevention is even important in early adult life as a 30-year follow-up study in UK showed that higher BMI at 21 years of age is associated with an increased diabetes incidence during follow-up, although not to such an extent as in middle age [20].

Type 2 diabetes mellitus is a disease that is often not recognized until the presentation of severe complications such as stroke or myocardial infarction. [21].

As prediabetes and diabetes usually do not present with clearly noticeable symptoms – early detection requires other strategies to identify these individuals. Although an oral glucose tolerance test is still the method used to identify these patients, it is an invasive procedure, costly and time-consuming when used on a large scale. Thus, finding simpler, more pragmatic methods to identify individuals at high risk of progression to diabetes and who might benefit from targeted prevention is an important goal. One way is to use screening questionnaires such as FINDRISK or to screen for increased HbA_{1c}. In this group, we found a considerable risk in 16% of the participants through the FINDRISK. As in the nondiabetic population, about 20% had their HbA_{1c} measured (at random), surprisingly, more than 18.5% of the people who had it measured, showed a HbA1c above 6.5%, which indicates a very high rate of manifest, yet undiagnosed, diabetes [22,23].

This is in a somewhat higher range than other observations on the basis of HbA_{1c} measurements in random samples showing undiagnosed type 2 diabetes in 7.3% in UK [12] and 9.4–9.7% in the USA [24], the latter figure being close to the age-adjusted prevalence of 8.2% in adults in the USA in 2010 [25].

As described earlier [1], conclusions which can be drawn from the evaluation of the data from the 'Knowing what Matters in diabetes: Healthier below 7' campaign have some limitations including the nonrepresentative population, the restricted information collected with the modified FINDRISK questionnaire and the random subsample of HbA_{1c} testing. Nonetheless, the results based on real-world data shed some more light on the condition of the general population in Germany who have not yet been affected by diabetes.

Information campaigns such as 'Knowing what Matters in diabetes: Healthier below 7' are an efficient way to reach individuals who are apparently healthy, but may have a potential risk of developing a clinically manifest diabetes in the near future.

Conclusion

Our findings in Germany confirm that the well-known risk factors for the development of diabetes, that is, overweight or obesity, unhealthy nutrition and decreased physical activity are very common and thus increase the risk for these apparently healthy individuals of developing type 2 diabetes within a couple of years. Surprisingly, a rather large proportion of those who had their HbA_{1c} measured were diagnosed as diabetic with an HbA_{1c} of at least 6.5%, indicating a high rate of undiagnosed individuals with diabetes and another 24% were at an increased risk for diabetes with an HbA_{1c} (≥ 6.0 and $< 6.5\%$).

We know that prevention through even moderate lifestyle modification is effective; this is evidence based. Therefore, we need to focus more on early detection and

early intervention. This all starts with providing information to the people. Campaigns such as this one, 'Knowing what Matters in diabetes: Healthier below 7', can help to address this issue as they help to increase disease awareness and prevention.

This not only applies to primary prevention, as in this subgroup, but also to secondary prevention in individuals already diagnosed with diabetes. In the long term, broad success can only be achieved by a sustained and consequent effort including all stakeholders.

Acknowledgements

Conflicts of interest

All authors were equally involved in the conception and design of the research and in the interpretation of the results. Stephan Jacob reports to have received honoraria from Abbott, Astra-Zeneca, Bayer, Berlin-Chemie, Bristol-Myers Squibb, Boehringer Ingelheim, Daiichi Sankyo Germany, Essex, Eumecom medical information training, GlaxoSmithKline, Janssen-Cilag, Johnson & Johnson, LighterLife UK, Lifescan, Lilly Germany, Merck, MSD Sharp & Dohme, Novo Nordisk, Novartis, Pfizer Germany, Roche, Sanofi-Aventis Germany, UCB, Solvay, Takeda and Viatris. Franz-Werner Dippel and Andrea Klimke-Huebner are employees of Sanofi-Aventis Germany. Werner Hopfenmueller has no conflicts of interest.

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