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Lifestyle Interventions for the Prevention of Type 2 Diabetes Mellitus

Prevention of diabetes requires using of the achievements of basic science in clinical practice. For the last many years it was established that lifestyle factors in preventing type 2 diabetes in people at risk. Subsequent studies have provided important information on the actual implementation of diabetes prevention programs. In some countries efforts for diabetes prevention were realized but it is difficult to extrapolate on work according a large regional or national programs, specific items which must be scheduled for execution. For trained professionals in the field of health care, medical profile economists, health professionals and representatives of public organizations, capable of interacting with influential politicians. Political support is a very important component of this work. The article presents the results of a study that could help in the successful implementation of diabetes prevention programs in the «Practice of the real world.

Key words: prevention of type 2 diabetes; diabetes mellitus; lifestyle interventions; health care.

Preface

In recent decades the world has experienced a significant increase in the number of patients with diabetes mellitus [1]. This is primarily type-2-diabetes. Parallel to this, the increase is mostly attributable to a significantly higher frequency of diabetes diagnosis in the age group below 60, but also below 35 years of age. The growing economic burden in complex socioeconomic structures becomes obvious. The development of the diabetes epidemic is predicted to have a significant impact on the global economic growth [2]. The situation requires fundamentally different approaches from national health care systems depending on national health care structures and their medical, environmental, social and economic means. In order to respond rapidly in a coordinated fashion to the health threat diabetes and its associated co-morbidities, it is necessary to plan and prioritize the quality and structures of diabetes prevention and care in a standardized way presenting the goals, processes, responsibilities, availability and accessibility of diabetes care as part of the implementation of a Chronic Care Management [3] as part of a National Diabetes Program (NDP) [4].

At the United Nations High Level Meeting for Non Communicable Diseases (NCD) in September 2011 in New York, Ministers of Health requested an international cooperation and policy decisions on diabetes according to the present context of globalization of health issues [5, 6]. There was a consensus across countries that national programs for prevention and control of chronic diseases have to be developed and implemented and that strategies to monitor progress on implementation needed to be established. In April 2012 the European Diabetes Leadership Forum [7] was held, to discuss developing strategies on political, medical and patient centered level for improving diabetes prevention, early detection and management. Kofi Annan said at the meeting «There is no other option than to act — we do not have enough money not to act.» In November 2012 a major breakthrough at the World Health Organization (WHO), governments agreed an aspirational set of targets to drive progress on diabetes and non-communicable diseases (NCDs), including the first ever global target to halt the rise of diabetes. The governments agreed a Global Monitoring Framework including 9 global targets and 25 indicators on diabetes and NCDs. The diabetes related target include a 25 % relative reduction in overall mortality from NCDs by 2025, a halt the rise in diabetes and obesity and a 10 % relative reduction in prevalence of physical inactivity. Furthermore a goal was set that 50 % of eligible people receive drug therapy and counseling (including glycaemic control) to prevent heart attacks and strokes [8].

The burgeoning health care costs associated with the treatment of type 2 diabetes and the consistent and high quality of evidence for the effectiveness and cost-effectiveness have been central elements in necessitating a major realignment in national health care priorities away from models based solely on treatment, to those that incorporate structures around primary prevention. This has been supported by high level international advocacy. The cooperation between the United Nations and World Health Organization is a major footstep on non-communicable disease prevention and control. This marks only the second time in the history of the United Nations that its General Assembly has been convened to tackle an emerging health issue.

This has necessitated a parallel shift in the focus to successful implementation of diabetes prevention research, to include the translation of effective prevention strategies into routine clinical practice. This work has been focused on addressing the major challenges to prevention, particularly around identifying resource-efficient risk identification and intervention strategies.

The global epidemic panorama

Currently, we are experiencing an epidemic growth in the number of people with diabetes worldwide [1]. An estimated 366 million people, corresponding to 8.3 % of the world's adult population has diabetes today but the prevalence is expected to grow to 552 million by 2030, corresponding to 9.9 % of the adult population. It goes hand in hand with «westernization» of lifestyle, with consuming more energy-dense food as well as with decreasing physical activity. Driven by this development, diabetes affects more and more young people.

These changes have driven a huge increase in type 2 diabetes — the most common form of diabetes mellitus, particularly in young people, especially in their working age [9]. The medical burden is rising as patients with diabetes mellitus are developing a growing number of metabolic and cardiovascular comorbidities. The growing economic burden in complex socioeconomic structures becomes obvious. The development of the diabetes epidemic is predicted and the World Economic Forum foresees the development of the diabetes epidemic as a disaster likely to occur in the near future with an significant impact on the global economic growth at least similar in scale to the recent banking crisis [2]. The number of people affected by chronic diseases globally necessitates better chronic care management. The central programs including early detection and treatment strategies as well as investment into the development and implementation of prevention programmes [4] prominence of lifestyle in the causal pathway of progression to diabetes represents an opportunity to utilize lifestyle promotion as a preventive strategy and key line of defense against the rising tide of T2DM.

Evidence for sustainable diabetes prevention

There is now consistent evidence from randomized controlled trials across diverse countries and populations that lifestyle interventions, aimed at promoting physical activity, a healthy diet and weight loss can successfully reduce the risk of progressing to T2DM by between 30 to 60 % in those with impaired glucose tolerance (IGT) [10]. IGT is an intermediary condition between normal glucose regulation and T2DM and is associated with a substantially elevated risk of progression to Type 2 diabetes [11]. In 2001 the Finnish Diabetes Prevention Study and in 2002 the US Diabetes Prevention Program as well as the Da Qing IGT and Diabetes Study [12–14] demonstrated that lifestyle modifications focused on losing weight, increasing physical activity and improving diet could reduce the risk of progression to diabetes by nearly 60 % [15–17]. Similar findings were also seen in India [18] Japan [19] and China [12]. There is a strong dose-response effect for people who adopted four or five lifestyle changes, the progression rate after seven years was reduced by 80 % compared to those making no changes [20]. There is consistent evidence that some pharmaceutical agents, such as Metformin, a drug that is effective for glucose-lowering in people with type 2 diabetes, can prevent the onset of diabetes in high risk populations by 31 % in people with IGT [15, 18] and also other agents have been proven to be effective [21, 22], but the evidence consistently suggests that lifestyle interventions are more effective than pharmacological interventions in preventing the onset of T2DM [23].

Economic evaluation has demonstrated the cost-effectiveness of primary prevention of T2D [24]. However despite the evidence, it remains questionable whether these programs are feasible at a population level. The challenge, therefore, is to establish a scientifically-based structural framework for efficiently managing nationwide prevention programs.

Currently the evidence about short-term reduction of diabetes risk and conversion to type-2-diabetes in people with IGT is very good. The major question is however, how sustainable this effect may be. A current report has summarized the long-term effect of type 2 diabetes prevention pointing out a significant sustainability of the effect if the initial intervention was able to achieve lifestyle change [25]. The first study suggesting a sustainable effect was the Malmö Feasibility Study [26]. Here the effect of exercise and diet was tested on incidence of type 2 diabetes among 161 men with impaired glucose tolerance. After a 5 year study period 11 % of the men in the intervention group developed diabetes compared to 29 % of the men in the reference group who did not want to join in lifestyle intervention. After the 12 years follow-up the all-cause mortality was significant lower in the former intervention group (6.5 versus 14.0 per 1000 person years, $p=0,009$) and was similar to healthy individual without any glucose disturbance [27].

The Da Qing study [28] undertaken in China included 577 men and women with impaired glucose tolerance who were randomized into an intervention and control group. The interventions included either diet alone, exercise alone and a combination of diet and exercise. The lifestyle intervention was for a period of 6 years and resulted in lower cumulative type 2 diabetes incidences in all 3 intervention groups (41–46 %) compared to the control group (68 %). Interestingly the participants in the study were relatively lean so that the weight reduction was relatively small. In the participating clinics assigned to the dietary intervention the recommendation included a high carbohydrate (55–65 E %) and moderate fat (25–30 E %) diet. This study indicated that it is not only bodyweight reduction alone that is important for the prevention of type 2 diabetes. Also other lifestyle issues are important and bodyweight may be a summary indicator for several dietary and activity factors [28, 29]. The 20 year follow-up of the study showed a sustained and persisting reduction in the incidence of type 2 diabetes (43 %) in the intervention group compared to the control participants [25]. Surprisingly there was no significant effect in the reduction of cardiovascular disease or mortality, but a sustained effect in reducing the prevalence of micro vascular disease in diabetes patients [30]. The Da Qing study is the study with the longest follow up. The quintessence of the study is — lifestyle intervention enables an significant delay in the conversion to diabetes mellitus in those at risk and, at least for a period of 20 years, significantly prevents diabetes mellitus. For persons who develop diabetes the intervention significantly reduces the development of microvascular complications [28, 30].

The Finish Diabetes Prevention Study (DPS) was a multi-centered trial carried out between 1993 and 2001 in Finland in 5 clinics [31]. The main objective of the study was to test the effect of a 3 years lifestyle intervention on the reduction and incidence of type 2 diabetes compared to a control group. 522 men and women were recruited into the study and randomly allocated into a control and intervention group. The reduction in incidence of type 2 diabetes was 58 % associated with a weight reduction of, on average, 4.5 kg in the intervention group versus 1.0 kg in the control group ($p < 0.001$) after one year, and similar results maintained after 3 years. Overall, visceral obesity, dietary habits and exercise habits improved significantly and were independently associated with diabetes risk reduction [32, 33]. The cumulative incidence of diabetes was 11 % (95 % CI 6 to 15 %) in the intervention group and 23 % (95 % CI 17 to 29 %) in the control group after four years, and thus the risk of diabetes was reduced by 58 % ($p < 0.001$) in the intervention group compared with the control group [17]. The following analysis utilising data collected during the extended follow up of the study showed that after a follow-up time of 7 years, a marked reduction of the cumulative incidence of diabetes was sustained, reaching a risk reduction of 43 % [34]. The corresponding incidence rates were 4.6 and 7.2 per 100 person years between the intervention group and control group. The 10 year follow-up results of the effect of the lifestyle intervention in the diabetes prevention study included total mortality and cardiovascular risk and showed a significant reduction in total mortality, but similar to the Da Qing study no effect on reducing cardiovascular morbidity [35]. Interestingly, when the DPS intervention and control groups together were compared with a population-based cohort including people with IGT, adjusted hazard ratios were 0.21 (95 % CI 0.09–0.52) and 0.39 (95 % CI 0.20–0.79) for total mortality and 0.89 (95 % CI 0.62–1.27) and 0.87 (95 % CI 0.60–1.27) for cardiovascular morbidity. Thus the risk of death among the DPS participants was markedly lower than in a population based IGT cohort [25].

The Diabetes Prevention Program (DPP) was a United States multicenter randomized clinical trial [36]. It compared the efficacy and safety of three interventions — an intensive lifestyle intervention, standard lifestyle recommendations combined with metformin, or placebo [25]. The goals of the dietary intervention were to achieve and maintain a 7 % weight reduction by consuming a healthy low-calorie, low-fat diet and to engage in physical activities of moderate intensity (such as brisk walking) 150 minutes per week or more. The intensive lifestyle intervention reduced type 2 diabetes risk after 2.8 mean follow-up by 58 % compared with the placebo control group. Lifestyle intervention was also shown to be superior to metformin treatment which resulted in a 31 % type 2 diabetes risk reduction compared with placebo. At the one-year visit the mean weight loss was 7 kg (about 7 %) [25]. After the publication of the main results in 2002 the randomized trial was stopped and the participants were invited to join the Diabetes Prevention Program Outcomes Study (DPPOS) [37]. During the follow-up, all participants regardless of their original treatment group were offered lifestyle counseling. During the overall follow-up of 10 years (calculating from the randomization to the DPP) diabetes incidence in the original lifestyle intervention group was reduced by 34 % compared with the control group. However during the post-intervention follow-up diabetes incidence was similar in all treatment groups (5.9 per 100 person-years in the former intervention group and 5.6 % in the placebo control group, confirming that lifestyle intervention that was initiated in the former placebo control group was successful even after several years of follow-up without any active intervention [25].

The elements for prevention: Identifying people at risk

The question of who should be targeted for diabetes risk reduction is not easy to answer because the effect of an intervention program to prevent type 2 diabetes in adulthood depends on the setting where the intervention is performed, the effectiveness of the intervention in addressing the high risk individual, accessibility and affordability and a variety of additional variables [38]. However, the main considerations when deciding who should be targeted for diabetes prevention are the effectiveness and affordability of the interventions available after the high risk person has been identified. Screening for diabetes risk makes no sense without availability of a successful and sustainable intervention program [39]. Interventions can have various approaches, strategies and concepts. Furthermore, strategies for targeting people at high risk will vary significantly between different settings and different population groups. The risk factors for T2DM are well recognized and T2DM is often preceded by a period of impaired glucose tolerance which is characterized by increasing insulin resistance and Beta cell dysfunction [40]. Visceral obesity plays a key role in triggering the development of insulin resistance and increasing diabetes risk [23]. It is also recognized that many people with T2DM remain undiagnosed and that patients with long diagnostic delays often have significant complications at diagnosis [41]. This suggests that combined screening for both impaired glucose tolerance and undiagnosed prevalent T2DM could be a pragmatic option. Indeed, data shows that screening for both conditions together is cost effective, particularly when lifestyle and pharmacological based interventions are then used to delay the onset of T2DM in high risk individuals [10, 42]. Screening for T2DM and impaired glucose tolerance in high risk populations is now recommended by a number of international Diabetes Associations [43–46] and there is a plethora of tools available to identify people at increased risk of T2DM and there is little evidence of detrimental, long term, physical or psychological harm from such screening [47, 48].

The consensus (based on screening approaches used in practice in the US, Germany, Australia, Finland, UK and other countries) [4, 46, 49, 50] seems to favor a targeted, staged approach with the first step being to identify those at high risk and a second step to confirm glycaemic status [51] (whether T2DM, impaired glucose tolerance or normoglycaemia). Preliminary data about these broad approaches suggest that it is more cost-effective to use a non-invasive screening tool as the first stage in screening rather than a blood test [52]. Risk scores tend to be based around risk factors such as age, gender, BMI, ethnicity, family history of diabetes and taking anti-hypertensive medication. Risk scores have been shown to have good sensitivity and specificity for identifying diabetes risk [51]. For example the FINDRISC, the Danish Risk Questionnaire, the Cambridge Risk Score, the Leicester Diabetes Risk Score and the Indian Score have all been associated with a sensitivity of between 76–77 % and specificity between 55–72 % with a positive predictive value varying between 7–11 % [53–58]. The most common approach used is the FINDRISC questionnaire which individuals use to self-assess their risk based on seven questions and which has been shown to have good validity at predicting future diabetes over a ten year period [59]. Importantly, FINDRISC has been validated for use in various countries [60]; but given the varying profile and prevalence of risk factors in different settings [40], the score performance cannot be generalized from one country to another. It is therefore important that risk scores are validated in the population in which they will be applied. The other approach is to use data which is routinely available to the general practitioner (for example, the Cambridge Risk Score, QD Score or the Leicester Practice Risk Score [51, 61–64]).

The second stage involves diagnostic testing. In practice, this usually consists of either a fasting glucose or HbA1c, although oral glucose tolerance testing can also be used. A recent statement by the International Expert Committee of the WHO, has advocated that HbA1c of $>6.5\%$ define T2DM [65]. Meanwhile there is an ongoing debate about the use of HbA1c $<6.5\%$ in defining impaired glucose tolerance, although this may be a pragmatic option for identifying people at high risk for T2DM [66]. A consensus approach by WHO recently included the use of HbA1c $>6.5\%$ as a diagnostic threshold for T2DM. However, there is no clear consensus on how or whether HbA1c should be used to classify diabetes risk below this level. The ADA tentatively suggested that an HbA1c value of between 5.7–6.4 % indicates a high risk of T2DM whereas an international expert committee suggested a range of 6.0–6.4 % [44, 67]. The latter range was also recently endorsed by NICE in the UK, which now recommends that HbA1c can be (48 mmol/L/mol) can now be used to of type 2 diabetes and that those with a value of between 6.0–6.4 % should be referred into a diabetes prevention programme [68]. This is supported by prospective data which found that those with an HbA1c of between 6.0–6.4 % had twice the risk of developing type 2 diabetes compared to those with a value of between 5.5–5.9 %. Prospective data from the United Kingdom supports the use of 6.0–6.4 % as those in this group were found to have a risk of future T2DM that was twice that in the range of 5.5–5.9 % [23]. Howev-

er, other data from Germany suggest 5.7 % is likely to have the best sensitivity and specificity at detecting future diabetes risk [66] but demonstrate that the combination of HbA1c and the 1-hour plasma glucose concentration in predicting future diabetes risk was significantly better in a multivariate model than either one of them alone. The 1-hour PG concentration has previously been shown to be a strong predictor of T2DM risk [69–71] and also other chronic disease [72, 73] but has major logistical issues. Further, the optimal HbA1c cut point for identifying subjects at increased diabetes risk is 5.65 % [66, 74] and not 6.0 % as originally suggested by the ADA expert committee [67]. If a HbA1c >6 % was used to identify subjects at increased risk for future T2DM, only about one third of subjects who developed T2DM would have been identified. Thus, use of a HbA1c cut point of 5.65 % together with the 1-hour PG concentration [75] would identify many additional high risk individuals who could benefit from an intervention program [66, 76, 77].

The most cost-efficient way to balance resources against risk has yet to be determined. In the meantime, the balance that is struck may depend to a large extent on pragmatic considerations, particularly financial constraints [49]. It is acknowledged that, along with strategies for identifying and intervening in those with a high risk of a widely prevalent condition such as type 2 diabetes, it is also fundamentally important to employ initiatives that are aimed at shifting the distribution of known risk factors, such as BMI in adults or BMI percentiles in childhood as well as waist circumference within the population as a whole [78]. Strategies for primary prevention on public health level and high risk strategies need to work in parallel [50].

Waist circumference

Waist circumference is a powerful indicator of metabolic dysfunction as it represents a surrogate indicator for the accumulation of visceral fat [79, 80]. It is well established that visceral fat does not only play a role in the human energy metabolism, but that it also actively secretes hormones and peptides (adipocytokines), such as MCP-1, Retinol binding protein 4 as well as a variety of interleukins together with TNF- α , which enhance the development and/or the progression of chronic diseases, including insulin resistance and chronic inflammation. There is a strong risk association between an increase in visceral fat mass and risk of developing T2DM [81].

From a public health point of view, waist circumference presents a clinically valuable measure because of accessibility [82], as no lab investigation is needed and no invasive procedure is necessary. In addition, direct patient feedback during an intervention program is possible. As it is known that the metabolic activity of visceral fat is higher than that of subcutaneous fat, alterations in baseline metabolic turnover from an individual patient during an intervention associated with increased physical activity would predominantly reduce the visceral fat depot [83]. It might be concluded that any reduction in the visceral fat depot is accompanied by a reduction in most of the visceral adipocyte-secreted hormones and therefore has beneficial effects for prevention of chronic diseases. Waist circumference provides a valid measure to predict diabetes risk in the adult population and has been included in the criteria to define the metabolic syndrome [84]. For consistency with the criteria for adults, the measurement of waist circumference has meanwhile also been included in the definition of the metabolic syndrome in children and adolescents [85].

The elements for prevention: Physical activity

Epidemiological, experimental, and randomized controlled clinical studies trial level evidence have all consistently demonstrated that levels of physical activity are centrally involved in the regulation of glucose homeostasis, independent of other factors including adiposity [10, 86–88]. A modest increase in walking activity, towards levels that are consistent with the minimum recommendations, significantly improved 2-hour glucose levels by 1.3 mmol/l over 12 months in high-risk overweight and obese individuals, despite no change was obvious in body weight or waist circumference [89]. This may correspond to a > 60 % risk reduction of developing T2DM within 24 months [90] and was consistent with findings from other studies [33] but an replication of the results is needed and is underway. Therefore, physical activity promotion should be the corner-stone of any diabetes prevention program. However, the role of physical inactivity in helping identify diabetes risk is less clear and more problematic for several reasons. First, physical inactivity is a nearly universal condition: it has consistently been shown that 50–80 % of the population in both developed and developing countries fail to meet the minimum recommendations for health [90–93]. Indeed, when physical activity levels are objectively measured, rather than by subjective self-report, a substantial fraction of the population are considered inactive [93, 94]. Therefore commonly used definitions of physical inactivity do not provide a clear mechanism for stratifying diabetes risk. Secondly, methods that rely on individuals self-reporting their activity levels are highly inaccurate and unreliable. For example, an internationally used and

validated self-reported measure of physical activity described as little as 10 % of the variation in objectively measured levels through accelerometry [95, 96]; being in contrast to simple measures of adiposity, such as BMI or waist circumference, which are reasonably accurate on a population level. For these reasons, self-recording levels of physical (in)activity has not been shown to add to the predictive power of diabetes risk scores or to be usefully incorporated into other methods of quantifying diabetes risk [97, 98]. However, it is important that physical inactivity, as with other lifestyle variables, is considered for the individual assessments of diabetes risk [23].

The spectrum of evidence underpinning the link between physical activity and health is particularly compelling in relation to metabolic health and the development of T2DM. Prospective observational research has consistently demonstrated that undertaking levels of physical activity that are consistent with current physical recommendations are associated with a 30–50 % reduction in the relative risk of developing T2DM [87]. Mechanistic studies have identified multiple pathways linking physical activity to improved glucose transport [96–98]. For example, acute and long-term changes in insulin action and fuel utilisation occur through mitochondrial biogenesis, increased fatty acid oxidation, and increased expression and translocation of key signalling proteins involved in the insulin mediated glucose uptake pathway, particularly GLUT-4. Furthermore, muscular contractions are known to induce glucose uptake through insulin independent pathways, which is likely to involve the up-regulation of AMP-activated kinase [96]. Finally, randomized controlled trials have demonstrated that physical activity interventions result in improved glucose tolerance and a reduced risk of diabetes in those with a high risk of the disease [10, 89]. Importantly, physical activity has also consistently been shown to reduce the risk of diabetes regardless of body weight status [33, 88], confirming that physical activity should be promoted for its own sake rather than simply to help achieve weight loss [23, 99–101].

National and international recommendations are based on achieving 30 minutes of moderate- to vigorous-intensity physical activity on at least 5 days or 150 minutes per week, accumulated through multiple bouts of at least 10 minutes [102–104]. However, particularly in relation to the prevention of type 2 diabetes and metabolic health, it should be emphasized that this is a minimum recommendation and that greater health benefits will be achieved through higher doses of physical activity.

In order to be successful, lifestyle intervention programmes should focus on types of physical activity that are acceptable to the majority of the population. Walking has consistently been shown to be the most popular choice of physical activity; including those with a high risk of T2DM [33]. Indeed, walking for 150 minutes per week during leisure time is associated with a 60 % reduction in the relative risk of type 2 diabetes compared with walking for less than 60 minutes per week [33]. Importantly, walking is associated with fewer barriers than other forms of physical activity in black and minority ethnic populations dwelling in developed countries, such as South Asians [23, 105].

Wearing a pedometer and keeping a daily step log have been widely advocated as effective self-regulatory strategies in the promotion of increased ambulatory activity and their use has consistently been shown to successfully promote increased physical activity [106]. The success of pedometer interventions is centered on the pedometer's ability to raise awareness of current activity levels, provide objective feedback to the individual and facilitate clear and simple goal setting. In order to be effective, it is essential that realistic and personalised step-per-day goals are used; goals that are too ambitious can often be de-motivating and lead to failure.

Sedentary individuals (let than 5000 steps per day) should initially aim for an average increase in ambulatory activity of around 2000 steps per day conducted at a moderate to vigorous-intensity, which is roughly equivalent to an additional 150 minutes of walking activity per week [107]. Alternatively, the categories of ambulatory activity shown in Table 1 can be used to guide lifestyle interventions. For example, those in the sedentary or inactive categories could initially aim to increase their ambulatory activity by at least 2000 steps per day. Those in the moderate category could be encouraged to try and enter the high category, whereas those achieving the high or very high categories should be helped to at least maintain their activity levels. For people who have significant barriers to walking, such as joint problems, alternative forms of physical activity, such as cycling, or swimming should be encouraged.

Exercise is well known to be the potential lifestyle intervention to treat and prevent type 2 diabetes. The evidence has been firmly established by several clinical trials. The challenge we have is to address the implementation of the evidence into clinical and public health practice — and here the question about the key items for changing lifestyle becomes relevant. Support for behavior change is the predominant issue. Physical activity such as step counts on a pedometer is a good sign of behavior change but maintaining physical activity requires sustained behavioral support.

Physical activity categories based on steps per day

Category	Steps per day
Sedentary	<5000
Low (Typical of daily activity excluding volitional activity)	5000–7499
Moderate (likely to incorporate the equivalent of around 30 minutes per day of moderate intensity physical activity)	7500–9999
High (likely to incorporate the equivalent of around 45 minutes of moderate intensity physical activity)	10,000–12499
Very High (likely to incorporate the equivalent of over 45 minutes of moderate intensity physical activity)	>12500

Adapted from Tudor Locke and Bassett, 2004 [107].

The more intuitive the behavioral strategy, the more success it will have in increasing physical activity. «Walking» is natural from an evolutionary point of view and may have the potential to reach a wide audience with the right behavioral support program and incentives. «Exercise therapy» is a therapy associated with a disease which can be highly successful but needs an individualized strategy and by this is only applicable for a fraction of our patients. In order that «Physical activity» becomes a core therapeutic element for diabetes prevention and most patients with type 2 diabetes mellitus» we have to improve our understanding of the behavioral and physiological as well as contextual mechanisms of the development of diabetes and the disease itself. To reach every patient we need an individual proposal which can become part of daily life. Nothing is more natural than «walking» and to ‘walk our diabetes away’ is effectively achievable.

Smart Health and Physical Activity

The recent very fast development of smart health technology enables a wide variation of new tools to target patients as customers and uses smart health tools to encourage a healthy lifestyle [108]. A recent evaluation identified a large number of smartphone apps as pedometer app or fitness and physical activity apps to encourage people for a healthier and more active lifestyle [109, 110]. Some of these apps are linked with clinical studies that show a very good success rate in encouraging daily physical activity [111]. One of the examples is the AnkerSteps App — www.ankersteps.com — which uses a gamification approach to sustainably encourage people to walk 10,000 steps a day. The AnkerSteps model was tested and shows a sustainable increase of daily physical activity of people reaching 10,000 steps a day at about 65 % of the days. AnkerSteps is an example, in which cost free smart technology helps to anchor motivation of people to reach a health goal sustainably, based on a sustainable social business model [112].

The elements for prevention: Nutritional aspects

Obesity is one of the most important risk factors for T2DM and population trends in obesity and diabetes run in parallel [113]. The pathophysiology of adiposity regarding the development of T2DM is not fully understood; however, several mechanisms that may interplay have been identified. Adipose tissue, especially the tissue surrounding internal organs (visceral fat) is today regarded as an active endocrine organ that secretes a variety of pro-inflammatory adipokines, which act at both the local and systemic level [114]. Increasing adipose tissue mass leads to changes in the secretion of these adipokines as well as increased turnover of free fatty acids which bring on insulin resistance, the harbinger of metabolic disturbances leading to T2DM, as reviewed by Cornier et al. [115].

Waist circumference is a powerful indicator of metabolic dysfunction as it represents a surrogate indicator for the accumulation of visceral fat [80, 116]. It is well established that visceral fat does not only play a role in the human energy metabolism, but that it also actively secretes hormones and peptides (adipocytokines), such as MCP-1, Retinol binding protein 4 as well as a variety of interleukins together with TNF-, which enhance the development and/or the progression of chronic diseases, including insulin resistance and chronic inflammation, providing evidence that there is a strong risk association between an increase in visceral fat mass and risk of developing T2DM [81]. On the other hand adiponectin, an additional adipocytokine secreted from (visceral) fat cells, has been shown to have beneficial effects on the development of insulin resistance and arteriosclerosis. From a public health point of view, waist circumference presents a clinically valu-

able measure because of accessibility [117], as no laboratory investigation is needed and no invasive procedure is necessary. In addition, direct patient feedback during an intervention program is possible.

Further evidence supporting the causative role of obesity in the development of T2DM comes from lifestyle intervention studies which have consistently shown that moderate weight reduction (5–7 %) prevents type 2 diabetes [17, 118]. In the DPP study weight loss was identified as the main driver of changes in diabetes incidence, with each kilogram of weight loss being associated with a relative reduction of 16 % in the risk of progression to T2DM [118].

Weight reduction seems to be beneficial, at least in the short term, regardless of the mechanism of weight loss (e.g. diet or physical activity or both) [119]. Interestingly, beneficial changes in glucose metabolism seem to appear soon after the initiation of energy-restricted diet, even before any significant reduction in body fat which suggests that there are several different simultaneous mechanisms in play [120]. Another important point is that weight reduction of only 5 to 10 % seems to have a large effect on diabetes risk [121].

Even though the basic cause of excess body fat accumulation is an imbalance between energy intake (=dietary intake) and expenditure, the factors predisposing to the development of overweight and obesity are multifactorial and poorly understood. Nevertheless, regular physical activity, high dietary intake of fibre and reduced intake of energy-dense micronutrient-poor foods were identified by the World Health Organization as lifestyle factors for obesity [122]. In the DPS energy density of diet was found to be associated with achieved weight reduction [20] which supports the intuitive recommendation to increase foods with low energy density such as vegetables and fruits to increase satiety while reducing total energy intake. An increased understanding of these mechanisms will be helpful in providing prioritization of behavioural targets for future prevention programs.

Nutritional recommendations

For the majority of people, weight reduction is difficult to sustain. Fortunately, diabetes prevention studies have shown that changing lifestyle is effective without significant weight reduction [12, 18, 89] (Tables 2, 3). An important contributor is physical activity; however the composition of diet seems to be important as well. Epidemiological studies have suggested that several dietary factors may either increase diabetes risk (e.g. intake of refined grains, red and processed meat, sugar-sweetened beverages, heavy alcohol consumption) or decrease it (e.g. intake of whole-grain cereal, vegetables, legumes, nuts, dairy, coffee, moderate alcohol consumption), independently of body weight change [23]. The suggested mechanisms behind these observations include improvement of insulin secretion and/or insulin resistance as a result of reduced glycaemia and lipidemia, reduced ectopic fat, reduced low-grade inflammation, changes in cell membrane phospholipids and improvement of intestinal peptide secretion [23].

Table 2

Nutrition and dietary guidance for sustained diabetes prevention

Goals for food intake	Goals for long-term nutrient intake
<ul style="list-style-type: none"> • Consuming fruit, vegetables, and legumes in abundance (≥ 500 g or five portions per day) • Choosing whole grain in all cereal products • Limit sugar to ≤ 50 g/day, including sugar in food and beverages • Consuming vegetable oil and/or soft margarines and/or nuts as the primary source of fat • Limiting butter, other saturated fat and partially hydrogenated fats • Choosing low-fat milk and meat products • Consuming fish regularly (≥ 2 per week) • Consuming alcoholic beverages in moderation (≤ 2 drink/day for men and ≤ 1 drink/day for women) if at all • Other goals according to individual needs (e.g. body weight, diseases, medications, age) 	<ul style="list-style-type: none"> • Energy intake balanced with physical activity levels to achieve or maintain healthy body weight • Total fat 25–35 E%* (60–80 g/day with 2000 kcal daily intake level), of which saturated or trans fat ≤ 10 E% • Dietary fibre 25–35 g/day • Salt (NaCl) ≤ 6 g/day • Alcohol ≤ 5 E%* <p>*E% = proportion of total energy</p>

The EAT CLEVER principle provides brief practical advice for counsellors to be applied within the framework of national dietary recommendations

E A T C L E V E R	
Estimation of the dietary pattern compared to the recommendations	Use the food diary, or interview to help your client to become aware of his/her dietary pattern and food consumption. Compare dietary intake to the recommendations. Consider special needs, resources and readiness to change food habits.
Aims in the long and short term	Discuss both short and long term goals: what is your client willing and able to do at the moment? Help to set practical, achievable targets and proceed with small steps. Make a plan with your client.
Tools, guidance and support	Which kind of tools, guidance, support or skills are needed and available? Involving the family and friends and group counseling are all worth considering.
Composition of the diet	A diet with high sugar and other refined carbohydrates and low fibre content, or high saturated and trans fat content may increase the risk for diabetes and other related disorders. Whole grains and moderate amounts of coffee and alcohol may decrease the risk. Encourage the use of herbs and spices to reduce salt. Refer to your national nutrition recommendations but consider the special requirements of people with high diabetes risk, such as the improvement of the components of the metabolic syndrome. Take into account any additional disease your client may have.
Lifestyle for the whole life	Diet is influenced by culture, religion, ethical, physiological, psychological, social and economical aspects, availability, and individual likes and dislikes. Help your client to find his/her own healthy way of life. Lifestyle change is a process and relapses are part of it. Help your client to learn from these experiences to develop successful strategies over time.
Energy	Excessive energy intake causes weight gain. If the client is overweight, make a plan with her / him to support gradual weight loss (step by step). Focus on substituting foods with high saturated fat and/or refined carbohydrate content with lower-energy items. How many meals and snacks, beverages and alcohol included, does he/she have during a day and night? Some regularity in the daily meal plan helps to control over-eating.
Variety	Emphasise variety instead of restriction. A health-promoting diet provides satiety and pleasure as well as protective nutrients. Encourage clients to try new foods. Give advice on how to read food labels. This can help your client to feel more confident and expand their healthy food choices.
Evaluation	Evaluation and self-monitoring help in achieving and maintaining new food habits. Body weight and/or waist circumference should be measured regularly. Encourage your client to use a food diary (see Appendix) or some other methods to monitor eating habits: the number of meals and snacks, the amounts of certain food stuffs, such as vegetables, whole grains, sugar, alcoholic beverages, vegetable oil and/or fat etc.
Risks management	Dietary guidance must be based on evidence from nutrition and behavioural sciences. Focus on the big picture: changing one aspect in the diet affects many others. Strict restrictions and 'crash dieting' may lead to an unhealthy diet, and can cause damage in the long term as well as psychological and social harm. A multi-disciplinary team, including a registered dietician and a psychologist, can give essential support to avoid these risks.

The Finnish DPS aimed, in addition to weight reduction and increased physical activity, at reduced total and saturated fat intake and increased fiber density of diet [123]. The post hoc analyses showed that diabetes risk reduction was clearly associated with the achievement of these lifestyle goals. In the DPP study from the USA, dietary goals were reduced energy intake (to achieve weight reduction) and reduced total fat [124]. The diabetes prevention studies from China, India and Japan aimed at reduced fat, energy, alcohol and refined carbohydrates and increased fiber [12, 18, 19]. A recent study from Spain showed that adopting a Mediterranean diet, characterized by high intake of vegetables, fruit, legumes, extra virgin olive oil, nuts, fish, whole grains and red wine, also decreases diabetes incidence remarkably [125], without body weight reduction.

A pragmatic way to prevent diabetes therefore would be to focus on diet composition and physical activity. A strict diet emphasising dietary restriction and avoidance of certain food groups (e.g. sources of fat or carbohydrates) and aiming solely at weight reduction may be more efficient for achieving weight loss in the

short term, but may not be sustainable in the long run [126]. Diet may well vary according to food culture, food availability and personal preferences, and yet follow the same general principles:

- High intake of vegetables and fruits should be encouraged.
- Grain products should mainly be unrefined, with high natural fibre content.
- The vegetable sources of fat with low saturated fat content (such as olive oil) should be preferred.
- As a source of protein nuts, legumes, dairy and fish should be favoured and red meat limited.

The intake of highly processed foods (e.g. processed meat, sweetened beverages, confectionery) should be limited.

*The elements for prevention: The right intervention to the person at risk.
Supporting behavior change*

As described above, there seem to be several possible routes to non-pharmacological diabetes prevention, but a common factor is the need to support sustained changes in lifestyle behaviors. However, achieving the required changes reliably is challenging. Both clinical intervention programs [127–129] and ‘real world’ diabetes prevention programs demonstrate wide variation in their ability to deliver weight loss or changes in physical activity [23]. It is therefore of importance to be able to characterise the components of lifestyle interventions that are reliably associated with increased effectiveness. Only by understanding what makes interventions effective, can we design diabetes prevention programs that will a) deliver the expected benefits and b) optimize cost-effectiveness in scalable, real world prevention programs [39].

A recent ‘review of reviews’ systematically examined a wide range of evidence from existing high quality reviews of RCTs of interventions to support changes in diet and /or physical activity in people at high risk of developing T2DM [118]. Based on the grading of 129 analyses that related intervention characteristics to effectiveness, evidence-based recommendations were developed and these are shown in Table 4. These recommendations are broadly consistent with other recent international guidelines on supporting lifestyle change in people with high cardiovascular risk [130], with type 2 diabetes [131] and obesity [132].

Table 4

The F.I.T.T. recommendations: general guidelines for individuals of moderate fitness

F.I.T.T. principle		Aerobic Endurance Training	Resistance Training
Frequency	How often	3x / week (minimum) Max. 2 days gap between training sessions	2–3x / week
Intensity	How hard	(a) light to moderate (40–60 % VO ₂ max. / 50–70 % HRmax) (e.g. brisk walking — 5–6 km/h) slightly increased breathing rate; (b) vigorous (e.g. jogging — 8–10 km/h) increased breathing rate and sweating	light to moderate (slight muscular fatigue)
Time	How long	(a) light to moderate 45–60 min (in total > 150 min/week) (b) vigorous 30–40 min (in total > 90 min/week)	1–3 sets of 8–15 repetitions for each exercise
Type	What kind	walking, jogging, cycling, swimming, hiking, skiing	about 8 different strength exercises using the major muscles of the body (e.g. with fitness machines, resistance-bands or just with your own body weight)

Applying these recommendations may help to guide the selection of intervention components in a way that maximises the likely effectiveness of diabetes prevention programs. However, it is worth noting that the evidence base on «the best strategies for supporting behavior change» is far from complete. Individuals with high diabetes risk from different backgrounds and cultures may be responsive to a number of different strategies that modify the cognitive, social, and emotional processes that underpin their lifestyle behaviors. There are also a number of possible modes of intervention beyond persuasive face-to-face interaction, including modifying the physical environment and changes in food-pricing or regulatory /taxation regimes. Hence, there may be considerable opportunities to further increase the efficiency and cost-effectiveness of programs to support lifestyle behavior change.

Considerable attention is also needed to address the issue of maintenance of lifestyle changes. Long term follow-up of weight loss interventions shows a clear pattern of weight regain over 5 to 10 years, even in the successful diabetes prevention research studies [37, 126]. It is likely that when weight loss is achieved through changes in diet or physical activity that are challenging for people to adhere to or that they do not enjoy, these changes will not be sustainable in the long term. Recent data from a meta-analysis of multiple long-term cohort studies indicates that a habitual energy imbalance of about 50 to 100 kcal per day seems sufficient to cause the gradual weight gain observed in most adults [133]. Consequently, «modest, sustained changes in lifestyle could mitigate or reverse such an energy imbalance». Hence, promoting a series of small changes that people can easily live with, rather than dramatic changes in diet or activity may be a strategy worth further investigation.

Recommendation for diabetes prevention practice

The European Union supported the IMAGE project (Development and Implementation of a European Guideline and Training Standards for Diabetes Prevention), a multi-professional initiative to develop practice recommendations for diabetes prevention practice [134]. More than 100 experts in this field worked for 2.5 years to prepare an evidence-based guideline on T2DM prevention [46], a Toolkit for diabetes prevention practice [49], a guideline for evaluation and quality management in T2DM prevention [135] and an European training curriculum for prevention managers [136]. The major output of the IMAGE project — relevant for prevention practice — is the practical diabetes prevention guideline called «Toolkit for the prevention of type 2 diabetes». This toolkit is developed for all professionals involved in diabetes prevention: those working in primary healthcare services, physicians, physical activity experts, dietitians, nurses, teachers, but also stakeholders and politicians. The Toolkit condenses the essence what is necessary to build up the management of a diabetes prevention program, financial, intervention and quality assurance aspects and refers to the latest evidence in diabetes prevention. The core of the Toolkit describes elements of an effective lifestyle intervention program and gives the core goals of lifestyles (behavior, physical activity and diet) and finishes with an overview on how to evaluate intervention programs and how to establish quality assurance. It provides several recommendations that may help in planning and implementing a type 2 diabetes prevention programs worldwide [4, 25, 137].

Intervention cost/scarcely resources: There is clearly a tension between the evidence-based recommendation for maximizing intervention intensity (number or frequency of contacts) and the practical availability of resources (suitably trained staff and funding) for diabetes prevention. However, this tension might be reduced in several ways. These include:

- Using group-based interventions. There are several good examples of group-based interventions that produce levels of weight loss similar to those in the large diabetes prevention studies, at least in the short term (Table 1). Group-based intervention also costs less than individual intervention [138, 139].

- Reducing staff costs: Lifestyle interventions can be delivered successfully by a range of staff, including doctors, nurses, dietitians /nutritionists, exercise specialists and lay people [118]. More research is needed to define the range of personal skills and type of training required to maintain program effectiveness [136].

- Self-delivered and internet based approaches. This type of intervention could potentially provide a low cost solution for a considerable sub-group of the population and may be a useful supplement for face-to-face programs. Given the success of such approaches to support smoking cessation [140] and recovery from depression [141], it should, in theory, be possible to use them to support changes in diet and physical activity. Although a number of programs are under evaluation, more robust evidence on effectiveness is still needed before this approach can be endorsed.

- Developing standardized recommendation for diabetes prevention practice [46, 49]: Applying the recommendations on supporting behavior change (Table 4) should enhance the efficiency of lifestyle intervention programs.

- Disclosing the economic benefits of diabetes prevention [142]. Economic modelling indicates that group-based diabetes prevention interventions in the US would provide a return on investment within a 3 year timeframe. This has resulted in the release of significant resources in the US from government and Health Maintenance Organisations.

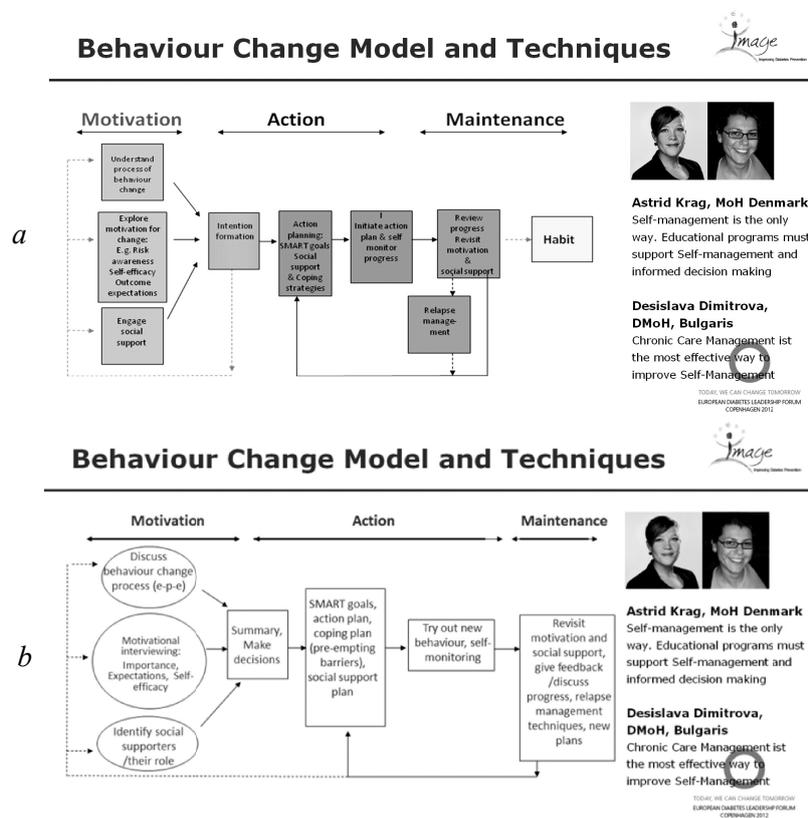
- Expertise: In order to deliver prevention programs on a large scale, we need to identify a sufficient number of people with the expertise and experience to design and deliver them. Investing in high quality training would seem to be essential for the implementation of successful programs [136].

- Maximising the uptake of both screening and intervention: Further research is needed in this area, but this may require multi-media approaches, involvement of multiple sectors (public health, voluntary sector, commercial /workplace programs, healthcare and social care) and the use of social marketing techniques to target messages to appropriate population sub-groups.
- Ensuring sustainability of funding and support within both healthcare and political arenas: This will require a sustained focus and willingness to invest in preventive healthcare. The forthcoming UN Summit on Non-Communicable Diseases presents an opportunity to more firmly and sustainably establish diabetes prevention on the global health agenda [143].
 - Developing quality management systems: Quality management systems are needed to provide continuous bench marking and monitoring of the effectiveness of prevention programs [135].
 - Further improving the technology to support behavior change: This could be achieved by establishing «networks of practice» so that we can learn how to improve the efficiency of interventions from practice /real world experience as well as from developments in theory /research. The Global Network «Active in diabetes prevention» — www.activeindiabetesprevention — provides a forum for exchanging knowledge and intervention materials as well as educational standards and recommendations for prevention practice.

Improving effectiveness in diabetes prevention practice

One of the challenges in developing intervention programs for diabetes prevention is to find the right intervention which has the highest probability to be successful in the individual with high diabetes risk. This strongly varies between different individuals. In today’s practice we should aim to be using standardized and structured intervention programs that we apply to all the people at risk which we have identified in a prevention plan. By this approach, we accept that sometimes only 20 % of the people achieve the highest effect and that in 80 % of the people the programme may be less efficient [144]. It is possible to increase the probability of success by developing intervention programs that follow a behavior change model. Such a model was developed as part of the IMAGE project whereas the patient is seen as being in 3 stages [145, 146]:

- the stage of motivation;
- the stage of action;
- the stage of maintenance.



Greaves CJ et al. BMC Public Health. 2011 Feb 18;11(1):119.

Figure. Behaviors Change Model and behavior change techniques based on [146]

The development of intervention programs following this behavior change model may generate a higher efficacy due to an increase in flexibility in the program execution. The key point in the IMAGE project was that the behavior change model (BCM) was accompanied by a collection of behavioral techniques for supporting the lifestyle changes (Figure). Specific tools and techniques for each stage of the BCM were elicited from more than 300 studies [146] and shown to be effective. The prevention manager can choose the techniques needed for the intervention in several stages. The use of the techniques allows a much more widespread implementation of an intervention plan and may be one step away from only focusing on structured and standardized intervention concepts by allowing a higher degree of flexibility of the intervention manager and focusing more on individual needs and preferences.

This behavior change model then was further developed by a working group derived from the IMAGE project [23, 146]. Daily practice in performing intervention shows that even the intervention planning by focusing on the BCM misses an effect in a large number of people receiving the intervention. One of the difficulties is associated with the use of standardized programs which follow a standardized curriculum. Furthermore, difficulties also arise by the effect that most of the intervention programs do not include different preferences and interests of the people receiving the intervention. This is followed by different stages of morbidity [39] which also define different preferences and interests which can be a barrier to an effect of a program if someone with the very low risk expression is sitting together in an intervention group with someone having a very high risk and different preferences and interests. Based on this background the further development of intervention programs have to take into account to develop an assessment to identify the most suitable intervention characteristics for a person at risk.

The elements for prevention: Moving Diabetes Prevention into practice

A challenging step is to translate the research findings into nationwide or regional diabetes prevention programmes that translated the research findings to the real-life health care settings. Finland has led the way with FIN-D2D, a large-scale implementation covering a quarter of the Finnish population [147]. Another landmark was the profusion of published implementation trials including GOAL and the Saxon DPP in Europe [148], the Greater Green Triangle DPP in Australia, the Walking Away from Type 2 Diabetes programme in the United Kingdom (UK) [39, 149] and programs in Indianapolis Pittsburgh and Montana in the United States [150, 151]. A great challenge will be the scaling up from these implementation trials to sizeable regional and national programs.

Political support is needed and this requires the development of a national or international action plan for diabetes prevention, which needs involvement of a number of stakeholders at a governmental and non-governmental level. Furthermore, the presentation of the evidence in the field for diabetes prevention on the scientific and practical level as well as the training of people to deliver preventive intervention is required.

The European experience

The two European funded Projects DE-PLAN [152] and IMAGE [153] have been addressing the implementation process. Especially the IMAGE project was able to collate this information in a systematic manner, including an evidence-based guideline on T2D prevention [46], a toolkit for the prevention [154] and a paper on quality indicators in T2D prevention [155]. Furthermore, IMAGE developed a curriculum for the training of prevention managers. This training includes a seven day curriculum for educators and to learn necessary skills to deliver preventive intervention, and acquire accreditation.

Toolkit for the prevention of type 2 diabetes

One major output of the IMAGE project is the practical guideline called «Toolkit for the prevention of type 2 diabetes». This toolkit is aimed at all people involved with diabetes prevention: those working in primary and specialised healthcare services, physicians, physical activity experts, dieticians, nurses, teachers, but also stakeholders and politicians. The IMAGE Toolkit contains useful information for local and national politicians and health policy makers interested in creating an environment which facilitates healthy ageing and the implementation of the WHO recommendation that «we must make the healthy choice the easy choice.»

The Toolkit [156] includes the essence of what is necessary to build up a diabetes prevention program covering management, financial, intervention and quality assurance aspects and refers to the latest evidence in the science of diabetes prevention and allows translating this knowledge into practice. The Toolkit addresses issues such as how to finance a prevention program and how to identify people at risk. The core of

the toolkit describes elements of an effective lifestyle intervention program. A process model for supporting lifestyle behaviour change is presented and described in its phases (motivation, action and maintenance). The Toolkit gives the core goals of lifestyles (physical activity and diet) and gives practical instructions about how to address these with the individual. Other behaviours to consider in diabetes prevention are, e.g., smoking, stress/depression and sleeping patterns. The Toolkit finishes with an overview on how to evaluate intervention programs and how to establish a quality assurance programme.

The toolkit provides a good balance between clear, accurate information and practical guidance, it is not however intended to be a comprehensive source of information. Specifically, detailed instructions about how to achieve and maintain weight reduction, which is one of the main issues in diabetes prevention are not given because local and national guidelines as well as other information are available elsewhere. Furthermore, intervention delivery staff are assumed to have basic knowledge about e.g. diet and physical activity and their health effects and about supporting behaviour change. Finally, the toolkit is not designed to be used to provide intervention materials to be delivered directly to those participating in prevention interventions, although it does contain some examples of information sheets and materials which might be used with participants.

Content of the toolkit

The toolkit starts with an executive summary including the rationale for diabetes prevention [49]. It is followed by a chapters representing the background (type 2 diabetes prevalence, risk factors, consequences, evidence of successful prevention), and giving instructions about the planning and development of prevention programmes and the identification, and recruitment of participants at high risk for T2DM. One of the core items of the toolkit is the description of what to do and how to do it. Behaviour change is a process which requires individual attention, and effective communication to achieve motivation, self-monitoring, sustained support and other intervention to prevent and manage relapses. This section includes a model of intervention including empowerment and patient-centred messages. It is followed by key messages on behaviour (physical activity and diet) that are important in prevention of diabetes, and practical advice for patient-centred counseling. The focus is on long-term, sustainable lifestyle changes.

Finally, a brief guide for evaluation and quality assurance in reference to the «Quality and outcome indicators» is included. This section is followed by a consideration of possible risks and adverse effects. The IMAGE Toolkit main text ends with a positive mission statement, emphasizing what can be achieved if we work together. The appendices give the reader a set of easy-to-use tools including a checklist for prevention programme development, templates for goal-setting and for food and physical activity diaries, an example of a risk screening questionnaire (the FINDRISC questionnaire) and a template for evaluation and quality assurance data collection [49].

Prevention manager

As part of the IMAGE project, a curriculum for the training of prevention managers was also developed [157]. The purpose was to develop common European learning goals, teaching methods and contents as well as teaching material for the training of health care professionals who want to carry out lifestyle interventions for diabetes prevention (Prevention managers^{T2Dm}). With this curriculum, for the first time a standardised state of the art training for health care professionals interested in offering preventive intervention can be performed Europe-wide in a comparable and consistent way. This is particularly useful because a standardised method to train the trainers for diabetes prevention can also pilot the same strategies for the prevention of other chronic diseases. All materials needed to train a prevention manager will be freely available at www.virtualpreventioncenter.com. National institutions, such as universities or associations interested in the training of eligible health care professionals are encouraged to download the specific teaching material and follow the curriculum for the training of prevention managers.

The idea behind the curriculum for the training of diabetes prevention managers was to develop a standardised training curriculum for people coming from different professional disciplines, but who, together want to deliver coordinated interventions for the prevention of type-2-diabetes. Currently 11 European countries and more than 20 extra European countries have started to train prevention managers following the IMAGE curriculum.

National Initiatives

Along with European level support, National governments and health care organisations are increasingly developing tailored national policies and guidance aimed at the prevention of chronic disease. For example, Finland has adopted a regional systematic whole system approach across all sectors of the health care community, including primary care, pharmacy and community settings, to the prevention of type 2 diabetes [147]. In the United Kingdom, the National Health Service Health Checks Programme has been rolled out nationally and aims to screen all individual between 45 and 70 years for the risk of chronic disease and treat high risk individuals accordingly (<http://www.healthcheck.nhs.uk/>) [158]. In addition, new NICE guidance has been published which provides a blueprint for the prevention of type 2 diabetes in the community and primary care [68]. A similar program is underway in Germany. A health check where all persons between 35 and 65 years are eligible will be established including FINDRISC, parameters of the metabolic syndrome, HbA1c and creatinine. A standardized management of persons screened at risk into primary and secondary prevention programmes will be established or inclusion into disease management programmes for newly identified diabetes patients.

In November 2011 Denmark has introduced a tax on saturated fatty acids. 1 kg saturated fatty acids increased taxes by 2,50 €. This has successfully reduced the sales of products with a high content of fat significantly. Unfortunately after 11 months Denmark has postponed the tax due to disruption of national business, because Danish people tended to cross boarder shopping in Germany. Both examples show that standardized guidelines and summarized evidence alone does not foster itself the implementation of diabetes prevention programs. National initiatives are the key targeting people at high risk which can be a success model on regional, local or national arena. Population based strategies for example including taxes for unhealthy food require pan national policies and activities, but can be very efficient on overall public health on a population.

The US experience

Reduction in the incidence of type 2 diabetes on a population level requires collaboration among community-based organizations, insurance payers, health care and public health professionals, academia, and others. In 2010, the U.S. Congress authorized the Centers for Disease Control and Prevention (CDC) to establish the National Diabetes Prevention Program (National DPP) to translate and systematically scale the U.S. DPP for individuals at high risk. The National DPP brings together the groups listed above and unifies delivery of proven lifestyle change programs in communities throughout the country. The National DPP consists of four components:

Training

CDC established the Diabetes Training and Technical Assistance Center (DTTAC) at Emory University to help increase the work force by providing training to lifestyle coaches and those who train lifestyle coaches. There are other organizations, such as the YMCA, that provide training so DTTAC also serves to coordinate training functions (<http://dttac.org>).

Program Recognition

The CDC Diabetes Prevention Recognition Program (DPRP) (www.cdc.gov/diabetes/prevention) assures program quality, consistency, provides a registry of recognized programs, and implements standardized reporting on performance of recognized programs.

Intervention Sites

The YMCA (Y) and United Health Group (UHG) are the first to participate in the National DPP and are collaborating on instituting community-based prevention programs in which the Y delivers the lifestyle change program while the UHG provides third-party reimbursement for its beneficiaries. This is a new payment model in which an insurer reimburses a community-based organization based on performance. With implementation of the DPRP, more organizations are involved in program delivery and reimbursement.

Health Marketing

Participant engagement and health care provider referrals are important for program success. CDC and others, such as the Diabetes Prevention and Control Alliance, are testing various marketing strategies to enhance program participation. The public health sector can play an important role in continuous evaluation and monitoring to ensure successful implementation of diabetes prevention programs. Furthermore, this is

vital for quality assurance and benchmarking of standardized procedures. Scientific outcome evaluation indicators and measurement recommendations (e.g., body weight, waist circumference, HbA1c, total energy intake, etc.) have been developed to monitor the effectiveness and efficiency of programs [135]. Recent experience demonstrates that monitoring alone, as function of quality management, is a driver for increasing the quality of intervention programs [159]. The CDC DPRP, as part of the National DPP, serves this monitoring function for diabetes prevention programs in the U.S.

*The elements for prevention: steps to develop a prevention program.
Basic science in diabetes prevention*

Exploration of the molecular physiology of the prevention of type 2 diabetes is key in both understanding the pathomechanisms of diabetes prevention and also in developing targeted intervention programs with improved outcome. Growing evidence suggests that insulin resistance, in a normoglycaemic person, is the key processor of the development of diabetes risk [40]. The role of visceral fat mass and visceral obesity seems to be a key trigger for the development of insulin resistance [160]. The visceral fat secreted adipokine profile directly influences inflammatory processes and insulin resistance development which then altogether directly influences diabetes risk [161]. Furthermore, together with an increasing level of circulating insulin, also proinsulin seems to become a major factor in triggering diabetes development and, subsequent cardiovascular disease and cardiovascular morbidity. Understanding these pathophysiological mechanism will make it necessary to explore the genetic basis of the regulation of insulin resistance and to understand visceral obesity and the combined pathophysiology behind it. Current evidence from genome-wide association studies explains a small proportion of diabetes pathophysiology [162, 163]. However, current investigations suggest that there is a link between genetic susceptibility and the outcome in preventive interventions [164, 165]. Furthermore, basic prevention studies show there is a substantial proportion of people at risk for diabetes, who do not respond to an intervention or do not benefit from an intervention, even without diabetes development. A significant challenge in the future is the development of pathophysiology-targeted prevention programs, as well as the identification of non-responders for preventive interventions.

Efficacy in diabetes prevention

To test intervention concepts and to generate evidence about intervention structures, diabetes prevention programs have to be tested in ideal randomized control trial (RCT) settings. In recent years considerable evidence showing that sustained lifestyle change enables a significant ability to prevent or delay type 2 diabetes has developed [15, 166]. A number of large randomized clinical trials have shown that interventions, focusing on improved physical activity and nutritional intake along with strategies and supports for behaviour change, enabled up to 58 % prevention of type 2 diabetes. Furthermore, using traditionally known diabetes drugs, enables prevention of type 2 diabetes [15, 17]. Lifestyle interventions and drug treatment do not show an additive effect; unfortunately, there is conflicting evidence about the combination. Lifestyle intervention was more effective in older adults and less in obese people than the drug metformin. Metformin was more effective in younger, heavier people and women with a history of GDM in the United States Diabetes Prevention Program (U.S. DPP) [15]. By summarizing the efficacy in diabetes prevention, we have learned that the prevention of diabetes is effective and feasible, but we have also identified barriers and the challenging task of how to implement this knowledge. [167].

The efficacy of diabetes prevention programs may be strongly influenced by pathophysiological differences. There is a huge variation for the conversion from impaired glucose tolerance to diabetes mellitus and the trigger mechanisms are not completely understood. The efficacy will increase as higher the conversion rate is, as well as higher the prevalence of impaired glucose metabolism in the population is. Due to the fact, that the prevalence of impaired glucose tolerance increases in nearly all populations, the efficacy of diabetes prevention programs may increase in the future [23].

Effectiveness in diabetes prevention

After obtaining the evidence derived from RCTs, it is necessary to translate this knowledge into real-world settings. This generates a number of new challenges and makes it necessary to start a critical discussion about necessity and practicability of what was done in the RCTs and what is applicable to real-world settings. A number of translation studies have tried to do this and have found ways to reduce costs and achieve the same or similar weight loss as the RCTs. There are challenges in moving from RCTs to real-world implementation in diabetes prevention. One issue is screening to identify those at high-risk. It is unre-

alistic to believe that performing two OGTTs for screening, which is done in some countries, can be appropriate for prevention programs in real-world settings, except for a very high risk individuals in the medical environment. A number of translational trials have been performed in several parts of the world, with different experiences. The implementation design often depends on limited financial resources and is driven by the circumstances in the environment to enable screening and intervention. Therefore, the translational trials are often driven by the practical need for diabetes prevention and the dimension of the clinical and public health problem in the environment. They adjust screening procedures and interventions to the existing environments, driven by the hypothesis to test the feasibility and applicability of an intervention program to the real-world setting [51]. The subsequent translation studies of the U.S. DPP have shown that by delivering the program in a group setting (instead of one-on-one) and utilizing lower-cost trained health educators and community organization staff, the program can be delivered effectively and cost-effectively [168].

Efficiency of diabetes prevention

After having learned from the implementation trials and having put together practical evidence from effectiveness studies, the next challenge is to modify the programs or their implementation to achieve the biggest impact for the most people who need the intervention. The efficacy research studies are often only applicable to a limited part of the population and studies often include a relatively small number of people. The effectiveness trials are more likely to use a more broadly defined high risk population, but the interventions that have been proven to be effective in real-world settings still may not address factors that will scale the intervention to reach the most people. At this stage, for the first time, policy perspectives and plans for cost-effective expansion of the intervention come into account. RCTs or effectiveness trials cannot tell us how to achieve the best effect for most of the people; this requires networking with a number of specialists and stakeholders from neighbouring fields in medicine and public health and expertise in fields such as management, economics and policy development.

To be efficient in the prevention of type 2 diabetes on a population-level, political support on local and national levels to build national diabetes prevention plans is needed. These plans help relevant players and stakeholders to network in order to agree on a concerted action involving different resources from societal and personal life to enable an efficient and wide reaching type 2 diabetes prevention program.

Availability of diabetes prevention

After addressing the efficiency of diabetes prevention through a practical framework of stakeholders, as well as, political support and necessary resources to enable a population impact, it is necessary to address program availability and accessibility and capacity. Availability includes an adequate number of programs in the community within easy access, the existence of adequate personnel resources to train the prevention managers, as well as, an adequate number of prevention managers. The development of the European curriculum for the training of prevention managers is a relevant achievement to standardise intervention procedures and to develop «train the trainer» strategies. As part of the National Diabetes Prevention Program, the United States has developed the Diabetes Training and Technical Assistance Center at Emory University to help train master trainers and lifestyle coaches and coordinate training efforts [168]. Policies that support adequate resources and coordination are important at this stage and support from scientists and medical experts in the field to drive the right political decisions and program availability is vital.

The industrialization of diabetes prevention programs becomes a relevant challenge. The Danish example with the tax on saturated fatty acids is an effective model for diabetes prevention on a national scale, but failed due to political reasons and the missing pan European policy. The industrialization can also be achieved by adequate and intensified training of medical professional and healthcare workers to perform diabetes prevention programs and to build a framework to implement business solutions for diabetes prevention. The extensive growth of new media and mobile health solutions may help to make healthy lifestyle information more available throughout the population, but also to enable mobile health intervention concepts. We have to expect that not one solution will address the needs of a large population. We will need a number of solutions providing adequate care and attention for diabetes prevention, based on target population, individual prevalence, readiness to change lifestyle, environmental and regional aspects and many more [23].

Distribution of diabetes prevention

The best program, if it is not reachable for people with increased risk, will fail [148]. Any preventive action will have to be performed in the environment in which the people with increased risk live and work

[3, 169]. Structures and policies to identify high-risk individuals and manage intervention follow-up, and evaluation have to be established. Scientific evaluation standards based on the RCTs need to be translated into the public health care setting with careful management of considerably more limited resources. This has been achieved in Europe by the international IMAGE consortium with a quality management structure [135]. In the United States, the National Diabetes Prevention Program contains a recognition program that set standards that help assure program quality and consistency. CDC is responsible for conducting this program and reporting on the distribution and quality of the diabetes prevention program across the United States [169].

Fulfilling the development of a national diabetes prevention program

Within the European Union, only five of 27 countries have a national diabetes plan and only one has a national diabetes prevention program [170]. In Asia, the situation is similar with a progressive increase in the number of countries including diabetes prevention in their national policies [171]. The United States is at the forefront of governmental initiatives for developing a diabetes prevention program with the CDC being the driving force for coordinating the national effort [168]. The existence of a national policy for supporting diabetes prevention does not always equate with a positive outcome, but it is a mandatory first step for successful public health implementation. The European Coalition for Diabetes, together with the EU Diabetes Working Group, has installed working groups to address the need for delivering adequate care for diabetes in Europe. Those working groups have elaborated recommendations to the EU institutions and other governments to take urgent action to address the major public health challenge that diabetes represents. Currently in the UK and Germany National programmes undergoing development include the NICE and the UK Vascular Check Programme and the German Check-up 35+ programme.

To prevent type 2 diabetes, an adequate scientific basis provided by research, efficacy studies in highly controlled environments, and effectiveness studies in real-world environments performed by clinical researchers and public health experts are necessary. To scale up diabetes preventive actions to the population, the program strategies have to be adjusted to have the best effect for a relevant proportion of the population as well as the supply and diffusion of the intervention into the population. Policy development is a necessary part of the latter three steps. The development of national diabetes plans, which are supported by local prevention management and adequate networking and stakeholder involvement, are necessary to address this challenge and guide implementation of diabetes prevention [4].

Health Literacy: barrier or improvement measure?

In addition to political and financial challenges of health systems, we are witnessing, that it is not enough to plan, implement, monitor and evaluate prevention by just looking at medical needs of patients. Scientific evidence shows, that people with low health literacy have a higher risk for a poor health status [172], higher hospitalization rates [173] and higher mortality rates [174]. Looking especially at type-2-diabetes, patients with low health literacy tend to have a poorer glycemic control [175] and are less aware of symptoms related to hyperglycemia [176]. Those who have the lowest health literacy competences have a higher risk for developing chronic conditions. On top of that, it is less likely that these patients receive the care they actually need. Additionally, they are having substantially poorer preconditions to seek, find, understand, and use (online) health information, to take informed decisions [177].

The adherence to medical treatments and behavioral lifestyle change primarily works for those with a considerable level of health literacy and systematically causes inequalities in terms of access to care, support and information [178]. Recent studies indicate that some patients seem to be systematically excluded from these benefits due to low health literacy skills, potentially leading to an extension of health inequalities and a growing amount of people not participating in care [179, 180]. A recent review of Morony emphasizes that more than 90 % of educational materials written for kidney disease is higher than an average patient's literacy, limiting the understanding of key messages [181].

A recent report from the European Commission indicated that more than 80 % of the European population is using the internet for private purposes on a daily basis but more than 40 % of the total population and even 59 % of citizens with low health literacy have never searched for health related information online [182]. However, improved digital health literacy and literacy-adequate health information represent a great opportunity to gain positive impact on the citizens' personal level regarding knowledge, motivation, self-confidence, treatment adherence, feelings of control, social involvement, improved decision making and empowerment [111].

For the prevention and care of diabetes it is therefore of utmost importance to incorporate the ability of patients in understanding, translating and applying health-related information.

Diabetes risk in childhood and adolescence

The prevalence of childhood obesity has increased dramatically during the past decades although there is emerging evidence that prevalence rates seem to have stabilized at present, albeit at high levels, especially in the younger age groups [183, 184]. Overweight and obesity now affects between 15–30 % of all children and adolescents in many industrialised countries. The rise in childhood overweight and obesity has dramatically altered the demographic profile of chronic disease in affected countries. For example, type 2 diabetes, once a clinical rarity in younger adults (< 40 years) and children, has now prevalence rates estimated to have increased by up to 10-fold in recent decades [185]. This shift in the profile of type 2 diabetes has a serious consequence as its emergence in younger age groups represents an extreme phenotype that magnifies the disease profile observed in adults. Risk factors for the development of T2DM in childhood and adolescents include [186, 187]:

- Type 2 diabetes of first- or second degree relatives;
- Morbid obesity (BMI > 99.5 percentile);
- Ethnic background (East Asians, African-American, Hispanics);
- Clinical signs of insulin resistance or associated features (syndrome of polycystic ovaries, acanthosis nigricans, dyslipidemia, elevated liver enzymes).

In addition to the development of T2DM, affected individuals are also at higher risk for the development of significant cardiovascular comorbidities early in life: Compared to age-matched healthy controls, incidence of myocardial infarct in younger people with type 2 diabetes has been shown to be fourfold higher than in late-onset type 2 diabetics and 14-fold higher than in people without diabetes [188]. Preliminary data from adolescents with type 2 diabetes in Canada, followed-up for 9 years, found that the mortality during this period was almost 10 %. Along with increasing the prevalence of chronic disease and mortality rates in younger age ranges, childhood obesity also significantly increases the risk of chronic disease into adulthood [189]. Thus the emergence of deleterious lifestyle practices and obesity in younger age ranges will have a devastating clinical and societal legacy that is only just beginning to emerge. The focus of health care policy and research, which has commonly targeted those over 40 years of age, has lagged behind this substantive shift in the demographic profile of obesity and chronic disease. However, if left unchecked, it is clear that this will become one of the primary clinical priorities within the next couple of decades. Therefore, high-quality research is urgently needed to investigate optimal methods of identifying and treating diabetes risk in children and adolescents. This includes the development of integrated risk scores that are lacking in this group. However, at present the World Health Organisation recommends that, starting at 10 years of age, an oral glucose tolerance test (OGTT) should be performed in overweight (BMI > 90. percentile) children or adolescents who present with at least 2 additional risk factors mentioned above or several clinical signs or associated sequelae of insulin resistance [186]. Once diagnosed, «conservative» approaches including lifestyle changes, promoting physical activity, and assessing and optimizing dietary habits should be the main focus of intervention at that age group. Metformin [190], a common first or second line therapy for adults, may also be appropriate for children and adolescents with diagnosed T2DM, and clinical studies for the use of metformin in impaired glucose tolerance in the pediatric population are underway. It is crucial that children and adolescents with type 2 diabetes are seen by a pediatric endocrinologist/diabetologist to receive comprehensive diabetes health education and long term clinical care within a specialized centre [187].

The clinical environment sets a number of limitations because only a selective clientele of adult patients is accessible — those who go to a physician due to disease burden, whereas the majority of the paediatric population is regularly seen by a paediatrician for routine medical checkups, vaccinations, or other reasons and might than be screened for relevant risk factors. On the other hand the clinical environment enables a more comprehensive and targeted approach due to the availability of diagnostic and treatment as well as intervention procedures. The public health environment offers a far more wide spread accessibility to target populations and to identify people at risk. The public health strategy is more related to address population embedded risk behaviour to be addressed by comprehensive health policy.

For a clinical applicable approach to target diabetes risk reduction we recommend

- screen the adult population by using the FINDRISK score or a comparable risk score as well as available clinical data by screening computer data bases;

- Where possible, those above a predefined high risk threshold level should have their risk status confirmed, and the presence of type 2 diabetes ruled out, by a simple measure of glycaemia, such as fasting glucose or HbA1c.
- In children > 10 years of age, an OGTT should be performed in overweight (BMI > 90. percentile) subjects who present with at least 2 additional risk factors (T2DM of first- or second degree relatives, morbid obesity (BMI > 99.5 percentile); ethnical background (East Asians, African-American, Hispanics), clinical signs of insulin resistance or associated features (syndrome of polycystic ovaries, acanthosis nigricans, dyslipidemia, elevated liver enzymes).
- Those children/adolescents and adults confirmed to have a high risk status or even confirmed IGT/T2DM, are eligible for lifestyle intervention programs (all age groups) or pharmaco-preventive strategies (mainly adults).

Conclusions

It seems that diabetes prevention is a major opportunity for global health and some have even referred to it as «the future of diabetology». The evidence that diabetes is a preventable disease is excellent. A number of large randomized clinical trials have shown that more than 50 % of diabetes risk can be reduced and diabetes can be postponed and prevented sustainably over more than a decade. Translational studies that tried to translate scientific evidence into clinical practice have proven that similar results are reachable in clinical practice and that it's feasible to implement diabetes prevention programs in different care processes and structures. But those translational studies also have shown that it's the responsibility of healthcare policies to harness existing care structures and infrastructure to structure the prevention program and what is the outcome for the person at risk and the community. Over recent years we have learned a lot about non pharmacological interventions and that they are effective in preventing diabetes from developing and we have gained a lot of knowledge regarding policies that still need to be developed [23]. Effective strategies to identify people with increased diabetes risk are available. Changing physical activity and eating habit can be effective in prevention diabetes but most effective seems to be to «walk the diabetes away» approach. 10000 steps and more a day prevent diabetes significantly but already importantly 1000 additional steps to the normal daily amount of steps — even if much less than 10000 — are as effective as 1000 mg metformin.

Now we have to play the ball from the research arena into political field. Political support is needed to build up the framework for a successful implementation of diabetes prevention programs. But finally we together with all relevant stakeholders have to build effective and sustainable prevention programs. This should not be an excuse for researchers not to act — like Kofi Annan said: «We have not enough money to do nothing».

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2-Типті диабеттің алдын алу мүмкіндігіне өмір сүру салтының ықпалы

Клиникалық тәжірибеде диабеттің алдын алу іргелі ғылымдар жетістігін қолдануды талап етеді. Соңғы он жыл ішінде клиникалық зерттеулер тәуекел тобының 2-типті диабет дамуын болдырмау мәселесінде өмір сүру факторларының маңыздылығы нақты тұжырымдалды. Қазіргі таңда диабеттің алдын алу бағдарламаларын нақты түрде ендіруде маңызды ақпараттарды соңғы зерттеулер беріп отыр. Жекелеген елдерде диабеттің алдын алу шаралары қабылданған, бірақ нақты тармақтар міндетті орындалу жоспарында ауқымды аймақтар немесе ұлттық бағдарламалары жұмыстарда қиындық тудырады. Жұмыс жүзеге асу үшін арнайы дайындықтан өткен медициналық қызмет көрсету, медицина саласындағы экономистер, денсаулық сақтау қызметкерлері және қоғамдық ұйымдар

өкілдері беделді саясаткерлермен өзара әрекеттесе қызмет жасауға бейім болулары қажет. Мақалада саяси қолдау өте маңызды құраушы болып табылады. «Қазіргі әлем тәжірибесінде» диабеттің алдын алу бағдарламасын жүзеге асыруда қажет зерттеулер нәтижелері көрсетілген.

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Влияние образа жизни на возможность предотвращения развития диабета 2 типа

Профилактика диабета требует использования достижений фундаментальной науки в клинической практике. В течение последних десятилетий клиническими исследованиями было твердо установлено значение факторов образа жизни в вопросах предотвращения развития диабета 2 типа среди лиц из группы риска. Последующие исследования предоставили важную информацию о реальном внедрении программ профилактики диабета. В отдельных странах предприняты усилия по профилактике диабета, однако при работе по большим региональным или национальным программам, конкретные пункты которых должны быть запланированы и выполнены, возникают определенные трудности: отсутствие подготовленных специалистов в области медицинского обслуживания, экономистов медицинского профиля, работников здравоохранения и представителей общественных организаций, способных взаимодействовать с влиятельными представителями политических кругов. Политическая поддержка является очень важным компонентом в работе по профилактике диабета. В статье представлены результаты исследования, которые могли бы помочь в успешном выполнении программы по профилактике диабета «Практика реального мира».