Contents available at ScienceDirect
Diabetes Research and Clinical Practice
journal homepage: www.elsevier.com/locate/diabres
International Diabetes Federation

Screening for people with abnormal glucose metabolism in the European DE-PLAN project

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ARTICLE INFO

Article history:
Received 10 November 2014
Received in revised form
9 March 2015
Accepted 12 April 2015
Available online xxx

Keywords:
Type 2 diabetes
Europe
FINDRISC
Prevention
Risk factors

ABSTRACT

Aims: The aim of this report is to describe the application of the FINDRISC in clinical practice within the DE-PLAN project as a step to screen for Type 2 diabetes.
Methods: Nine out of 24 possible centers were included. Six centers used opportunistic screening methods for participant recruitment whereas three centers provided study participants of a random population sample. Men ($n = 1621$) and women ($n = 2483$) were evaluated separately. In order to assess the prevalence of abnormal glucose tolerance (AGT) disorders across different risk categories, the FINDRISC was used. Anthropometric measurements included blood pressure, height, weight, and waist circumference. Blood lipids and an oral glucose tolerance test were performed in all participants. The primary outcome was identified risk of AGT and type 2 diabetes.
Results: There was no difference in the prevalence of smoking between the FINDRISC categories, people with a FINDRISC below 15 points tend to be more physically active and to eat more frequently fruits and vegetables. Men with a FINDRISC from 15 to 19 points had a prevalence of abnormal glucose tolerance of approximately 60% and women 50%. The prevalence for men and women with a FINDRISC >20 points was 80%. 30% of men and 20% of women with a FINDRISC between 15 and 19 points had Type 2 diabetes. Among people with a FINDRISC more than 20 points, 50% had previously undiagnosed Type 2 diabetes.
Conclusions: The FINDRISC may be a practical tool to be used in primary health-care systems throughout the European population.

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http://dx.doi.org/10.1016/j.diabres.2015.04.016
0168-8227/

1. Introduction

Type 2 diabetes is one of the fastest growing public health problems worldwide imposing both a high burden on individual with the disease and high financial burden on health care systems. The International Diabetes Federation (IDF) has estimated that the number of adults with diabetes in the world is expected to rise from 382 million in 2013 to 592 million by 2035 [1]. According to these IDF estimates the prevalence of Type 2 diabetes in Europe will increase approximately 22% within the next 22 years to reach 68 million. Type 2 diabetes is difficult to treat, thus, efforts need to be undertaken to identify people at high risk of Type 2 diabetes as early as possible as it has been shown that individuals with impaired glucose tolerance (IGT) may prevent Type 2 diabetes by lifestyle changes targeting physical activity and nutritional habits [2–7]. It is a challenge how to implement results from scientific studies into clinical practice in regard to effectiveness and efficiency. The DE-PLAN (Diabetes in Europe—Prevention using Lifestyle, Physical Activity and Nutritional intervention) project builds up on the results of the Finnish Diabetes Prevention Study aiming at integrating the experience in the general population within Europe [6–8]. The main objective of the DE-PLAN Project was to establish a model for the efficient identification of individuals at high risk of Type 2 diabetes in the community in the primary health care settings in most EU member countries followed by lifestyle interventions in people identified as having abnormal glucose metabolism. People were consider high risk if they were found to have impaired Glucose Tolerance (IGT; 2 h glucose between ≥7.8 and <11.1 mmol/l), Impaired Fasting Glucose (IFG; 6.1–6.9 mmol/l) or both conditions.

The first step in the prevention of Type 2 diabetes is the detection of people at high risk of Type 2 diabetes. One of the screening tools with an adequately high sensitivity and specificity is the Finnish Diabetes Risk Score (FINDRISC) developed in Finland [9,10]. The FINDRISC was originally developed to identify people with increased risk to get Type 2 diabetes in the future [9] but has been tested in cross-sectional setting also [10]. The FINDRISC has been successfully implemented into the Finnish primary health care system [11]. However, at the start of the DE-PLAN project in the early 2000s, such screening activities had not been introduced yet, in a large scale within the primary health care system within Europe or other parts of the world.

The aim of this report is to describe the application of the FINDRISC in clinical practice in the DE-PLAN project as a tool to screen for type 2 diabetes.

2. Methods

2.1. Study population

The concept of the DE-PLAN has been described previously [8]. Only centers that provided data on opportunistic or population screening activities using the FINDRISC were included in this analysis. Table 1 presents the study centers, the sample characteristics, and the sample size of the DE-PLAN collaborative centers that contributed data to this study ($n = 9$, out of 24 total centers). Three centers selected the study participants randomly whereas the remaining centers used an opportunistic screening strategy mostly recruiting study participants at the primary health-care center. The participating centers first translated the common study questionnaires into their local language. Thereafter, they collected the information on lifestyle habits, risk factors for Type 2 diabetes and cardiovascular disease (CVD) using a validated self-administered questionnaire that included among other the original FINDRISC questions, and blood samples from the participants for biochemical analyses were drawn. People were asked to join

Table 1 – Study sampling method and sample description of each collaboration center of WP2..

Local center	Study sample	Screening strategy	Sample size
Athens, Greece	Opportunistic sample of four districts in Athens	Patients visiting their health-care center, volunteers, response rate 25%	Women: 54 Men: 25
Barcelona, Spain	Random sample of Catalonians taken from primary health-care register (covers 87% of population) of 18 health-care centres in Catalonia	People without diagnosed type 2 diabetes, response rate 80.6%	Women: 96 Men: 123
Belgrad, Serbia	Opportunistic sample of people living in municipality of New Belgrade	Volunteers recruited by mass media and from register of obesity and occupational medicine	Women: 156 Men: 95
Helsinki, Finland	Representative population sample	Finnish men and women drawn from population register, response rate 67%	Women: 207 Men: 147
Kaunas, Lithuania	Representative population sample	Lithuanian men and women drawn from population register	Women: 267 Men: 144
Krakow, Poland	Opportunistic sample of volunteers of citizens of Krakow	Participants recruited during 2004–2007	Women: 15 Men: 3
Leicester, United Kingdom	Opportunistic sample of regions Leicester city and Leicestershire	Healthy volunteers recruited from GP lists, response rate 20%.	Women: 986 Men: 636
Pisa, Italy	Opportunistic sample of patients in Pisa district	Volunteers free of diagnosed type 2 diabetes recruited by their GP	Women: 202 Men: 67
Santa Maria Imbaro, Italy	Opportunistic sample	People without diabetes but with at least one CVD risk factor	Women: 500 Men: 381

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10-12 3 notes:

the study and to fill in the study questionnaire that was handed out in paper. Thereafter, they were invited to an oral glucose tolerance test (OGTT). Only people who provided data on both questionnaires and an OGTT were included in this study. After excluding observations with missing data, the final sample comprised 1621 men and 2483 women.

13-14 2 notes:

2.2. Non-invasive measurements

In order to assess the probability of glucose metabolism disorders, the FINDRISC was used. Details on the development and validation of the FINDRISC in a prospective setting have been published elsewhere (9). Since the aim was to produce a simple risk calculator that could be conveniently used in primary care and also by individuals themselves, only those variables that were easy to assess without any laboratory tests or those clinical measurements that did not require special skills were included. The FINDRISC form is a one-page questionnaire comprising eight questions with categorized answers: age, BMI, waist circumference, physical activity, daily consumption of fruits, berries or vegetables, history of antihypertensive drug treatment, history of high blood glucose, and family history of diabetes. These variables predicted diabetes incidence in the original study cohort from which the risk score was developed. Each of the answers to the questions in the form was weighted, corresponding to the risk increase associated with the respective variable in the original model. The total risk score is a simple sum of the score of each variable. The total score ranges from 0 to 26.

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16-18 3 notes:

Risk categories were assigned as follows: <11 points (low or slightly increased), 12 to 14 (moderate), 15 to 20 (high), and over 20 (very high).

BP was measured twice from the right arm of the participant, who was seated for five minutes before the measurement and the mean of these two BP measurements was used in the analyses.

Height and weight were measured without shoes and with light clothing. BMI was calculated as weight (kg) divided by height squared (m^2). Waist circumference was *measured* at a level midway between the lowest rib and the iliac crest to the nearest centimeter (cm).

2.3. Invasive measurements

An oral glucose tolerance test (OGTT) was carried out according to the WHO recommendations [12] with a 75 g anhydrous glucose load. The test started after overnight fasting, and after the fasting sample the post-load blood sample was obtained 2 h after the ingestion of the glucose solution. Plasma glucose was determined at each local laboratory. For this report, diagnosis of all glucose disorders was based on the results of a single OGTT, a commonly accepted procedure for screening large populations.

19-20 2 notes:

The glucose tolerance status was classified according to the WHO criteria [12] as follows: Type 2 diabetes (fasting plasma glucose ≥7.0 mmol/l or 2 h glucose ≥11.1), impaired glucose tolerance IGT (2 h glucose ≥7.8 mmol/l but <11.1 mg/dl, and fasting plasma glucose <7.0 mmol/l), impaired fasting glucose IFG (fasting plasma glucose ≥6.1 mmol/l but <7.0 mmol/l, and 2 h glucose <7.8 mol/l) and normoglycemia (fasting plasma glucose <6.1 mg/dl and 2 h glucose <7.8 mmol/l). Furthermore, individuals with either IGT, IFG or Type 2 diabetes were categorized as having abnormal glucose tolerance (AGT). Individuals who reported that they have diabetes were excluded from the screening activity and the analysis.

Non-fasting or fasting serum total cholesterol concentrations after the precipitation of beta-lipoproteins with dextran sulphate and magnesium chloride were determined using an enzymatic method.

2.4. Ethical considerations

All study centers followed the Good Clinical Practice guidelines and the guidelines of the Helsinki Declaration. All the data have been collected using previously tested questionnaires and methods as much as possible. Besides blood samples, no invasive methods was used. The study protocol was approved by the research ethics committees of each participating center. All the participants gave their written or oral informed consent prior participation to the study.

2.5. Statistical analysis

The data was analyzed using IBM SPSS statistics version 19.0 for Windows. The variables were checked for normality using Kolmogorov–Smirnoff tests. The χ^2 test was used to test differences in the distribution between categorized variables. Trends testing a linear relationship among continuous variables according to FINDRISC categories were assessed using linear regression analysis. The results are expressed as percentages, means and standard errors/standard deviations. The threshold for statistical significance was set to 0.05.

3. Results

The characteristics of the study sample are presented in Table 2. Both men and women had an unfavorable overweight or obesity indicators. The mean waist circumference was 110 cm in men and 101 cm in women. Mean BMI was close to 32 kg/m^2 in both genders. The prevalence of daily fruit and vegetable intake was 61% in men and 68% in women.

Daily physical activity was reported by 56% of the women and by 51% of the men. Of men 55% and of women 43% had AGT.

Table 3 shows the risk factors of Type 2 diabetes and cardiovascular diseases in the study sample according to FINDRISC categories. In both men and women, age, systolic blood pressure, triglycerides, BMI and waist circumference increased with the increasing FINDRISC value. There was no difference in the prevalence of smoking between the FINDRISC categories, while people with lower FINDRISC values tended to be more physically active and to eat more frequently fruits and vegetables.

Figs. 1 and 2 present the prevalence of AGT and screen-detected Type 2 diabetes according to the FINDRISC category. Men and women with a FINDRISC less than 12 points had a lower probability to have AGT compared with people in the higher FINDRISC categories (Fig. 1).

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Table 2 – Baseline characteristics, measurements and FINDRISC parameters of study sample aged 45–74-years by sex.

	Men (n = 1621) Mean (SD[a])	Women (n = 2483) Mean (SD)
Age	60.1 (7.6)	59.4 (7.8)
Systolic blood pressure (mmHg)	143 (18)	139 (18)
Diastolic blood pressure (mmHg)	88 (11)	85 (10)
22-23 2 notes: Triglycerides (mmol/l)	1.87 (1.25)	1.59 (0.86)
Total cholesterol (mmol/l)	5.58 (1.06)	5.92 (1.08)
HDL cholesterol (mmol/l)	1.27 (0.40)	1.50 (0.58)
Body mass index (kg/m^2)	31.78 (3.64)	31.78 (5.13)
Waist circumference (cm)	111 (8)	101 (10)
	% (n)	**% (n)**
24-26 3 notes: FINDRISC category		
0–11 points	14 (228)	17 (426)
12–14 points	33 (542)	34 (858)
15–20 points	43 (690)	40 (979)
>20 points	10 (161)	9 (220)
Regular daily physical activity	51 (830)	56 (1386)
Regular daily vegetable/fruit intake	61 (990)	68 (1697)
Not smoking	80 (1292)	86 (2142)
Glucose tolerance		
Normoglucemic	45 (726)	57 (1415)
Isolated glucose intolerance (IGT)	10 (159)	11 (284)
Isolated impaired fasting glucose (IFG)	13 (219)	8 (196)
IGT and IFG	7 (118)	6 (154)
Screen-detected type 2 diabetes	15 (399)	18 (434)

[a] Standard deviation.

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Men and women with a FINDRISC of 15–19 points had a prevalence of AGT of approximately 60% and 50%, respectively. Approximately 80% of the people with FINDRISC above 20 points had AGT. Men and women with a FINDRISC 15–19 points had an approximately 30% and 20% probability to have screen-detected Type 2 diabetes (Fig. 2). People with a FINDRISC more than 20 points, had a 50% chance to have Type 2 diabetes.

4. Discussion

People with 15 points or more in FINDRISC presented a higher risk to have AGT and screen detected Type 2 diabetes. People categorized in the higher FINDRISC categories showed a worse CVD profile compared with those with a lower FINDRISC. The cut-off level FINDRISC ≥15 for "high risk" has been chosen according to the best available evidence from validation studies conducted in the Finnish, Catalan, Italian and Greek populations with essentially identical results [10,17–19].

Many risk scores have been developed to detect people at high risk of Type 2 diabetes or people with existing AGT [13–15]. The main idea behind risk scores is to have a first-step screening tool that can be applied to the target population without any laboratory tests (non-invasive tools). Even though they vary in some ways, such as the number of variables for prediction and their weighting the core indicators such as adiposity and family history of diabetes are included in most of them. Risk scores may offer an excellent tool to identify those at risk in different populations easily and at low cost. Recently, a European study validating existing non-laboratory-based models and assessing the variability in predictive performance in European populations found that existing diabetes prediction models can be used to identify individuals with high risk of Type 2 diabetes in the general population [16]. The challenge is how to implement the use of risk scores within the primary health care system and Type 2 diabetes prevention programmes in order to detect people at high risk of Type 2 diabetes or AGT. Whereas the FINDRISC is already part of the Finnish National Diabetes strategy [11], other countries use Type 2 diabetes screening tools in only some parts of the primary health care system [20–22]. Population testing of blood glucose is not recommended as it is not sure whether the prognosis of Type 2 diabetes can be improved by early detection and treatment [23,24]. Therefore, it has been suggested that screening of AGT should be targeting high risk individuals. A recent study has shown that the probability of a false negative test result, compared with the OGTT, is high when trying to detect Type 2 diabetes by only fasting plasma glucose (FPG) and/or glycated haemoglobin (HbA1c) measurements, indicating that FPG and HbA1c are rather insensitive [25]. Furthermore, a study in a Spanish high-risk population revealed that 8.6% had undiagnosed Type 2 diabetes detected by FINDRISC followed by an OGTT whilst only 1.4% had an HbA1c >6.5% (48 mmol/mol) confirming the relative insensitivity of HbA1c for detecting undiagnosed Type 2 diabetes as a second step of a screening program for asymptomatic Type 2 diabetes [19]. Thus, the argument in favor of using FPG or HbA1c rather than an OGTT is primarily related to feasibility.

The current approaches for early detection of Type 2 diabetes and other disorders of glucose metabolism are: (i) measuring PG or HbA1c to explicitly determine prevalent Type 2 diabetes and impaired glucose regulation; (ii) using demographic and clinical characteristics and previous laboratory tests to determine the likelihood for Type 2 diabetes; or (iii) collecting questionnaire-based information that provides information on the presence of etiological risk factors for Type 2 diabetes [19]. The last two approaches do not clearly determine the glycaemic state and blood glucose testing is necessary in all three approaches to accurately define whether AGT exist. However, the results from a simple first-level screening can markedly reduce those who need to be referred for further testing of glycaemia and other CVD risk factors. Option two is particularly suited for those with pre-existing CVD and women with previous gestational diabetes, while the third option is better suited for the general population and also for overweight/obese people. The guideline of the European Society of Cardiology and European Association for the Study of Diabetes recommends that the appropriate screening strategy in the general population and people with assumed abnormalities is to start with a Type 2 diabetes risk score and investigate individuals with a high value with an OGTT or a combination of HbA1c and FPG [26]. In CVD patients, no diabetes risk score is needed but an OGTT is indicated if HbA1c

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Table 3 – Risk factors of type 2 diabetes and cardiovascular diseases in the study sample 45–74-years-of-age by gender and FINDRISC category.

	0–11 Points Mean (SD)	12–14 Points Mean (SD)	15–20 Points Mean (SD)	>20 Points Mean (SD)	p-Value[a]
Men					
Age (years)	58.0 (7.0)	60.2 (8.1)	60.4 (7.4)	61.5 (7.6)	<0.001
Systolic blood pressure (mmHg)	139 (15)	142 (19)	143 (17)	148 (20)	<0.001
Diastolic blood pressure (mmHg)	87 (11)	88 (11)	88 (11)	88 (11)	0.694
Triglycerides (mmol/l)	1.63 (0.88)	1.87 (1.39)	1.93 (1.27)	1.91 (1.09)	0.009
Total cholesterol (mmol/l)	5.62 (1.04)	5.59 (1.04)	5.56 (1.07)	5.56 (1.12)	0.413
HDL cholesterol (mmol/l)	1.32 (0.39)	1.27 (0.41)	1.24 (0.38)	1.31 (0.50)	0.201
Body mass index (kg/m^2)	30.29 (3.42)	31.43 (3.40)	32.24 (3.71)	33.08 (3.63)	<0.001
Waist circumference (cm)	109 (8)	111 (7)	112 (8)	113 (8)	<0.001
	% (n)	**% (n)**	**% (n)**		**p-Value[b]**
Regular daily physical activity	82 (187)	63 (341)	38 (259)	27 (43)	<0.001
Regular daily vegetable/fruit intake	71 (161)	68 (369)	57 (392)	42 (68)	<0.001
Not smoking	77 (175)	79 (428)	81 (556)	83 (133)	0.462
Women					**p-Value[a]**
Age (years)	57 (7)	60 (8)	60 (8)	62 (8)	<0.001
Systolic blood pressure (mmHg)	134 (19)	138 (19)	141 (19)	144 (17)	<0.001
Diastolic blood pressure (mmHg)	84 (10)	85 (10)	86 (11)	85 (9)	0.006
Triglycerides (mmol/l)	1.51 (0.89)	1.55 (0.86)	1.60 (0.81)	1.84 (0.96)	<0.001
Total cholesterol (mmol/l)	5.93 (1.07)	6.01 (1.14)	5.85 (1.03)	5.85 (1.08)	0.031
HDL cholesterol (mmol/l)	1.50 (0.42)	1.50 (0.43)	1.50 (0.76)	1.46 (0.46)	0.561
Body mass index (kg/m^2)	29.14 (4.40)	31.36 (4.78)	32.94 (5.13)	33.43 (5.58)	<0.001
Waist circumference (cm)	97 (8)	100 (9)	103 (10)	105 (13)	<0.001
					p-Value[b]
Regular daily physical activity	80 (340)	62 (535)	43 (421)	41 (90)	<0.001
Regular daily vegetable/fruit intake	76 (324)	72 (614)	65 (640)	54 (119)	<0.001
Not smoking	85 (361)	85 (730)	87 (850)	87 (201)	0.074

[a] p-Value for testing linear trend.
[b] Chi-square test.

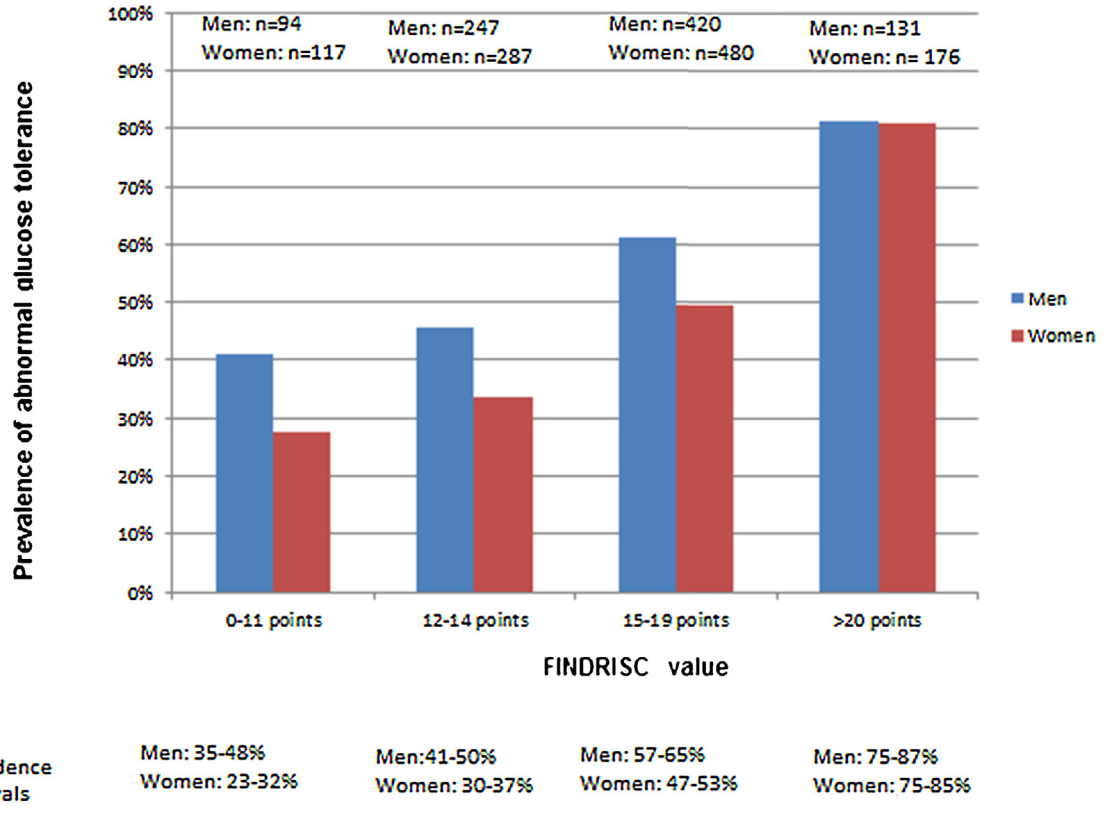

Fig. 1 – Prevalence of abnormal glucose tolerance (AGT) by gender and FINDRISC value of the DE-PLAN participants.

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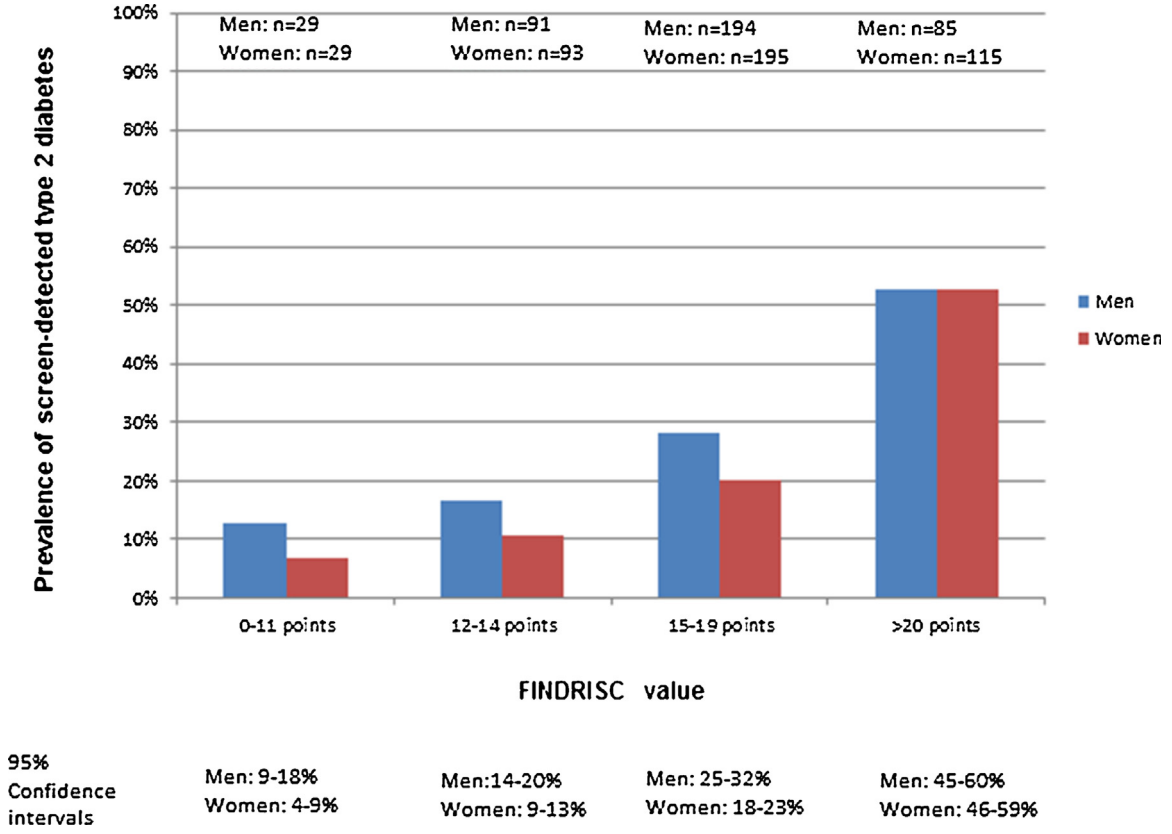

Fig. 2 – Prevalence of screen-detected type 2 diabetes by gender and FINDRISC value of the DE-PLAN participants.

31-32 2 notes:

and/or FPG are inconclusive, as people belonging to these groups may often have Type 2 diabetes revealed only by an ele[illegible] 2-h plasma glucose [27–30].

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As shown in this study, people with AGT have a higher prevalence of overweight, obesity and central obesity than those with normoglycemia. In addition, obesity related indicators independently seemed to be associated with a higher risk of AGT. Randomized controlled trials have clearly shown that in people with IGT the progression to Type 2 diabetes can be prevented or delayed by lifestyle changes [2–7]. In those randomized controlled trials a decrease in excess body weight was associated with a reduced risk of Type 2 diabetes. Thus far there are limited data to show that the progression from IFG to Type 2 diabetes can be halted by lifestyle intervention. The only trial that recruited people with IFG demonstrated a 59% relative risk reduction in people who had IFG and IGT combined, but failed to show any benefit in people who had isolated IFG [31]. It is important that the results of those clinical studies are implemented into clinical practice in the primary health-care system throughout Europe. The use of non-invasive risk scores is more likely to be cost effective and feasible for large-scale screening than is use of invasive risk scores. Furthermore, some studies have shown that strategies for early detection of persons with Type 2 diabetes are cost-effective when combined with lifestyle interventions in those identified with AGT [32–34].

34-35 2 notes:

36-38 3 notes:

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40-41 2 notes:

Naturally, our study has some limitations. It has to be kept in mind that the study population consisted of an opportunistic sample and not a representative sample of the population. In our study, men and women in the lowest FINDRISC category already had a remarkable risk of AGT. This is most likely due to the fact that our study sample consisted mostly of participants identified by opportunistic screening methods, and thus these people already had some indication for an elevated risk of Type 2 diabetes such as overweight or obesity.

Contrary to population-based studies, this project essentially focused on a large sample of undiagnosed high-risk individuals, where the likelihood of developing glucose abnormalities and diabetes clearly increases. Given that each center used a different strategy to recruit participants, the risk factor profile cannot be extrapolated to the general population. However, the main aim of the DE-PLAN was not to conduct a cross-sectional population survey but to implement findings of clinical research on the detection of high risk people into everyday clinical practice.

In conclusion, the FINDRISC questionnaire has the capacity of predicting current undiagnosed diabetes and pre-diabetes as defined by glucose-based diagnostic criteria in this cross-section of the European population. Thus, the FINDRISC may be a practical tool to be used in primary health care systems. Most people attending primary health care facilities could be screened for the risk of diabetes first with a simple method such as the FINDRISC tool. It is essential to identify people at risk as early as possible to prevent Type 2 diabetes; and to detect previously unknown Type 2 diabetes in order to initiate

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betes treatment in an early phase to avoid chronic diabetes complications such as micro- or macro-vascular harms.

Financial support

This project was funded by the Commission of the European Communities, Directorate C—Public Health, grant agreement no. 2004310.

Conflict of interest statement

None declared.

Acknowledgment

The DEPLAN group of this publication consists of the following co-authors and institutions.

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Please cite this article in press as: Cos FX, et al. Screening for people with abnormal glucose metabolism in the European DE-PLAN project. Diabetes Res Clin Pract (2015), http://dx.doi.org/10.1016/j.diabres.2015.04.016

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Screening for people with abnormal glucose metabolism in the European DE-PLAN project

Cos, Francesc Xavier; Barengo, Noël C.; Costa, Bernardo; Mundet-Tudurí, Xavier; Lindström, Jaana; Tuomilehto, Jaakko O.

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FINDRISC in clinical practice to screen Type 2 diabetes

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cites 2 a 7 són de treballs previs de intervenvio amb E/V

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09 Xavier Cos Page 2

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Taula 1

a)que pot comportar el tamanys mostrals diferents

b) diferents estartegies de cribratge ...

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- s'han analitzar les perdues?

- quina va ser la taxa d'acceptació de participació en el projecte (quans del particiapnts convidats van acceptar iu finalment van poders er inclossos en el projecte)?

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16 Xavier Cos Page 3

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17 Xavier Cos Page 3

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Com implementar. FACTIBILITAT!!

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Leicester , danish risk scores?

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principal objectiu dels qüestionaris de risc

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34 Xavier Cos Page 6

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important statement that confirm the limited external validity of this results

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Cost-efectivitat

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