

Lifestyle Intervention for Prevention of Type 2 Diabetes in Primary Health Care

One-year follow-up of the Finnish National Diabetes Prevention Program (FIN-D2D)

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OBJECTIVE — To investigate 1-year outcomes of a national diabetes prevention program in Finland.

RESEARCH DESIGN AND METHODS — Altogether 10,149 individuals at high risk for diabetes were identified with the Finnish Diabetes Risk Score (FINDRISC; scoring ≥ 15 points), by a history of impaired fasting glucose (IFG) or impaired glucose tolerance (IGT), cardiovascular disease, or gestational diabetes mellitus in 400 primary health care centers. One-year follow-up data were available for 2,798 participants who were nondiabetic at baseline (919 men and 1,879 women, aged 56.0 ± 9.9 and 54.0 ± 10.7 years [mean \pm SD] with BMI 30.9 ± 4.6 and 31.6 ± 5.4 kg/m²).

RESULTS — The incidence of diabetes was 2.0 and 1.2% in men and women with normal glucose tolerance at baseline, 13.5 and 7.4% in those with IFG, and 16.1 and 11.3% in those with IGT, respectively. Altogether 17.5% of the subjects lost $\geq 5\%$ weight with no sex difference. The relative risk of diabetes was 0.31 (95% CI 0.16–0.59) in the group who lost $\geq 5\%$ weight, 0.72 (0.46–1.13) in the group who lost 2.5–4.9% weight, and 1.10 (0.77–1.58) in the group who gained $\geq 2.5\%$ compared with the group who maintained weight.

CONCLUSIONS — The FIN-D2D was the first national effort to implement the prevention of diabetes in a primary health care setting. Methods for recruiting high-risk subjects were simple and easy to use. Moderate weight loss in this very high-risk group was especially effective in reducing risk of diabetes among those participating in the program.

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Randomized clinical trials have shown that type 2 diabetes can be prevented or at least postponed by rather modest lifestyle changes (1–4). In contrast to the rapidly vanishing effect of

drug treatment on prevention of diabetes (5,6), the effects of lifestyle intervention seem to be long lasting (7,8). The reduction in risk of type 2 diabetes among high-risk subjects was 58% over ~ 3 years both

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in the Finnish Diabetes Prevention Study (DPS) and the American Diabetes Prevention Program (DPP). This risk reduction was achieved by frequent visits to the clinic and individual and group counseling sessions.

The fundamental question is how the knowledge and expertise from randomized clinical trials can be applied in various clinical settings in real life. Everyday clinical practice worldwide is facing a lack of resources and is under heavy economic constraints (9,10). However, the diabetes epidemic is here and will overcome health care resources if prevention strategies are not urgently implemented. Therefore, the first large-scale nationwide diabetes prevention program in the world, the National Program for the Prevention of Type 2 Diabetes (FIN-D2D), was implemented in five hospital districts in Finland during 2003–2008, covering a population of 1.5 million (11,12). The FIN-D2D had three major concurrent strategies: a high-risk strategy, early treatment strategy, and population strategy. The primary strategy was a high-risk strategy, the aim of which was to include prevention of diabetes and reduction of cardiovascular risk factor levels among high-risk individuals in daily routines in health care centers and occupational health care outpatient clinics. A population strategy focused on raising awareness of diabetes and its risk factors in the overall population, and an early treatment strategy focused on care of diabetes in individuals who had screening-detected diabetes. This article reports outcomes achieved in the high-risk cohort during a 1-year follow-up.

RESEARCH DESIGN AND METHODS

The aim of the high-risk strategy was to identify individuals who have a high risk of developing type 2 diabetes and to provide them with support for lifestyle changes required to reduce their future risk. To this end, each of the 400 participating primary health care centers and occupational health care outpatient clinics locally developed flowcharts for the implementation of

prevention of diabetes programs using existing resources. The flowcharts were based on the FIN-D2D project plan (11). The rationale, design, and the detailed protocol of the FIN-D2D have been published earlier (11,12).

The high-risk individuals were identified using the modified Finnish Diabetes Risk Score (FINDRISC), which included a question on family history of diabetes in addition to the original seven questions (13). The FINDRISC was used for opportunistic screening in primary health care centers and pharmacies and at public events such as health fairs and ice hockey games as well as in a nationwide advertising campaign. Screening was done by local nurses and pharmacy personnel. People could also fill in the FINDRISC test on the Internet. Tests done at health centers and clinics were successful in bringing high-risk individuals to lifestyle counseling, whereas tests done in public campaigns outside health care centers or on the Internet rarely led to contacts. It has been estimated that at least 200,000 people were screened for risk of type 2 diabetes in the project area, but the exact number was not registered. Those who had FINDRISC scores ≥ 15 were considered to be at high risk for diabetes, and they were referred to the FIN-D2D (12). In addition, individuals who had a history of impaired fasting glucose (IFG) or impaired glucose tolerance (IGT), an ischemic cardiovascular disease event, or gestational diabetes mellitus were considered to have a high risk for diabetes and were referred to the FIN-D2D (12).

Altogether 10,149 individuals (3,379 men and 6,770 women) aged 18–87 years (53.6 ± 10.9 years [mean \pm SD]) fulfilling these criteria were initially contacted. Of them, 8,353 had an oral glucose tolerance test (OGTT) at baseline and 5,523 had any follow-up data. One-year follow-up data were available for 3,880 (70.3%) participants. Of them, 638 individuals did not have an OGTT at baseline and 444 individuals had screening-detected diabetes at baseline and were therefore excluded from this report. Thus, 2,798 individuals were nondiabetic at baseline and had 1-year follow-up data and they form the high-risk cohort for this report. The majority of the participants were referred to the FIN-D2D based on a FINDRISC score ≥ 15 points (51% of men and 57% of women). Altogether 34% of men and 21% of women had a history of IFG or IGT. Referral to the FIN-D2D was based on a history of ischemic cardiovas-

cular disease in 8% of men and 2% of women. A history of gestational diabetes mellitus was the reason for referral in 13% of women. The majority of the women with a history of gestational diabetes mellitus were <45 years.

The baseline visits occurred between 17 January 2004 and 28 August 2007. The 1-year visits were between 17 January 2005 and 12 June 2008. The time window for 1-year visits was 9–18 months after the baseline visits. The mean follow-up time was 14 months.

In the primary health care setting, evaluation of risk factors and glucose tolerance, interventions, and follow-up took place as part of standard care. Measurements were done by local nurses according to the working instructions in the project plan (11). Height was measured to the nearest centimeter. Weight was measured to the nearest 0.1 kg with the subject in light clothing. Waist circumference was measured to the nearest centimeter. BMI was calculated as weight in kilograms divided by the square of height in meters. Blood pressure was measured twice from the right arm with the subject in the sitting position to the nearest 1 mmHg, and the mean reading was recorded. The examination also included an OGTT with a glucose load of 75 g and fasting and 2-h plasma samples (14). The test started in the morning after overnight fasting; 20% of the tests used capillary and 80% used venous plasma samples at baseline (15 and 85%, respectively, at 1-year follow-up). Venous blood samples were drawn for fasting lipid and lipoprotein determinations. Plasma lipids and lipoproteins were determined locally using enzymatic methods. Identical examinations were performed at baseline and at the 1-year visit.

Glucose tolerance was classified according to the World Health Organization 1999 criteria (14). Individuals who reported at baseline that they have diabetes were not included in the OGTT. Those with fasting venous or capillary plasma glucose levels ≥ 7.0 mmol/l or 2-h venous plasma glucose ≥ 11.1 mmol/l or 2-h capillary plasma glucose ≥ 12.2 mmol/l were classified as having diabetes. Those with 2-h venous plasma glucose ≥ 7.8 and <11.1 mmol/l or 2-h capillary plasma glucose ≥ 8.9 and <12.2 mmol/l and fasting plasma glucose <7.0 mmol/l were classified as having IGT. IFG was defined as fasting plasma glucose ≥ 6.1 but <7.0 mmol/l and 2-h venous plasma glucose <7.8 mmol/l or 2-h capillary plasma glu-

cose <8.9 mmol/l. Individuals who had previously diagnosed or screening-detected diabetes at baseline were excluded from this report.

Intervention visits were either individual counseling visits or group sessions, during which the intervention visit form was filled out. Counseling based on intervention experiences in the DPS study (15) and application of different stages of change in behavior was recommended. The focus of the visits was on weight, meal frequency, fat intake, quality of fat, use of salt, fiber intake, use of alcohol, exercise, or smoking, based on which topic the individual preferred. Group sessions varied from weight maintenance groups to exercise groups and lectures on diabetes and lifestyle changes. The frequency of intervention visits varied among health centers, depending on local circumstances and resources.

Statistical methods

Statistical analyses and data management were performed using SAS for Windows (version 9.2). Continuous variables are presented as mean \pm SD and categorical variables are presented as percentages.

ANCOVA was used to compare means of risk factor levels at follow-up with means at baseline adjusting for age. Mixed models of repeated analyses were used to analyze changes during follow-up in risk factor levels according to weight loss groups (weight loss $\geq 5\%$, weight loss 2.5–4.9%, stable weight, and gained $\geq 2.5\%$), adjusting for age; stable weight was used as the control group. The likelihood ratio test was used to compare differences of probabilities of incident diabetes according to weight loss. Risk ratios with 95% CI were calculated by log-binomial regression analysis to examine the association between incident diabetes and weight loss.

RESULTS — Baseline characteristics of the participants and the changes in risk factor levels from baseline to the 1-year follow-up are shown in Table 1. Mean age was 56 years in men (range 23–81 years) and 54 years (20–84 years) in women. The mean FINDRISC score was 17. The majority of the participants were obese (BMI >30 kg/m²) and central obesity was common among them. Weight loss during the 1-year follow-up was on average 1.3 kg in men and 1.1 kg in women. This was accompanied by a 1.3-cm reduction in the waist circumference. In addition, blood pressure decreased, and the lipid

Table 1—Baseline characteristics and changes in risk factors from baseline to 1-year visit in men and women

	n	Baseline	Change from baseline to one-year follow-up	P value*
Men				
Age (years)	919	56.0 ± 9.9		
FINDRISC score	536	16.6 ± 3.7		
Weight (kg)	919	95.8 ± 15.9	−1.2 ± 5.3	<0.0001
BMI (kg/m ²)*	914	30.9 ± 4.6	−0.4 ± 1.5	<0.0001
Waist (cm)	888	107.3 ± 11.4	−1.3 ± 4.9	<0.0001
Systolic blood pressure (mmHg)	903	141.0 ± 16.2	−0.8 ± 14.8	0.0932
Diastolic blood pressure (mmHg)	903	87.2 ± 9.6	−1.5 ± 8.9	<0.0001
Total cholesterol (mmol/l)	822	5.06 ± 1.01	−0.25 ± 0.86	<0.0001
HDL cholesterol (mmol/l)	814	1.25 ± 0.33	0.02 ± 0.22	0.0030
LDL cholesterol (mmol/l)	779	3.03 ± 0.87	−0.23 ± 0.76	<0.0001
Triglycerides (mmol/l)	811	1.80 ± 1.19	−0.11 ± 1.12	0.0050
Women				
Age (years)	1,879	54.0 ± 10.7		
FINDRISC Score	1,259	17.2 ± 3.0		
Weight (kg)	1,879	83.8 ± 15.4	−1.1 ± 5.8	<0.0001
BMI (kg/m ²)	1,872	31.6 ± 5.4	−0.4 ± 2.1	<0.0001
Waist (cm)	1,821	99.4 ± 12.4	−1.3 ± 5.9	<0.0001
Systolic blood pressure (mmHg)	1,845	138.4 ± 17.8	−1.9 ± 14.8	<0.0001
Diastolic blood pressure (mmHg)	1,845	85.3 ± 9.2	−1.6 ± 8.4	<0.0001
Total cholesterol (mmol/l)	1,658	5.24 ± 0.95	−0.14 ± 0.79	<0.0001
HDL cholesterol (mmol/l)	1,639	1.50 ± 0.43	0.04 ± 0.31	<0.0001
LDL cholesterol (mmol/l)	1,616	3.07 ± 0.86	−0.16 ± 0.76	<0.0001
Triglycerides (mmol/l)	1,632	1.48 ± 0.77	−0.03 ± 0.64	0.0769

Data are means ± SD. *P value for ANCOVA comparing the mean at follow-up to the mean at baseline; analyses were adjusted for age.

profile changed in a less atherogenic direction. The decrease in systolic blood pressure was more marked in women than in men, whereas the decrease in diastolic blood pressure was of similar magnitude in both sexes. Total cholesterol, LDL cholesterol, and triglyceride levels decreased 5–8% in men and 2–5% in women. The increase in HDL cholesterol level was ~2% in men and 3% in women.

The incidence of diabetes during a mean follow-up of 14 months was 2.0% among men ($n = 299$) and 1.2% among women ($n = 865$) with normal glucose tolerance. Diabetes developed in 13.5% of men ($n = 230$) and in 7.4% of women ($n = 272$) who had IFG at baseline. The incidence of diabetes was even higher in men (16.1%, $n = 254$) and in women (11.3%, $n = 435$) who had IGT at baseline. Thus, abnormal glucose homeostasis increased the risk of diabetes by six- to ninefold in these high-risk subjects compared with those with normal glucose homeostasis at baseline.

The incidence of diabetes according to loss of body weight in the whole group is illustrated in Fig. 1. The incidence of diabetes was about twofold higher in men (2.6, 7.5, 10.4, and 10.4%, $P = 0.026$, in

groups with weight loss of $\geq 5\%$, weight loss 2.5–4.9%, stable weight, and gained $\geq 2.5\%$, respectively) compared with women (1.9, 3.6, 4.8, and 6.9%, $P = 0.011$; data are adjusted to 50 years) in every weight loss group. However, there was no interaction between weight loss and sex in regard to incidence of diabetes ($P = 0.789$ for interaction). The relationship between weight loss and incidence of diabetes was almost stepwise. The relative

risk of diabetes was only 0.31 (95% CI 0.16–0.59), which translates to 69% risk reduction in the group who lost $\geq 5\%$ weight compared with the group who maintained weight. The relative risk was 0.72 (0.46–1.13; risk reduction of 29%) in the group who lost 2.5–4.9% weight and 1.10 (95% CI 0.77–1.58; risk increase 10%) in the group who gained 2.5% compared with the group who maintained weight.

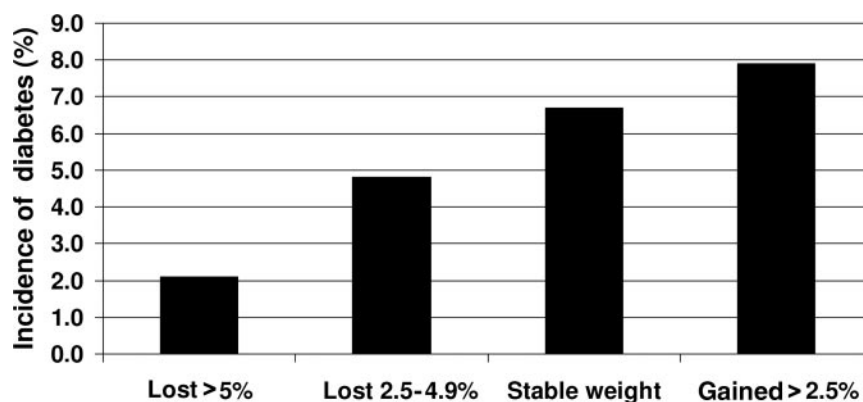


Figure 1—Incidence of type 2 diabetes during the 1-year follow-up according to weight loss. Data are adjusted to age 50 years. $P < 0.001$ for the likelihood ratio test for the difference of probabilities according to weight loss.

Table 2—Changes in risk factors from baseline to 1-year visit according to weight loss

	Weight loss $\geq 5\%$		Weight loss 2.5–4.9%		Stable weight*		Gained $\geq 2.5\%$		ANCOVA P value†
	n	Mean \pm SD	n	Mean \pm SD	n	Mean \pm SD	n	Mean \pm SD	
Weight (kg)	490	$-8.5 \pm 6.5\ddagger$	471	$-3.1 \pm 0.9\ddagger$	1,290	-0.1 ± 1.2	546	$4.5 \pm 3.7\ddagger$	<0.001
BMI (kg/m ²)	489	$-3.0 \pm 2.3\ddagger$	470	$-1.1 \pm 0.3\ddagger$	1,285	-0.04 ± 0.46	541	$1.6 \pm 1.0\ddagger$	<0.001
Waist (cm)	477	$-6.6 \pm 6.1\ddagger$	449	$-2.7 \pm 4.2\ddagger$	1,258	-0.4 ± 4.2	525	$2.6 \pm 5.1\ddagger$	<0.001
Systolic blood pressure (mmHg)	480	$-4.4 \pm 14.4\ddagger$	464	$-3.1 \pm 15.4\ddagger$	1,267	-0.7 ± 14.5	536	$0.5 \pm 15.1\ddagger$	<0.001
Diastolic blood pressure (mmHg)	480	$-3.8 \pm 8.4\ddagger$	464	-2.2 ± 8.3	1,267	-1.1 ± 8.4	536	-0.1 ± 8.7	<0.001
Lipids (mmol/l)									
Total cholesterol	438	-0.35 ± 0.78	411	-0.23 ± 0.92	1,148	-0.15 ± 0.78	482	$-0.02 \pm 0.81\ddagger$	<0.001
HDL cholesterol	430	$0.10 \pm 0.25\ddagger$	408	0.05 ± 0.29	1,138	0.02 ± 0.27	476	-0.01 ± 0.31	<0.001
LDL cholesterol	420	$-0.33 \pm 0.71\ddagger$	400	-0.22 ± 0.89	1,111	-0.17 ± 0.72	463	$-0.07 \pm 0.74\ddagger$	<0.001
Triglycerides	430	$-0.29 \pm 0.66\ddagger$	406	$-0.15 \pm 0.95\ddagger$	1,133	-0.01 ± 0.76	473	$0.12 \pm 0.95\ddagger$	<0.001

*Weight loss <2.5% or weight gain <2.5%. †ANCOVA for overall and pairwise comparisons of mean changes between the groups; analyses were adjusted for age (‡) or for age and sex (§). ‡Pairwise comparisons between groups, $P < 0.05$ (stable weight served as the reference group). §Pairwise comparisons between groups, $P < 0.05$ (stable weight served as the reference group).

Changes in risk factor levels according to weight loss are presented in Table 2. Altogether 17.5% of the subjects lost $\geq 5\%$ weight. On average this meant an 8.5-kg reduction in weight and a 6.6-cm reduction in waist circumference. During the follow-up, 16.8% of the subjects lost 2.5–4.9% weight and 46.1% maintained weight. Only 19.6% of the subjects gained $\geq 2.5\%$ weight. Men were as successful as women in losing weight. Systolic blood pressure decreased 4.4 mmHg and diastolic blood pressure 3.8 mmHg in the men and women who lost $\geq 5\%$ weight compared with a reduction of 0.7 mmHg in systolic and 1.1 mmHg in diastolic blood pressure in the group who maintained weight ($P < 0.05$). The decrease in systolic blood pressure was more marked in women (5.2 vs. 1.0 mmHg decrease, $P < 0.05$) than in men (2.7 vs. 0.2 mmHg decrease; NS), but there was no sex difference in the decrease in diastolic blood pressure (women 3.7 vs. 1.2 mmHg, $P < 0.05$; men 4.0 vs. 1.1 mmHg, $P < 0.05$). Even a weight loss of 2.5–4.9% was associated with a significant reduction in systolic blood pressure in the whole group (3.1 vs. 0.7 mmHg, $P < 0.05$). There were no sex differences in the reduction of blood pressure levels in the group who lost 2.5–4.9% weight.

The beneficial effect of weight loss on lipid and lipoprotein levels was mainly seen in the group who lost $\geq 5\%$ weight. Levels of serum cholesterol, LDL cholesterol, and triglycerides decreased and the levels of HDL cholesterol increased compared with those in the group who maintained weight. Even a weight loss of 2.5–

4.9% was associated with a reduction in triglyceride levels although changes in other lipid and lipoprotein levels did not differ from those who maintained weight. There were no sex differences in changes in lipid and lipoprotein levels.

A weight gain of $\geq 2.5\%$ translated to a 4.5-kg increase in weight and 2.6-cm increase in waist circumference. This was associated with an increase in systolic blood pressure and triglyceride levels.

Participants had on average 2.9 intervention visits during the 1-year follow up. The proportions of individuals who had three or more, two, and one intervention visit were 29.1, 12.9, and 26.1%, respectively. Individuals who had three or more intervention visits were more obese at baseline than those who had only two or one or no intervention visits (BMI 32.6 ± 5.6 , 31.3 ± 5.1 , 30.7 ± 4.8 , and 30.9 ± 5.0 kg/m², respectively, $P < 0.05$). However, age and the proportion of men did not differ between the groups with different numbers of intervention visits. The group who lost $\geq 5\%$ weight had on average 3.5 intervention visits, whereas those who maintained weight had 2.9 intervention visits during the follow-up ($P < 0.001$). The mean number of intervention visits was not different in the group who lost 2.5–4.9% weight and in the group who gained $\geq 2.5\%$ weight compared with the group who maintained weight (3.0 and 2.5 vs. 2.9, respectively).

Altogether 32.0% of the subjects had no recorded intervention visits during the follow-up. Among participants who had intervention visits, 51% had individual counseling visits only, 13% attended

group sessions only, and 10% participated both in individual and group visits. The type of visits was not recorded in 26% of individuals who had intervention visits.

CONCLUSIONS— The FIN-D2D is the first national effort to implement the prevention of diabetes in a primary health care setting. The results of this study depict what can be achieved by such a big undertaking in terms of diabetes prevention and reduction of cardiovascular risk factors. Methods for recruiting high-risk subjects in this study were simple and easy to use. Experiences derived from the DPS study were applied to the intervention visits.

The incidence of diabetes during a mean follow-up of 14 months was exceptionally high in subjects with IFG or IGT in this study. In previous studies, progression from IGT to diabetes has varied between 5 and 6% per year (1,16,17) and from IFG to diabetes between 3 and 6% per year (16,17). However, in the Anglo-Danish-Dutch Study of Intensive Treatment in People with Screen Detected Diabetes in Primary Care (ADDITION) study, progression rates were particularly high in the 1st year of follow-up, namely 16.0% for IFG and 23.8% for IGT, which are closer to the numbers observed in this study (18). Thus, screening strategies for high-risk subjects used in the FIN-D2D as well as in the ADDITION study tend to identify subjects who have a very high early conversion rate from abnormal glucose tolerance to diabetes. The conversion rate from normal glucose tolerance to

diabetes in this study was about twofold higher than that in some previous studies (16,19) and four- to sixfold higher than in the Inter99 study (17).

Weight loss of $\geq 5\%$ was accompanied by a 69% reduction in the risk of diabetes over 1 year compared with that in subjects who maintained weight. This is an unexpectedly high decrease in diabetes risk. The risk reduction was 58% over 3 years in the DPS and DPP studies (1,2). Our results emphasize that moderate weight loss in this very high-risk group representing early converters is especially effective in reducing risk of diabetes or at least postponing diabetes. Longer follow-up is needed to see whether this effect will last over time.

The average weight loss during the 1-year follow-up was ~ 1 kg. This is very modest compared with a 4.2-kg weight loss at 1 year in the intervention group of the DPS study (1). However, even this fairly small weight loss was accompanied by multiple beneficial changes in cardiovascular risk factors. It is not known whether these changes were mainly due to weight loss or were explained by changes in diet and exercise level. Moreover, 17.5% of the participants lost $\geq 5\%$ weight. This is $\sim 50\%$ of the proportion of individuals reaching $\geq 5\%$ weight loss during the 1st year in the placebo groups in large randomized weight reduction trials (20,21) and implies that individuals participating in a diabetes prevention program are motivated to make lifestyle changes. Weight loss of $\geq 5\%$ was associated with marked beneficial changes in blood pressure and lipid and lipoprotein levels, which were of the same magnitude as in the intervention groups of the DPS (1) and DPP (22) studies.

From the perspectives of feasibility and economics, it is important that the lifestyle changes and risk reduction of diabetes achieved in this study required a very modest number of visits to health centers or occupational health care outpatient clinics. At baseline, subjects had one or two visits to the nurse for measurements and to collect data on diet and exercise. This baseline interview was designed to serve as a mini-intervention in addition to data collection. In addition, the subjects had on average 2.9 intervention visits over 1 year. Those who lost $\geq 5\%$ weight had on average 3.5 intervention visits. It is possible that the real number of intervention visits was somewhat larger, because the intervention visit form was not always filled out during group sessions.

Only 50% of the total cohort had any follow-up data. The first loss to follow-up occurred after screening; only 78% of the screened high-risk subjects had an OGTT. The second loss to follow-up occurred after the OGTT. Only 69% of subjects who had an OGTT at baseline had any follow-up data. These data reflect a real-life setting and the difficulty in following up on patients in primary health care settings. Altogether 70% of the cohort participating in follow-up had 1-year follow-up data available.

Despite some weaknesses, this is the largest study so far on implementation of screening and prevention of diabetes among high-risk individuals in the primary health care setting. Because the magnitude of the diabetes epidemic is so overwhelming, cross-disciplinary health promotion activities that lead to lifestyle changes at the population level are needed to combat it. A good example of an effective strategy is the North Karelia project launched in 1972, which raised public awareness of the importance of lifestyle behaviors in the whole of Finland, contributing to a marked decrease in coronary heart disease and stroke mortality (23,24).

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