Type 2 Diabetes Prevention in the "Real World"

One-year results of the GOAL Implementation Trial

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OBJECTIVE — "Real-world" implementation of lifestyle interventions is a challenge. The Good Ageing in Lahti Region (GOAL) Lifestyle Implementation Trial was designed for the primary health care setting, with lifestyle and risk reduction objectives derived from the major diabetes prevention efficacy trials. We report on the program's effectiveness as well as findings related to the program's reach, adoption, and implementation.

RESEARCH DESIGN AND METHODS — A total of 352 middle-aged participants with elevated type 2 diabetes risk were recruited from the health care centers in Päijät-Häme Province in Finland. The intervention included six group counseling sessions, delivered by trained public health nurses. Measurement was conducted at baseline and 12 months. Clinical risk factors were measured by study nurses, and lifestyle outcomes were analyzed from self-reports. Lifestyle outcomes were compared with the outcomes achieved in relevant efficacy trials, and within-subject changes were tested for risk reduction.

RESULTS — At baseline, mean BMI was >32 kg/m^2, and 25% of the participants had impaired glucose tolerance. At 12 months, 20% of participants achieved at least four of five key lifestyle outcomes, with these results being comparable with the reference trials. However, physical activity and weight loss goals were achieved significantly less frequently (65 vs. 86% and 12 vs. 43%, respectively). Several clinical risk factors decreased, more so among men than women.

CONCLUSIONS — This trial demonstrates that lifestyle counseling can be effective and is feasible in real-world settings for individuals with elevated risk of type 2 diabetes. To increase program impact, program exposure and treatment intensity need to be increased.

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Lifestyle modification has been proven effective in reducing type 2 diabetes risk in efficacy and effectiveness trials among adults with prediabetes (1–3); indeed, it has been shown to be even more effective than drug treatment (1). The Finnish Diabetes Prevention Study (DPS) (2) demonstrated that while the overall intervention effect was a 58% reduction in diabetes risk, attainment of specific nutrition, physical activity, and weight loss objectives prevented manifestation of the disease during an average of 3.2 years ' follow-up. These findings have subsequently provided the basis for a nationwide type 2 diabetes prevention program in Finland (4).

Implementation of effective lifestyle interventions in routine health care poses a very big challenge (5). In the published efficacy trials, the lifestyle interventions have all lasted several years (1–3,6); for example, in the DPS, the median number of counseling sessions during a 3-year intervention was 20 (6). Can the results obtained in the efficacy trials be replicated in routine health care with much more limited resources available for program implementation and delivery?

In the Good Ageing in Lahti Region (GOAL) Program, a lifestyle implementation trial (7,8) was designed for the primary health care setting, with lifestyle objectives derived from the DPS (2). We first assess the program's reach, adoption, and implementation in the health care setting. We then evaluate the program's effect on diabetes risk by assessing attainment of these objectives with the DPS as the benchmark. Finally, we examine sex and baseline risk status differences in the intervention's impact.

RESEARCH DESIGN AND METHODS

— This study was developed and evaluated as a real-world implementation trial (9) in order to establish whether it is possible to replicate the findings achieved in the DPS, an earlier efficacy trial (2). Success is measured by comparing the lifestyle outcomes at 12 months with the same measures taken in the DPS. A longitudinal pretest and posttest study design is used for examining the risk factor changes.

The GOAL program is a community health promotion program in Päijät-Häme, Finland, in an area covering 14 municipalities and a total of 208,000 inhabitants (8). Program partners are the municipalities, regional and local health care organizations, the National Public Health Institute, the UKK Institute for Health Promotion, the Lahti University of Applied Sciences, and the University of Helsinki. In the Lifestyle Implementation Trial, GOAL was responsible for program

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Abbreviations: DPS, Finnish Diabetes Prevention Study; GOAL, Good Ageing in Lahti Region.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

design, materials, user training, and evaluation.

Intervention program and its delivery

The content and design of the intervention was underpinned by the five key lifestyle change objectives that were the focus of the DPS (2). These objectives included the following:

1. Less than 30% of total energy intake from fat;
2. Less than 10% of total energy intake from saturated fat;
3. At least 15 g of fiber/1,000 kcal;
4. At least 4 h/week moderate level physical activity; and
5. More than 5% weight reduction.

The DPS (2) demonstrated that attainment of at least four of these objectives was sufficient to prevent type 2 diabetes.

A group-based, task-oriented counseling model was developed based on the Health Action Process Approach, a social-cognitive health behavior model (7,10). The program components have been described in detail previously (7). They included information provision, group discussions, self-monitoring of behavior, goal setting, and planning. Program sessions were structured and scheduled for 2 h. Printed materials for program users and participants included existing health education leaflets, materials adapted from earlier studies (11), and materials developed for the intervention (the intervention is described in more detail at http://www.palmenia.helsinki.fi/ikihyva/InEnglish.html).

In Finland, routine preventive health services, including risk factor control measures and health education, are typically delivered by public health nurses. This group of health professionals delivered the GOAL intervention program as part of their existing work schedule. Depending on each center's resources, the nurses facilitated groups either solo or together with another nurse or a physiotherapist. Facilitators received 2 days of training with a standardized training program, training manuals, and practical exercises. A project dietitian supported facilitators and gave dietary counseling during one group session. Municipal sports officers introduced the groups to local sports facilities and guided one exercise session (e.g., gym, aquatic exercise, Nordic walking). The first five sessions extended over 8 weeks, with 2-week intervals in between sessions. The last session took place at 8 months. Participants requiring medical care during the program were referred to their general practitioner.

Recruitment of participants

In each primary health care center, a study nurse was appointed for recruitment, laboratory referrals, and clinical measurements. Over a 2-month recruitment period, physicians and nurses referred prospectively patients (age 50–65 years) with already-identified risk factors (obesity, hypertension, elevated blood glucose, or lipids) to the study nurse.

Risk status was screened in 462 patients using a standardized type 2 diabetes risk questionnaire that included questions concerning lifestyle-related, hereditary, and clinical risk factors (12). The risk test took ~5 min to complete. The inclusion criterion was set at risk score ≥12 (17% 10-year risk). Thirty-seven women and 20 men did not fulfill the criteria. The remaining 405 patients were recruited to the trial, unless they had any of the following conditions: *1*) mental health problem or substance abuse likely to interfere with participation ($n = 3$), *2*) acute cancer ($n = 6$), *3*) type 2 diabetes requiring pharmacological treatment ($n = 7$), or *4*) myocardial infarction during the past 6 months ($n = 0$). Thus, 389 participants (103 men and 286 women) were recruited to the intervention. In the baseline group, 14 men (14%) and 18 women (6.4%) had glucose levels showing type 2 diabetes after a 2-h glucose challenge, and 2 men and 3 women did not take the glucose challenge test. They all participated in the counseling but are excluded from the analyses, leaving 352 study participants assigned to 36 groups.

Measures

All clinical and nutritional data were collected by the study nurses. Baseline anthropometric measurements were taken at recruitment, followed by referral for relevant laboratory tests. At 12 months, participants were mailed an invitation to anthropometric measurements, a referral to laboratory tests, and a 3-day food diary. Questionnaire data were collected from the participants at 1 month preintervention (response rate 97.5%), 9 months (81%), and 12 months (83%).

The key lifestyle measures taken at 12 months were total fat intake (%E), saturated fat intake (%E), fiber intake (g/1,000 kcal), physical activity (min/day), and relative weight change from baseline (%). Nutrient intake was analyzed by a licensed dietitian using Nutrica software (13). The study nurses had given instructions for the food diary and checked that it was properly completed upon return. If any further information was required, the dietitian contacted the participants by telephone. Physical activity was measured with a 1-week self-monitoring sheet, with every 10 minutes of physical activity recorded into categories including commuting, everyday chores, anaerobic exercise (e.g., gym), and aerobic exercise (e.g., brisk walking or jogging). Average minutes per day were calculated from the sum of all activities during the week. Weight in light clothing was measured by the study nurse.

Additional secondary outcomes included changes in clinical risk factors from baseline to 12 months, including waist circumference, blood pressure, serum lipids (total cholesterol, HDL, and triglycerides), plasma fasting glucose, and plasma 2-h glucose tolerance. Serum total cholesterol, HDL, and triglycerides were determined using an enzymatic assay method. Plasma glucose was determined according to standard guidelines. All laboratory tests were made and analyzed in local health care centers following the laboratory quality guidelines set by the Päijät-Häme Central Hospital, using the same methodology during the whole study period.

Level of education, employment status, and marital status were measured as background characteristics in the baseline questionnaire. Program participation was measured at follow-up. Fidelity of program delivery was measured with a facilitator questionnaire after each completed counseling period (response rate 88%).

Program evaluation and statistical analysis

The RE-AIM (Reach, Efficacy/Effectiveness, Adoption, Implementation, Maintenance) evaluation framework for complex implementation trials was utilized to analyze the reach, effectiveness, adoption, and implementation of the intervention (5,9). The χ^2 statistic was used to compare the "success rates" between DPS and GOAL participants for each lifestyle objective, according to differences in risk status and glucose tolerance at 12 months. Repeated-measures ANOVA were used for analyzing changes in clinical risk factors from baseline to 1-year follow-up, with sex and risk status as fixed

factors. Computations were performed using the SPSS software for Windows version 13.0.

Ethical consent

The study followed the principles of the Declaration of Helsinki. The Ethics Committee of Päijät-Häme Central Hospital reviewed the study protocol. All participants gave their informed consent for the study.

RESULTS

Adoption and Implementation

All 16 health care centers in the area participated in the study. Thirty-six mixed-sex groups were conducted during 2003. The average number of participants per group was 11. The groups were conducted by 24 public health nurses and 6 physiotherapists. Twenty-three groups were facilitated solo and 13 by a pair of facilitators. The facilitators reported an average (means ± SD) of 61 ± 29 min of preparation for each session. Program components were more frequently added (40%) than omitted (28%). Additions included health education leaflets, exercise instructions, and recipes for healthy cooking. The most frequently omitted component was a role play for social support, which was omitted in five groups.

Fifty-seven percent of the participants reported having attended all six counseling sessions. Attendance in the first five sessions remained steadily over 90% but dropped to 81% in the last session. Seven men and 26 women dropped out of the study during the follow-up. Those completing the study were more likely to be married or cohabiting than the dropouts (73 vs. 51%, $\chi^2 = 6.501$, $P < 0.05$). No statistically significant socioeconomic differences were found in the drop-out rates.

Reach

Background characteristics of the 352 participants are reported in Table 1. The majority of the participants had only primary education, and almost half were already retired. Two-thirds were either married or cohabiting.

In this moderate to high-risk sample, 70% of participants were obese (BMI >30 kg/m^2). Mean waist circumference was >100 cm among women and 110 cm among men (Table 2). Mean blood lipid levels and blood pressure were only slightly elevated. On average, participants had normal glucose levels. However, 30% of men and 21% of women were found to have impaired glucose tolerance (plasma glucose 7.8–11.0 after 2-h glucose challenge; see Table 1). Except for lower blood glucose levels and higher BMI among GOAL participants, mean risk factor levels were very similar to the DPS sample.

Table 1—*Age and frequencies of other background characteristics of the GOAL intervention participants*

	Female subjects	Male subjects
n	265	87
Age (years)	58 ± 4.3	59 ± (3.7)
Basic education*		
Elementary	164 (63)	63 (74)
Secondary	65 (25)	17 (20)
High school	31 (12)	5 (6)
Employment†		
Employed	98 (38)	35 (41)
Unemployed	39 (15)	9 (11)
Retired	124 (47)	41 (48)
Marital status†		
Married or cohabited	183 (69)	66 (76)
Glucose tolerance‡§		
Normal	205 (77)	57 (66)
Impaired	60 (23)	30 (34)

Data are *n* (%) or means ± SD. *Missing values *n* (female subjects) = 5 and *n* (male subjects) = 2. †Missing values *n* (females) = 4 and *n* (males) = 2. ‡Plasma glucose after 2-h challenge: normal <7.8 mmol/l and impaired = 7.8–11.0 mmol/l. §Statistically significant difference between the sexes ($\chi^2 = 4.826$, $P < 0.05$).

Effectiveness

Attainment of the lifestyle change objectives. At baseline, 71 participants (20% of the total sample) showed both nutrient intake and physical activity levels compatible with the lifestyle objectives of our study, while 281 participants failed to meet one or more of the objectives. Significant differences in attainment of lifestyle objectives were found at the 1-year follow-up, with the highest success rates being among those who had already met the objectives at baseline (Table 3). In comparison to the DPS, the success rate in the GOAL total sample was significantly lower for the physical activity objective but significantly higher for the fiber objective. In the fat intake objectives, no significant differences were found. Even though the success rate for four to five lifestyle change objectives was equal in both studies, weight loss attainment as the final outcome was significantly lower in GOAL compared with the DPS. (Table 3).

Lifestyle change objectives were analyzed separately for participants with normal and impaired glucose tolerance at baseline. No differences were found in the number of objectives attained, but participants with impaired glucose tolerance met the fiber objective more often (63 vs. 48%, $\chi^2 = 6.235$, $P < 0.05$), whereas participants with normal glucose tolerance were more physically active (69 vs. 57%, $\chi^2 = 4.301$, $P < 0.05$). Women attained the total fat intake objective more often than men (61 vs. 46%, $\chi^2 = 4.958$, $P < 0.05$), but otherwise no statistically significant sex differences were found.

Risk factor changes from baseline to follow-up

At the 1-year follow-up, several risk factors had decreased significantly, with a stronger program effect for men (Table 2). Diastolic blood pressure, weight and BMI (only men), and waist circumference (both sexes) decreased. Mean fasting plasma glucose level increased slightly, but statistically significantly, among women. Despite the increase, it remained within normal range. A further analysis showed a significant risk status effect on changes in 2-h glucose levels ($F = 8.682$, $P = 0.003$): an increase (5.8–6.1 mmol/l) among participants with normal glucose tolerance at baseline but a decrease (8.9–8.5 mmol/l) among those with baseline impaired glucose tolerance.

Attainment of objectives and glucose tolerance at follow-up

Success rates in attainment of objectives were associated with glucose tolerance at 12 months. Among those who were able to reach four to five objectives, 83% had

Table 2—*Risk factor means ± SD at baseline and 1-year follow-up*

	Female subjects			Male subjects		
	Baseline	Follow-up	*F* value	Baseline	Follow-up	*F* value
n	270	226		91	77	
Weight	86.0 ± 13.2	85.5 ± 13.3	NS	100.0 ± 18.1	98.5 ± 18.1	7.556*
BMI	32.5 ± 4.6	32.3 ± 4.7	NS	32.0 ± 5.3	31.5 ± 5.2	8.046*
Waist circumference (cm)	102.8 ± 10.7	101.6 ± 10.9	13.143†	110.6 ± 12.6	108.3 ± 13.1	22.345†
Plasma glucose (mmol/l)						
Fasting glucose	5.6 ± 0.8	5.7 ± 0.7	6.998*	5.9 ± 0.7	6.1 ± 0.8	NS
2-h tolerance test	6.5 ± 1.7	6.6 ± 1.9	NS	6.9 ± 1.8	6.8 ± 2.3	NS
Serum lipids (mmol/l)						
Total cholesterol	5.5 ± 1.0	5.5 ± 0.9	NS	5.3 ± 0.9	5.1 ± 0.8	NS
HDL cholesterol	1.5 ± 0.4	1.5 ± 0.4	NS	1.3 ± 0.3	1.4 ± 0.3	NS
Triglycerides	1.6 ± 0.8	1.5 ± 0.7	NS	1.6 ± 0.8	1.6 ± 1.0	NS
Blood pressure (mmHg)						
Systolic	141 ± 17	140 ± 18	NS	146 ± 20	143 ± 16	NS
Diastolic	87 ± 9	86 ± 9	NS	91 ± 11	87 ± 8	9.873*

Data are means ± SD. Repeated-measures ANOVA *F* test. *$P < 0.01$; †$P < 0.001$.

normal and 11% had impaired glucose tolerance and 6% had developed diabetes, while the respective figures for those able to reach only three or less objectives were 73, 25, and 3%, respectively ($\chi^2 = 7.120$, $P < 0.05$).

CONCLUSIONS — The aim of this trial was to establish whether comparable results with those achieved in efficacy trials could be achieved under more real-world conditions by existing health care personnel. The DPS (2) has provided an international benchmark for lifestyle objectives in diabetes prevention and was therefore used as a reference for our study. In summary, the participants in the present study were as likely as those in the DPS to adopt a number of these lifestyle changes. However, despite favorable success rates for diet and reasonable success for physical activity, the 5% weight loss objective was significantly less frequently achieved in our trial. Diabetes risk, as measured by glucose tolerance at follow-up, was associated with attainment of the lifestyle objectives. The program also achieved favorable outcomes for several clinical risk factors, including BMI and waist circumference, and diastolic blood pressure.

Use of the DPS sample as a reference population (and, thereby, utilizing a single group pretest and posttest study design) has a number of benefits. Most importantly, given that the efficacy of this type of treatment has now been well established, it is arguably unethical not to offer this treatment to a group of individuals, as would have been the case if a "traditional" randomized controlled trial study design had been used (14). Data on nutrient intake were collected similarly to the DPS, but while the DPS (2) reported physical activity results based on one item on the participants' "usual mode of activity," we used a 7-day physical activity diary. This might have contributed to the lower physical activity rates in our study. We wanted to develop a local model for prevention including patient identification and outcome evaluation, so all clinical measurements were done locally. A potential bias to the measurements is our unmasked study nurses, but being employed by the municipalities and not by our research project, they had no incen-

Table 3—*Success rates (%) in reaching the intervention objectives at 1-year follow-up in the GOAL study* (participants by baseline status on meeting the lifestyle objectives and the total sample) and in the DPS (2)*

Intervention objective	GOAL participants not meeting lifestyle objectives at baseline	GOAL participants meeting lifestyle objectives at baseline	GOAL total sample	DPS intervention sample
n	281	71	352	265
Total fat <30 E%†	44	61	48	47
Saturated fat <10 E%‡	29	55	34	26
Fiber ≥15 g /1,000 kcal§	47	73	52	25
Moderate-intensity physical activity ≥30 min/day¶	60	86	66	86
Weight reduction >5%‖	11	18	12	43
Four to five objectives attained#	14	38	20	18

*Intention to treat, nonrespondents regarded as not reaching the intervention objectives. †Statistically significant difference between the GOAL subsamples ($\chi^2 = 5.874$, $P < 0.05$). ‡Statistically significant difference between the GOAL subsamples ($\chi^2 = 17.189$, $P < 0.001$) and between DPS and GOAL total sample ($\chi^2 = 4.614$, $P < 0.05$). §Statistically significant difference between the GOAL subsamples ($\chi^2 = 16.091$, $P < 0.001$) and between DPS and GOAL total sample ($\chi^2 = 46.070$, $P < 0.001$). ¶Statistically significant difference between the GOAL subsamples ($\chi^2 = 16.232$, $P < 0.001$) and between DPS and GOAL total sample ($\chi^2 = 33.068$, $P < 0.001$). ‖Statistically significant difference between DPS and GOAL total sample ($\chi^2 = 75.613$, $P < 0.001$). #Statistically significant difference between the GOAL subsamples ($\chi^2 = 21.697$, $P < 0.001$).

tives for improved outcomes. Our main interest with the clinical measurements was on within-subject changes, and the repeated measurements of any one patient were done by the same laboratory at each measurement point with the quality guidelines from the central hospital. Therefore, reliability of our data should be adequate.

The above limitations notwithstanding, our results show that good evidence-based lifestyle change objectives can be achieved in the routine health care context. However, as we recruited among health care patients, a substantial proportion of our participants probably had previously received lifestyle counseling, and many were in fact found to follow the key lifestyle recommendations already at baseline. This might partly explain why weight reduction was relatively low in our study in comparison with the average 4.2 kg in the DPS (1.5 kg among men and 0.5 kg among women) (2). Program exposure significantly correlates with weight loss (3), and in the published efficacy trials, it has been much greater than in our study (1,6). In the DPS intervention, treatment intensity was also high with 20% of the participants assigned to a very-low–caloric diet (15). However, as body weight increases in the general population by 0.5 kg per year (16), and as even the ability to maintain one's weight may be helpful for disease prevention, the meager weight loss results can be regarded as satisfactory. Furthermore, the GOAL participants succeeded in achieving fiber and fat intake goals, shown to decrease diabetes risk independently of body weight change (15), and two-thirds of them were able to reach the 30-min-per-day physical activity objective. Favorable nutrition outcomes may partly be attributed to investment in a program dietitian. To further increase physical activity, collaboration with sports organizations should also be better institutionalized.

In Finland, at least one-quarter of both men and women in the age-group of 55–64 years are obese (BMI $\geq$30 kg/m^2) (17). With such high-risk factor prevalence in the population, identification and recruitment of participants was easy. While our participants did not differ from the same-aged general population in terms of education (10), the study was especially likely to draw those unemployed and retired. The employed tend to use occupational health care and might also have difficulties in participating during work days. However, reaching the unemployed is reassuring, since those with lower socioeconomic status tend to use less health care services despite being in poorer health (18). Women were more likely to participate in our study. Also in the DPS (2), and in many other lifestyle interventions (1), a majority of the participants were female. Women's meager success, also found earlier (19), calls for further research on underlying sex-specific mechanisms in lifestyle change.

Group-based lifestyle counseling is a feasible method for evidence-based prevention in real-life settings. Low attrition during the study reflects acceptability among participants. The implementation requires only a moderate amount of training, and when delivered to a group of 11 people, each participant gets 12 h of counseling with an average input of 1.6 h per participant from the facilitator. Explicit lifestyle change objectives provide practical targets for counseling, and their attainment also predicts risk factor change, but ways to further promote physical activity and weight loss need to be considered. A modified version of this program is disseminated in the Päijät-Häme region, and another application in the Greater Green Triangle in Australia has shown encouraging short-term results (20).

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