

Type 2 diabetes prevention in the “real world”: One-year results of the GOAL implementation trial

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Abstract

Objective

“Real world” implementation of lifestyle interventions is a challenge. The 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

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 over 32, and 25% of the participants had impaired glucose tolerance. At 12 months, 20% of participants achieved at least 4 of the 5 key lifestyle outcomes, with these results being comparable to the reference trials. However, physical activity and weight loss goals were achieved significantly less frequently (65% vs. 86%; 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 pre-diabetes (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 nation-wide 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), and 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 GOAL Program for **Good Ageing in Lahti** region, 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 gender and baseline risk status differences in the intervention's impact.

Research Design and Methods

Design

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 an earlier efficacy trial, the DPS (2). "Success" is measured by comparing the lifestyle outcomes at 12 months with the same measures taken in the DPS. A longitudinal pre-test and post-test study design is used for examining the risk factor changes.

Setting

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 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:

- 1) less than 30% of total energy intake from fat;
- 2) less than 10% of total energy intake from saturated fat;
- 3) at least 15g of fiber / 1,000 kcal;
- 4) at least 4 hours / 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 a social-cognitive health behavior model, the Health Action Process Approach (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 hours. 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 two days of training with a standardized training program, training manuals and practical exercises. A project dietician 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 eight weeks, with two-week intervals in-between sessions. The last session took place at eight months. Participants requiring medical care during the program were referred to their GP.

Recruitment of participants

In each primary health care center, a study nurse was appointed for recruitment, laboratory referrals and clinical measurements. Over a two-month recruitment period, physicians and nurses referred prospectively patients (age 50-65) 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 which included questions concerning lifestyle-related, hereditary and clinical risk factors (12). The risk test took approximately 5 minutes 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 six months ($n = 0$). Thus, 389 participants (103 men, 286 women) were recruited to the intervention. In the baseline, fourteen men (14%) and 18 women (6.4%) had glucose levels showing type 2 diabetes after a 2-hour glucose challenge, and two men and three 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 three-day food

diary. Questionnaire data were collected from the participants at one month pre-intervention (response rate 97.5%), nine 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 dietician using the 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 dietician contacted the participants by telephone. Physical activity was measured with a one-week self-monitoring sheet, with every ten 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-hour 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 evaluation framework for complex implementation trials was utilized to analyze the reach, effectiveness, adoption, and implementation of the intervention (5,9). The Chi Square 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 analyses-of-variance were used for analyzing changes in clinical risk factors from baseline to one-year follow-up, with gender 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 gender groups were conducted during 2003. The average number of participants

per group was eleven. The groups were conducted by 24 public health nurses and six physiotherapists. Twenty-three groups were facilitated solo and 13 by a pair of facilitators. The facilitators reported an average of 61 minutes (SD=29) 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, 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 socio-economic 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). Mean waist circumference was above 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 hour 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.

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 one-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 GOAL total sample was significantly lower for physical activity objective, but significantly higher for fiber objective. In the fat intake objectives, no significant differences were found. Even though the success rate for 4-5 lifestyle change objectives was equal in both studies, weight loss attainment as the final outcome was significantly lower in GOAL compared to 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 IGT 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 gender differences were found.

Risk factor changes from baseline to follow-up

At one 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 genders) 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-hour glucose levels ($F = 8.682$, $p = 0.003$): an increase (5.8 to 6.1 mmol/l) among participants with normal glucose tolerance at baseline, but a decrease (8.9 to 8.5 mmol/l) among those with baseline IGT.

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 4-5 objectives, 83% had normal and 11% 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% ($\chi^2 = 7.120$, $p < 0.05$).

Conclusions

The aim of this trial was to establish whether comparable results to those achieved in efficacy trials could be achieved under more “real world” conditions by existing health care personnel. The Diabetes Prevention Study (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 five percent 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 pre-test and post-test study design - has a number of benefits. Most importantly, given that the efficacy of this type of treatment has now been well established, arguably, it is unethical not to offer this treatment to a group of individuals, as would have been the case if a “traditional” RCT study design had been used (14). Data on nutrient intake was 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 are our unmasked study nurses, but being employed by the municipalities and not by our research project, they had no incentives 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 to the average 4.2 kilograms in the DPS (2): 1.5 kg among men and 0.5 kg among women. 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, also treatment intensity was 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, also 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-minutes per day physical activity objective. Favorable nutrition outcomes may partly be attributed to investment in a program dietician. 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 ($BMI \geq 30$) (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) majority of the participants were female. Women's meager success, also found earlier (19), calls for further research on underlying gender-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 hours of counseling with an average input of 1.6 hours 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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Table 1. Mean (SD) age and frequencies (%) of other background characteristics of the GOAL intervention participants

	<i>Female</i>	<i>Male</i>
	<i>N</i> = 265	<i>N</i> = 87
Age	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)

* Missing values N(females) = 5, N(males) = 2

† Missing values N(females) = 4, N(males) = 2

‡ Plasma glucose after 2-hr challenge: normal < 7.8 mmol/l; impaired = 7.8 – 11.0 mmol/l

§ Statistically significant difference between the genders, $\chi^2 = 4.826$, $p < 0.05$

Table 2. Risk Factor Means (SD) at Baseline and One-Year Follow-Up. Repeated Measures ANOVA F-Test.

	<i>Female</i>			<i>Male</i>		
	<i>Baseline</i>	<i>Follow-Up</i>	<i>F-value</i>	<i>Baseline</i>	<i>Follow-Up</i>	<i>F-value</i>
	<i>N = 270</i>	<i>N = 226</i>		<i>N = 91</i>	<i>N = 77</i>	
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 hr 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 (mm Hg):						
Systolic	141 (17)	140 (18)	Ns.	146 (20)	143 (16)	Ns.
Diastolic	87 (9)	86 (9)	Ns.	91 (11)	87 (8)	9.873**

* $p < 0.05$

** $p < 0.01$

*** $p < 0.001$

† Based on partial Eta squared

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

	<i>GOAL participants NOT meeting lifestyle objectives at baseline</i> n = 281	<i>GOAL participants meeting lifestyle objectives at baseline</i> n = 71	<i>GOAL total sample</i> N = 352	<i>DPS intervention sample</i> N = 265
Intervention objective:				
Total fat < 30 E% [†]	44	61	48	47
Saturated fat < 10 E% [‡]	29	55	34	26
Fibre ≥ 15 g / 1000 kcal [§]	47	73	52	25
Moderate intensity physical activity ≥ 30 minutes / day	60	86	66	86
Weight reduction > 5% [¶]	11	18	12	43
4-5 objectives attained [#]	14	38	20	18

* Intention to treat, non-respondents regarded as not reaching the intervention objectives

[†] Statistically significant difference between the GOAL sub-samples ($\chi^2 = 5.874$, $p < 0.05$)

[‡] Statistically significant difference between the GOAL sub-samples ($\chi^2 = 17.189$, $p < 0.001$), and between DPS and GOAL total sample ($\chi^2 = 4.614$, $p < 0.05$)

[§] Statistically significant difference between the GOAL sub-samples ($\chi^2 = 16.091$, $p < 0.001$), and between DPS and GOAL total sample ($\chi^2 = 46.070$, $p < 0.001$)

^{||} Statistically significant difference between the GOAL sub-samples ($\chi^2 = 16.232$, $p < 0.001$), 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 sub-samples ($\chi^2 = 21.697$, $p < 0.001$)