OBSERVATIONS

Recruiting High-Risk Individuals to a Diabetes Prevention Program

How hard can it be?

Lifestyle prevention programs in Finland (Diabetes Prevention Study [DPS]) (1,2) and the U.S. (Diabetes Prevention Program [DPP]) (3) have shown that the development of type 2 diabetes can be prevented. A cost-effectiveness study revealed that lifestyle intervention was effective in all ages (4). Whether lifestyle intervention will be cost-effective in the general population is determined by *1*) the recruitment of the majority of high-risk individuals and *2*) the compliance to lifestyle changes.

We studied the recruitment rate in an open, randomized, and controlled trial aiming to reduce the incidence of diabetes. Intervention consisted of physical activity and dietary information that was to be organized by a nonprofit organization for the intervention group and information about lifestyle change in the control group. We consecutively recruited 40-, 50-, and 60-year-old participants with impaired glucose tolerance (IGT) and/or impaired fasting glucose (IFG) from the ongoing Västerbotten Intervention Program (5), from September to November 2004. A drop-out questionnaire with fixed and open-ended questions was distributed. Exclusion criteria included patients with diseases or medication interfering with glucose and lipid metabolism. A second oral glucose tolerance test was planned to confirm IGT and/or IFG before randomization. Participants gave their informed consent, and the study was approved by the ethics committee at Umeå University, Umeå, Sweden.

Fifty (22 male subjects and 28 female subjects, mean 54 ± 7.8 years) of 404 subjects (12%) were eligible and informed about the intervention study. Only eight (16%) subjects accepted to participate. In the follow-up examination, 7 patients reverted to normal glucose tolerance; thus, one patient remained eligible for inclusion. A total of 11 of 42 (26%) subjects filled in the drop-out questionnaire. The main reasons for not participating were lack of time ($n = 5$), nonaccessibility to the nonprofit organization ($n = 3$), disabling diseases ($n = 1$), and no reason for not participating ($n = 2$). A total of 8 of 11 individuals intended to change their lifestyle on their own, and 4 were interested in medical treatment for risk reduction.

The main limitation of our study is the small sample size. Nevertheless, only a minority of the identified individuals were motivated to enroll in the intervention. The reasons for not participating are potentially numerous; thus, we could not cover them all with our drop-out questionnaire. The majority of the nonparticipators referred to lack of time. Most of the identified subjects were healthy and had no obvious symptoms of disease. The information given in the Västerbotten Intervention Program may have motivated some individuals to initiate lifestyle interventions, whereas the small fee ($44 per year) for membership with the nonprofit organization may have discouraged some.

When scrutinizing the inclusion procedure in DPP (6) and DPS (7), we estimate that a small proportion of the subjects at risk, as also found in our study, agreed to participate, which indicates that the DPP and DPS missed the majority of high-risk individuals. Thus, intervention programs with low participation rates will result in lower overall societal impact on the incidence of diabetes and subsequent complications.

In conclusion, since most eligible individuals chose not to participate in this and other prevention trials, one should be cautious in extrapolating positive results from such trials to the overall population with IGT. Other strategies should be used to translate research results in primary prevention programs for type 2 diabetes to clinical practice.

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