The effects of adding group-based lifestyle counselling to individual counselling on changes in plasma glucose levels in a randomized controlled trial: The Inter99 study

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Abstract

Aim. – This study aimed to assess whether group-based lifestyle counselling offered to a high-risk population subgroup had any effect beyond individual multifactorial interventions on fasting plasma glucose (FPG) and 2-h plasma glucose (2hPG) changes.

Methods. – In a population-based study of 6784 participants, 4053 were determined to be at high risk based on a risk estimate of ischaemic heart disease or the presence of risk factors (smoking, hypertension, hypercholesterolaemia, obesity, impaired glucose tolerance). Of these subjects, 90% were randomized to high-intensity intervention (group A) and 10% to low-intensity intervention (group B). All participants went through health examinations, risk assessments and individual lifestyle counselling. Participants in group A were further offered group-based lifestyle counselling. The intervention was repeated after 1 and 3 years. A total of 2738 participants free of diabetes at baseline (1999–2001) and with at least one FPG and/or 2hPG measurement during 5 years of follow-up were included in the analyses. Differences in changes of plasma glucose between groups A and B were analyzed using multilevel linear regression.

Results. – For FPG, crude 5-year changes were significantly different between the two groups (group A: −0.003 mmol/L vs group B: −0.079 mmol/L; P = 0.0427). After adjusting for relevant confounders, no differences in FPG changes were observed (P = 0.116). Also, no significant differences in the 5-year changes in 2hPG between the two groups were observed (group A: −0.127 mmol/L vs group B: −0.201 mmol/L; P = 0.546).

Conclusion. – Offering additional group-based intervention to a high-risk population subgroup had no clinical effects on changes in plasma glucose beyond those of individualized multifactorial interventions.

Keywords: Randomized trial; High-risk population; Lifestyle counselling; Group-based counselling; Plasma glucose

Résumé

Effet de l’ajout de conseils de style de vie, donnés en groupe, aux conseils individuels sur la glycémie : l’étude Inter99 – une étude randomisée avec groupe témoin.

Objectif. – Évaluer dans quelle mesure des conseils de style de vie, donnés en groupe, proposés à une sous-population à haut risque, avaient un effet au-delà de l’intervention multifactorielle individuelle sur la glycémie à jeun (GPJ) et à deux heures (GP2 h).

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2. Introduction

Fasting plasma glucose (FPG) and 2-h plasma glucose (2hPG) levels increase years before diabetes diagnosis [1], and are predictors of cardiovascular disease (CVD) mortality in individuals without diagnosed diabetes [2].

Intensive lifestyle intervention decrease the incidence of diabetes in individuals with impaired glucose tolerance (IGT) participating in clinical trials [3–5]. One recent study indicated that individual combined with group-based lifestyle interventions offered to high-risk individuals at a population level also appear to be effective [6]. However, a large proportion of individuals at risk of diabetes is unaware of their risk and remains untreated in terms of recommendations for exercise and diet [7]. More evidence for the effects of different preventative strategies focused on this large proportion of high-risk individuals is therefore needed.

Previous studies have shown that group counselling compared with individual care may have an equal or better effect on parameters of self-management in patients with type 2 diabetes, including lowering FPG [8,9]. However, the potential specific effects of adding group-based interventions to individualized interventions have not been studied.

Group counselling, with the potential benefits of emotional support and the shared experiences of others [10], may enhance the effects of individual lifestyle intervention. For this reason, the present study aimed to examine whether group-based lifestyle counselling for diet and physical activity or smoking cessation/reduction had any effects beyond individual multifactorial interventions on changes in levels of FPG and 2hPG in a high-risk population subgroup.

2. Methods and materials

2.1. Study population

The present study used data from the Danish Inter99 study, a population-based primary prevention study with the primary aim to evaluate a multifactorial lifestyle interventional approach on the prevention of ischaemic heart disease (IHD); its secondary objectives were to evaluate any effects on other lifestyle-related diseases, including diabetes. This primary prevention study has been previously described elsewhere [11].

An age- and gender-stratified randomized sample of 13,016 individuals born in 1939–40, 1944–45, 1949–50, 1954–55, 1959–60, 1964–65 and 1969–70 and living in Copenhagen County was drawn from the Civil Registration System using computer-generated random numbers. The population was pre-randomized into two intervention groups (high-intensity intervention, group A, n = 11,708 [90%] and low-intensity intervention, group B, n = 1308 [10%]) (Fig. 1). Of the 13,016 subjects, 12,934 were eligible and 6784 (52%) participated in the study at baseline [11]. All individuals examined at baseline were included in a multifactorial lifestyle intervention and followed for 5 years. In addition, a randomized sample of 5264 individuals (control group) was drawn and followed by questionnaires. However, the control group is not included in the present study as no biochemical measures are available for this group.

Written informed consent was obtained from all participants. The Inter99 study was approved by the local ethics committee (KA 98 155) and is registered with ClinicalTrials.gov (registration number: NCT00289237).

2.2. Intervention

All individuals in the interventional groups had a health examination and had their absolute risk of developing IHD assessed at baseline. Information on age, gender, familial occurrence of acute myocardial infarction, previous IHD, diabetes, systolic blood pressure, cholesterol, height, weight and smoking status were entered into the PRECARD® programme (the Copenhagen risk score system) to assess the individuals’ absolute risk of IHD within the next 10 years [12].

Individuals were considered at high risk if they had either an absolute risk of IHD in the upper quintile of their age and gender strata, or at least one of the following risk factors: daily smoker; systolic blood pressure ≥160 mmHg or receiving antihypertensive treatment; fasting serum total cholesterol ≥7.5 mmol/L;
Random sample of n = 13,016 pre-randomized to
Group A, high intensity: n = 11,708
Group B, low intensity: n = 1,308

<table>
<thead>
<tr>
<th>Eligible</th>
<th>n = 12,934</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attended</td>
<td>n = 6,906</td>
</tr>
<tr>
<td>Include at baseline</td>
<td>n = 6,784</td>
</tr>
<tr>
<td>High risk †</td>
<td>n = 4,053</td>
</tr>
<tr>
<td>Considered for analyses at baseline</td>
<td>n = 3,609</td>
</tr>
<tr>
<td>Included in analyses of change during follow-up</td>
<td>n = 2,738</td>
</tr>
<tr>
<td>Group A</td>
<td>n = 2,454</td>
</tr>
<tr>
<td>Group B</td>
<td>n = 284</td>
</tr>
</tbody>
</table>

Non-eligible n = 82
Non-responders n = 6,028
Excluded* n = 122
Low risk n = 2,731
Excluded** n = 444
Lost to follow-up ‡ n = 871

Fig. 1. Study participation flow chart. *Excluded due to alcohol or drug abuse, or language barriers; **excluded due to self-detected diabetes (n = 263), self-reported diabetes (n = 139) or missing fasting plasma glucose and/or 2-h plasma glucose (n = 42) at baseline. †Individuals were considered at high risk if they had either an absolute risk of ischaemic heart disease (IHD) in the upper quintile of their age and gender strata, or at least one of the following risk factors: regular smoker; systolic blood pressure ≥ 160 mmHg or receiving antihypertensive treatment; fasting serum total cholesterol ≥ 7.5 mmol/L; body mass index ≥ 30 kg/m²; and/or a history of diabetes or impaired glucose tolerance (IGT). ‡Individuals were considered lost to follow-up if they had no glucose measurements after baseline.

Body mass index (BMI) ≥ 30 kg/m²; and/or a history of diabetes or IGT [11].

In addition to health examination and risk assessment, all individuals received individual lifestyle counselling at baseline. High-risk individuals were additionally re-invited after 1 and 3 years for repeated individualized lifestyle counselling and health examination. High-risk participants in group A were further offered group-based lifestyle counselling at baseline, and after 1 and 3 years, while all participants were re-invited after 5 years for a health examination (Fig. 2).

The individual lifestyle counselling addressed those who smoked, took less than 30 min/day of physical activity, had a diet dominated by high intakes of saturated fat with less than 300 g/day of fruit and vegetables, and/or consumed alcohol at levels above the recommended limits [11]. A central educational tool for counselling was the computerized programme PRECARD, based on concepts from the Health Belief Model, which uses the belief in susceptibility to disease to induce motivation for behavioural changes [13]. The participants were given a thorough interpretation of the results for both their health examination and individual risk estimate from PRECARD. They also received guidance on how to make beneficial changes in their health behaviours to improve their risk status. The counselling focused on habits of smoking, physical activity, dietary intake and alcohol use, with the participants being advised to aim for the current recommendations for each of the four lifestyle factors. The session lasted for up to 45 min and was conducted by a physician, nurse or dietitian trained in motivational interviewing techniques [14]. Individuals with raised levels of fasting serum total cholesterol, blood pressure, plasma glucose or BMI were encouraged to contact their general practitioner for the usual healthcare check-up (www.inter99.dk). In Denmark, all citizens have a general practitioner for usual care who can visit free of cost.

The group-based counselling was offered to high-risk participants in group A only. Regular smokers were offered participation in smoking-cessation or smoking-reduction groups [15,16]. Participation in diet and physical-activity groups was also offered where relevant (for example, for overweight individuals). The groups were led by a physician, dietitian or nurse and consisted of 15–20 participants each, and met up to six times for 2 h during the 6-month period after baseline, and after 1 and 3 years (Fig. 2). Each session covered a specific topic, with written material available for the interventionists that outlined points to be addressed to ensure consistency in the information delivered. The aim of the group sessions was to promote awareness of lifestyle habits and their influence on the risk of IHD and diabetes, identify barriers against lifestyle changes, promote better self-management through goal-setting and modelling (using the group members as role models) and support changes. Smoking groups helped participants to quit smoking (including nicotine products) and offered counselling on weight maintenance. The diet and physical activity course focused on the importance of the amount and type of dietary fat, and of the intake of fruit and vegetables as well as fish in the prevention of IHD and diabetes. Participants were encouraged to be physically active for 30 min/day. Those who were overweight, or had IGT, hypertension or hypercholesterolaemia were also counselled on weight loss if relevant.

2.3. Assessment of outcome and glucose tolerance status

Blood samples for analyses of venous plasma glucose were taken after an overnight fast and 120 min after a standard oral glucose tolerance test (OGTT), which was part of the health examination. Blood samples were placed on ice immediately and centrifuged within 60 min in a cool centrifuge. Plasma glucose was analyzed using the hexokinase/glucose-6-phosphate dehydrogenase (G6P-DH) technique (Boehringer Mannheim, Germany), which has an intra-assay precision of CV% = 1.1 and an interassay precision of CV% = 2.3. The conditions under which plasma glucose was taken were identical at baseline, and...
at the 1-, 3- and 5-year follow-ups. Impaired glucose regulation and diabetes were defined according to World Health Organization (WHO) 1999 criteria [17].

2.4. Other assessments

Information on age, gender, physical activity, dietary intake, alcohol, smoking, weight-reducing drugs, family history of diabetes and known diabetes was obtained from questionnaires. Construction of the variable physical-activity (min/day) has been described elsewhere [18]. Dietary intake was assessed by a validated 198-item food-frequency questionnaire of dietary intake during the previous month [19,20]. Body weight was measured to the nearest 0.1 kg, and height was measured to the nearest 0.5 cm.

2.5. Inclusion and exclusion criteria for analyses

Of the 6784 individuals participating at baseline (1999–2001), 4053 (60%) were high-risk at baseline and considered for the analyses. Excluded were those with screen-detected diabetes (SDM; n = 263), self-reported diabetes (n = 139) or missing glucose measurements (n = 42) at baseline. An additional 871 participants were lost to follow-up, defined as those individuals with no glucose measurements after baseline either because the participant failed to attend or because plasma glucose was not measured. Of the 2738 individuals included in

Table 1
Baseline characteristics for the 2738 high-risk individuals in the Inter99 study.

<table>
<thead>
<tr>
<th></th>
<th>Group A(^a) (high-intensity intervention; n = 2454)</th>
<th>Group B (low-intensity intervention; n = 284)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>FPG (mmol/L)</td>
<td>5.52 ± 0.53</td>
<td>5.62 ± 0.49</td>
<td>0.002</td>
</tr>
<tr>
<td>2hPG (mmol/L)</td>
<td>6.33 ± 1.82</td>
<td>6.38 ± 1.77</td>
<td>0.719</td>
</tr>
<tr>
<td>Age (years)</td>
<td>47.1 ± 7.6</td>
<td>47.1 ± 8.0</td>
<td>0.935</td>
</tr>
<tr>
<td>Men, % (n)</td>
<td>49.8 (1223)</td>
<td>53.4 (153)</td>
<td>0.198</td>
</tr>
<tr>
<td>Family history of diabetes, % (n)</td>
<td>19.0 (467)</td>
<td>19.7 (56)</td>
<td>0.774</td>
</tr>
<tr>
<td>Daily smoker, % (n)</td>
<td>58.7 (1441)</td>
<td>57.8 (164)</td>
<td>0.829</td>
</tr>
<tr>
<td>Physical activity (min/day)</td>
<td>40.3 ± 23.0</td>
<td>43.9 ± 24.2</td>
<td>0.015</td>
</tr>
<tr>
<td>Energy intake (kcal/day)</td>
<td>2326 ± 920</td>
<td>2362 ± 943</td>
<td>0.547</td>
</tr>
<tr>
<td>Total fat (E%/day)</td>
<td>33.2 ± 7.0</td>
<td>33.1 ± 7.0</td>
<td>0.845</td>
</tr>
<tr>
<td>Unsaturated/saturated fat ratio</td>
<td>1.37 ± 0.35</td>
<td>1.37 ± 0.33</td>
<td>0.766</td>
</tr>
<tr>
<td>Fibre (g/MJ)</td>
<td>2.47 ± 0.73</td>
<td>2.43 ± 0.70</td>
<td>0.345</td>
</tr>
<tr>
<td>Fish (g/week)</td>
<td>212 ± 195</td>
<td>215 ± 232</td>
<td>0.820</td>
</tr>
<tr>
<td>Fruit and vegetables (g/day)</td>
<td>278 ± 227</td>
<td>270 ± 222</td>
<td>0.554</td>
</tr>
<tr>
<td>Alcohol, drinks/week</td>
<td>11.5 ± 15.6</td>
<td>11.2 ± 11.8</td>
<td>0.743</td>
</tr>
<tr>
<td>Body mass index(^b) (kg/m(^2))</td>
<td>27.2 ± 5.1</td>
<td>27.5 ± 4.9</td>
<td>0.402</td>
</tr>
</tbody>
</table>

Data are expressed as means ± SD unless otherwise indicated; FPG: fasting plasma glucose; 2hPG: 2-h plasma glucose; E%: energy percentage.

\(^a\) Individuals offered group counselling for diet and physical activity or smoking cessation/reduction in addition to individual counselling.

\(^b\) Weight-reducing drugs were being taken by 3.4 and 2.1% in groups A and B, respectively.
the analyses, 2454 (90%) had been pre-randomized to group A and offered the additional group counselling (the high-intensity intervention), while 284 (10%) were pre-randomized to group B (the low-intensity intervention group; Fig. 1).

2.6. Statistical analysis

Linear- and logistic-regression models were used to test the differences in baseline characteristics between the two interventional groups (A and B), and between study attendees and those lost to follow-up.

The effects of offering group counselling in addition to individual counselling were modelled on repeated measurements of plasma glucose concentrations over the 5-year study period. Changes in plasma glucose in groups A and B were compared. There were up to four occasions (baseline, and at 1, 3, and 5 years) when FPG and/or 2hPG measures were available. The outcome variables FPG and 2hPG were each modelled separately. Each individual contributed their information to the analyses only as long as known diabetes or treatment for diabetes was not reported, as such individuals may have artificially low PG values because of antidiabetic treatments. Random-effect models were used (PROC MIXED by SAS procedures); all included random effects of person and time (year), and fixed effects of time and interventional group (A or B). To minimize bias, adjustments were made for the relevant covariates differently distributed between groups A and B at baseline.

A level of significance of 5% was used. All analyses were carried out using SAS version 9.1 software (SAS Institute, Cary, NC, USA).

3. Results

3.1. Baseline characteristics

Baseline characteristics are presented in Table 1 for each interventional group. Group A had significantly lower FPG and physical activity levels compared with group B. Overall, 63% had normal glucose tolerance (NGT; 63.5% and 59.9% in groups A and B, respectively; $P = 0.231$).

3.2. Changes during follow-up period

A total of 208 (7.6%) participants developed self-reported diabetes during the follow-up period (7.6% and 7.4% in groups A and B, respectively; $P = 0.892$). Overall, the 5-year change in FPG was $-0.011$ mmol/L ($P = 0.341$), and $-0.134$ mmol/L in 2hPG ($P < 0.001$). FPG was significantly decreased in group B, whereas 2hPG was significantly decreased in group A (Table 2). Of those in group A, 53% ($n = 1302$) agreed to participate in group-based counselling for diet and physical activity or smoking cessation/reduction at baseline, or after 1 or 3 years.

Table 2 shows the differences in the 5-year changes in FPG and 2hPG between the two interventional groups. For FPG, a significant trend towards a greater decrease in FPG was observed in group B compared with group A. This trend persisted after removing the individuals in group A who did not have at least one follow-up plasma glucose measurement.
accept the group-counselling offer. However, after adjusting for
time spent on physical activity at baseline, no significant differ-
ences in FPG changes between the two groups were observed. As for 2hPG, there were no significant differences in the 5-
year changes between the two interventional groups (Table 2). In addition, no significant differences in the 5-year changes in
smoking, physical activity, dietary intake, alcohol intake and
BMI were observed between the two interventional groups (data
not shown).

3.3. Individuals lost to follow-up

The baseline characteristics of those lost to follow-up and the study attendees are presented in Table S1 (see supplemen-
tary material associated with this article online). Individuals lost
to follow-up were more likely to be women of younger age
and regular (daily) smokers, and to have lower levels of physi-
cal activity, FPG and 2hPG at baseline than those attending the
follow-ups. In group A, individuals lost to follow-up also had
lower intakes of alcohol. In group B, those lost to follow-up were
significantly less obese. Among those lost to follow-up, no sig-
nificant differences in baseline characteristics between groups
A and B were observed.

4. Conclusion

Offering group-based interventions to high-risk individuals
had no additional effects beyond individualized interventions
in terms of changes in PG levels. To our knowledge, no other
studies have assessed the separate contribution of additional
group counselling to individual counselling for PG levels or
diabetes prevention. However, the Inter99 study provides a
unique possibility for addressing this issue. Previous findings
for the high-risk population subgroup, including individuals at
all stages of glucose tolerance, in the Inter99 study showed slight
improvements in dietary intake for group A participants [21]. For
this reason, it was thought that group counselling might enhance
the effects of individual counselling in terms of improvements
in FPG and 2hPG. However, our present findings in high-risk
nondiabetic individuals found no greater reduction of FPG or
2hPG in those offered group-based counselling, not even in the
subgroup who accepted the offer. In fact, the group not offered
group counselling tended to lower their FPG by $\sim$0.08 mmol/L
over 5 years compared with no changes observed in those offered
the additional group counselling. However, this difference was
explained by differences in physical activity at baseline between
the groups.

From the present study, it is clear that the efforts made towards
the additional group-based counselling were clinically irrele-
vant. The lack of effects of group-based counselling is difficult
to explain. There were no significant differences in the observed
5-year changes in smoking, physical activity, dietary intake,
alcohol intake and BMI between the two interventional groups in
this subset of the high-risk population. Also, being lost to follow-
up was non-differential between groups A and B. However, study
attendees in group B tended to have the highest plasma glu-
cose levels, thus possibly leaving them with a greater potential
for change. Furthermore, the difference in intervention intensity
between the two groups may have been too small to demonstrate
any positive effects of the group-based counselling.

For the entire high-risk group considered in the present study,
no change in FPG and a limited, but significant, decrease in 2hPG
were observed. However, it cannot be ruled out that the observed
lack of change and decrease in FPG and 2hPG, respectively,
may have occurred in the general population at the same time as
well. Indeed, based on findings from the observational White-
hall II study [1] and the Northern Sweden MONICA study [22],
an increase in both FPG and 2hPG during follow-up might not
have been unexpected. The intervention in the Inter99 study can
be implemented in a real-life setting, and was less intensive and
probably less expensive compared with previous highly effec-
tive lifestyle interventional studies [3–5]. Thus, even the lack of
change in PG over a 5-year period, as seen in our present study,
appears to be clinically relevant and noteworthy.

The fairly low participation rate of 52% suggests a selected
sample that may question the external validity of the findings.
Previous analyses of non-responders in the Inter99 study [11]
and another population-based study in the same geographical
area [23] have shown a ‘healthy participator effect’ at baseline.
On the other hand, it cannot be ruled out that those participat-
ing in the study at baseline were also those motivated to make
lifestyle changes. In addition, individuals lost to follow-up in
the present study tended to have better risk profiles at baseline
(including lower levels of FPG and 2hPG) than the study attend-
dees. Altogether, the implications of the low participation rate
at baseline and those lost to follow-up are not clear, although
external generalizability is questionable.

In conclusion, this primary prevention study of multifacto-
rrial lifestyle intervention implementable in everyday life may
have postponed the expected increases in FPG and 2hPG. How-
ever, offering group-based interventions to high-risk individuals
had no additional effects beyond individualized intervention
on reducing plasma glucose levels. Thus, the implication is
that offering group-based lifestyle counselling is unnecessary in
high-risk individuals if well-conducted individual counselling
is already provided.

Disclosure of interest

Cathrine Lau and Dorte Vistisen are employed by the Steno
Diabetes Centre A/S, a research hospital working in the Dan-
ish National Health Service and owned by Novo Nordisk A/S.
Knut Borch-Johnsen, Oluf Pedersen, Charlotte Glümer, Dorte
Vistisen and Cathrine Lau hold shares in Novo Nordisk Inc.
The other authors declare that they have no conflicts of interest
concerning this article.

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cipal Investigator), Knut Borch-Johnsen (Principal Investigator,
diabetes part), Hans Ibsen and Troels Thomsen. The Inter99
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Johnsen and Charlotta Pisinger. The authors thank all the
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Appendix A. Supplementary data

Supplementary data (Table S1) associated with this article can be found, in the online version, at http://www.sciencedirect.com, at doi:10.1016/j.diabet.2011.06.001.

References