

Does dietary modification and/or physical activity reduce the progression from impaired glucose tolerance to type 2 diabetes?

Trial: Pan XR, Li GW, Hu YH, et al. *Effect of diet and exercise in preventing NIDDM in people with impaired glucose tolerance: the Da Qing IGT and diabetes study.* *Diabetes Care* 1997; 20: 537-544.

Question

Can changes in diet and/or physical activity levels reduce the progression to type 2 diabetes in people with impaired glucose tolerance (IGT)?

Trial details

Design: A cluster-randomised controlled trial with four arms.

Setting: 33 health clinics in Da Qing, China.

Patients: 557 people (mean age, 46.5 years; mean body mass index [BMI], 25.8 kg/m²; 46.6% female) of more than 110 000 screened for diabetes who were found to have impaired glucose tolerance (IGT) on the basis of a two-hour glucose tolerance test (GTT) and who agreed to participate.

Interventions: The arms were control, diet only, physical activity only, and diet plus physical activity. For people who were not overweight (BMI < 25 kg/m²), the diet was much the same as the Australian dietary guidelines (10%–15% energy from protein, 25%–30% energy from fat, 55%–60% energy from carbohydrate, reduce simple sugar intake, eat more vegetables, control alcohol intake). People in the diet groups (BMI > 25 kg/m²) who were overweight were encouraged to lose weight gradually but details of the diet were not specified. Patients received individual counselling and also attended group sessions. The exercise intervention was to increase physical activity by one unit, and preferably two units, per day (eg, 1 unit was 30 minutes of slow walking or five minutes of swimming). The control group was given general information about diabetes and IGT and a pamphlet about diet and exercise.

Main outcome measure: Diabetes (glucose level > 11.1 mmol/L), determined by biennial two-hour GTT and confirmed by a repeat GTT. Patients also had three-monthly urine tests; if results were positive, plasma glucose was tested after a standard breakfast (100 g steamed bread). If plasma glucose was > 11.1 mmol/dL, or if the doctor suspected diabetes, a 75 g GTT was performed. Subjects also received a GTT if they had signs of diabetes at any time.

Main results: Compared with the control group (six-year incidence, 15.7/100 person-years [py]) the incidence of diabetes was significantly reduced in all three intervention groups: 10.0/100 py in the diet group, 8.3/100 py in the exercise group and 9.6/100 py in the combined group. The interventions also reduced the incidence of diabetes within subgroups of those who were overweight and not overweight at baseline. Among those who were not overweight, all groups gained a small amount of weight, whereas among those overweight at baseline all groups lost weight, with the control and exercise groups both losing an average of 0.9 kg/m². There was no significant difference in the proportion of dietary energy derived from fat between the groups at follow-up. The two exercise groups significantly increased their exercise by 0.6 units/day (exercise only) and 0.8 units/day (exercise and diet), compared with 0.1 units/day in the control group.

Conclusion: The authors concluded that increasing physical activity or altering the diet reduced the incidence of conversion from impaired glucose tolerance to diabetes. Combining physical activity with dietary modification was not more efficacious than altering one component alone.

Commentary

Rationale for the trial

Before this trial, there had been only a small number of non-randomised studies investigating the value of lifestyle change in reducing the conversion of IGT to diabetes.

Trial methods

The losses to follow-up were small, with only seven people declining follow-up, 11 dying and 29 moving to another location. Techniques to allow for clustering in the design appear to have been used.

There are two main methodological questions in this trial. The first relates to assessing endpoints and the second to the lifestyle modifications actually achieved.

The decision about who reached an endpoint at the three-monthly visits was made by the chairman of the committee using the single GTT; whether the chairman was blinded to the randomisation code is not stated. Diagnoses made at the biennial visits were based on two consecutive GTTs. However, people diagnosed with diabetes between biennial visits were retested at the next biennial exam. Why this was done if they had already reached an endpoint is unclear. The article does not state whether the 21% diagnosed between scheduled visits were evenly distributed across the four groups, or whether the date of the interim or biennial exam was used when calculating person-time. Hence, it is unclear whether all endpoints were assessed using the same criteria and whether there was differential bias in outcome assessment between the groups.

The diet-related information presented does not show that any dietary differences were achieved between the four groups, and overweight people in the control group lost nearly as much weight as those in the diet group. Hence, it is not clear what the dietary intervention actually was. Dietary quality may have improved in the diet groups (eg, a higher intake of micronutrients), but this is not described. The change in incidence of conversion to diabetes in the combined group was no better than that in either of the single intervention groups, although it should have been greater under a no-interaction assumption. This suggests a negative interaction between the two interventions which would be unexpected.

New information

This was the first study to have a control group that was randomly allocated concurrently with the intervention

groups to test the theory that lifestyle modification could alter the conversion to diabetes. It is still the only trial to examine the effects of diet and physical activity separately.



Implications for clinical practice

If this were the only trial available, it would be hard to recommend the interventions to delay the onset of diabetes in patients with IGT (although the intervention could be recommended for general health) owing to the methodological uncertainties. However, two subsequent, much larger and well-conducted studies have examined the combined effect of dietary and physical activity change.^{1,2} Both have documented the intervention that was achieved, and this provides a basis for identifying the level of change in diet and physical activity needed for effect. However, neither of these trials had separate arms examining the effect of diet alone or physical activity alone. As the relative effects of the two

interventions are still unknown, patients should be advised to change both dietary and physical activity.

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Competing interests

None identified.

References

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Flow of participants in randomised studies

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IN JUDGING THE RESULTS OF RANDOMISED TRIALS it is important to know from where and how participants were recruited, to what extent they received the intended interventions, whether they were followed up as planned, and whether their data were analysed as stated. These details are to ensure that readers of trial reports can appreciate both how closely participants reflect those more generally suffering from the condition under investigation, and how reliably the trial's results test its hypothesis.

Participant flow diagram

Enrolment

Item 13 of the CONSORT statement recommends a flow diagram to aid in the reporting of participant flow (see Box 1).¹ Box 2 provides a checklist for tracking subject participation throughout the trial. In this scheme Part A refers to the number of participants with the condition of interest screened for eligibility criteria as specified in the trial protocol. For a recent example see the Second Australian National Blood Pressure trial.² This study clearly details the process resulting in the final 6083 participants recruited. With 54 288 people screened to participate, 31 255 had the

1: CONSORT checklist of items to report when reporting a trial

Section and topic	Item no.	Descriptor
Participant flow	13	Flow of participants through each stage of a clinical study (a diagram is strongly recommended). Specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and with data analysed for the primary outcome. Describe deviations from the planned study protocol, together with reasons.

condition of interest (hypertension). Of these, 8273 were found to be ineligible and 16 899 refused to participate. The remaining 6083 were randomly allocated, corresponding to Part C of the flowchart in Box 2. The ratio of participants randomly allocated to those initially assessed helps determine how generalisable the results of the trial will be, and consequently may also affect the extent to which the results of the trial might influence health policy. Part B of Box 2 indicates assessed participants who do not subsequently participate, with reasons for non-participation given. Enough information should be given to identify separately the numbers who were deemed ineligible, refused to participate and those not randomly allocated to an intervention for other reasons.

The ratio of the number of participants to the number of people initially assessed for eligibility may also provide an insight into the acceptability and practicability of the intervention. For example, if 2000 people were assessed and only

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