

Training in flexible intensive insulin management improved glycemic control and quality of life in type 1 diabetes

Training in flexible, intensive insulin management to enable dietary freedom in people with type 1 diabetes: dose adjustment for normal eating (DAFNE) randomised controlled trial. *BMJ*. 2002;325:746-9.

QUESTION

Does training in flexible intensive insulin management (combining dietary freedom and insulin adjustment) improve glycemic control and quality of life in patients with type 1 diabetes?

DESIGN

Randomized (allocation concealed*), unblinded,* wait-list controlled trial with 6-month follow-up (Dose Adjustment for Normal Eating [DAFNE]).

SETTING

3 hospital diabetes clinics in Sheffield, Northumbria, and London, England, UK.

PATIENTS

169 patients > 18 years of age with clinical features of type 1 diabetes, moderate or poor glycemic control (glycated hemoglobin [HbA_{1c}] 7.5% to 12%), and duration of diabetes > 2 years without advanced complications. Exclusion criteria were inability to understand English, severe psychiatric illness, pregnancy, and unawareness of hypoglycemia. 136 patients (80%) completed baseline and 6-month assessments (mean age 40 y, 56% women).

INTERVENTION

84 patients were allocated to the intervention, which comprised a 5-day skills course delivered by 2 to 3 educators (diabetes specialist nurses or dieticians) to groups of 6 to 8 participants in each center. Patients were taught the skills to adjust their insulin by matching it to the desired carbohydrate intake at each meal (rather than adjusting the timing and content of meals to match prescribed doses of insulin). 85 patients were allocated to usual care for 6 months, after which they received the training intervention.

MAIN OUTCOME MEASURES

HbA_{1c} levels, patient-recorded episodes of severe hypoglycemia (i.e., episodes causing coma or requiring the assistance of another person), and impact of diabetes on quality of life (Audit of Diabetes-Dependent Quality of Life [ADDQoL] questionnaire, 19-point scale).

MAIN RESULTS

At 6 months, patients in the intervention group had better glycemic control (Table) and weighted impact of diabetes on quality of life (mean difference between groups 0.4, $P < 0.01$) than the usual-care group. The groups did not differ for episodes of severe hypoglycemia (18% vs 15%, $P = 0.68$).

CONCLUSION

In patients with type 1 diabetes, training in flexible intensive insulin management (combining dietary freedom and insulin adjustment) improved glycemic control and quality of life at 6 months.

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*See Glossary.

Training in flexible intensive insulin management (intervention) vs usual care for type 1 diabetes at 6 months

Outcome	Intervention	Usual care	Mean difference (95% CI)
HbA _{1c}	8.4%	9.4%	1.0% (0.5 to 1.4)

COMMENTARY

Randomized trials tell us what *can* work. What *will* work in a specific setting with a particular patient is a different matter, especially for educational or behavioral interventions. The DAFNE study is important because it provides convincing experimental evidence that glucose control can be improved with more intensive insulin therapy without hazard or perceived burden. The intervention, a 5-day course without long-term case management, is reasonably efficient.

Many patients and physicians believe, with support from the DCCT (1), that the long-term benefits of intensive insulin therapy must be purchased at substantial cost: a burdensome regimen, a restricted diet and lifestyle, more frequent hypoglycemia, and intensive case management. The DAFNE study dispels this myth by providing evidence that win-win alternatives are possible. The DAFNE educational program advocates dietary freedom and teaches skills to adjust insulin to suit personal preferences. There is no talk of dietary restrictions, consistency, or strict dietary regimens. Although many clinicians have advocated a similar approach for years, others still fear that promoting dietary freedom increases risk for weight gain and wild swings in blood sugar.

The absolute difference of 1% in HbA_{1c} at 6 months (half the difference shown in the DCCT [1]) is equivalent to a one-third reduction in progressive retinopathy, assuming the difference is maintained. In the DAFNE study, the usual-care group used an average of 3 to 4 injec-

tions daily, and the intervention group used 5 to 6. Thus, the DAFNE study compared 2 versions of intensive insulin therapy that differed primarily in redefining who is in control—the person or the disease.

One criticism is that outcomes at 6 months are unimportant for chronic disease. However, if a randomized trial establishes the benefits of an educational program at 6 months, then other modalities, such as quality improvement methods, can be used to augment and sustain benefits and improve efficiency. Another concern is safety. Although the 2 groups had a similar low incidence of hypoglycemia, the measurements were unblinded patient self-reports, and the results are contrary to those of the DCCT. Local application may produce different results.

More evidence is needed before endorsing a similar program for patients who take insulin for type 2 diabetes.

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Reference

1. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. The Diabetes Control and Complications Trial Research Group. *N Engl J Med*. 1993;329:977-86.