Training in flexible intensive insulin management improved glycaemic 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 glycaemic control and quality of life in patients with type 1 diabetes?

Design

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

Setting

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

Patients

169 patients >18 years of age with clinical features of type 1 diabetes, moderate or poor glycaemic control (glycated haemoglobin [HbA_{1c}] 7.5–12%), and duration of diabetes >2 years without advanced complications. Exclusion criteria were inability to understand English, severe psychiatric illness, pregnancy, and unawareness of hypoglycaemia. 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 2–3 educators (diabetes specialist nurses or dieticians) to groups of 6–8 participants in each centre. 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} concentrations patient recorded episodes of severe hypoglycaemia (ie, 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 glycaemic 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 hypoglycaemia (18% v 15%, $p = 0.68$).

Training in flexible intensive insulin management (intervention) v 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)

Conclusion

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

*See glossary.

COMMENTARY

Randomised 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 behavioural 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 hypoglycaemia, and intensive case management. The DAFNE study dispels this myth by providing evidence that win-win alternatives are possible. The DAFNE educational programme 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 of 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 DCCT¹) 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 3–4 injections daily, and the intervention group used 5–6. 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 randomised trial establishes the benefits of an educational programme 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 hypoglycaemia, 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 programme for patients who take insulin for type 2 diabetes.

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1 The Diabetes Control and Complications Trial Research Group. *N Engl J Med* 1993;329: 977–86.

Source of funding:
Diabetes UK.

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Abstract and
commentary also
appear in *ACP Journal
Club* and a modified
version of the abstract
appears in
*Evidence-Based
Nursing*.