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The Dose Adjustment For Normal Eating (DAFNE) project: the end of the diabetic diet in Type 1 diabetes.

The DAFNE Study Group

Aim: Current treatment of Type 1 diabetes in the UK, fails to engage patients and is associated with poor glycaemic outcomes and reduced quality of life. We tested the feasibility of a German approach involving an unrestricted diet plus skills training to adjust insulin to maintain glycaemic control.

Method: We randomised 169 adults with Type 1 diabetes in 3 centres to either undergo 5 days outpatient training immediately, (immediate DAFNE (ID)) or be controls (delayed DAFNE (DD)), delaying training for 6 months. Biomedical and psychological outcomes (impact of diabetes on QoL (ADDQoL), treatment satisfaction (DTSQ), well-being (W-BQ12)) were compared at baseline, 6 and 12 months (3x2 mixed design ANOVA with quadratic planned comparisons).

Results: HbA1c improved 6 months after training (ID and DD) and was partially maintained at one year (ID) ($F=57.2, p<0.0001$) (mean \pm SEM): 6 months: $-1.0\pm 0.1\%$, $p<0.0001$; 12 months: $-0.5\pm 0.2\%$, $p=0.001$). ADDQoL scores showed a similar pattern of improvement (e.g. dietary freedom item: $F=54.6, p<0.0001$), fully maintained at 1 year as were DTSQ ($F=125.9, p<0.0001$) and W-BQ12 ($F=40.3, p<0.0001$). Severe hypoglycaemia, weight and lipids remained unchanged.

Conclusion: The principles of intensive flexible insulin therapy with an unrestricted diet translate well to people with Type 1 diabetes in the UK, resulting in improved glycaemic control and quality of life and should be more generally available.