

The Dose Adjustment For Normal Eating (DAFNE) Trial

Improvements in HbA_{1c} still apparent and quality of life benefits well-maintained at 4-year follow-up



Speight J¹, Amiel S², Bradley C³, Heller S⁴, James P⁵, Oliver L⁵, Roberts S⁵, Rogers H², Taylor C⁴, Thompson G⁵

¹ AHP Research, Uxbridge ² Diabetes Research Group, King's College London School of Medicine ³ Department of Psychology, Royal Holloway University of London ⁴ Division of Clinical Sciences, Northern General Hospital, Sheffield ⁵ Northumbria Diabetes Service, Northumbria Healthcare NHS Trust.

Introduction

The Dose Adjustment For Normal Eating (DAFNE) trial was a waiting-list-controlled study of a 5-day training course in flexible, intensive insulin therapy in 135 adults with Type 1 diabetes in the UK. At 6 months, DAFNE improved glycaemic control without increasing severe hypoglycaemia, while significantly reducing the negative impact of diabetes on quality of life (QoL) and improving other psychological outcomes [1]. On average, there was no significant increase in BMI or other cardiovascular disease (CVD) risk factors, suggesting that over-eating and/or unhealthy eating were not inevitable following increased dietary freedom.

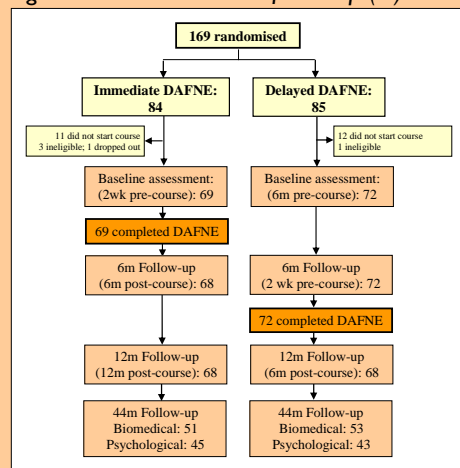
Thus, the DAFNE trial demonstrated short-term benefits for biomedical and psychological outcomes. Long-term improvements in biomedical outcomes had been shown for the Structured Teaching and Treatment Programme (STTP) [2, 3] upon which the DAFNE curriculum is based but had not previously been established in the UK.

Our aim was to determine the extent to which improvements in biomedical and psychological outcomes (at 6 and 12-months after a single DAFNE course) were sustained in the long term.

Methods

Fig 1 shows randomisation of participants in the DAFNE trial and follow-up rates at 44 months (m) (range: 37-51m).

Fig 1: Randomisation and follow-up (N)



Biomedical data (HbA_{1c}, BMI, HDL, total cholesterol, triglycerides) were collected. Participants also completed questionnaires, including ADDQoL [4, 5] (measuring impact of diabetes on QoL) and a 3-item version of the DTSQ [6].

Acknowledgements

We thank the patients who participated in the DAFNE trial. The DAFNE Trial (providing baseline, 6 and 12m data) was funded by Diabetes UK: grants to Heller, Roberts & Amiel (RD99/0001871 & 2057) and Speight & Bradley (RD99/0001871 & 2058). Long-term analyses were funded by the DAFNE Collaborative.

Results

At 44m, HbA_{1c} (8.96±1.2%) had declined from 12m levels (8.75±1.2%, p<0.05) but remained improved from baseline (9.32±1.1% p<0.01) [Fig 2].

Fig 2: HbA_{1c}

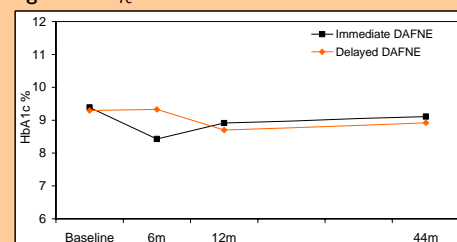


Fig 3: Impact of diabetes on QoL domains

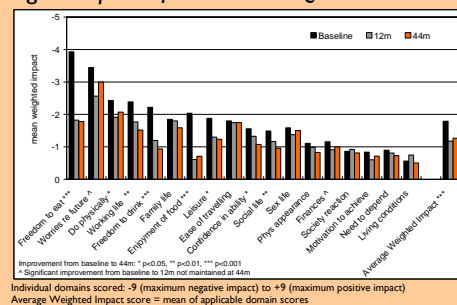
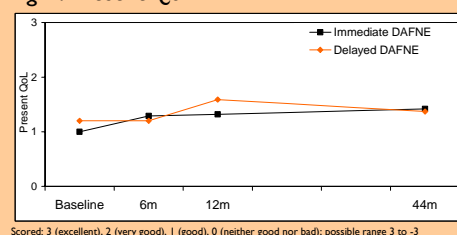


Fig 4: Present QoL



Scored: 3 (excellent), 2 (very good), 1 (good), 0 (neither good nor bad); possible range 3 to -3

Results (cont.)

At 44m, 8/10 short-term improvements in QoL domains remained improved from baseline [Fig 3]. Impact of diabetes on dietary freedom at 44m (-1.78±2.33) remained improved from baseline (-4.27±2.94, p<0.001) with no difference from 12m (1.80±2.32, ns). Overall, the 'average weighted impact' of diabetes on QoL remained significantly improved (p<0.001). In addition, improvements in general 'present QoL' at 12m (p<0.01) were well-maintained at 44m (ns) [Fig 4].

Despite an increase in weight (Δ1.5±1.8kg) between baseline and 44m (p<0.01), mostly from 12-44m (Δ1.2±1.2 kg, p<0.05), other CVD risk factors did not increase. HDL cholesterol improved from baseline (1.55±0.46) to 44m (1.67±0.53, p<0.05).

Discussion

Partially maintained improvement in HbA_{1c} (Δ0.36%) suggests a need for further interventions (e.g. refresher courses to boost skills maintenance, goal setting), which are being explored currently in routine and research DAFNE settings.

Highly significant improvements in QoL outcomes were well-maintained at 44m, indicating that participants still appreciate DAFNE's wide-ranging QoL benefits even if clinically significant glycaemic benefits are not fully maintained.

Long-term DAFNE use does not increase risk for CVD other than the increase in weight (<0.5kg/year), which may be an expected age-related gain [7] rather than the result of increased dietary freedom.

Conclusions

The impact of a single DAFNE course on glycaemic control is reduced but still apparent in the long term. Additional input may be needed to maintain initial response. In contrast, QoL improvements were well maintained over almost 4 years.

References

1. DAFNE Study Group (2002) *Brit Med J* **325**: 746-9
2. Muhlhauser I et al (1983) *Diabetologia* **25**(6):470-476.
3. Muhlhauser I & Berger M (2002) *Diabetologia* **45**(12): 1723-33.

4. Bradley C et al (1999) *Qual Life Res* **8**(1-2):79-91.
5. Bradley C & Speight J (2002) *Diabet/Metab: Res & Rev* **18**(Suppl 3): S64-S69.
6. Bradley C (1994) DTSQ. In: Bradley C, Editor. *Handbook of Psychology and Diabetes*. Chur, Switzerland: Harwood Academic Publishers.
7. Martikainen PT & Marmot MG (1999) *Amer J Clin Nut* **69**(4): 719-26.