ABSTRACT

Objective: To audit and describe the effects of participation in the Dose Adjustment for Normal Eating (DAFNE) course on clinical outcomes in people with type 1 diabetes mellitus (T1DM).

Design, setting and participants: Audit of clinical outcomes before and 1 year after DAFNE training for 145 people with T1DM who participated in courses at seven Australian diabetes centres between February 2005 and March 2007. Participants had been diagnosed with T1DM at least 1 year before and were beyond the “honeymoon phase”, with glycated haemoglobin (HbA1c) < 12% and no severe diabetes complications. They were aged over 17 years and able to understand written and spoken English.

Intervention: A 5-day structured education program covering T1DM management with an emphasis on unrestricted diet, precise carbohydrate estimation and prandial insulin dosing using insulin-to-carbohydrate ratios.

Main outcome measures: Glycaemic control (HbA1c levels), weight, severe hypoglycaemia, and quality of life scores on general (Hospital Anxiety and Depression) and diabetes-specific (Problem Areas in Diabetes) scales.

Results: Mean HbA1c fell from 8.2% to 7.8% (95% CI for change, −0.5% to −0.2%; \( P < 0.0001 \)) and weight from 75.1 to 74.2 kg (95% CI for change, −1.6 to −0.2 kg; \( P = 0.012 \)). Severe hypoglycaemia was less frequent after DAFNE training (\( P = 0.0001 \)). Quality of life improved (\( P < 0.0001 \) for both scales).

Conclusions: One year after participation in the DAFNE program of structured education, people with T1DM showed improved glycaemic control, reduced incidence of severe hypoglycaemia, slightly reduced weight and improved quality of life. The DAFNE course offers one means of improving clinical outcomes in T1DM.

METHODS

Clinical data collection

Pre-specified inclusion criteria for DAFNE training included confirmation of T1DM at least 12 months previously; being in the post-“honeymoon phase”, glycated haemoglobin (HbA1c) level < 12%; age over 17 years; and ability to understand written and spoken English. To be included in this study, we required participants to have HbA1c levels recorded both before and after DAFNE training. De-identified clinical data from people undergoing DAFNE training were collected at seven specialist (secondary/tertiary) diabetes centres and community diabetes organisations and entered into a secure web-based database. The OzDAFNE database was locked on 31 March 2008.

Participants agreed to the use of their de-identified collective data for quality assurance purposes, but no formal consent form was used. The data collection and reporting process was reviewed by the Mater Health Services Human Research Ethics Committee and the study was exempted as a quality assurance activity, consistent with National Health and Medical Research Council guidelines. Data items included participants’ demographics, anthropometric data, history of diabetes and its complications, biochemical variables and scores from two measures of quality of life — the Hospital Anxiety and Depression Scale (HADS)9 and the Problem Areas in Diabetes (PAID) Scale10 — which have been validated in people with diabetes. The HADS is used to assess both anxiety and depressive symptoms. From a possible total score of 21 over both domains, scores < 7 are considered normal, 8–10 suggestive of anxiety or depression, and ≥ 11 indicative of a probable mood disorder. The PAID score covers a range of emotional states frequently reported in diabetes. These data were collected within 1 month of beginning and 1 year after participation in the DAFNE program. Biochemical variables were analysed using routine methods at each local DAFNE centre, without standardisation across centres.
1 Comparison of baseline characteristics of participants in the DAFNE program who were included and excluded from this study

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>With follow-up HbA1c level* (n = 145)</th>
<th>Without follow-up HbA1c level† (n = 127)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>133 43.3 (14.3)</td>
<td>125 41.2 (13.5)</td>
<td>0.22</td>
</tr>
<tr>
<td>Duration of diabetes (years)</td>
<td>134 16.7 (11.5)</td>
<td>127 15.6 (10.3)</td>
<td>0.39</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>145 8.2% (1.2%)</td>
<td>121 8.3% (1.3%)</td>
<td>0.66</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>142 75.1 (13.8)</td>
<td>124 74.4 (13.7)</td>
<td>0.75</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>141 26.5 (4.7)</td>
<td>122 25.9 (3.9)</td>
<td>0.23</td>
</tr>
<tr>
<td>Known diabetes complications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>145 95 (66%)</td>
<td>127 86 (68%)</td>
<td>0.62</td>
</tr>
<tr>
<td>Diabetic retinopathy</td>
<td>115 33 (29%)</td>
<td>104 28 (27%)</td>
<td>0.77</td>
</tr>
<tr>
<td>Diabetic neuropathy</td>
<td>113 11 (10%)</td>
<td>102 3 (3%)</td>
<td>0.04</td>
</tr>
<tr>
<td>Microalbuminuria</td>
<td>113 13 (12%)</td>
<td>125 36 (29%)</td>
<td>0.09</td>
</tr>
<tr>
<td>Severe hypoglycaemia‡ in previous year</td>
<td>143 48 (34%)</td>
<td>125 36 (29%)</td>
<td>0.26</td>
</tr>
<tr>
<td>Ketoacidosis in previous year</td>
<td>145 8 (6%)</td>
<td>124 8 (6%)</td>
<td>0.31</td>
</tr>
</tbody>
</table>
| BMI = body mass index, DAFNE = Dose Adjustment for Normal Eating, HbA1c = glycated haemoglobin. * Participants for whom HbA1c levels were recorded before and 1 year after DAFNE training (included in this study). † Participants for whom HbA1c levels were only available before DAFNE training (excluded from this study). ‡ Defined as an episode requiring the assistance of a third party.

Statistical analysis

Data items were tested for normality of distribution using the Shapiro–Wilks test and results verified by examining Q-Q plots. Normally distributed data were analysed primarily using paired t-tests and are reported as mean ± SD or mean difference (95% confidence interval). Non-normally distributed data were analysed using the Wilcoxon signed rank test and are reported as median (interquartile range). Statistical comparisons were by unpaired t-tests for continuous variables. Categorical results are reported as frequencies (%) and were analysed using the χ² test or Fisher exact test. Exact P values are noted unless P is less than 0.0001. Statistica, version 8.0 (StatSoft, Tulsa, Okla, USA) was used for all analyses.

RESULTS

Participants

Baseline data for 446 DAFNE course participants were recorded in the system. Of these, 272 had completed DAFNE training at least 1 year before the locking of the database and were eligible for inclusion. One-hundred and fifty-five people had at least some recorded data 1 year after training, and 145 (53%) had HbA1c levels recorded both before and after DAFNE training. These 145 people form the cohort for this report. The number of participants with data recorded varies for different characteristics. Baseline characteristics of the people included and excluded from this study are presented in Box 1. Only the frequency of diabetic peripheral neuropathy varied significantly between these two groups. Nearly all of our final cohort (97%) were white. Participants’ mean body mass index (BMI) was in the overweight range. Twenty-eight per cent had known complications of diabetes.

Major clinical outcomes

Mean HbA1c levels for the whole cohort fell from 8.2% to 7.8% (95% CI for change, −0.5% to −0.2%; P < 0.0001), and the change in HbA1c varied according to baseline glycaemic control, being greater for participants with HbA1c levels in the highest quartile before DAFNE training (Box 2).

DISCUSSION

Our audit of clinical outcomes suggests that the DAFNE program benefits people with

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Type 1 diabetes is a profoundly vexatious problem, from attempting more intensive glycaemic control to the weight gain associated with intensive insulin regimens. People with diabetes, and their treating doctors, from attempting more intensive glycaemic control.

However, both our data and the UK and German reports demonstrate that it is possible to lower HbA1c levels without these unwanted effects using the DAFNE structured education program. We suggest that these benefits may derive from the very detailed 5-day program of patient education that comprises the DAFNE course and from the less stringent glycaemic targets used in DAFNE. While the DCCT program was largely doctor-, dietitian- and nurse-driven, with prescription of dietary regimens, and insulin doses adjusted by clinicians, DAFNE promotes self-management with dietary flexibility and self-titration of insulin doses.

Type 1 diabetes is a profoundly vexatious chronic disease for many people, as it involves complex juggling of insulin doses according to food intake, glucose concentrations, exercise and other, often apparently random, factors on an unremitting daily basis. This clearly can impair quality of life. Although quality of life was not markedly abnormal in our cohort at baseline, all measures did improve after participation in the DAFNE course. The reasons for this may include reduced hypoglycaemia, improved self-management skills and confidence, and building a relationship with the health professional team, as well as the supportive environment and sharing of experiences of the “diabetic life” which, anecdotally, are always part of the DAFNE group dynamic.

Some limitations of our data should be noted. All data items were collected in a routine clinical environment, without standardised assays, dedicated staff or uniform data collection systems.

People with T1DM participating in DAFNE may not be representative of the population of people with T1DM as a whole. However, the mean baseline HbA1c level and BMI for our cohort were very similar to reported values for the cohort of T1DM patients who participated in the 2006 Australian National Diabetes Information Audit and Benchmarking survey of patients attending specialist diabetes clinics in Australia (HbA1c 8.1% ± 1.6%; BMI, 26.2 ± 4.5 kg/m2). The distribution of HADS scores in our cohort at baseline was also similar to that reported in a UK cohort of adults with T1DM. The reasons why
some participants did not attend for data collection 1 year after DAFNE training are not known, but these participants do not appear to differ in terms of baseline clinical characteristics from those who did attend. This audit reports outcomes on a pre- and post-intervention basis, with no control group to assess changes over time without the intervention. However, such data are available from the UK DAFNE study4 and our results are consistent with other published reports.2,6

Structured patient education has been endorsed as a routine part of diabetes management by the National Institute for Clinical Excellence in the UK,12 with DAFNE being recognised as one program suitable for people with T1DM. Cost modelling in the UK has suggested that DAFNE is cost-saving, due to reduced diabetic complications, rather than just cost-effective.13 Other structured education courses, such as the Empowerment program developed and conducted in Newcastle, Australia,14 and flexible insulin therapy teaching courses in Basel, Switzerland,15 have also shown benefits, including reduced hypoglycaemia and improved quality of life, although reductions in HbA1c levels have not always been shown, perhaps due to differing participant populations.

Despite the positive outcomes of DAFNE in Australia, funding for this type of intensive, structured education program remains difficult to secure. Limited support for group education is available to people with type 2 diabetes.16 However, the current Medicare Benefits Schedule rebate of $16.00 per group service (Item 81105) is clearly inadequate to fund an intensive education program, and TIDM is excluded. Many OzDAFNE centres have been charging no or minimal fees for the DAFNE course. This allows some people with TIDM to access the program, but limits the number of courses that centres are able to provide.

In summary, our audit of people with TIDM undergoing the DAFNE course demonstrates clinical benefits similar to those reported in other health care settings. DAFNE provides one potential means of improving glycaemic control and other important health outcomes in people with TIDM. We believe that OzDAFNE merits consideration for more widespread availability, predicated on more systematic funding.

COMPETING INTERESTS

David McIntyre has received speaker fees and travel assistance from companies involved in provision of insulin/delivery systems for type 1 diabetes care, including Novo Nordisk, Eli Lilly, sanofi-aventis and Medtronic. He is a previous President of the DAFNE Association of Australia Inc (now delisted) and Director of a diabetes centre involved in the provision of DAFNE courses, but has derived no personal profit from this.

REFERENCES