

# The effectiveness of a “4-step” education programme on HbA<sub>1c</sub>, weight, hypoglycaemia awareness and quality of life

Sinead Dawes, Julie Ellis-Gowland, Maureen Wallymahmed

**Citation:** Dawes S, Ellis-Gowland J, Wallymahmed M (2013) The effectiveness of a “4-step” education programme on HbA<sub>1c</sub>, weight, hypoglycaemia awareness and quality of life. *Journal of Diabetes Nursing* 17: 66–71

## Article points

1. Following the success of DAFNE (Dose Adjustment for Normal Eating), many centres have developed their own programmes teaching insulin dose adjustment and carbohydrate counting.
2. In this article, the authors assess the effectiveness of their “4-step” programme.
3. The authors conclude that although their programme did not demonstrate a significant improvement in HbA<sub>1c</sub>, it did appear to improve quality of life and there was a trend towards hypoglycaemia awareness. It was also concluded that the dietary freedom enjoyed by participants did not result in weight gain.

## Key words

- Diabetes education
- Glycaemic control
- Quality of life
- Weight

## Authors

Sinead Dawes, Diabetes Specialist Nurse; Julie Ellis-Gowland, Advanced Diabetes Dietitian; Maureen Wallymahmed, Diabetes Nurse Consultant. All are based at Aintree University Hospital, Liverpool.

**Diabetes self-management education is now widely recognised as a critical element of care for all people with diabetes and is considered necessary in order to improve patient outcomes. Following the success of the DAFNE (Dose Adjustment for Normal Eating) programme, which teaches carbohydrate counting and insulin dose adjustment, many centres have developed their own programmes, including Aintree University Hospital, where the authors of this article run the “4-step” programme. Diabetes UK (2003) recommends evaluating the effects of education programmes on HbA<sub>1c</sub>, BMI, quality of life and hypoglycaemia awareness. In accordance with those recommendations and in an effort to inform future service delivery, this article evaluates the impact of the authors’ “4-step” programme.**

Specific structured education programmes aiming to teach carbohydrate counting and insulin dose adjustment have been gaining momentum in the international diabetes community for a number of years. The publication of the DAFNE (Dose Adjustment for Normal Eating) study group trial in 2002 demonstrated significant positive outcomes in terms of glycaemic control, weight and quality of life (DAFNE Study Group, 2002). As a result, many regional centres have developed their own carbohydrate counting education programmes for people with type 1 diabetes, and associated improvements in clinical and non-clinical parameters have been reported (Speight et al, 2010).

The “4-step” programme at Aintree University Hospital was developed and implemented in 2007, and offers carbohydrate counting and insulin dose adjustment training with structured support and education. The course is available to people with type 1 diabetes who are using a multiple daily injection regimen, and is a prerequisite

to insulin pump therapy. Diabetes UK (2003) recommends evaluating the effects of education programmes upon patient care. In response to this recommendation, we have assessed the impact of the 4-step programme on HbA<sub>1c</sub>, weight, quality of life and hypoglycaemia awareness.

## A person-centred structured education programme

Diabetes self-management education is now widely recognised as a critical element of care for all people with diabetes and is considered necessary to improve patient outcomes. The National Service Framework for Diabetes (Department of Health, 2001) states that “person centred structured education can improve knowledge, reduce blood glucose levels without increasing frequency of hypoglycaemia, reduce weight and improve psychological well-being.” Emphasis is placed upon patient empowerment, with a person-centred approach being outlined as a vital part of successful treatment. A strong body of evidence demonstrates the effectiveness of this approach

in terms of improvements in quality of life and clinical outcomes (Deakin et al, 2006; Davies et al, 2008).

### Carbohydrate counting and insulin dose adjustment

Carbohydrate counting and insulin dose adjustment are now synonymous with the management of type 1 diabetes (NICE, 2004). This approach involves more sophisticated insulin regimens that encourage people with diabetes to alter insulin doses according to current blood glucose levels, carbohydrate intake and physical activity. The DAFNE Study Group (2002) demonstrated the potential benefits of this approach in terms of positive clinical and lifestyle outcomes – for example, a baseline HbA<sub>1c</sub> of 79 mmol/mol (9.4%) improved by 11 mmol/mol (1%) at 6 months – and reported improvements in quality of life and psychological well-being, along with the benefits of greater "food freedom". The focus of such education is to improve patient participation in managing their condition, and increase autonomy in making treatment decisions.

Enabling people with diabetes to self-manage their food intake and insulin doses has been shown to result in increased autonomy and empowerment (Everett et al, 2003). These factors are crucial in managing long-term health conditions and have become an integral part of diabetes care.

### What improvements might we expect? Glycaemic control

Tight glycaemic control is paramount to modern diabetes care. The DAFNE Study Group (2002) demonstrated a reduction in HbA<sub>1c</sub> of 11 mmol/mol (1%) at 6 months versus baseline ( $P < 0.0001$ ). At the 1 year follow-up, this had dropped to 5.5 mmol/mol (0.5%) versus baseline ( $P < 0.001$ ). This reduction in HbA<sub>1c</sub> tends to reflect the results obtained in regional programmes, which generally report reductions in HbA<sub>1c</sub> at 6 months of between 3.3 mmol/mol (0.3%) and 5.5 mmol/mol (0.5%; Diabetes Education Network, 2010). While some programmes have not published results for follow-up beyond 6 months, a follow-up of the DAFNE participants demonstrated the maintenance of a reduction in HbA<sub>1c</sub> of 5.5 mmol/mol (0.5%)

at 2 years (Speight et al, 2010). In addition, the BERTIE programme (Bournemouth's Type 1 Intensive Education Programme) reported data at a 5-year follow-up demonstrating the maintenance of a 5.5 mmol/mol (0.5%) reduction in HbA<sub>1c</sub> from baseline (Everett et al, 2003). A regional programme called SADIE (Skills for Adjusting Diet and Insulin in East Sussex) similarly reported a reduction in HbA<sub>1c</sub> of 5.5 mmol/mol (0.5%) at 3 months, which was also sustained at 12 months (Diabetes Education Network, 2010; Faulkner and Jackson, 2011). While DAFNE appeared to achieve a greater initial reduction in HbA<sub>1c</sub> than regional programmes, it seems from those that have published 12-month follow-up data that an HbA<sub>1c</sub> reduction of 5.5 mmol/mol (0.5%) is realistic at 12 months.

### Hypoglycaemia awareness

Hypoglycaemia unawareness has been defined as "the lowering of the glycaemic threshold for responses to lower levels of glycaemia" (Meneilly et al, 1994) and is clearly linked to the frequency of hypoglycaemia (Fanelli et al, 1993), with reduced frequency being associated with improved awareness. DAFNE-style training has been shown to be associated with a positive and significant reduction in severe hypoglycaemia, and improvements in self-reported hypoglycaemia awareness (Sämann et al, 2006). The Diabetes Education Network (2010) reported that, prior to attending a regional programme called CIGS (Carbohydrate and Insulin Group Sessions), five participants reported no hypoglycaemic awareness, and after a 3-month follow-up, three participants had regained their awareness and two had not. Although the DAFNE trial reported no significant changes in the frequency of hypoglycaemia, this still provides important reassurance that the intervention is not associated with an increased frequency in hypoglycaemic episodes. Thus, any resulting improvements in the frequency and awareness of hypoglycaemia can be seen as a "bonus".

### Quality of life

It is well documented that type 1 diabetes is associated with a high prevalence of psychiatric and psychological disorders, such as depression,

### Page points

1. Carbohydrate counting and insulin dose adjustment are now synonymous with the management of type 1 diabetes.
2. Enabling people with diabetes to self-manage their food intake and insulin doses has been shown to result in increased autonomy and empowerment.
3. As a result of their education programme, the authors expected possible improvements in HbA<sub>1c</sub>, hypoglycaemia awareness, quality of life and weight.

***"It is useful to measure the effects upon weight to ensure that significant weight gain does not occur and to assess whether beneficial weight loss occurs as a positive outcome of the programme."***

anxiety and eating disorders, and improving the quality of life of people with diabetes has become a primary goal (Petra et al, 2003). The DAFNE Study Group (2002) reported significant improvements in quality of life at a 6-month follow-up versus baseline ( $P=0.0001$ ). In line with Aintree's "4-step" programme, many other regional programmes use the fully validated PAID (Problem Areas in Diabetes) scores to assess the impact on quality of life (Polonsky et al, 1995). The scores range from 0 to 80, with lower scores indicating a better quality of life. The BERTIE programme reported significant reductions in PAID scores from 21.4 at baseline to 16.8 ( $P<0.001$ ; Everett et al, 2003) and, similarly, the SADIE programme reported reductions from 27.8 to 16.9 (Diabetes Education Network, 2010).

#### **Weight and BMI**

Any intervention that involves dietary adjustment has the potential to cause weight gain or weight loss. It is useful to measure the effects upon weight to ensure that significant weight gain does not occur and to assess whether beneficial weight loss occurs as a positive outcome of the programme. The DAFNE Study Group (2002) reported no significant changes in weight at the 6-month follow-up. Similar findings were reported by the Diabetes Education Network in 2010, which analysed results from 209 participants who attended courses from seven centres across the UK. They also reported no significant difference in weight from baseline to 1-year follow-up, importantly demonstrating that newfound dietary freedom does not cause weight gain.

#### **Outline of Aintree University Hospital's "4-step" programme**

Eligible participants are given a date to attend based upon personal convenience. Each group includes a maximum of 8 participants and meets for 3 hours per week over a period of 4 weeks. The total contact time is 12 hours over 1 month. Service evaluation and data collection are discussed with the participant and verbal permission is obtained for the collection of data at the start of the programme and again at the follow up appointment 3 months after completion. The sessions are delivered by a DSN and a diabetes

specialist dietitian. The intervention includes one follow-up appointment at 3 months after completion of the programme.

#### **Data collection**

HbA<sub>1c</sub>, weight, quality of life and symptom awareness of hypoglycaemia were measured at baseline and then at 3 months after completion of the programme. Quality of life was assessed by completion of the PAID questionnaire developed by Polonsky et al (1995), including questions such as "are you feeling overwhelmed by your diabetes?" and "do you feel scared when you think about living with diabetes?" Symptom awareness of hypoglycaemia was measured by completion of the "hypo awareness" questionnaire devised by Clarke et al (1995). A score of four or more "Rs" indicates reduced hypoglycaemia awareness and examples of questions include "how low does your blood sugar need to go before you feel symptoms?" and "how often in the last month have you had readings of less than 3.5 mmol/L?"

#### **Programme structure**

- **Week 1:** Identifying carbohydrates; methods of counting carbohydrates; calculating long-acting insulin dose; blood glucose monitoring; and food diaries.
- **Week 2:** Further carbohydrate counting practice; relating blood glucose patterns to foods consumed; calculating ratios of rapid-acting insulin to carbohydrate; and commencing dose adjusting.
- **Week 3:** Digestion rates of different carbohydrates; splitting insulin boluses; advanced label reading; calculating individual correction doses.
- **Week 4:** Fine-tuning carbohydrate counting and insulin adjustment; troubleshooting problems; how to manage body weight and making healthy food choices.

#### **Teaching methods**

The sessions were designed to include a variety of methods and to encourage participation. Teaching methods include talks, practical demonstrations, "hands-on" activities, group discussions and home work. A variety of media have been included to allow for different learning styles, including

PowerPoint® presentations, flipchart work, group activities such as weighing foods and reading labels with the use of overhead projectors, and individual workbooks. Patient participation is actively encouraged and the group size of six to eight people lends itself to an interactive approach.

## Results

A total of 28 people with diabetes undertook the carbohydrate counting programme from May 2011 to May 2012, 16 of whom were male, with a mean age of 32.5 years. For the measures of weight, HbA<sub>1c</sub>, hypoglycaemia awareness and PAID, we were only able to obtain paired data for 16 participants as four did not attend their 3 month review session and eight were commenced on insulin pump therapy. Please see *Table 1* for the results.

### HbA<sub>1c</sub>

Although there was a trend towards an improvement in glycaemic control, this did not reach statistical significance at the 3-month follow-up, as the HbA<sub>1c</sub> level was 76.4 mmol/mol (9.1%) compared with 78.4 mmol/mol (9.3%) at baseline, a reduction of 2.2 mmol/mol (0.2%). This is disappointing as we had expected a reduction of 5.5 mmol/mol (0.5%), in line with other regional programmes and our previous audit results, as this measurement provides credibility to the carbohydrate counting programme in terms of improving clinical outcomes. However, it is important to note that

HbA<sub>1c</sub> levels did not deteriorate and participants still appeared to obtain significant non-clinical benefits.

### Weight

The baseline weight was 75.7 kg. At the 3-month follow-up, this had not changed significantly and was recorded as 75.1 kg. As expected, participants did not lose weight, but importantly they did not gain weight while enjoying greater dietary freedom.

### Quality of life

The quality of life measures for our participants revealed a significant improvement in their emotional and psychological well-being. The baseline PAID score was measured at 21.1 and, at the 3-month follow-up, this had improved to a score of 7.87 ( $P < 0.01$ ). In a long-term condition such as type 1 diabetes, this is an important finding.

### Hypoglycaemia awareness

Participants reported an improvement in their hypoglycaemia awareness. The baseline score was 1.33, which had decreased to 1.0 at the 3-month follow up, although this did not reach statistical significance.

### Participant feedback

Participants were asked to complete an evaluation of the 4-week programme, in which 13 rated the course as "very useful" and three rated it as

### Page points

1. A total of 28 people with diabetes undertook the authors' "4-step" education programme.
2. Although the authors observed a trend in participants towards improved glycaemic control, no significant improvement in HbA<sub>1c</sub> was found in the duration of the study.
3. The authors reported no change in the weight of participants, a slight improvement in hypoglycaemia awareness and a statistically significant improvement in quality of life.

**Table 1. HbA<sub>1c</sub>, weight, quality of life and hypoglycaemia awareness in 16 people with diabetes attending the "4-step" education programme at Aintree University Hospital.**

	Baseline (n=16)	3-month follow-up (n=16)	P-value
HbA <sub>1c</sub> (mmol/mol [%])	78.4 (9.3)	76.4 (9.1)	Not significant
Weight (kg)	75.7	75.1	Not significant
PAID (Problem Areas in Diabetes) score	21.1	7.87	<0.01
Hypoglycaemia awareness score	1.33	1.0	Not significant

**"While the Aintree '4-step' programme did not demonstrate a significant improvement in glycaemic control, it did demonstrate a significant improvement in quality of life."**

"useful". When asked to rate the overall content of the course, 12 rated it as "excellent" while four rated it as "very good". The comments included:

*"The method of counting what I eat for my insulin, it's better to do this rather than eating for my insulin."*

*"Counting carbs, never been told about this, just avoid sugar!!"*

### Discussion

Although the decrease in HbA<sub>1c</sub> of 2.2 mmol/mol (0.2%) did not reach statistical significance, there was still a trend towards improvement, and the reduction observed was only slightly lower than the regional results from the Diabetes Education Network, reporting improvements of between 3.3 mmol/mol (0.3%) and 5.5 mmol/mol (0.5%) at 6 months.

We acknowledge that checking HbA<sub>1c</sub> after only 3 months may not accurately reflect the impact of carbohydrate counting on participants. Recording HbA<sub>1c</sub> values at 6 and 12 months would provide more robust and accurate data on clinical and non-clinical outcomes. The result may have also been skewed by the small sample size. As mentioned earlier, the weight of the participants remained unchanged throughout the 3-month follow-up and this supports the findings of the DAFNE Study Group (2002) and Diabetes Education Network (2010). As a result of carbohydrate counting, the greatest improvement in our participants was observed in regard to their quality of life and day-to-day feelings about their condition. The majority of our participants reported a more positive outlook towards managing their diabetes.

Living and managing a long-term health condition has a big impact on a person's psychological well-being with many appearing to feel overwhelmed and anxious. These results demonstrate an overall improvement which may have a positive impact on HbA<sub>1c</sub> levels in the long term. There was also a trend towards reported improvements in participants' hypoglycaemia awareness; however, it could be argued that this perceived improvement could be a result of more intensive home blood glucose monitoring and a greater focus on blood glucose levels.

### Conclusion

While the Aintree "4-step" programme did not demonstrate a significant improvement in glycaemic control, it did demonstrate a significant improvement in quality of life. Although there was no reported weight loss, it is reassuring to know that the dietary freedom enjoyed by participants did not result in weight gain. It was also encouraging to note that there was a trend towards improved hypoglycaemia awareness in spite of the short study duration.

We recognise the limitations of checking clinical and non-clinical data at 3 months and would recommend repeating this at 6 and 12 months. We also recognise that people with type 2 diabetes on multiple daily injections should be considered for carbohydrate counting, as emerging evidence is demonstrating the benefits of this type of education to people with this form of diabetes. Because HbA<sub>1c</sub> did not improve significantly in this instance, we would recommend setting targets and specific goals for participants to achieve from the first week.

We have recently started introducing a bolus calculator at 4 weeks. This may help to achieve an improvement in sHbA<sub>1c</sub> and enable participants to achieve their targets and goals. We plan to re-assess the effects on HbA<sub>1c</sub>, weight, quality of life and hypoglycaemia awareness at 12 months. ■

Clarke WL, Cox DJ, Gonder-Frederick LA et al (1995). Reduced awareness of hypoglycemia in adults with IDDM. A prospective study of hypoglycemic frequency and associated symptoms. *Diabetes Care* **18**: 517-22

DAFNE Study Group (2002) 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* **325**: 746-9

Davies MJ, Heller S, Skinner TC et al (2008) Effectiveness of the diabetes education and self management for ongoing and newly diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes: cluster randomised controlled trial. *BMJ* **336**: 491-5

Deakin TA, Cade JE, Williams R, Greenwood DC (2006) Structured patient education: the diabetes X-PERT Programme makes a difference. *Diabet Med* **23**: 944-54

- Department of Health (2001) *National Service Framework for Diabetes: Standards*. DH, London. Available at: <http://bit.ly/1ABi4B> (accessed 02.02.13)
- Diabetes UK (2003) *Care Recommendation: Education of people with diabetes*. Diabetes UK, London. Available at: <http://bit.ly/RWN0bx> (accessed 02.02.13)
- Diabetes Education Network (2010) *2010 Annual Conference*. Available at: <http://bit.ly/12xnmvo> (accessed 13.02.13)
- Everett J, Jenkins E, Kerr D, Cavan D (2003) BERTIE: Implementation of an effective outpatient intensive education programme for patients with type 1 diabetes. *Pract Diab Int* **20**: 51–63
- Fanelli CG, Epifano L, Rambotti AM et al (1993) Meticulous prevention of hypoglycemia normalizes the glycemic thresholds and magnitude of most of neuroendocrine responses to, symptoms of, and cognitive function during hypoglycemia in intensively treated patients with short-term IDDM. *Diabetes* **42**: 1683–9
- Faulkner S, Jackson J (2011) SADIE: Type 1 diabetes education in Eastbourne. *Journal of Diabetes Nursing* **15**: 354–7
- Meneilly GS, Cheung E, Tuokko H (1994) Altered responses to hypoglycemia of healthy elderly people. *J Clin Endocrinol Metab* **78**: 1341–8
- NICE (2004) *Type 1 diabetes: Diagnosis and management of type 1 diabetes in adults. Clinical guidelines 15*. NICE, London. Available at: <http://guidance.nice.org.uk/CG15> (accessed 02.02.13)
- Petrak F, Hardt J, Wittchen HU et al (2003) Prevalence of psychiatric disorders in an onset cohort of adults with type 1 diabetes. *Diabetes Metab Res Rev* **19**: 216–22
- Polonsky WH, Anderson BJ, Lohrer PA et al (1995) Assessment of diabetes-related distress. *Diabetes Care* **18**: 754–60
- Sämman A, Mühlhauser I, Bender R et al (2006) Flexible intensive insulin therapy in adults with type 1 diabetes and high risk for severe hypoglycemia and diabetic ketoacidosis. *Diabetes Care* **29**: 2196–9
- Speight, J, Amiel, S, Bradley, C et al (2010). Long-term biomedical and psychosocial outcomes following DAFNE (Dose Adjustment For Normal Eating) structured education to promote intensive insulin therapy in adults with sub-optimally controlled type 1 diabetes. *Diabetes Res Clinical Pract* **90**: 22–9