Psychosocial outcomes in adults with type 1 diabetes following a novel ‘short course’ structured flexible MDI therapy self-management programme

**Abstract**

Our objectives were to evaluate the psychosocial impact of a novel education programme, comprising an abbreviated curriculum based on the ‘core elements’ of insulin self-management education, with a view to identifying education options for those unable to attend a five-day Dose Adjustment for Normal Eating (DAFNE) programme.

The novel programme was developed by DAFNE course facilitators and trialled using participants naive to flexible multiple daily injection (MDI) education. Post-course treatment satisfaction, wellbeing and diabetes distress were compared to baseline.

Twenty-one adults attended the programme and 16 participants returned three months post-course. Significant improvements were seen in W-BQ12 total score, PAID score and DTSQ, equivalent to those observed following participation in the five-day programme.

It was concluded that short course flexible MDI education is well tolerated by adults with type 1 diabetes, with improvements in treatment satisfaction and psychosocial outcomes that are consistent with the five-day DAFNE programme. Further investigation of the longer-term impact on psychosocial and glycaemic outcomes of this novel curriculum is warranted. Copyright © 2017 John Wiley & Sons.

**Key words**

multiple injection therapy; education; type 1 diabetes; structured education

**Introduction**

Since the Diabetes Control and Complications Trial (DCCT), where insulin management was mostly ‘physician led’ with fixed insulin dose prescription, there has been a move toward patient-based insulin management using flexible multiple daily injection (MDI) therapy. There has also been greater recognition of the value of a structured curriculum in patient self-management education. Structured flexible MDI education programmes have demonstrated improvements in HbA1c, reductions in hypoglycaemia, and improvements in quality of life, and patient reported outcome measures (such as treatment satisfaction, diabetes distress and wellbeing). Structured education programmes are characterised by: a clear underlying philosophy; a structured written curriculum; a quality assurance process in programme development and outcome assessment; and delivery by trained facilitators. This ensures that education is guided by an established curriculum and all patients receive the same teaching, regardless of participant variables (e.g. previous education or diabetes duration) and facilitator variables.

Flexible MDI education programmes differ in design and delivery. Most programmes focus on: carbohydrate counting; flexible insulin dosing according to carbohydrate content of meals; corrective insulin to return blood glucose towards target range; and management strategies based on daily activities that impact blood glucose levels, such as physical activity, alcohol consumption and illness. Programmes address day-to-day dose determination as well as ongoing proactive insulin dose optimisation and may include a psychosocial component and individual goal setting. Many programmes are based on adult learning principles and support skills-based teaching including learning from experience and observation. The complex nature of such programmes results in a lengthy time commitment with some programmes conducted over four to five days. Many programmes deliver this education in a group format which, in addition to...
potentially being more resource efficient, has been shown to enhance learning opportunities, as group members are able to contribute varied individual experiences and strategies in diabetes management.\textsuperscript{18}

Five-day structured education programmes for flexible MDI, which include the Dose Adjustment for Normal Eating (DAFNE) programme\textsuperscript{1} and the Diabetes Teaching and Treatment Program (DTTP),\textsuperscript{8} have consistently demonstrated beneficial clinical outcomes across different countries;\textsuperscript{7,8,10,13} however, there are barriers to access and delivery of a five-day programme, which include the impact on work/home life, loss of income and increased demand for hospital resources. Short-duration flexible MDI education programmes include a programme reported by Oswald and colleagues, where improvements in glycaemic control were seen following participation in a programme consisting of group and 1:1 consultations, with a mean of 90 minutes of professional contact per patient.\textsuperscript{19} Bendik and colleagues report reduced frequency of severe hypoglycaemia, improved quality of life and increased autonomy in a programme delivered in weekly 90-minute sessions over seven weeks.\textsuperscript{20}

Successful flexible MDI self-management requires the patient to: (1) understand day-to-day insulin dose adjustment according to a variety of factors, such as carbohydrate intake, blood glucose, physical activity and illness; and (2) identify the requirement for proactive optimisation of basal insulin doses and bolus insulin algorithms. The curriculum topics that address these skills are carbohydrate counting, insulin dose algorithms and pattern-based evaluation, which have been identified by Grant and colleagues\textsuperscript{21} as ‘core’ curriculum items for structured flexible MDI self-management education. Participants in the five-day programme manage the daily dose calculation with little difficulty, but struggle to perform proactive insulin optimisation despite practising this on a daily basis in the five-day programme.\textsuperscript{18} Many five-day programme participants stated a preference to rely on trained health professionals to manage this flexible MDI task.\textsuperscript{22} Offering proactive insulin optimisation education and support post-course may enable the day-to-day insulin determinations to be taught in a short course format, with proactive insulin optimisation tailored to individual requirements post-course.

We developed the curriculum with the aim of combining the following attributes of flexible insulin self-management education in a novel programme, which to the authors’ knowledge currently does not exist: short course format focusing primarily on skills of carbohydrate counting and flexible insulin algorithms; use of established insulin algorithms (from DAFNE); use of a structured curriculum and with proactive insulin support offered by experienced facilitators on a 1:1 basis, post-course. Compared to the five-day programme, the shortened programme is less time consuming (10 vs 40 hours) and includes only the ‘basic’ components involved in daily determination of insulin doses in the setting of flexible MDI therapy. It does not include a number of (five-day programme) curriculum components aimed at improving overall knowledge (such as diabetes physiology, exercise physiology, ketone development, pregnancy diabetes and travelling with diabetes) and motivation (goal setting). The risk of shortening this education is that participants may struggle to learn often complex calculations over this time frame and that it may lead to distress or dissatisfaction.

We sought to pilot the programme in adults with type 1 diabetes (T1DM) and evaluate:  
- The impact on treatment satisfaction, diabetes distress and wellbeing.  
- The frequency that participants contacted facilitators for assistance with ‘proactive insulin optimisation’ support.

Figure 1. Course schedule and follow up
• Participant feedback on the curriculum items that were deemed useful.

Methods
Two specialised DAFNE facilitators (diabetes specialist nurse and diabetes specialist dietitian) with experience in DAFNE dosing strategies and adult learning principles developed the curriculum to be delivered in two, five-hour sessions, one week apart. The curriculum topics were: carbohydrate counting, blood glucose targets, hypoglycaemia management and basal insulin titration strategies (session 1); and bolus insulin dosing algorithms, snack dosing, adjustment for exercise, alcohol and sick days and brief introduction to proactive insulin optimisation (session 2).

Patients were encouraged to email between sessions 1 and 2 for carbohydrate counting support. Proactive insulin optimisation was briefly addressed in session 2 to ensure that participants understood that this was also an important part of insulin self-management and would be conducted post-course. Post-course proactive insulin optimisation support was offered in the form of email/phone contact, which was encouraged on a weekly basis for four weeks after session 2. A structured curriculum was used and participants were provided with learning materials (worksheets, carbohydrate counting resources, blood glucose diary, insulin adjustment rules and blood glucose targets). End of study data collection was conducted three months post-course. At this time, participants were asked to identify topics they found useful and not useful in a shortened curriculum. Figure 1 outlines the schedule of course delivery, follow up and data collection.

Adults with T1DM were recruited from this study centre and via referrals from local endocrinologists. Participants who met the study criteria were sequentially recruited into one of four group programmes, with up to eight participants per group. This ‘patient only’ programme did not include partners or other family members. Inclusion criteria for the programme and study were consistent with the five-day DAFNE programme with the following exceptions: HbA1c 7–10% (53–86mmol/mol), using rapid-acting analogue insulin for meals and long-acting analogue insulin once or twice/day and agreement to test blood glucose four to six times/day. Exclusion criteria were: illness preventing group participation, inaccessibility to email or fax, pregnancy or breast feeding, and previous attendance at a five-day DAFNE course.

At baseline, the following data were collected: age, gender, duration of diabetes and history of diabetes complications, and at baseline and study-end data collected were HbA1c, body mass index (BMI), number of severe hypoglycaemic episodes in the previous three months, number of blood glucose tests performed (over the previous two weeks), number of blood glucose tests recorded (over the previous two weeks), Problem Area in Diabetes (PAID questionnaire, available from garry@silverfernhealthcare.com), Wellbeing questionnaire (W-BQ12, available from www.healthpsychologyresearch.com) and Diabetes Treatment Satisfaction Questionnaire (DTSQs, available from www.healthpsychologyresearch.com). DTSQs total score comprises the composite score from six items and total score ranges from 0 to a maximum score of 36, with higher scores indicating greater treatment satisfaction. The W-BQ12 instrument is a measure of depressed mood and anxiety (negative wellbeing subscale), energy and positive wellbeing; however, none of the subscales are diabetes-specific. Each of the three subscales has four items scored 0 to 3 and a total scoring range of 1–12, which contribute to the total score (range 0–36) with higher scores indicating greater wellbeing. The PAID questionnaire comprises 20 questions that address a range of emotions frequently expressed in diabetes and the total score (range 0–100) is a measure of diabetes-related distress, with higher scores indicating greater distress.

Baseline data and change variables were tested for normality using the Shapiro-Wilk test. Variables were compared at baseline and post-course using the paired t-test for normally distributed change variables and the Wilcoxon matched pairs test for the remainder. For categorical data, Fisher’s exact test was used. Statistical calculations were performed using STATISTICA (data analysis software system), version 12.0 (StatSoft Inc).

All participants gave their written consent. The study was approved by the Mater Health Services Human Research Ethics Committee.

Results
Twenty-one participants were recruited to four groups, with six participants per group for two groups, five in one group and four in one group. Sixteen of the 21 participants (76%) returned for three-month follow up. There was loss to follow up in three groups, one participant in two groups and three participants in one group. The reasons for failure to return for follow up were unknown. Baseline characteristics of participants who failed to return for follow up were similar to those who attended follow up, with the exception of the W-BQ12 energy subscale. Participants who failed to return had a lower baseline mean (SD) W-BQ12 energy score (4.2[1.9]), indicating less energy, compared to those who attended follow up (6.8[2.3], p=0.039).

Table 1 summarises the short course outcome data. The novel programme demonstrated significant improvements in all psychosocial scores: mean (SD) W-BQ12 from 25(5) to 28(7), mean (SD) DTSQ from 25(4) to 31(5) and median (IQR) PAID 19(14–36) to 8(5–14).

No statistically significant change was seen post-course for HbA1c, either on a whole cohort basis or when participants with baseline HbA1c <7.5% (7/21 participants) were excluded from the analysis. Weight and BMI were also unchanged. Participants failed to conduct self-monitoring of blood glucose (SMBG) as recommended (four per day, or 56 performed over two weeks) at baseline and post-course. There was no change in the frequency of SMBG or SMBG recording or in BMI. Severe hypoglycaemia was reported by three (14%) participants at baseline three months prior to baseline assessment, compared to nil post-course (data not shown).
Post-course, two participants sent three to four emails over the four weeks post-course, two participants sent two emails and six participants sent one email. Seven participants made no contact with the facilitator for assistance for post-course proactive insulin optimisation.

Of the 16 participants who returned for the three-month follow-up assessment, 15 were using carbohydrate counting and ratio dosing with insulin algorithms, compared to none at baseline. Participants identified the following curriculum topics as most useful: carbohydrate counting, using insulin:carbohydrate ratios and learning the process of insulin adjustment. Two participants nominated ‘learn how to evaluate own insulin doses’ as useful.

Discussion

Treatment satisfaction, wellbeing and diabetes distress improve in adults with T1DM following participation in a novel ‘short course’ structured flexible MDI education programme.

This cohort were similar to the five-day DAFNE participants in terms of mean (SD): HbA1c (8.0[1%]; 64[1]mmol/mol), diabetes duration (18[11] years), BMI (27[3]kg/m²) and frequency of severe hypoglycaemia (29%); however, they were slightly younger (34.8[10.7] vs 43.5[14.3] years), and fewer had retinopathy (14 vs 29%) and neuropathy (0 vs 10%).

The first Australian audit of the five-day DAFNE programme demonstrated a ‘clinically relevant’25 median (IQR) drop in PAID from 25(15–45) to 16(10–30); (p<0.0001), which is consistent with the mean (SD) drop for the UK audit of 25(17) to 17(14); (p<0.001). A more recent Australian audit of the five-day programme22 also demonstrated a 10-point drop in the PAID score post-course. The 10-point reduction in PAID in the current study suggests the short course has a positive impact on diabetes distress equivalent to the five-day programme despite lower PAID scores for this cohort at baseline.

The increase in treatment satisfaction in this cohort is also clinically relevant;28 although the magnitude of improvement was slightly less than that seen in the five-day programme,1 where mean (SD) DTSQ increased from 25(6) to 32(4) at six months, the post-course scores were similar. The higher treatment satisfaction at baseline for this cohort, versus the comparison five-day course, may limit the ability to detect an improvement due to the ‘ceiling effect’ of this tool,29 where ‘close to maximum’ scores at baseline limit the ability to see a change or improvement post-course. We chose the DTSCs (status version) which is known to be limited by the ceiling effect, to enable comparison to the five-day DAFNE programme.7

The improvement in total wellbeing score of 4 points was similar to that seen in the five-day programme,1 where mean (SD) total wellbeing score increased from 21(6) to 24(6), six months post-course. The lower mean ‘energy’ wellbeing scores in those who failed to return for follow up may have limited the improvement seen post-course as the greatest gains in quality of life measures are seen with ‘poorer’ measures of quality of life at baseline.30

As with the five-day programme, participants in this study were not confident with the process of proactive dose optimisation and there was a heavy reliance on the facilitators to direct proactive dose decisions. The limited use of the blood glucose diary (an essential tool in proactive insulin optimisation) and the low numbers of participants (n=2) suggesting inclusion of the topic, ‘learn how to evaluate your own insulin doses’ in the short course format, support the notion that participants in this cohort were also reluctant to take on the role of proactive insulin optimisation. The use of email/phone proactive insulin optimisation support in less than 50% of participants suggests either an unwillingness to take on this activity, or that the mode of delivery of this support was not suitable, or both. Most participants (15/16 (94%)) were carbohydrate counting and using insulin algorithms by the end of the course.

The short course programme failed to influence SMBG frequency and many participants failed to conduct SMBG as recommended. Despite the majority of participants making changes to their daily

<table>
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<th>Variable</th>
<th>Pre-course</th>
<th>Post-course</th>
<th>P-value</th>
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<td>HbA1c – %</td>
<td>8.0 (0.7)</td>
<td>8.0 (0.9)</td>
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<td>– mmol/mol</td>
<td>64 (8)</td>
<td>64 (10)</td>
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<td>Weight (kg)</td>
<td>74.6 (70.2–82.5)</td>
<td>74.1 (69.1–81.9)</td>
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<td>Body mass index (kg/m²)</td>
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<td>26.5 (3.1)</td>
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<td>No. of blood glucose tests</td>
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<td>51.9 (20.9)</td>
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<td>performed per 2 weeks</td>
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<td>No. of blood glucose tests</td>
<td>0 (0–52)</td>
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<td>recorded per 2 weeks</td>
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<td>Rapid insulin TDD (U/d)</td>
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<td>24.5 (8.3)</td>
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<tr>
<td>Basal insulin TDD (U/d)</td>
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<td>30.3 (9.9)</td>
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<td>W-BQ12 total score</td>
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<td>25 (4)</td>
<td>31 (5)</td>
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<td>PAID overall score</td>
<td>19 (14–36)</td>
<td>8 (5–14)</td>
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</table>

N = 16 (14 female, 2 male). Normally distributed variables described as mean (SD), otherwise as median (IQR). Normally distributed baseline variables compared using independent t-test, otherwise Mann-Whitney U test was used. HbA1c = glycosylated haemoglobin. TDD = total daily dose (U/d). DTSQ = Diabetes Treatment Satisfaction Questionnaire. PAID = Problem Areas in Diabetes. W-BQ12 = 12-item Wellbeing Questionnaire.

Table 1. Short course outcomes for the 16 participants who returned for the three-month follow-up assessment
diabetes management (carbohydrate counting and dosing with insulin algorithms), change in management did not translate to increasing SMBG frequency. Such a change may represent a greater degree of behaviour modification than changing how the insulin is calculated at each meal. This highlights the limitation of this short course curriculum, which does not address behaviour modification. In addition, the duration of the group interaction may not provide adequate opportunities for participants to observe the value of regular SMBG. More selective inclusion criteria that require participants to be demonstrating appropriate SMBG frequency prior to course enrolment may be required for those participating in the short course programme.

The failure to see an improvement in HbA1c with the short course programme may be due to limited power to detect a change in HbA1c associated with study size. Given that the majority of participants were conducting intensive management at the end of the course, we would hope to see this translate to improvements in glycaemic control; however, a more rigorous evaluation of glycaemic outcome is warranted.

Limitations
Compared to five-day DAFNE participants, this cohort was slightly younger with fewer diabetes complications. However, given the similar baseline characteristics and the enrolment of only adults, we do not expect this difference to contribute any bias in our study. The predominance of female participants is consistent with general experience at this site for the five-day DAFNE course and the clinical implications of this bias are expected to be minimal.

The comparison of psychosocial data in this cohort (after a briefer three-month follow up) with the five-day DAFNE programme (after six and 12 months) may introduce some bias. However, the magnitude of change in PAID, W-BQ12 and DTSQ scores was equivalent to that seen at six and 12 months with the five-day programme; in view of this, and the relative stability in these quality of life scores from six to 12 months in the five-day programme, we consider it most likely that these changes are seen relatively promptly post-course and sustained up to six and 12 months, enabling comparison with these longer-term studies.

Conclusion
Short course flexible MDI self-management education is well received by adults with T1DM and may be an alternative or adjunctive option for those who are unable to access a five-day programme. The poor utilisation of post-course proactive insulin optimisation support reflects the previously observed reluctance to take on this aspect of flexible MDI therapy, and alternative approaches to supporting proactive insulin optimisation both in the five-day as well as the short course format are required. Evaluation of any longer-term impact on psychosocial as well as glycaemic outcomes for this novel programme is also warranted.

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Declaration of interests
Brigid Knight is a member of the OzDAFNE advisory board and involved in the delivery of DAFNE courses and training. Janet Taylor is an accredited DAFNE facilitator. H David McIntyre is a member of the OzDAFNE advisory board. Ingrid J Hickman and Kristen Gibbons have no conflicts of interest.

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References
References are available in Practical Diabetes online at www.practicaldiabetes.com.
References


