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Abstract:	Background: Few studies have identified determinants of glycemic control (HbA1c) and diabetes-specific quality of life (DSQoL) in adults with type 1 diabetes. Purpose: To identify factors predicting outcomes following structured diabetes education. Methods: 262 participants completed biomedical and questionnaire assessments before, and throughout one year of follow-up. Results: The proportion of variance explained ranged from 28-62% (DSQoLS) and 14-20% (HbA1c). When change in psychosocial variables were examined, reduced hypoglycemia fear, lower 'perceived diabetes seriousness', greater self-efficacy and well-being predicted QoL improvements from baseline to 3-months. Increased frequency of blood glucose testing predicted improvements in HbA1c from baseline to 6-months. Conclusions: Greater benefits may be achieved if programs focus explicitly on

	psychosocial factors. Self-care behaviours did not predict HbA1c suggesting existing assessment tools need refinement. Evaluation of treatment mechanisms in self-management programs is recommended.
Response to Reviewers:	Thank you for your email. As requested, we have now indented paragraphs throughout the manuscript and put journal titles, volume and book titles etc. in italics. We hope that we have carried out the required edits.

Modeling predictors of changes in glycemic control and diabetes-specific quality of life amongst adults with type 1 diabetes one year after structured education in flexible, intensive insulin therapy

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Introduction

Diabetes education programs designed to both inform and promote effective self-management have evolved from didactic knowledge transfer (by healthcare professionals viewed as the experts) to experiential, skills-based training based on the principles of adult education (Assal et al., 1997; Funnell et al., 2012). Structured Education Programs (SEPs) have been shown to improve diabetes knowledge, glycemic control, weight and dietary management, physical activity and psychological well-being, particularly when this skills-based learning is tailored to the needs of the individual (Norris et al., 2002). In particular, SEPs based on the Düsseldorf structured teaching and treatment program (STTP) (Muhlhauser et al., 1983), have demonstrated a wide range of positive health and psychological outcomes (DAFNE Study Group, 2002; McIntyre et al., 2010; Plank et al., 2004).

An adaptation of the Dusseldorf STTP, known as the Dose Adjustment for Normal Eating (DAFNE) program, has transformed type 1 diabetes management in the UK (DAFNE Study Group, 2002). DAFNE consists of 38 hours of skills-based structured training provided (typically) over five consecutive days in an outpatient setting, to groups of up to eight adults with type 1 diabetes, facilitated by a diabetes nurse educator and dietician. The aim is to promote autonomy, competency, confidence and flexibility in the self-management of type 1 diabetes by providing skills-based training in carbohydrate counting and insulin dose adjustment in a comprehensive range of situations (Oliver & Thompson, 2009). While the Dusseldorf STTP, as delivered in Germany, has demonstrated long-term improvements in

HbA1c (Muhlhauser et al., 1995), DAFNE has demonstrated only partially maintained improved HbA1c but fully maintained improvements in diabetes-specific QoL for up to four (Speight et al., 2010) or seven years (Gunn & Mansell, 2012).

Despite the overall success of these programs, important questions remain unanswered. Whilst improvements in QoL seem to be maintained in the long term, some participants' HbA1c results remain unchanged or worsen after the course; 20% of DAFNE graduates have an HbA1c >9.0% (75mmol/mol) (Speight et al, 2010). In terms of glycemic control, these results mirror those found in other studies of intensive insulin therapy and education in type 1 diabetes (EDIC Research Group, 2002; EURODIAB IDDM Study Group, 1994). While the outcomes of SEPs are relatively consistent across studies, it remains unclear whether specific participant characteristics or experiences predict optimal and sub-optimal outcomes. If it were possible to determine subgroups that are more likely to benefit, follow-up support could be tailored accordingly to ensure that more people derive and sustain positive outcomes. For example, to maintain optimal self-management, some participants may need additional input, e.g. a different type of course, group follow-up, one-to-one follow-up or coaching (Rankin et al., 2012).

The reasons for improvements in QoL outcomes following diabetes SEPs are unclear, as many are not specifically designed to influence QoL (Cochran & Conn, 2008). While it is now recognized that QoL benefits are important in sustaining self-care behaviors required to manage diabetes (Wolpert & Anderson, 2001), a review found that only 17% of clinical trials evaluating diabetes self-management training assessed QoL or related patient-reported outcomes (Glasgow, 1999). A meta-analysis of 20 studies reported improved QoL following diabetes self-management interventions (Cochran & Conn, 2008). The relationship between depression, poorer QoL and glycemic control is well-established although the direction of the relationship and causal mechanisms are unclear (Schram et al., 2009). Part of the reason for

the lack of clarity about the causal mechanisms underlying the relationship between poorer QoL and glycaemic control is due to how the concept of QoL has been operationalized (Speight et al., 2009). Studies that have focused on generic QoL have tended to operationalize this concept with measures of health status (often referred to as health-related QoL measures), which may not capture aspects of QoL that are important in this population and/or impacted by treatment demands.

As in the general population, men, younger people and those with higher socioeconomic status tend to report better health status (or health-related QoL) (Rubin, 2000). Psychosocial factors such as social support, coping strategies and illness perceptions have been implicated as affecting QoL and related outcomes in people with diabetes and being more predictive than clinical characteristics (Rose et al., 1998; Rubin & Peyrot, 1999). Higher levels of self-efficacy have been shown to relate to better health-related QoL (using the SF-20 measure) in people with type 1 diabetes (Aalto et al., 1997). In a large study of people with type 1 and 2 diabetes, a variety of factors, including self-efficacy, explained 62% of the variance in generic QoL (using the WHOQOL measure), but only 5% of the variance in glycemic control (Rose et al., 2002). Self-efficacy, mood and optimism were more predictive of generic QoL than disease characteristics or data collected on the clinician-patient relationship but the study was limited by a cross-sectional design. In a study of 437 adults with type 1 diabetes followed up for one year after a diabetes self-management program, those with higher baseline levels of anxiety, diabetes-related distress and HbA1c were the most likely to experience improvements in diabetes-specific QoL (Byrne et al., 2012). It is likely that, because these participants had a greater need related to those health outcomes at baseline, it was easier to demonstrate improvement by one-year follow-up.

Relatively few studies have identified determinants of HbA1c in adults with type 1 diabetes, as most research has focused on childhood and adolescence or on type 2 diabetes. A

review of correlates of long-standing sub-optimal HbA1c (DeVries et al., 2004) implicated genetic factors supported by twin studies, since there are consistent individual differences in HbA1c levels, whereby HbA1c values at diagnosis correlate with those taken five years later (Goldstein et al., 1991; Snieder et al., 2001). This review also found that there was some evidence to implicate several demographic and psychosocial factors in determining glycemic control, including lower socio-economic status, motivational difficulties, emotional distress, depression and eating disorders (DeVries et al., 2004). Much of this work has been limited by cross-sectional study designs. Only one study has attempted to identify determinants following participation in SEPs where seven factors independently predicted 17% of the variance in glycemic control during the 3-year follow-up period. Higher HbA1c values were associated with being female, lower socioeconomic status, younger age at onset of diabetes, smoking, less frequent self-monitoring of blood glucose (SMBG), less diabetes-related knowledge and lower perceived coping abilities (Bott et al., 1994). In newly diagnosed adults with type 1 diabetes, greater levels of diabetes knowledge and lower alcohol consumption independently predicted lower HbA1c values one year after diagnosis, explaining 16% of the variance (Taylor et al., 2003). Few psychological predictors were considered in either of these models.

Focusing on the *process* of self-management rather than the outcome (e.g. QoL or HbA1c), other studies have identified transient situational factors, such as psychological stress and social support, to be important determinants (Glasgow et al., 2000; Goodall & Halford, 1991). Beliefs about treatment effectiveness and the seriousness of diabetes have been shown to predict certain self-management behaviors (Hampson et al., 1995). A meta-analysis reported small but significant associations between illness perceptions and glycemic control (McSharry et al., 2011). Fear of hypoglycemia is also thought to have a behavioral impact on diabetes self-management and HbA1c but the relationship between these factors is

complex and not well understood (Wild et al., 2007). Self-efficacy has been hypothesized as a principal attribute associated with behavioral outcomes in chronic disease management (Holman & Lorig, 2004) but there are mixed results regarding the relationship between self-efficacy and HbA1c (Glaister, 2010). Our objective was to identify factors that may predict change in HbA1c and diabetes-specific QoL, and which operate as possible predictors of these outcomes, over a one-year follow-up period among adults with type 1 diabetes undergoing the DAFNE SEP to acquire skills in flexible intensive insulin therapy.

Research Design and Methods

The design, methods, procedure and eligibility criteria for this study have been reported previously (Cooke et al., 2013a). Participants were recruited from 73 courses at 12 hospitals. Ethical approval was obtained from King's College Hospital Research Ethics Committee (Ref: 08/H0808/53). HbA1c data were collected from medical records up to eight weeks before DAFNE training and at 6 and 12 months post-course. Questionnaire data were collected up to two weeks before course enrolment and at three, six and 12 months after course completion. These follow-up periods were selected as they were most likely to coincide with points when HbA1c was routinely collected at outpatient clinic appointments. In addition, the 3-month follow-up was included because we reasoned that this would allow sufficient time after the booster session (at 6 weeks) to see improvements in psychological and social variables. In an attempt to increase recruitment rates and reduce attrition at follow-up, participants were given the option of completing the questionnaires electronically (via email) or in paper format (by post). A meta-analysis has demonstrated the equivalence of paper vs. electronic administration of patient-reported outcome measures (Gwaltney et al., 2008). In addition to demographic data, the questionnaire comprised a number of standardised scales:

- Personal Models of Diabetes (PMD; Hampson et al., 1990; Hampson et al., 1995): 10 items comprising two subscales: 'perceived treatment effectiveness' and perceived seriousness of diabetes. Each item is scored on a 5-point Likert scale with higher scores indicating greater beliefs. Reliability coefficients for the two scales are acceptable (perceived seriousness of diabetes α=0.6; 'perceived treatment effectiveness' α=0.7). This measure has been used to predict self-management behavior thus supporting its validity (Glasgow et al., 1997).
- Revised Self-Care Inventory (SCI-R; Glasgow et al., 1997): 15 items measuring perceived adherence to diabetes self-care recommendations. Higher scores indicate greater levels of self-care. Internal consistency is high (α=0.9) and responsiveness has been demonstrated with improvements in scores following a psycho-educational intervention (Weinger et al., 2005).
- Confidence in Diabetes Self-care (CIDS; van der Ven et al., 2003): 20 items designed to assess diabetes-specific self-efficacy in adults with type 1 diabetes. Higher scores indicate greater levels of self-efficacy. The scale has high internal consistency (α=0.9; Weinger et al., 2005) and has demonstrated responsiveness following cognitive behavioral therapy (Snoek et al., 2008).
- Revised Michigan Diabetes Knowledge Test: 23 items with high internal consistency ($\alpha \geq 0.7$) and test-retest reliability that has been shown to be suitable for type 1 populations (Fitzgerald et al., 1998).
- Social Support Questionnaire (SSQ6; Sarason et al., 1987): 6-item scale providing a measure of the number of supportive relationships available and an indication of the level of satisfaction with that support. Higher scores indicate greater levels of satisfaction with social support. It has high internal consistency (α=0.90-0.93) and re-test reliability (Weinman et al., 1995).

- WHO-5 well-being index (Bonsignore et al., 2001): a 5-item questionnaire measuring general emotional well-being using positively--worded items has been shown to be a valid instrument for detecting depressive symptoms in people with diabetes (De Wit et al., 2007). It has good internal consistency (α=0.70-0.85). Higher scores indicate greater general emotional well-being, while lower scores indicate impaired well-being, and scores <13 may be indicative of depressed mood.
- Hypoglycemia Fear Survey Worry subscale (HFS-W; Cox et al., 1987): a 13-item subscale assessing anxieties related to hypoglycemia, with higher scores indicating more worry. The HFS-W scale has been shown to have acceptable to good internal consistency reliability (α=0.60-0.84) in a review of seven studies (Irvine et al., 1992). The scale has also demonstrated responsiveness with reduced scores following interventions designed to minimise frequency and fear of hypoglycemia (Gonder-Frederick et al, 2000).
- Diabetes-Specific Quality of Life Scale (DSQOLS) was designed specifically to evaluate the Dusseldorf STTP, on which DAFNE is based (Bott et al., 1998). The scale has recently been validated in English (UK) (Cooke et al., 2013b) and has demonstrated responsiveness with improvements following DAFNE (Cooke et al., 2013b). It includes 57 diabetes-specific items forming six subscales: Social Aspects, Fear of Hypoglycemia, Dietary Restrictions, Physical Complaints, Anxiety about the Future and Daily Hassles. These have excellent internal consistency (α=0.74-0.94). Higher scores correspond to better outcomes in each area. Notwithstanding the identification of six distinct subscales, these are moderately to strongly positively inter-correlated (r=0.50-0.72) and can be combined to form a single scale: total diabetes-specific QoL, where higher scores indicate more optimal QoL (α=0.97).

Data are presented as mean ± standard deviation or number (%). To examine change over time in each of the psychosocial variables examined, we carried out likelihood ratio tests where we compared the chi-square value for the model where the means are constrained to be equal with that where they are not constrained. With the HbA1c outcome, we analysed change from baseline to 6 months and, separately, from 6 to 12 months using piecewise growth models. In general, there were large changes from baseline to 6 months but little change from 6 to 12 months, and this nonlinear pattern could not be modelled as a single function over the 12 month period; it was better described by looking at the two periods separately. Accordingly, piecewise growth models were used to model change between baseline and 3 months and then the linear change from 3 to 12 months. Differences were computed as the later time minus the earlier time. Piecewise growth models within a latent variable modelling framework have some advantages over simple difference scores in terms of handling missing data for which we used full information maximum likelihood (Bollen & Curran, 2006). The models were specified so that we could also look at predictors of both HbA1c and diabetes-specific QoL at baseline.

In relation to HbA1c, the focus of this study was on predictors of improvements in HbA1c, among those with a sub-optimal level of ≥7.5% (≥58 mmol/mol); the UK's National Institute for Health and Clinical Excellence (NICE) recommends an HbA1c target of <7.5% (<58 mmol/mol) in adults with type 1 to minimise the risk of hypoglycemia (NICE Guidance, 2004). To analyse predictors of change in HbA1c, 65 (25%) participants with a baseline HbA1c <7.5% (<58 mmol/mol) were excluded, on the basis that further reduction in their HbA1c may not be beneficial; indeed, some of these individuals may have been encouraged to relax their glycemic control to avoid hypoglycemia.

Results

Of 474 adults with type 1 diabetes who were approached to take part in the study, 269 (57%) consented. Seven were subsequently excluded because they did not attend the DAFNE course hence the final sample included 262 (55%) participants. Anonymous clinical and demographic data were available allowing a comparison between those who had either declined participation or were uncontactable (n=254) and those who were recruited (n=262). There were no statistically significant differences between the two groups regarding diabetes duration or gender. Non-participants had significantly higher baseline HbA1c values (8.8±1.6% or 73±18mmol/mol) than participants (8.5±1.5% or 69±16mmol/mol; t=2.3, df=501, p=0.02). A follow-up rate of 74% was achieved at the 6 and 12 month data collection points. Participants who completed questionnaires at the 6- and 12-month follow-up points were significantly older and had lower HbA1c values than those that did not (data available upon request. At baseline, there were no statistically significant differences on any of the self-reported questionnaire measures collected between those who completed questionnaires at each of the follow-up points and those that did not (data available upon request).

There were equal numbers of men and women, with an average age of 40±14 years (range: 17-73 years). The majority, 234 (89%) were White British. Mean duration of diabetes was 18±13 years (range: 6 months to 55 years). Around half (n=116, 44%) had a degree and a similar proportion (n=128, 49%) were in professional or managerial occupations. Two-thirds were home owners, the majority (n=159, 61%) were in full-time employment and two-thirds (n=179, 68%) were married or in a stable relationship. Mean baseline HbA1c was 8.5±1.5% (70±16mmol/mol), ranging from 5.4-14.2% (36-132 mmol/mol; Table 1).

We found statistically significant improvements (i.e. reductions) in HbA1c from baseline to 6 months that were maintained at 12 months, with a slight deterioration in HbA1c from 6 to 12 months (Cooke et al., 2013a). This pattern of change was the same for the total group and for the sub-sample (n=197) who had sub-optimal glycemic control (HbA1c levels

≥7.5%, ≥58 mmol/mol) at baseline. The average improvement in HbA1c was a 0.3% reduction in the total group and a 0.5% reduction in the group with a baseline HbA1c ≥7.5%. Pooled within groups standard deviations were calculated across the three time points for HbA1c, in order to calculate the standardized mean difference effect sizes. For the subgroup with sub-optimal HbA1c (≥7.5%), these effect sizes were 6 months minus baseline (-0.363) and for 12 months minus 6 months (0.125). For the full sample, the values were -0.218 and 0.102 respectively. In the sub-sample who had HbA1c levels <7.5% (<58 mmol/mol) at baseline, HbA1c increased significantly by 6 months, and this increase was maintained at 12 months (Table 1).

We found significant improvements in diabetes-specific QoL from baseline to 3 months that were maintained at subsequent follow-up periods, 6 and 12 months (Cooke et al., 2013b). As with HbA1c, these changes in diabetes-specific QoL represented clinically significant improvements, equivalent to a medium effect size. For DSQOLS, calculated standardized mean difference effect sizes were 0.448 for 3 months minus baseline; and -0.011 for 12 months minus 3 months. For the full sample, the values were 0.427 and -0.024.

Change over time in psychological variables. In the total sample, most psychological and behavioral variables showed statistically significant improvements from baseline to 3 months, including diabetes knowledge, 'perceived treatment effectiveness', diabetes-specific self-efficacy and self-care behaviors, average number of daily blood glucose tests, fear of hypoglycemia and general emotional well-being (Table 2). Whilst these represented statistically significant improvements, diabetes self-efficacy and self-care behaviours also showed clinically significant improvements. For self-efficacy this represented an improvement of approximately 0.6 standard deviation units, corresponding to a medium effect. For self-care behaviors, this represented an improvement of approximately 1 standard deviation unit, equivalent to a large effect. Most of these were maintained at subsequent

follow-up periods. Social support (as measured by the number of people named) increased significantly from 3 to 12 month follow-up. There was no statistically significant change over time for satisfaction with social support or perceived seriousness of diabetes. There was a statistically significant deterioration in diabetes self-care scores (SCI-R) from 3 to 12 months.

Baseline Analyses. In the bivariate analyses, the following variables were associated with lower HbA1c levels at baseline: older age, longer diabetes duration, not owning your own home, higher levels of education, lower occupational status and greater frequency of SMBG, better diabetes-specific QoL, higher levels of diabetes knowledge, stronger belief in 'perceived treatment effectiveness', self-efficacy and self-care behaviors (Table 3). None of the other variables were associated significantly with lower HbA1c at baseline, that is, prior to attending the SEP.

The following variables were associated with better diabetes-specific QoL at baseline: lower HbA1c, higher educational level, lower perceived seriousness of diabetes, greater number of people named as providing social support, higher levels of self-efficacy, higher levels of self-care behaviors, less worry about hypoglycemia and higher levels of well-being (Table 4). Not all of these relationships were statistically significant using multivariate analysis, reflecting the inter-correlations between these predictor variables. Lower perceived seriousness of diabetes, higher levels of self-efficacy, less worry about hypoglycemia and higher levels of general emotional well-being were all associated with better diabetes-specific QoL at baseline in the multivariate analysis.

Predicting change in HbA1c from factors assessed at baseline. Whilst there were some significant associations between various background and psychological factors and HbA1c at baseline, there were no baseline factors that were associated with change in HbA1c either from baseline to 6 months or 6 to 12 months in the bivariate analysis, that were also then supported in the multivariate analysis (Table 3). In the bivariate analysis, male gender

was significantly associated with greater improvements in HbA1c from 6 to 12 months but this was not supported in the multivariate analysis. In the multivariate analysis, estimated R^2 values showed that the proportion of variance in HbA1c explained by the model was 20% at baseline, 16% at 6 months and 14% at 12-month follow-up.

Predicting change in diabetes-specific QoL from factors assessed at baseline. When we examined which of the baseline factors were associated with changes in diabetes-specific QoL during the initial period from baseline to 3 months, several factors were significant in the bivariate analyses (Table 4). However, only one of these relationships was significant in the multivariate analysis, reflecting the fact that correlation among these variables is such that they do not have an independent effect. Perceiving diabetes as more serious at baseline was significantly associated with greater improvements in diabetes-specific QoL from baseline to 3 months. Consistent with the absence of significant change, there were few baseline factors associated with improvements in diabetes-specific QoL during the latter part of the study period from 3 to 12 months. In the bivariate analyses, a higher HbA1c and lower levels of self-care behaviors were significant, but in the multivariate analysis, no baseline variables were significant. In the multivariate analyses, estimated R^2 values showed that the proportion of variance in diabetes-specific QoL explained by the model was 62% at baseline and 28%, 34% and 38% at 3, 6 and 12 months respectively. The greater proportion of variance explained pre-intervention (DAFNE) is because of the inclusion of the baseline variables.

Predicting change in HbA1c from change in psychosocial and behavioral predictors (n=197). Table 5 presents the results from the piecewise growth model where change in HbA1c from baseline to 6 months (and from 6 to 12 months) is predicted from the difference in the psychosocial and other variables for the equivalent timepoints. Overall, the model provided a good fit (χ^2=28.96, df=16, p = .02, CFI=0.96, RMSEA=0.064, SRMR=0.026). From baseline to 6 months, improvement in HbA1c was associated with

greater frequency of SMBG. Improvement in HbA1c, from 6 to 12 months, was associated with perceiving diabetes as less serious and the treatment as less effective. Change in other psychosocial variables was not associated with change in HbA1c at either timepoint.

Predicting change in diabetes-specific QoL from change in psychosocial and behavioral variables. Our model, which examined whether change in psychosocial variables was associated with change in diabetes-specific QoL, fitted the data well (χ^2=62.51, df=40, p=0.01, CFI=0.97, RMSEA=0.046, SRMR=0.025; Table 5). Perceiving diabetes as less serious, increases in diabetes-specific self-efficacy, reduction in fear of hypoglycemia and improvement in general emotional well-being also predicted improvements in diabetes-specific QoL over this initial period. These results were supported in both the bivariate and multivariate analyses. For the 3 to 12 month period, reductions in fear of hypoglycemia, improvements in general emotional well-being were associated with improvements in diabetes-specific QoL over the same period. Change in the other psychosocial variables examined was not significantly associated with change in diabetes-specific QoL.

Discussion

Our aim was to identify factors that predict change in HbA1c and diabetes-specific QoL, and possible predictors of these outcomes, among adults with type 1 diabetes up to one year after attending a SEP in flexible, intensive, insulin therapy. Both HbA1c and diabetes-specific QOL showed statistically and clinically significant improvement by 6-month follow-up. It is notable that the mean HbA1c of participants was still 8.2% despite these improvements, which suggests that there is scope for programs like DAFNE to result in more substantial HbA1c improvements, which are then maintained. Most of the psychosocial variables assessed as hypothesized predictors showed significant improvements by the first follow-up and were maintained subsequently. The number of people named as providing

social support increased significantly from 3 to 12 months. This mirrors the qualitative findings from a sub-sample of this study population (Rankin et al., 2014), indicating that social support tended to increase post-course, perhaps in response to individuals' new found enthusiasm for self-management.

In the multivariate analysis, longer diabetes duration, not owning one's own home, and greater frequency of SMBG were not significantly associated with lower HbA1c at baseline but approached statistical significance. Lower perceived seriousness of diabetes, higher levels of self-efficacy, less worry about hypoglycemia and higher levels of general emotional well-being were all associated with better diabetes-specific QoL at baseline in the multivariate analysis. It may be that some of the relationships found in the bivariate analyses arose spuriously due to confounding with other variables, although it is also the case that the multivariate analysis holds constant variables that inevitably co-vary in reality, and thereby some of the more complex interactions between possible predictors and HbA1c may fail to emerge.

When we examined which baseline factors predicted changes in diabetes-specific QoL and HbA1c over the course of the study, few were identified as significant predictors. Regarding diabetes-specific QoL, only one relationship was supported in the multivariate analysis: perceiving diabetes as more serious at baseline was associated with greater improvements in diabetes-specific QoL from baseline to 3 months. We know that the initial improvement in QoL at 3-months is equivalent to just under a medium effect size (Cooke et al., 2013a). The proportion of variance in QoL explained by this model was good with 38% of the variance explained at one year follow-up. At baseline, greater 'perceived treatment effectiveness' predicted greater improvements in HbA1c from baseline to 6 months, consistent with other work in this area (Hampson et al., 1995). In addition, from 6 to 12 months, male gender and more frequent SMBG predicted greater improvements in HbA1c.

This is also consistent with previous research and Dusseldorf STTP results, i.e., that being female was associated with higher HbA1c three years after structured education (Cochran & Conn, 2008; DCCT, 1993). Thus, the baseline demographic and psychosocial variables assessed here had minimal explanatory value in terms of improvements in HbA1c at 6 and 12-month follow-up, explaining 16% of the variance in HbA1c at 6 months and 14% at 12-month follow-up.

The proportion of the variance in HbA1c levels explained corresponds to previous research (16-17%), although the variables hypothesised as affecting glycemic control differ somewhat (Cochran & Conn, 2008; Glasgow, 1999). Psychosocial variables were not assessed to the same extent in those earlier studies and Taylor's study followed a cohort of adults with newly diagnosed type 1 diabetes, a different population than that of the current study in which the mean duration of diabetes was 18 years (Taylor et al., 2003). It is notable that demographic characteristics show little explanatory power in terms of both outcomes. This implies that people will derive benefit whatever their background characteristics. However, a relatively large proportion of the sample were educated to degree level and in high status occupations, so an alternative explanation may be that this is a homogeneous sample, somewhat unrepresentative of the wider type 1 diabetes population. Associations with educational level and occupational status may have been found had the sample been more heterogeneous in relation to these factors.

The additional analysis looked more dynamically at the variables assessed. At the outset of the study, the importance of assessing the relationship not only between baseline variables and change in outcome but also between change over time in our independent variables and how this may or may not relate to change in our outcome variables (HbA1c and QoL) was emphasised. Higher numbers of average daily blood glucose tests was the only factor associated with significant improvement in HbA1c from baseline to 6 months. From 6-

12 months, perceiving diabetes as more serious and diabetes treatment as less effective were significantly related to improvements in HbA1c.

Perceiving diabetes as less serious, improvements in diabetes-specific self-efficacy, reductions in fear of hypoglycemia and improvements in general emotional well-being predicted improvements in diabetes-specific QoL from baseline to 3 months. This model fitted the data well. Improvements in the latter two variables also significantly predicted improvements in diabetes-specific QoL from 3 to 12 months. In this study, improvements in glycemic control appeared to be mirrored by improvements in diabetes-specific QoL. This reflected the findings of the original DAFNE trial (DAFNE Study Group, 2002). As discussed earlier, it is likely that inconsistencies in the relationship between glycemic control (HbA1c) and 'QoL' reported in the literature (Schram et al., 2009; Speight et al., 2009) are due to the use of generic QoL or health status measures and/or cross-sectional study designs.

The results of this work appear to present a somewhat paradoxical finding: coming to perceive diabetes as less serious was associated with improvements in diabetes-specific QoL. In parallel, as diabetes was perceived as more serious and its treatment as less effective, HbA1c improved from 6 to 12-months. This may partly explain the modest effect of the intervention on HbA1c. It may be that those who think of their diabetes as more serious are those who are struggling with the self-care behaviors needed to improve HbA1c thus reinforcing their belief in the severity of the condition. This paradox may also be partly explained by the fact that there is very little change in these illness perception variables from 6 to 12 months. In terms of HbA1c, those who benefit from DAFNE do so initially but then the effect drifts, whereas their perceived diabetes seriousness may continue to increase and perceptions of treatment effectiveness continue to reduce. These patterns of change can be seen by looking at how both of these variables change over time (see Tables 1 and 2). Previous work has found negative associations between perceived seriousness of diabetes and

glycemic control but these studies have been cross-sectional and conducted in childhood, adolescence or type 2 diabetes (e.g. Hampson et al., 1995; Pattison et al., 2006). It seems that a degree of reconciliation is needed between these measures of process so that optimal outcomes are achieved both in terms of QoL and glycemic control.

The relatively high proportion (25%) of participants with optimal HbA1c (<7.5% or 58mmol/mol) at baseline had implications for analysis of improvements in glycemic control. We decided to exclude these participants from this analysis, reducing the sample size by one quarter. While the response rate for completed questionnaires was good (74% returned questionnaires at all timepoints), only 52% of the sample had HbA1c and questionnaire data available at all timepoints. The use of many timepoints in longitudinal modelling helps to increase power but this benefit is reduced by increasing attrition (Muthen & Curran, 1997). While 55% of the 474 eligible DAFNE participants consented to take part in this study, non-participants had significantly higher mean HbA1c (8.8% vs 8.5%). We were unable to compare participants and non-participants on characteristics such as educational attainment and occupational status, as these data were not available. It is well established that those with higher educational attainment are more likely to participate in research studies (Galea & Tracy, 2007). It is also possible that healthcare professionals referring people to these courses may do so on the basis of these characteristics because this population is expected to gain more or find the SEP less challenging. Other characteristics and contextual variables that may increase the explanatory power of the model investigated here may also need to be considered. Qualitative research conducted alongside the statistical modelling suggested that key to sustaining the self-care behaviors recommended within the flexible, intensive, insulin therapy approach, and hence improving HbA1c, are having or cultivating routines that support these; and receiving ongoing input and support from medical staff with training in

this approach (Lawton et al., 2012; Rankin et al., 2011; Rankin et al., 2012). Such factors were not included in the quantitative assessment.

Goal setting, a behaviour change technique included in the DAFNE program and similar SEPs, is one such technique for cultivating routines to support adoption of healthy lifestyle behaviours. It has been argued that goal setting and increasing self-efficacy may be sufficient to change self-care behavior (Strecher et al., 1995). Existing models of self-regulation have been criticised though for failing to consider how emotions influence self-regulatory strategies and not explaining how people cope with being distracted from achieving goals they have set (De Ridder & Kuijer, 2006).

It was surprising that our measure of self-care behavior was not related to HbA1c in the bivariate analysis, hence our reason for not analysing this variable as a possible mediator. Although it is often assumed that this is a simple relationship, medication and other physiological processes may act as confounders (Glasgow et al, 2000). The ability to test models is reliant upon the availability of reliable and valid measures of the process and outcome variables (Peyrot, 1999). Researchers have urged attribution of the same importance to behavioral outcomes in diabetes, as is accorded to biological outcomes (Colagiuri & Eigenmann, 2009; Glasgow, 1999) but presumably they should only be accorded the same importance if they affect biological and other health outcomes. Existing measures of diabetes self-care behavior, including the SCI-R used in this study, do not appear to capture accurately modern diabetes self-management, represented by the approach adopted during DAFNE training. Existing scales do not appear to reflect key recommendations for diabetes self-care, such as behaviors focused on insulin dose adjustment and carbohydrate counting or capture self-care behaviors with the precision that is probably necessary to predict outcomes. There is research evidence highlighting the importance of key behaviours, including insulin dose adjustment, that relate to glycemic control (Peyrot & Rubin, 1994). It was also not possible to

disaggregate the SCI-R, to look at the effect of individual or groups of behaviors, as it is designed and constructed as a single measure. Most existing measures of diabetes knowledge and self-efficacy are similarly flawed. This lack of face and content validity is a clear methodological limitation and may explain the inability of the model tested here to predict more of the variance in outcomes.

The improvements in self-efficacy reported here as predicting improvements in diabetes-specific QoL from baseline to 3 months are consistent with existing literature, which have shown that the success of self-management interventions seems to depend upon participants feeling more in control of their long-term condition (Lorig & Holman, 2003). These findings were reflected in the qualitative work. Participants' reported feeling more confident about managing their diabetes after DAFNE and attributed this to acquiring a more logical, precise and effective set of management skills than their former insulin treatment approaches had provided (Lawton et al., 2012; Lawton & Rankin, 2010). When interpreting these results, it is important to consider that many of the predictor variables may have some conceptual and/or methodological overlap with the dependent variable, diabetes-specific QoL. It is possible that the questionnaire tools selected here (e.g. to assess diabetes-specific QoL, fear of hypoglycemia, and general emotional well-being) may be underpinned by a broader, latent variable.

Baseline assessments of gender (male), perceiving diabetes as more serious, lower levels of self-efficacy and diabetes self-care behaviors, greater worry about hypoglycemia and more impaired well-being, were associated with greater improvements in diabetes-specific QoL by 3-month follow-up. This suggests that targeting the DAFNE intervention at those with room for improvement in some or all of these domains may be beneficial in terms of QoL gain. Caution must be noted though, as only one of these variables, perceived seriousness of diabetes was supported in the multivariate analysis. When we examined how

the predictor variables in our model had changed over time, reductions in HbA1c, lower perceived seriousness of diabetes, improvements in diabetes-specific self-efficacy, reductions in fear of hypoglycemia and improvements in well-being predicted improvements in diabetes-specific QoL over the same time period, from baseline to 3 months.

This fits with the findings from the bivariate analyses focussing on baseline predictors. Interestingly, the DAFNE intervention targets these factors implicitly rather than explicitly. There is no DAFNE program content focussed specifically, for example, on improving general emotional well-being or self-efficacy. It is known that medium effect sizes for improvement in diabetes-specific QoL are obtained when DAFNE is delivered in routine care in the UK (Cooke et al., 2013a). If simple intervention components explicitly targeting these factors were introduced, it is possible that greater effects on outcomes (HbA1c and diabetes-specific QoL may be achieved.

The low proportion of variance in HbA1c explained in this study reflects other similar published work (Cochran & Conn, 2008; Glasgow, 1999). Given the significance of HbA1c as a surrogate for blood glucose control and thus as an indicator of future health and risk of diabetes-related complications (DCCT, 1993), more work is needed to refine existing measurement tools that assess barriers to and enablers of diabetes self-management, as a means to improve HbA1c. Any such tools must reflect current clinical practice and recommendations. In addition, qualitative findings indicate that quantitative measures of habit formation and healthcare professional support may be relevant in predicting HbA1c. Self-management interventions are inherently complex and studies evaluating their mechanisms are rare. This type of study is essential if we are to develop our understanding of how to deliver and target interventions effectively.

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Table 1: HbA1c at baseline, 6 and 12 months for total sample and sub-samples

	Time-point: Mean (SD)			Likelihood ratio tests (χ^2)			
Sample	Baseline	6 months	12 months	All equal Chi sq 2 df	Baseline vs 6m Chi sq 1 df	Baseline vs 12m Chi sq 1 df	6m vs 12m Chi sq 1 df
Total sample (n=262)	8.52 (1.50)	8.19 (1.45)	8.35 (1.58)	25.08***	21.97***	6.0*	10.1**
Sub-optimal baseline HbA1c ≥7.5% (n=197, 75%)	9.10 (1.26)	8.58 (1.42)	8.76 (1.59)	37.98***	36.76***	14.80***	8.5**
Baseline HbA1c <7.5% (n=65, 25%)	6.79 (0.51)	7.04 (0.75)	7.12 (0.68)	13.68**	6.17*	13.55**	1.39

Data are means (standard deviations)

*p<0.05, **p<0.01 ***p<0.001; m=months

Table 2: Change in psychosocial and behavioral variables over time (n=262)

Variable	Time-point Mean (SD)				Likelihood ratio tests (χ^2)			
	Base-line	3m	6m	12m	All equal df=3	Baseline vs. 3m df=1	3m vs. later df=2	6m vs. 12m df=1
DSQOLS: Diabetes-Specific Quality of life	68.08 (17.85)	75.52 (17.67)	75.63 (16.67)	75.11 (17.58)	73.13**	63.50**	<1	<1
Diabetes knowledge	20.13 (2.00)	20.67 (1.87)	20.67 (1.75)	20.77 (1.73)	25.12**	14.38**	1.09	<1
PMD: Perceived Treatment Effectiveness	22.54 (3.99)	23.36 (3.57)	23.39 (3.58)	23.19 (3.43)	13.33**	10.50**	1.22	1.02
PMD: Perceived Seriousness of Diabetes	8.98 (2.43)	8.93 (2.22)	8.89 (2.17)	9.07 (2.40)	2.67	<1	2.67	2.51
SSQ: Social Support (Number)	3.34 (2.12)	3.30 (2.06)	3.42 (2.16)	3.59 (2.28)	6.32	<1	6.09*	1.97
SSQ: Social Support (Satisfaction)	1.82 (0.94)	1.78 (0.88)	1.75 (0.87)	1.75 (0.89)	2.62	<1	<1	<1
CIDS: Self-Efficacy	73.88 (14.49)	81.83 (12.45)	80.74 (12.84)	80.70 (12.71)	76.47**	64.34**	3.45	<1
SCI-R: Self-Care Behaviors	59.26 (12.65)	70.21 (10.24)	69.11 (10.84)	67.52 (11.53)	136.85**	129.45**	13.90**	4.95*
HFS-W: Fear of Hypoglycemia	30.18 (10.64)	28.41 (10.23)	29.01 (10.95)	28.28 (10.34)	20.36**	17.29**	2.35	2.23
WHO-5: General Emotional Well-being	13.73 (5.65)	14.95 (5.35)	14.76 (5.47)	14.86 (5.91)	19.95**	15.06**	<1	<1
SMBG: Average no. of blood tests per day	3.15 (1.78)	4.22 (1.37)	4.09 (1.53)	4.63 (1.48)	66.67***	64.86***	<1	<1

*p<0.05, **p<0.01 ***p<0.001; SD=standard deviation; m=months

Table 3: Prediction of change in HbA1c from baseline background and psychosocial variables using a piecewise model (unstandardized coefficients); sub-sample with baseline HbA1c levels ≥7.5% (n=197)

	Bivariate analyses			Multivariate analysis		
Variable	Baseline	Baseline to 6m	6 to 12m	Baseline	Baseline to 6m	6 to 12m
Background variables						
Sex (Female)	0.136	0.063	0.235*	0.087	0.011	0.228^{+}
Age	-0.018**	0.003	-0.006	-0.006	0.004	-0.001
Diabetes Duration	-0.019**	-0.002	-0.002	-0.015^{+}	-0.001	-0.003
BMI[a]	-0.007	-0.017	-0.006	0.011	-0.027	0.002
Home Owner (Not)	0.636**	-0.218	0.108	0.345^{+}	-0.136	0.070
Education Level (High)	-0.097*	-0.024	0.022	-0.013	-0.095	0.069
Occupation Level (Low)	0.178**	0.020	-0.005	0.077	0.063	0.047
Employment status (employed full-time)	-0.260	-0.206	0.011	-0.201	-0.221	0.034
SMBG: average no. of blood tests per day at baseline	-0.132*	0.077	-0.060	-0.105^{+}	0.083	-0.079^{+}
Psychosocial variables						
DSQOLS: Diabetes-Specific Quality of Life	-0.013*	0.003	-0.002	-0.007	0.010	0.001
Diabetes Knowledge	-0.136**	0.041	-0.006	-0.065	0.050	-0.001
PMD: Perceived Treatment Effectiveness	-0.062**	-0.019	0.004	-0.022	-0.046+	-0.008
PMD Perceived Seriousness	0.025	0.006	0.034	0.008	0.062	0.040
SSQ: Social Support (number)	-0.017	0.018	0.026	0.002	0.054	-0.003
SSQ: Social Support (satisfaction)	0.029	0.051	-0.091	-0.009	0.127	-0.051
CIDS: Self-Efficacy	-0.015*	-0.004	0.003	0.002	-0.012	0.009
SCI-R: Self-Care behaviors	-0.023*	0.006	-0.001	-0.006	0.007	0.000
HFS-W: Fear of Hypoglycemia	0.006	0.006	0.006	-0.000	0.006	0.009
WHO-5: General Emotional Well-being	-0.013	0.001	0.003	-0.002	0.016	0.000

$^{+}$p<0.10, *p<0.05; **p<0.01; m=months

Table 4: Prediction of change in diabetes-specific QoL from baseline background and psychosocial variables using a piecewise model (unstandardized coefficients); total sample (n=262)

	Bivariate			Multivariate		
	Baseline	Change from baseline to 3m	Change from 3m to 12m	Baseline	Change from baseline to 3m	Change from 3m to 12m
Background variables						
Baseline HbA1c	-2.04**	0.73	0.33*	-0.61	0.39	0.22
Diabetes duration	0.08	0.04	0.00	0.09	-0.01	0.02
BMI	-0.21	0.22	0.02	-0.06	0.07	0.01
Age	0.12	0.00	0.02	0.01	0.06	-0.03
Sex	-3.81	3.27*	0.33	1.24	1.77	0.30
Home Owner (Not)[1]	-0.87	0.92	0.32	0.64	1.26	-0.51
Education level (High)[2]	1.31*	-0.50	-0.07	0.33	-0.44	0.06
Occupation level (Low)[3]	-0.19	-0.82	0.12	-0.01	-1.14	0.15
Employment Status (In full-time employment)	3.52	-2.58	-0.52	2.56	-1.51	-0.64
SMBG: Average no. of blood tests per day at baseline[4]	-0.05	-0.47	-0.28	-0.06	-0.27	-0.17
Psychosocial variables						
Diabetes Knowledge	1.07	-0.19	-0.18	0.12	0.19	-0.08
PMD: Perceived Treatment Effectiveness	-0.09	0.06	-0.07	-0.17	-0.06	0.00
PMD: Perceived Seriousness	-4.57**	1.62**	0.05	-3.02**	1.22**	0.16
SSQ: Social Support (Number)	1.70**	-0.25	0.17	0.36	0.00	0.14
SSQ: Social Support (Satisfaction)	-4.33**	-0.18	-0.05	-0.39	-0.95	0.29
CIDS: Self-Efficacy	0.53**	-0.12*	0.00	0.21**	-0.01	0.01
SCI-R: Self-Care Behaviors	0.25**	-0.14*	-0.05*	0.03	-0.09	-0.04
HFS-W: Fear of Hypoglycemia	-0.86**	0.25**	-0.02	-0.38**	0.11	-0.04
WHO-5: General Emotional Well-being	1.64**	-0.35*	0.01	0.75**	-0.06	0.05

*p<0.05, **p<0.01; m=months

[1] n=256, [2]n=260, [3]n=235, [4]n=222

Table 5: Predicting changes in HbA1c and diabetes-specific QoL from change in psychosocial and behavioral variables (multivariate analysis; unstandardized coefficients)

Change in …	Piecewise model: HbA1c (N=197)	
	Change from baseline to 6m	Change from 6m to 12m
Diabetes Knowledge	-0.054	0.054
PMD: Perceived Treatment Effectiveness	0.005	0.066*
PMD: Perceived Seriousness	-0.049	0.128*
CIDS: Self-Efficacy	0.011	0.018+
SCI-R: Self-Care Behaviors	-0.002	-0.009
HFS-W: Fear of Hypoglycemia	0.006	-0.017
WHO-5: General Emotional Well-Being	-0.014	-0.018
SMBG: Average no. of blood tests per day	-0.111*	-0.062

	Piecewise model: QoL (N=262)	
Change in…..	Change from baseline to 3m	Change from 3m to 12m
Diabetes Knowledge	0.344	0.233+
PMD: Perceived Treatment Effectiveness	-0.280	0.033
PMD: Perceived Seriousness	-1.483**	-0.201
CIDS: Self-Efficacy	0.191**	0.044
SCI-R: Self-Care Behaviors	0.111+	-0.005
HFS-W: Fear of Hypoglycemia	-0.526**	-0.147**
WHO-5: General Emotional Well-Being	0.401**	0.185**
SMBG: Average no. of blood tests per day	0.492	0.474*

** p <.01; * p <.05 + p <.10