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Predictors of quality of life gains among people with type 1 diabetes participating in the Irish DAFNE Study.

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Abstract

Purpose: To examine predictors of quality of life gains for type 1 diabetes patients after taking part in a self management training programme (DAFNE).

Method: Clinical and questionnaire data were collected from 437 patients with type 1 diabetes from 6 hospital centres at baseline before participation in the DAFNE programme and at 3 further time points (at 6, 12 and 18 month post-DAFNE training). The Diabetes-Specific Quality of Life Scale (DSQOLS) and the Problem Areas in Diabetes Scale (PAID) provided quality of life data, and the Hospital Anxiety and Depression Scale (HADS) provided data on psychological wellbeing. Glycated haemoglobin (HbA_{1c}), weight and height, and blood pressure levels were recorded by health practitioners at patients' clinic appointments. Age, gender, marital status, education level, years since diagnosis and smoking status were recorded at baseline. Linear mixed models were fitted to identify predictors of change in quality of life at 18 month follow up.

Results: Those with high levels of diabetes-related distress experienced greatest improvement in DSQOLS quality of life scores ($p=0.001$). Those with poor glycaemic control (higher levels of HbA_{1c}; $p=0.03$) and those with high levels of anxiety ($p=0.001$) experienced greatest reductions in diabetes-related distress.

Conclusions: Those with higher baseline levels of anxiety, higher levels of diabetes-related distress and higher baseline levels of HbA_{1c} are most likely to benefit (in terms of quality of life gain) from participation in self-management programmes like DAFNE.

Keywords: Diabetes mellitus type 1; Quality of Life; Predictors; Self management programmes; DSQOLS

1. Introduction

Type 1 diabetes is a chronic disease in which individuals are unable to produce insulin, which is essential for regulating blood sugar. As a result, those with type 1 diabetes need to carry out daily blood sugar monitoring and insulin injections to maintain tight glycaemic control in order to avoid diabetic complications. Many people with diabetes find their complex daily monitoring and medication regimen challenging and stressful to maintain [1], especially as tight control can result in hypoglycaemia (abnormally low blood sugar levels) posing a serious health threat.

Quality of life has been shown to be lower in those with diabetes compared to similar individuals without diabetes [2]. Those with type 1 diabetes also show a faster rate of decline in quality of life over time when compared to the general population [3].

Self-management training programmes have been shown to result in a number of positive outcomes for people with type 1 diabetes. Although clinical indicators, such as glycated haemoglobin (HbA1c), are most commonly used as markers of the success of interventions, the importance of psychological indicators of success (such as quality of life) has also been stressed [4,5]. One of the most consistent findings in the literature is that self-management training programmes result in increased quality of life among people with diabetes [6].

The Dose Adjustment for Normal Eating (or DAFNE) programme is a self-management training programme for individuals with type 1 diabetes [7]. DAFNE is a five-day outpatient programme which employs principles of adult learning and takes place in a group setting. The programme promotes dietary freedom, aiming to empower participants with the skills to enable them to replace insulin in a way which suits their current lifestyle rather than having to rigidly adapt the timing and content of meals to more fixed doses of insulin.

DAFNE has been shown to result in significant improvements in quality of life and glycaemic control in people with type 1 diabetes, without worsening severe hyperglycaemia or cardiovascular risk [7]. Indeed, improvements in quality of life have been shown to be maintained at four years post-DAFNE intervention [8].

There is little published research exploring factors which predict increases in quality of life associated with participation in diabetes self-management training programmes. It is likely that individual characteristics of programme participants will affect how well they engage with the programme and how much they benefit from participation. Negative attitudes, coping difficulties and psychological problems such as depression and anxiety have been shown to present barriers to effective self care among those with diabetes [9]. It is important for service providers to be aware if there are particular categories of patients who are likely to benefit from participation in the self-management programmes more than others. This information also enables providers to identify individuals who may need additional support to benefit from their programmes.

In the Irish DAFNE Study (Dinneen SF, O' Hara MC, Byrne M, Newell J, Daly L, O' Shea D, et al. Comparing two different methods of follow-up after group structured education for type 1 diabetes: a cluster randomised controlled trial, in preparation), we showed improvements in (1) perceived burden of diabetes (measured by PAID) and (2) both the total quality of life

and treatment satisfaction scores on the DSQOLS among a cohort of 437 DAFNE graduates, at an 18 month follow-up, post-participation in the DAFNE intervention. From baseline to 18 month follow-up, PAID scores decreased on average by 9.13 percentage points, where lower scores indicated lower levels of distress (95% CI -10.63 to -7.64, $p < 0.001$). From baseline to 18 month follow-up, DSQOLS treatment satisfaction scores increased on average by 2.61 percentage points (95% CI 1.80–3.43, $p < 0.001$) and DSQOLS quality of life scores increased on average by 9.23 percentage points (95% CI 7.56–10.90, $p < 0.001$). Higher scores on DSQOLS indicate a higher level of quality of life.

The aim of this paper is to examine which baseline characteristics (including age, gender, marital status, education level, smoker/non-smoker, years since diagnosis, body mass index, blood pressure recordings, HbA1c, anxiety (HADS-A) and depression (HADS-D)) predict level of improvements in health related quality of life (as measured by PAID and DSQOLS) at the 18 month follow-up.

2. Method

Subject and Methods

Details of the study methodology for the Irish DAFNE Study have been published elsewhere [10]. Briefly, six outpatient hospital diabetes clinics delivering the DAFNE programme in Ireland participated. 437 study participants were recruited from waiting lists of individuals who had expressed an interest in receiving DAFNE training in participating centres. 62 patients from the DAFNE training waiting list were not recruited as they did not meet the inclusion criteria. Recruitment commenced in October 2006 and finished in February 2009. Inclusion criteria were broad and included a diagnosis of type 1 diabetes of at least 12 months duration, the ability to read and speak English, a willingness to engage in regular self monitoring of blood glucose and a glycated haemoglobin (HbA1c) level below 13 percent at recruitment. Participants had to be using a basal/bolus insulin regimen or be willing to convert to such a regimen prior to participation. Patients were excluded if they had advanced diabetes complications, were pregnant or planning pregnancy in the next 2 years, were currently using an insulin pump to manage their diabetes or had significant co-morbidities likely to interfere with study participation. Data were collected from participants at baseline (taken one week prior to receiving DAFNE) and at 18 months post-DAFNE training. Data were collected for 415 participants at an 18 month follow-up assessment. Approval was obtained from Research Ethics Committees in each hospital.

3. Materials

3.1. DAFNE intervention

The content and organisation of the education delivered to patients within the DAFNE programme has been described in detail elsewhere [11]. In short, DAFNE consists of 38 h of skills based structured education provided over five consecutive days in an outpatient setting, to groups of six to eight people with type 1 diabetes. The principal aim is to facilitate autonomy, competency and confidence in the self-management of diabetes by providing skills-based training in the areas of carbohydrate counting and insulin dose adjustment in a comprehensive range of situations. It encourages a liberal approach to diet but emphasises matching of quick-acting insulin to food. The Irish DAFNE Study was a randomised controlled

trial comparing two different methods of follow-up after DAFNE intervention. Participants in control arm centres were invited back to traditional clinic visits where they received one-to-one visits with a doctor, nurse and/or dietician. Follow-up care in intervention arm centres involved participants returning in their original group and receiving “booster” group education sessions from DAFNE educators at 6 and 12 months post- DAFNE.

3.2. Measures

3.2.1. Quality of life data

Quality of life was assessed using two diabetes-specific instruments, the Diabetes-Specific Quality of Life Scale (DSQOLS) and the Problem Areas in Diabetes (PAID) Scale. The DSQOLS is a reliable and valid measure of quality of life specific for people with type 1 diabetes [12]. It consists of 2 sections: the treatment satisfaction score and the quality of life score. Scores are reported on a percentage scale, with a higher score indicating higher satisfaction and quality of life. The PAID Scale [13,14] is a widely used measure of psychosocial adjustment to diabetes. Scores are reported on a percentage scale, with higher scores indicating higher levels of diabetes related distress. A cut-off score of ≥ 33 on the PAID indicates clinically significant high levels of distress [15]. The psychometric properties of the PAID Scale have been established [16]. Although the PAID Scale is not a specific quality of life measure, it was included as it has been suggested that the inclusion of a diversity of measures of quality of life type variables may improve the validity of the quality of life construct [6].

3.2.2. Clinical and demographic data

Glycated haemoglobin (HbA1c) was measured centrally in a laboratory with a track record of supporting large multi-centre studies. The method used was a DCCT-aligned HPLC assay (ADAMS-A1c HA-8160). Weight (measured to the closest gram on a Seca Medical Scales) and height (measured to the closest cm by a stadiometer) was used to assess baseline body mass index and blood pressure levels were recorded using a digital clinical blood pressure monitor. Age, gender, marital status, education level, years since diagnosis and smoking status were recorded at baseline.

3.3. Psychological data

Anxiety and depression were measured using the Hospital Anxiety and Depression Scale (HADS) [17]. Total scores for anxiety and depression range from 0 to 21, with higher scores indicating higher levels of symptomatology. Various cut-off points have been used, though Zigmond and Snaith recommend a cut-off score of 8 for both scales to include all possible cases. The psychometric properties of the HADS have been confirmed [18].

3.4. Data analysis

A linear mixed model was fitted to identify predictors of improvement in quality of life (as measured by PAID and DSQOLS) at 18 month follow-up, while adjusting for cluster structure due to hospital centre. The choice of which predictor variables to include in the model was determined a priori, age, gender, marital status, smoker/non-smoker, educational status, years since diagnosis, body mass index, blood pressure, HbA1c and the psychological variables relating to anxiety (HADS-A), depression (HADS-D) and quality of life (DSQOLS, PAIDS). Given the correlation between the psychological variables multicollinearity was an issue when including all psychological variables in the final model. To correct for this,

variable selection techniques and regression tree models were used to identify the most useful psychological variables for inclusion. Missing data were dealt with by multiple imputation using a Bootstrap Based Method [19] where each missing value was replaced by 5 imputed values. Continuous Responses were transformed for Normality as necessary. In order to compare the sensitivity of the overall conclusions to missingness the results of each 'complete' model (that is, with imputed values) were pooled using the Barnard–Rubin adjustment method [20]. The assumptions underlying each model were checked using suitable residual plots. All analyses were performed using R version 2.10.

4. Results

Demographic and clinical characteristics of the sample are shown in Table 1. Overall participants were on average 40 years of age and had been diagnosed with type 1 diabetes for around 15 years. Just over half the sample are female (54%), the majority were married (62%) and nearly half the sample completed 3rd level education (48%). For each participant, the response variables (change in PAID score and change in DSQOLS quality of life score) were calculated as the improvement at 18 months follow-up compared with the score at baseline. Table 2 shows the results of the two linear mixed models to identify predictors of improvement in PAID and DSQOLS scores.

4.1. Predicting changes in PAID scores

Participants with higher HbA1c levels at baseline exhibited a greater improvement in PAID score (that is, a greater reduction in diabetes-related distress levels) as shown by the positive coefficient for HbA1c ($p = 0.03$). Participants with higher HADS anxiety scores at baseline also exhibited a greater decrease in PAID score ($p\text{-value} = 0.001$). No other variables significantly predicted changes in PAID scores within this model or when using Multiple Imputation.

4.2. Predicting changes in DSQOL QOL scores

Participants with higher PAID scores at baseline showed increased DSQOLS scores (that is, an improvement in quality of life) as shown by the positive coefficient for PAID score at baseline ($p = 0.001$). No other variables significantly predicted changes in DSQOLS scores within this model and when using Multiple Imputation.

5. Discussion

This paper aims to explore whether there are baseline variables which predict health-related quality of life gains as a result of participating in a self-management training programme for people with type 1 diabetes. In line with previous research [7], participants in the Irish DAFNE Study experienced significant improvements in diabetes specific quality of life related measures (PAID and DSQOLS) as a result of participation in the programme, which were maintained at 18 month follow-up. The improvements observed in our study compare favourably to those found in other interventions studies [21].

In summary, patients with higher levels of diabetes-related distress experienced significantly greater improvements in DSQOLS quality of life scores than those with lower levels of diabetes-related distress. In addition, patients with poorer levels of glycaemic control (higher levels of HbA1c) and those with higher levels of anxiety, as measured by the HADS at

baseline, experienced significantly greater reductions in diabetes-related distress than those with better levels of glycaemic control or those with lower levels of anxiety.

With regard to the finding that patients experiencing greater levels of diabetes-related distress at baseline experienced greater quality of life gains as a result of participating in the DAFNE programme, this makes sense, as this group presumably have more scope for improvement than those with lower levels of diabetes-related distress. The finding that patients with higher levels of anxiety, as measured by the HADS at baseline, experienced significantly greater reductions in diabetes-related distress than those with lower levels of anxiety at baseline, also fits in with this finding. Research has shown that diabetes and high anxiety levels frequently coexist [22]. In the current sample, around a quarter of patients reported levels of anxiety at baseline that would be considered to indicate clinically elevated levels. These findings suggest that, where resources are limited and only a limited number of patients can be offered a place on a self-management programme, baseline PAID scores or HADS anxiety scores may be used effectively to select those who will benefit most from participation in the programme.

Poor glycaemic control predicted reductions in diabetes related distress but not improvements in DSQOLS quality of life scores. Patients with poorer glycaemic control experienced significantly greater reductions in diabetes-related distress as a result of participating in our programme. Previous studies examining the relationships between glycaemic control and quality of life in cross-sectional studies have reported inconsistent findings. For example, in a large review paper, Rubin and Peyrot [23] reported that better glycaemic control is associated with better quality of life. However, such a relationship was not found by Redekop et al. when they controlled for other factors in multivariate analysis [24]. Specifically examining the impact of therapeutic education on quality of life, Debaty et al. [25] found that among a group on adults with type 1 diabetes, those with poorer glycaemic control before the programme appeared to derive greater benefit from therapeutic education.

In the current study, although it is not statistically significant, there is a suggestion that patients with a higher level of educational attainment (having completed 3rd level education; coefficient for DSQOLS score 5.68, $p = 0.07$) experienced greater increases in quality of life (improvement in DSQOLS score) as a result of participation in the programme compared with those with lower levels of educational attainment (having completed secondary/high school education only). Previous research has suggested that lower socioeconomic status, as measured by income or educational level, has been a robust predictor of lower levels of quality of life among people with diabetes [23]. Our study suggests that those who have lower educational attainment may not gain as much from participating in a self-management programme and may suggest that such programmes are targeted at more educated patients. The methods of insulin adjustment taught as part of DAFNE require reasonable English literacy and numeracy, which may exclude some patients. Patients with lower educational attainment levels may benefit from further supports being put into place when participating in DAFNE or similar programmes. Further research is required to confirm this suggestion however.

Two other variables approach significance as predictors of quality of life gain: marital status (being single/widowed compared with being married; coefficient for DSQOLS score -4.99, $p = 0.06$) and smoking status (being a regular smoker compared with being a non-smoker; coefficient for PAID score 6.88, $p = 0.06$). The suggestion that single people are more likely to gain from participation in the programme is likely to be caused by random variation as there are only a small number of single participants included in the model. The suggestion that smokers gain more than non-smokers from participation may well point to a real relationship, as it could be expected that smokers have more to gain from a programme aiming to improve self-management of risk factors. Current smoking has been shown to predict significantly lower quality of life among those with type 2 diabetes [26]. If this finding were replicated in the current sample, then there is more scope for improving quality of life among smokers than non-smokers. This relationship would need to be explored further in research to be confirmed.

It is of interest that a number of other variables examined, for example duration of diabetes, age, gender, marital status and body mass index do not appear to significantly predict quality of life gains as a result of participating in DAFNE. This suggests that, in general, self-management training programmes are effective in improving quality of life across a broad range of people with type 1 diabetes.

A limitation of the current study is that we were not testing a priori hypotheses regarding relationships between study variables, and therefore our findings should be interpreted with some caution. As one might expect, multicollinearity was observed when including all psychological variables in our models, so we had to select variables for inclusion to make the most parsimonious subset of variables for the final models. Some degree of subjective judgement was involved in this process. This may mitigate the strength of some of the relationships reported.

In conclusion, our study suggests that, where resources are stretched and only a limited number of patients can be offered a place on a self-management programme, patients with higher baseline levels of anxiety, higher baseline levels of diabetes related distress and higher baseline levels of HbA1c are more likely to benefit most (in terms of quality of life gain) from participation in the programme. These findings are significant, especially as patients experiencing elevated levels of anxiety or distress may be more likely to be deemed 'unsuitable' by educators for participation in a self-management programme.

Conflict of interest

The authors declare that they have no conflict of interest.

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Table 1 Characteristics of participants at baseline (n=437)

| | Mean | SD |
|--------------------------------------|---------------|-----------|
| Age (years) | 40.8 | 11.7 |
| Years since diagnosis | 15.9 | 10.8 |
| Baseline BMI (kg/m ²) | 26.0 | 4.1 |
| Systolic BP (mmHg) | 124.9 | 18.9 |
| Diastolic BP (mmHg) | 74.1 | 10.9 |
| Baseline HbA _{1c} (%) | 8.3 | 1.4 |
| | Number | % |
| Gender | | |
| - Female | 235 | 53.8% |
| - Male | 202 | 46.2% |
| Married | 236/ 378 | 62.4% |
| Education | 178/371 | 48.0% |
| - Completed 3 rd level | | |
| Occupation | | |
| - Employed | 277/379 | 73.1% |
| - Retired | 11 | 2.9% |
| - Other | 91 | 24.0% |
| No. of regular/ occasional smokers | 79/ 382 | 20.7% |
| Self-reported diabetic complications | 93/ 434 | 21.4% |
| Baseline HADS Anxiety < 8 | 326/ 427 | 76.4% |
| Baseline HADS Anxiety 8 – 11 | 78/ 427 | 18.3% |
| Baseline HADS Anxiety > 11 | 23/ 427 | 5.4% |
| Baseline HADS Depression < 8 | 355/ 426 | 83.3% |
| Baseline HADS Depression 8 – 11 | 56/ 426 | 13.2% |
| Baseline HADS Depression > 11 | 15/ 426 | 3.5% |
| Baseline PAID ≥ 33 | 166/ 423 | 39.2% |
| Baseline PAID < 32 | 257/ 423 | 60.8% |

Table 2 Prediction of improvements in PAIDS and DSQOLS from baseline to 18 month follow-up

| Explanatory Variable | Improvement in PAID Score | | | Improvement in DSQOLS | | |
|--|---------------------------|------|--------------|-----------------------|------|--------------|
| | Coef. | ese | p-value | Coef. | ese | p-value |
| DAFNE (control) versus DAFNE plus group follow up (intervention) | 0.08 | 2.23 | 0.97 | 1.74 | 2.29 | 0.49 |
| HbA _{1c} | 1.86 | 0.86 | 0.03 | 0.05 | 0.87 | 0.95 |
| Age | 0.08 | 0.12 | 0.47 | 0.04 | 0.13 | 0.73 |
| Gender (Female) | -1.54 | 2.26 | 0.50 | -1.17 | 2.29 | 0.61 |
| Years with disease | -0.13 | 0.11 | 0.22 | -0.01 | 0.11 | 0.95 |
| Systolic blood pressure | -0.01 | 0.08 | 0.85 | -0.04 | 0.08 | 0.65 |
| Diastolic blood pressure | 0.03 | 0.14 | 0.80 | 0.01 | 0.14 | 0.98 |
| Marital Status (Married/ Partner) | | | | | | |
| Separated/Divorced | -1.66 | 5.75 | 0.77 | 3.50 | 6.7 | 0.60 |
| Single/Widowed | -1.65 | 2.54 | 0.52 | -4.99 | 2.65 | 0.06 |
| Education Level (Completed Second Level) | | | | | | |
| Primary/Some Second Level | -0.48 | 4.06 | 0.91 | 1.83 | 4.04 | 0.65 |
| Some Third Level | 0.65 | 3.53 | 0.85 | 2.12 | 3.56 | 0.55 |
| Completed Third Level | 2.70 | 3.14 | 0.39 | 5.68 | 3.13 | 0.07 |
| Smoking Status (Non-smoker) | | | | | | |
| Ex-smoker | 0.85 | 2.75 | 0.76 | -0.09 | 2.83 | 0.97 |
| Occasional | 6.59 | 3.86 | 0.09 | 6.58 | 4.09 | 0.11 |
| Regular | 6.88 | 3.61 | 0.06 | 0.74 | 3.91 | 0.85 |
| BMI | 0.26 | 0.27 | 0.33 | 0.48 | 0.27 | 0.08 |
| HADS Anxiety Score | 0.96 | 0.30 | 0.001 | - | - | - |
| PAID Score | - | - | - | 0.29 | 0.06 | 0.001 |

* Bold values are statistically significant, i.e. p-value \leq 0.05.

The reference categories for gender, marital status, education level and smoking status are given in brackets.

* - indicate that this variable was not included in the model, i.e. PAID score at baseline was not deemed necessary as a predictor when modelling change in PAID score and HADS Anxiety Score at baseline was not deemed necessary as a predictor when modelling change in DSQOLS.