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A mixed methods study exploring the factors and behaviors that impact on glycaemic control following a structured education programme: the Irish DAFNE Study

INTRODUCTION

Diabetes is now the commonest non-communicable illness in the world and is associated with significant morbidity and mortality; over 371 million people worldwide have diabetes (IDF 2012a). It is associated with microvascular and macrovasular complications. As there is no diabetes registry in Ireland, it is difficult to establish the true prevalence rates. However, the International Diabetes Federation estimates that there are 191,380 people with diabetes in Ireland (with a prevalence of 6.1% in the population), approximately 7-9% of whom have type 1 diabetes (T1D) (IDF 2012b).

Some of the longer-term complications of diabetes can be avoided by maintaining good glycaemic control. Glycosylated haemoglobin (HbA_{1c}) is used to identify the average plasma glucose concentration over a period of approximately 3 months. Best practice would recommend testing HbA_{1c} every 3 months if the person is trying to improve their glycaemic control or every 6 months if glycaemic control is already achieved and they want to maintain it. HbA_{1c} goals usually determine how tight people with type 1 diabetes have to run their blood sugar, which is usually individualised to the person's treatment needs. Current guidelines recommend a target HbA_{1c} of between 53 mmol/ mol (7%) and 59 mmol/ mol (7.5%) (ADA 2013). Landmark trials such as the Diabetes Complications and Control Trial demonstrated that poorer glycaemic control (higher HbA_{1c}) was associated with an increased risk of some of the complications of diabetes such as retinopathy, however, tighter control (lower HbA_{1c}) was associated with an increase in the frequency of severe hypoglycaemia (Kilpatrick et al 2008). Hypoglycaemia can be very debilitating to those who experience it and can negatively impact on people's quality of life

(Lawton et al 2013). The challenge in day-to-day management of T1D is to find a balance between an acceptable low level of HbA$_{1c}$ without frequent hypoglycaemia.

Literature Review

Self management is considered key to effective care for persons with diabetes (Mensing et al 2007; NICE 2003). Diabetes self management supports informed decision making and collaborative partnerships and focuses on providing the person with the necessary knowledge and skills to manage their condition, enabling the person to monitor their symptoms, identify and solve problems, taking into account the persons needs, goals and life experiences (Haas 2012). Many factors have been identified that influence self management in persons with diabetes. These include helplessness and frustration from lack of glycaemic control (Murphy et al 2011; Casey et al 2011; Nagelkerk et al 2006); perceptions of blood glucose monitoring/ testing (Peel et al 2004); interpersonal conflicts and depression (Gazmararian et al. 2009); fear of hypoglycaemia (Wild et al 2007); the presence of comorbidities (Nam et al 2011); diabetes knowledge (Howorka et al 2000; Nagelkerk et al 2006; Carbone et al 2007; Xu et al 2008; Brooker et al 2008; Enwistle et al 2008; Osborn et al 2010; Zhong et al 2011); and social support (Glasgow et al 2001; Nagelkerk et al 2006; Stamler et al 2006; Brooker et al 2008; Xu et al.2008; Osborn et al 2010; Nam et al 2011; Zhong et al 2011).

Motivation is "the process whereby goal-directed activity is instigated and sustained" (Schunk et al (2008 p.4) and goals are considered motivational triggers for action (Karoly et al 2005). Motivators for behaviour have also been found to influence self management such as self efficacy (Bandura 1977; Glasgow et al 2001; Bodenheimer et al 2002b; Norris et al 2002; Sousa et al 2005; Peyrot & Rubin 2007; Funnell et al 2008; Xu et al 2008; Zhong et al 2011; Qiu et al 2012); personal values (Williams et

al 2008) and attitudes (Zhong et al 2011). Self Determination Theory (SDT) focuses on the process

through which individuals obtain the motivation to initiate and sustain behaviour (Ryan et al 2008).

Autonomy, competence and relatedness are perceived to govern the extent to which a person self

regulates and maintains a behaviour or not (Ryan et al 2008). Ryan and Deci (2000) describe a

continuum of extrinsic to intrinsic motivation. Intrinsic motivation is the "doing of an activity for its

inherent satisfactions rather than for some separable consequences" (p. 56). In contrast extrinsic

motivation involves the person engaging in a given behaviour because they seek an external reward such

as approval from others or wealth and fame (Kasser & Ryan 1996). Intrinsic motivation is associated

with autonomous motivation, where the aim is to achieve personal growth, good physical health and

meaningful relationships (Kasser & Ryan 1996). A high level of autonomous motivation has been linked

with improved quality of life, medication adherence, improvement in diet and cholesterol levels as well

as improvements in HbA_{1c} (Shigaki et al 2010; Williams et al 2009; Williams et al 2005; Williams et al

2004; Williams et al 1998). Behaviours associated with extrinsic motivation are less likely to lead to

sustained behaviour change (Ryan et al 2008). Environmental resources are important sources of

motivation (Golay et al 2007). Social support is one environmental resource that has been identified as a

key element influencing patients adherence to medical treatments (DiMatteo et al 2004) and effective

diabetes self management (van Dam et al 2005; Jacob & Serrano-Gil 2010). Others conclude if the

changes made during a diabetes educational programme are to be maintained then ongoing support is a

necessary part of diabetes self management (Funnell 2010). Williams (2009) found that persons with

diabetes whose autonomy and competence was supported by health professionals reported improved

quality of life and were more likely to adhere to their medications. However, access to specialist

diabetes services where professional advice can be sought is not always available (Funnell & Siminerio,

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2004; Tibbetts, 2006). Likewise Casey et al (2011) and Lawton et al (2012) reported that participants with T1D often struggled to access responsive support from health professionals.

The Dose adjustment for Normal Eating (DAFNE) programme which originated in Germany has been introduced to equip people with T1D with the knowledge and skills necessary to effectively self manage their condition and to address the delicate balance between achieving good glycaemic control to avoid long-term diabetes complications without increasing the incidence of hypoglycaemia (Bott et al 1997; Sämann et al 2005; DAFNE Study Group 2002; Dinneen et al 2013). This structured education programme is underpinned by empowerment and self efficacy and the aim is to promote effective self management skills, via goal setting and problem based learning (McIntyre 2006). DAFNE is delivered over 5 consecutive days by a multi-disciplinary team (Oliver and Thompson 2009). The curriculum focuses on how to live well with diabetes and emphasises blood glucose testing, carbohydrate counting and matching quick-acting insulin to food. The final session of the DAFNE curriculum takes place approximately six weeks after the 5-day course where participants meet to review progress and goals.

Studies evaluating structured education programmes in diabetes have predominantly been quantitative and none could be identified that employed a mixed methods design. These studies reveal that such programmes have resulted in improvements in glycaemic control in terms of HbA_{1c} levels (Mühlhauser et al 1983; Bott et al 2000; Norris et al 2001 ; DAFNE Study Group 2002 ; Trento et al 2002 ; Everett et al 2003; Oswald et al 2004; McIntyre 2006; van Dulmen et al 2007), however, these improvements appear to diminish over time (Speight et al 2010; Cooper et al 2008; Plank et al 2004; Bott et al 1997) and in some instances this occurs within six months of completing the programmes (Piatt 2010). The precise cause of this decline in HbA_{1c} levels is not yet fully understood.

AIMS AND METHODS

The aim of this mixed methods concurrent triangulation study is to explain the factors that impact on glycaemic control, measured by HbA_{1c}, following the Dose Adjustment for Normal Eating (DAFNE) programme. Mixed methods research involves the collection of both quantitative and qualitative data within the same study and combining the strengths of each approach to answer a research question (Creswell & Plano Clarke, 2011). The purpose of using a concurrent mixed methods triangulation approach was to provide a complete picture of the factors that impacted on HbA_{1c} control and to more fully explain and understand the circumstances under which participants sought to control their HbA_{1c}.

In 2007 a large 5 year multi-centred randomised controlled trial (RCT) was initiated to introduce and evaluate the effectiveness of two different methods of follow-up/ support after participants has completed DAFNE training on the island of Ireland (Dinneen et al 2013).. Ethical approval for the study was obtained from the NUI Galway Research Ethics Committee (Ref: 06/MAY/04), Galway University Hospitals (Ref: CA-19) and relevant local hospital Research Ethics Committees. Written consent was obtained from all participants and confidentiality was ensured by the removal of all identifying material.

Inclusion criteria for the larger DAFNE RCT included a diagnosis of T1D for at least 12 months, be able to read and speak English, be willing to engage in regular blood glucose self-monitoring and have a glycated haemoglobin (HbA_{1c}) level below 119mmol/ mol (13%) at recruitment. Participants were excluded if they had advanced diabetes complications, were pregnant or planning pregnancy within two years, were currently using an insulin pump to manage their diabetes or had significant co-morbidities likely to negatively impact on their ability to participate in the study.

Initially a list of all participants from five DAFNE centres across the island of Ireland who met the inclusion criteria were obtained ($n = 437$). Utilising maximum variation to ensure a diversity of perspectives, a purposive sample of 40 participants, approximately 10% of the total sample, were invited to participate in the mixed methods study. Qualitative and quantitative data were collected from participants at three different time periods, 6 weeks, 6 months and 12 months post-DAFNE in the form of semi-structured interviews and various quantitative measurements.

The qualitative semi-structured interviews were conducted by two researchers using an interview guide over a 36 month period from 2006-2009. First round interviews (at 6 weeks post-DAFNE) explored initial experiences of participating in DAFNE. Second and third round interviews (at 6 and 12 months post-DAFNE) focused more on how participants were using the DAFNE principles over time. Concurrent with the collection of the qualitative data, quantitative data on participants' anxiety and depression were collected using the Hospital Anxiety and Depression Scale/ HADS (Zigmond et al 1983, Bjelland et al 2002), quality of life using the Diabetes-Specific Quality of Life Scale/ DSQOLS (Bott et al 1998; Cooke et al 2013), their diabetes-related distress using the Problem Areas in Diabetes/ PAID questionnaire (Polonsky et al 1995; Welsh et al 1997) and clinical data on HbA_{1c} were also collected. The HbA_{1c} levels were measured centrally using a DCCT-aligned HPLC assay (ADAMS-A1c HA-8160). Unfortunately quantitative measurements were not available at all three time points for five participants, and one participant commenced an insulin pump and was therefore no longer eligible to participate in the study. Therefore the total number of participants included in the mixed methods study was thirty four. Participant age, length of time since diagnosis, and gender are provided in Table 1. Both data sets were initially analysed separately, and then merged.

Insert Table 1 here

Data Analysis

The qualitative longitudinal analysis was guided by the work of Holland et al (2006) Saldana (2003) and Lewis (2007). Initially, a within time analysis was completed. This involved analysing each data set at 6 weeks, 6 months and 12 months. All data were open coded using thematic analysis and then axial coding was used to identify categories (Strauss & Corbin 2003). The next stage was a cross sectional analysis of the data investigating changes between the different time points for individual participants. The final stage involved a thematic analysis investigating the changes over time. N-Vivo (version 8), a qualitative software indexing package was used to support the analysis in terms of managing and organising the data, managing ideas, querying data, graphically modelling ideas and concepts and reporting the data (Bazeley 2007).

Maintaining Rigour

Four criteria; credibility, auditability, confirmability and applicability were used to ensure the rigour of the qualitative data. A sample of transcripts were analysed independently by the two researchers who collected the data and codes, categories and themes were then compared and agreed. Participants were also sent a copy of their transcripts and asked to confirm accuracy of same. The findings were also shared with medical and nursing experts in the field of diabetes all of whom confirmed that the findings were consistent with their experiences. Three relevant themes were identified from the qualitative longitudinal analysis; enduring knowledge, enduring motivation and on-going support.

In terms of quantitative data analysis a linear mixed model was used to identify predictors of improvement in quality of life (PAID and DSQOLS). Missing data were dealt with by multiple imputation using a Bootstrap Based Method (Welch et al 1997) where each missing value was replaced by 5 imputed values. Continuous responses were transformed for normality as necessary. The details regarding the data analysis and findings specific to these psychological variables are reported elsewhere (Byrne et al 2012; Dinneen et al 2013). The focus of this paper is on the clinical outcome of the DAFNE programme and the 2 different methods of follow-up, namely glycaemia control (assess by HbA_{1c} levels). Quantitative data from participants involved in the RCT ($n = 437$) comparing structured (curriculum-based) group follow-up (intervention arm centres) and a return to traditional one-to-one clinics (control arm centres) following DAFNE training, including HbA_{1c} were collected at baseline and 6, 12 and 18 months post-DAFNE. These data were then inputted into a quantitative database and analysed. No significant difference in HbA_{1c} was observed between the intervention or control arm centres and no difference was observed over time (Dinneen et al 2013). However, individuals with a baseline $HbA_{1c} > 7.5\%$ (59 mmol/ mol) showed a statistically significant decrease in HbA_{1c} over time (mean difference -0.16 percent, 95% CI -0.27 to -0.06; $p<0.001$). Individuals with a baseline HbA_{1c} less than or equal to 7.5% (59 mmol/ mol) showed a statistically significant increase in HbA_{1c} over time (mean difference 0.61 percent, 95% CI 0.48 to 0.74; $p<0.001$).

Integration/merging of the data

Both qualitative and quantitative datasets were then merged into a single database for the sub-group of participants who were enrolled in the quantitative and qualitative aspects of the study to offer a more holistic and integrated view of their diabetes experience and self management. This new integrated

database enabled the research team to filter previously created thematic codes against the clinical (and other quantitative) data in a single database environment using queries. For example, content coded against the node 'Empowerment' contained qualitative comments from participants who cited being empowered. Running a matrix coding query against these codes cross referencing the recorded results of HbA_{1c} offered two discrete views of the data which could be described as; form and content. The 'form' view offers a tabular and more strategic view of the coding patterns to show the extent to which participants who felt empowered were gaining glycaemia control or not (lowering their HbA_{1c} levels, Table 2). This view also shows how many quotes (in each cell in column 1) were coded to empowerment from each of the three interviews and the background HbA_{1c} levels (at that time shown in the same row). This query allowed us to correlate improvements/disimprovments in HbA1c levels and what participants were saying/feeling at the time based on their qualitative coding. The 'content' view, allowed the researchers to drill down and see qualitative comments contained in any cell in the table to gain a deeper understanding of possible reasons behind these patterns and relationships between feeling empowered and having improved glycaemia control (lower or higher HbA_{1c} levels) (Figure 1).

Insert Table 2 here
Insert Figure 1 here

Being able to view the qualitative data, correlated with the quantitative data, assisted researchers in classifying participants into three categories; out-of-control (participants whose HbA_{1c} remained >8%/ 64mmol/ mol); out of control but getting-into relative control (participants whose HbA_{1c} at commencement was >8%/ 64mmol/ mol but came down to less than or equal to 7.9%/ 63mmol/ mol) and in relative control and remained there (participants whose HbA_{1c} remained at less than or equal to 7.5%/ 58mmol/ mol).

Separately each data set provided an answer to a piece of the puzzle, the qualitative data informed us as to the factors that influenced overall self management while the HbA_{1c} results told us whether participants were or were not attaining an optimal HbA_{1c} or in clinical terms whether they were actually in control or not. It was only by utilising a concurrent mixed methods approach which involved merging and integrating the findings from each dataset, linking the quantitative and qualitative data for each participant, that allowed the exploration of attitudes, beliefs and behaviours across and between these groups leading to explanatory accounts of human responses to support the numeric quantitative data so that a clearer picture emerged. This unique picture provides a more comprehensive understanding of glycaemic control (HbA_{1c} levels) and illustrates more clearly why some participants were better able to attain control while others were either maintained or worsened their control.

FINDINGS

The merged and integrated data for participants ($n = 34$) was re-analysed and interrogated in relation to HbA_{1c} levels using a framework comprised of the three qualitative themes; 'enduring knowledge', 'enduring motivation', and 'on-going support'. The findings from this integration will be presented under the three categories of participants, mentioned earlier, and within these categories the three qualitative themes will be used to add structure to the findings.

A. Out-of-control (HbA_{1c} greater then 8.0%/ 64mmol/ mol)

Of the 34 participants included in the mixed method study, 17 had a HbA_{1c} level above 8.0% (64mmol/ mol) at baseline and at 12 months. Of these participants, ten reduced their HbA_{1c} levels over the duration of the study, five had their HbA_{1c} levels increase and two reported no change. At 12 months five

participants recorded an HbA$_{1c}$ levels greater than10% (86mmol/ mol), two were between 9.0% to 9.9%

(75-85mmol/ mol), and 10 were between 8.0% and 8.9% (64-74mmol/ mol). (Figure 2).

Insert Figure 2 here

<u>Enduring Knowledge</u>
The integrated data were analysed to see if there was any explanation related to knowledge as to why

participants HbA$_{1c}$ level remained above 8.0% (64mmol/ mol). It was evident from the data that

participants perceived that they had the knowledge required to manage their blood glucose levels. They

reported that their knowledge of carbohydrates portions (CP) and insulin requirements were at a level

where they knew what to do to manage blood glucose levels. One participant with a HbA$_{1c}$ of 11.8%

(106mmol/ mol) at baseline that reduced to 10.9% (96mmol/ mol) at 12 months stated that the most

useful part of DAFNE was:

> *"the understanding of blood sugars, knowing why they have gone up and the CP counts "*
> (P-050)

This participant acknowledged however that it was his lifestyle rather than knowledge that contributed

to his erratic HbA$_{1c}$ levels:

> "*Like I was out every weekend and I know, I know it sounds silly but I was out every weekend
> and I might eat 2 meals today and I might eat one meal tomorrow, I might just take only one
> insulin. Like I might forget to take one or I'd be out messing and just go home and forget to take
> insulin … I was sort of just enjoying life*" (P-050)

Another participant with an HbA$_{1c}$ of 10.3% (89mmol/ mol) at baseline rising to 10.7% (93mmol/ mol)

at 12 months described how she had developed coeliac disease. She stated that her knowledge after

DAFNE was good:

> "*I was getting' more confident with the DAFNE, I knew how to adjust the things, and I tend to
> remember the results from the day before or two days before and if I felt they were high you
> know I would have known how to readjust the Lantus you know*". (P-048)

. However she had to develop new knowledge about CP related to gluten-free foods because of developing this new condition. She reported that:

> "*The diet has changed and you are cutting out pasta, lucozade and its taken me quite a while…its just the way it is with gluten free products and that disappoints me… with DAFNE because I was just trying (starting) to try new foods*" (P-048)

She also felt that all her vigilance and knowledge were to no avail, as she found at times that DAFNE principles just did not work for her and she found the variability in blood glucose levels, despite eating the same foods and injecting the same amounts of insulin, very frustrating:

> "*No matter how much I follow all the…points of DAFNE it still didn't help, but it was just that I was at a loss, you know, my blood sugars were still very high readings, you know, and there was no answer for the high readings, you know. It wasn't like I hadn't taken enough insulin, or I was eating anything more sugary, you know, or the portions weren't being counted right, and I suppose that's why I felt at a loss. So I suppose I found it frustrating*" (P-048)

This frustration was also evident for another participant whose HbA_{1c} at baseline was 8.3% (67mmol/ mol) but rose to 8.6% (70mmol/ mol) at 12 months:

> "*I couldn't keep them balanced (blood sugar levels). You know they were…they were… I was going high, I was going high when…and I was convinced I was doing things right, you know I was looking after…I was weighing my…I was doing my food, I was reading the CPs on the back of it. In my own head I was doing everything right*" (P-064)

It was the lack of explanation for the variance in HbA_{1c} levels that these participants found most difficult. They believed they had the knowledge to manage their blood glucose levels and were doing what they should, but their HbA_{1c} levels remained high and for both of these participants their HbA_{1c} levels increased over the duration of the study.

Enduring Motivation

The integrated data was next re-analysed in relation to motivation to identify any explanation for the continued high levels of HbA_{1c} . This revealed that issues related to testing, fear of hypoglycaemia, and setting targets were factors that influenced HbA_{1c}.

Some participants found the constant monitoring of blood glucose levels difficult and intrusive. One participant described how demotivated and fed up she became with all the testing:

> "*I said to them I have had enough of all the (testing) I was doing all my testing but not writing it down. I just felt it was non stop*" (P-048)

Another participant who had an HbA_{1c} at baseline of 9% (75mmol/ mol) that did not change over the course of study also found the counting and monitoring too much:

> "*The constant monitoring, and watching, and counting has taken over. My life is not as free as it used to be in so far as you took 4 injections a day, and you just went about your business.   But now every morsel of food over 10 grams of carbohydrate requires an injection*" (P-035)

Fear of hypoglycaemia was also a concern for some participants in the out-of-control group, particularly if they had taken alcohol. One participant who commenced the study with a HbA_{1c} of 11.4% (101mmol/ mol) at baseline improved to 10.8% (95mmol/ mol) at 12 months, described how he would deliberately keep his blood glucose high after a nights drinking in order to avoid hypoglycaemia:

> "*In general Saturday night would be the only night I would go a bit over the normal, as they say. I'd inject a certain amount but there is no way I'd try to get it 100%. I'd be afraid I might go (hypoglycaemic). I would rather get up on Sunday morning with a big high and bring it back down to normal and its not a problem after that*" (P-040)

It was also evident that while participants in this category were motivated to maintain good glycaemic control for fear of developing complications, there was little evidence of that they set individualised glycaemic targets. Some of these participants seemed satisfied as long as their HbA_{1c} levels were

reducing, even when the overall level was unacceptably high. One participant whose HbA_{1c} never fell below 10.9% (96mmol/ mol) described his perception of his glycaemic control:

> "*its going very good now…I am not getting as much high sugars as I was getting…they are coming down to 8 or 9*" (P-050)

When the data between groups was compared there appeared to be a difference between participants' perceptions of acceptable HbA_{1c} targets across groups. In contrast to the out-of-control participants, the in-control or getting-into-control participants usually set HbA_{1c} targets below 7.9% (63mmol/ mol).

Ongoing Support

Support of healthcare professionals (HCP), support from family and support from the DAFNE patient group were all explored to identify any explanation for continued high levels of HbA_{1c}.

Participants described how their relationships had changed with HCP over the DAFNE programme and follow-up. Most participants described the relationships they developed with the DAFNE HCP as collaborative, helpful and supportive. The data of the five participants who had an HbA_{1c} of greater than 8.0% (64mmol/ mol) at baseline and whose HbA_{1c} at 12 months had increased, were analysed with a particular focus on their perceptions of support. This revealed that many of these participants found controlling their blood sugar levels difficult, most had other health problems and often sought help from the diabetes nurse specialist. In addition, most reported that support was available and that HCP worked collaboratively with them to try and resolve problems. A participant with a baseline HbA_{1c} of 10.3% (89mmol/ mol) and a HbA_{1c} 10.7% (93mmol/ mol) at 12 months who was struggling with health problems and wide variations in blood glucose levels described her support as responsive and supportive:

"Like having the diabetic nurse (name) and being able to ring her, you know when there are problems, I think to me that is a great help".(P-048)

A few participants however found it difficult to access support from HCP. These participants were frustrated by not being able to get direct expert help when they needed it to discuss unexplained highs and to get advice about what should be done. One participant who had an HbA_{1c} at baseline of 8.4% (68mmol/ mol), 9.3% at 6 months (78mmol/ mol) and 8.2% (66mmol/ mol) at 12 months described his struggle to get help:

"I had a few major problems there come February and March. I was always getting a very high result in the morning, and I was able to communicate with the hospital's diabetic nurses there on two occasions, and they got me to do a 3.a.m blood test to see how things were going during the night, and then eventually all communication seemed to stop with emails, and there was no reply to my telephone calls. So eventually I just became proactive, and I came off the DAFNE system, and I went back on to my old system, which solved the problem for me". (P-104).

However, data comparison across groups revealed that there were no substantial differences in perceived levels of support as described by participants in the out-of-control category and the other two categories. For these out-of-control participants there was also nothing different in their stories of family or group support that would help explain the differences in HbA_{1c} levels. However for this out-of-control group a lack of support compounded by a lack of motivation may be a factor in a person renouncing the DAFNE principles they acquired during the 5-day course.

B. Out of control but getting into Control (HbA_{1c} greater than 8%/ 64mmol/ mol but reduced to less than or equal to 7.9%/ 63mmol/ mol)

Out of the 34 participants included in the mixed method study, six started with an HbA_{1c} levels above 8% (64mmol/ mol) and finished the study with levels between 7.3 and 7.9% (56-63mmol/ mol). Of these

four started the study with a baseline of between 8 and 8.9% (64-74mmol/ mol) and two had a HbA_{1c} of greater than 9% (75mmol/ mol), see Figure 3.

Insert Figure 3 here

Enduring Knowledge

It was evident from the data that the participants in this category had the knowledge they required to manage their blood glucose levels. They felt they had learnt a lot from the DAFNE programme and felt confident that they knew how to manage and adjust their insulin. One participant who had an HbA_{1c} at baseline of 9% (75mmol/ mol) and 7.3% (56mmol/ mol) at 12 months explained that the DAFNE programme had given him new knowledge:

> *"Before DAFNE I would not know how much insulin to take to bring me down so I would take a guess and sometime that guess would bring me to a hypo…now I'm more aware of hypo's, more aware of what food I am eating and what I need to do to counteract the CPs"*. (P-046)

It was clear also that at times he felt he was struggling to attain glycaemic control and that lifestyle factors were impacting on his control. Despite this however he managed to keep focused and get to control:

> *"My wife had a baby so…everything was harder to control through that period, and I had – ah - the blood sugar test HbA_{1c} test after that, you know coming into probably 2, 3 months after that, and I would put it down to that really…what I'm saying is if my wife wasn't having the baby it would have been a lot easier do you know…My mind was in another place"*. (P-046)

Knowledge levels therefore did not appear to differ to those in the out-of-control category, however differences were evident when motivation was explored.

Enduring Motivation

The integrated data were next analysed in relation to motivation to identify any explanation for reduced levels of HbA_{1c}. Motivational issues identified that appeared to influence HbA_{1c} levels related to blood glucose level targets, tenacity and vigilance.

Participants in this category set blood glucose targets below 8% (64mmol/ mol) and worked to reach these. One participant who had a HbA_{1c} at baseline of 8.2% (66mmol/ mol), 7.6% (60mmol/ mol) at 6 months and 7.3% (56mmol/ mol) at 12 months described how he was focusing on getting his HbA_{1c} down because it was:

> "*Running higher than I would like it to*". (P-079)

Likewise another participant with a HbA_{1c} of 8.0% (64mmol/ mol) at baseline and 7.6% (60mmol/ mol) at 12 months reported how he was striving to reduce his HbA_{1c} levels:

> "*I am hoping my HbA_{1c} will be down…it was always around 7.5 or 8.0 but obviously I want it to be in the 7s*". (P-054)

In contrast to the out-of-control group participants suggested that while testing took more time if you were benefiting the extra time was not a factor. These participants described testing as a way of identifying patterns and that this information was essential for good control. One participant described how he had tested very frequently in the beginning to see patterns but as time went on he was able to reduce testing overall:

> "*I do yea,(test) maybe not as much as I started with, but I still record. The way I do it is, if my reading start to run off, then I will really start recording do you know and get them back*". (P-046)

This participant therefore remained vigilant and when his blood glucose readings start to rise he tested and recorded more frequently until his bloods glucose levels were under control again.

Ongoing Support

Participants' accounts of support in this category were comparable to those articulated in the out-of-control category. Some participants described support from HCP as responsive and helpful, while others described support as difficult to access when needed. These accounts therefore mirrored the experiences of the out-of-control participants and the in-control participants as described below.

In-control and remained in control (HbA$_{1c}$ remained at less than or equal to 7.5%/ 58mmol/ mol)

There were five participants who had an HbA$_{1c}$ level below 7.5% (58mmol/ mol) at baseline and 12 months. Of these three had an HbA$_{1c}$ of between 6 and 6.9% (42-52mmol/ mol), one between 7 and 7.4% (53-57mmol/ mol) and one between 5 and 5.9% (31-41mmol/ mol), please see Figure 4.

Insert Figure 4 here.

Enduring Knowledge

Participants in this category also reported that DAFNE had provided them with the knowledge they needed to manage their blood glucose levels. A participant who had an HbA$_{1c}$ of 6.9% (52mmol/ mol) at baseline, rising to 7.4% (57mmol/ mol) at 12 months described what she had learnt:

> "*I think it's the two nuggets knowing that 1 CP is going to raise your blood sugar by, 2-3, or that 1 unit of insulin for me will drop me by 2 – to have that in the background all the time. I think, you know, you just relate to that when you're out, and you kind of think – well I wasn't sure about that sauce at dinner, so I know why I'm out. Because before – before DAFNE if your blood sugar was high you never knew why*". (P-100)

Participant knowledge appeared to be comparable to the other two categories. Hence it is unlikely that knowledge levels provide an explanation for differing HbA$_{1c}$ levels between categories .

Enduring Motivation

Motivational issues related to blood glucose target levels and the avoidance of complications were

identified as important to participants within this category.

Participants who were in-control often set blood glucose targets below 7% (53mmol/ mol) and who

worked to reach these were often very frustrated if they did not achieve their targets. One participant

who had an HbA$_{1c}$ of 6.4% (46mmol/ mol) at baseline , 7.6% (60mmol/ mol) at 6 months and 7.4%

(57mmol/ mol) at 12 months described how dissatisfied she was when her blood glucose levels rose:

> "*I had it tested 3 months ago, and it was 8.1, and prior to that it was 7.2, so I wasn't happy with*
> *the 8.1. I changed my insulin to[a different analogue} Apidra and it's 6.8 now so I'm a lot*
> *happier with that*". (P-100)

This participant had set herself a target of 6.5% (48mmol/ mol) and was very unhappy and demotivated

when this was not reached:

> "*I hate having a target that I can't meet, and I just find it really frustrating…it affects your*
> *motivation then for the rest of the day… you go ah sure what's the point…it's the same thing as*
> *having a target and hoping to get to 6.5 and not being able to make it*". (P-100)

Another participant explained:

> "*As long as you strive to have your HbA$_{1c}$ between 6.0 and 7.0, then everything is going to be*
> *fairly decent*". (P-073)

It was evident that these participants were very motivated to reach their targets and worked tenaciously

to do this. For these participants preventing complications was also a large motivating factor:

> "*Well, I suppose it's the talk of complications of diabetes. And my biggest fear is losing my*
> *sight. You know people talk about toes and stuff. I think, should it happen, I could very well feel*

differently, but here I feel I could live without my toes, but I certainly couldn't manage without my sight. And that alone for me is motivation to keep my blood sugar under control". (P-100)

Another participant who had a HbA$_{1c}$ of 6% (42mmol/ mol) at baseline and 6.2% (44mmol/ mol) at 12 months likewise reported:

"*You do not like your blood sugars too high, you know the problems it can cause and its not ideal you know*". (P-073)

While another with a HbA$_{1c}$ of 6.2% (44mmol/ mol) at baseline and 6.5% (48mmol/ mol) at 12 months explained that her HbA$_{1c}$:

"*was always below 7.0 (before DAFNE), because I was so regimented what I was doing I never deviated, ever, from what I was told, because I was too afraid of the risks, or what might happen if I got high blood sugars*". (P-044)

Tight control was therefore important to avoiding complications and a real motivating factor for participants in the in-control category.

Ongoing Support

Participants in this category expressed more concern when their blood glucose levels were not meeting their individual targets. When they failed to meet their target they often sought help from a HCP but as with the other groups they were not always successful in obtaining it:

"*If I could spoken to somebody, because I think some times in your head that you know what the right thing to do is, but you need somebody else, mm.. you know, be it a professional or whatever else to say "yes you're right" – you know when you're wary of the impact that it's going to have – somebody else who knows to say "yes this is the right thing to do" or "maybe you should try this first". I suppose its just the lack of confidence to do it by yourself in isolation without help – just touching base with some body who knows*". (P-100)

However in contrast to participant (P-104) in the out-of-control group mentioned earlier, this participant stayed with DAFNE and worked the problems out herself:

"No. I did try and phone here, and I couldn't get through to anybody and I left a message, and they were supposed to phone back, and I never got a call back. So I suppose I felt quite alone in that then, and I suppose I just said I'm going to re-adjust my ratios and stuff myself". (P-100).

Overall across the three categories there appeared to be little differences in knowledge or support. The differences that did emerge were mainly related to motivation, and in particular HbA$_{1c}$ targets and expectations of control, differences in how testing was perceived and differences in how concerned participants were in relation to developing complications.

DISCUSSION

It was evident from the findings of this study that setting appropriate targets and goals and overall motivation were important factors in explaining glycaemic control behaviours of participants. Knowledge, while it was reported in the qualitative data to be valued and important to all participants, did not appear to be a determining factor in getting HbA$_{1c}$ levels into control when the qualitative and quantitative datasets were analysed concurrently. This finding is not surprising however, given that researchers have consistently found that knowledge while a pre-requisite of behaviour change, does not in itself change behaviour (Brooker et al 2008; Enwistle et al 2008; Osborn et al 2010; Zhong et al 2011).

Persons with diabetes and in particular those engaged in a new method of self management such as the self management principles advocated by the DAFNE programme need access to expert advice and support when interpreting and responding to abnormal blood glucose readings so they can handle the problem at the time, feel reassured and learn about what to do in the future. What is surprising is to find that although the participants in this study valued HCP support the support provided or the lack of it, did not appear to explain participants' behaviour in relation to getting-into-control or being out-of-control;

there were participants in all categories who perceived they had access to good or poor support. However, it was also evident that the lack of support may have a differential impact on those in the out-of-control category as it may bring a person, already demotivated, to a tipping point that results in them giving up when they perceive that they could not access support. Other studies highlight professional support as an essential factor that underpins a person's motivation to self manage (Thorne & Patterson 2001; Enwistle et al 2008; Williams 2009; Murphy et al 2011). Therefore, lack of support for the out-of-control person may compound a lack of motivation. It is not known if there was a difference in the intrinsic or extrinsic motivation for the out-of-control and the in-control participants but it may play a role. Extrinsic motivation involves the person engaging in a given behaviour because they seek an external reward such as approval from others (Kasser & Ryan 1996). Although extrinsic motivation is less likely to lead to sustained changes in behaviour (Ryan et al 2008) it may be that some of the out-of-control participants were more extrinsically motivated and therefore more dependent on HCP support to galvanise their motivation. The function and quality of social relationships is also a key element of social support..   Di Matteo (2004) who carried out a meta-analysis of social support and patient adherence to medical treatment, found that social support has a sizeable effect on patient adherence and these effects vary depending on the type of social support. It was also concluded that social support may not always be beneficial and this will depend on a number of factors including the type and severity of the condition and the complexity of the disease management process. The apparent limited influence, when provided, of HCP support on participants' ability to attain optimal HbA$_{1c}$ levels in this study might be more fully explained by examining the type, structure and function of the social relationships between HCP and participants which was not in the remit of this study to measure. Future research is therefore needed to focus on these issues and to ascertain which type of HCP support works well for

individuals with T1D and which approach best suits individual self management behaviours over the trajectory of their chronic condition.

This current study identified the importance of setting ambitious HbA$_{1c}$ targets and having the motivation to work tenaciously towards achieving these. Motivation has been identified as essential to self management in many other studies (Shigaki et al 2010; Williams et al 2009; Williams et al 2005; Williams et al 2004; Williams et al 1998) but it is the linking of target and goal setting with motivation that is an interesting, if not novel, finding in this current study. Karoly and colleagues (2005) consider goals to be motivational triggers that enact action and this current study would support this. These findings also suggest that the time spent by HCP working with people to identify and agree appropriate goals for HbA$_{1c}$ levels is important, as participants in this study with T1D who set and worked towards achieving ambitious HbA$_{1c}$ targets were more likely to remain in-control.

This current study also found that participants who were out-of-control were more likely than those who were in-control to view testing blood glucose levels as intrusive and difficult. Likewise Peel et al (2004) found that participants who had good control of their diabetes were more positive about monitoring and self-testing their blood glucose levels than those who had poorer control. This finding suggests that it may be important for HCP to explore how a person with T1D feels about conducting blood glucose testing as it may indicate their underlying motivation to work to achieve HbA$_{1c}$ targets and may help identify those who need additional support.

STUDY LIMITATIONS

Analysis and merging of qualitative and quantitative datasets are not common techniques and are not reported frequently in the literature. Analytical approaches are therefore less structured and there is little guidance about how merging and interrogation of data should be conducted. It is not known if the approach taken was the best approach and therefore a detailed description of what was done is provided. With mixed method longitudinal research there is also the challenge of maintaining a sample over time. In this study six participants were lost to follow-up. This occurred at the 12 month stage and was mainly due to illness, or lack of a HbA_{1c} result. It is not know if these participants' experiences and results differed from those who were included in the sample.

CONCLUSION

The use of a concurrent mixed method design within NVivo (version 8) enabled the exploration, interrogation and merging of the qualitative and quantitative datasets in ways that would not be possible if quantitative or qualitative datasets were analysed and considered separately. This study provides a description of how these large mixed data sets can be managed and knowledge maximised. It is essential however to have in place the qualitative, quantitative and technological expertise required to analyse and merge mixed method data sets rigorously.

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