“HbA1c, weight, quality of life and hypoglycaemia awareness after a structured education programme teaching carbohydrate counting and insulin dose adjustment”

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By

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Ethical Approval

The project was registered with Clinical Audit department at Aintree University Hospitals NHS Trust in May, 2009 as a service evaluation. Following assessment of the study design, they advised me that ethical approval was not required. This was confirmed by the Research Director at University of Chester. Please see registration documents in Appendix 1

"HbA1c, Weight, Quality of life and Hypoglycaemia awareness after a structured education programme teaching carbohydrate counting and insulin dose adjustment"

Julie Ellis-Gowland

Objective The primary aim was to assess the effects of Aintree Hospital's '4-Step' programme which teaches carbohydrate counting and insulin dose adjustment to patients with Type 1 diabetes, on HbA1c, Weight, Quality of life and Hypoglycaemia awareness. A secondary aim was to compare the effects of group education and one to one clinics in HbA1c, Weight, Quality of life and Hypoglycaemia awareness.

Methods All parameters were measured at baseline and four months later. HbA1c is measured by blood test, Quality of Life using the Problem Areas in Diabetes questionnaire and Hypoglycaemia Awareness using the 'Symptom Awareness of Hypoglycaemia' questionnaire.

A convenience sampling technique was used whereby patient data was collected over a 6 month period from all patients who fit the criteria. Those excluded were patients with patients receiving nutritional support and those undertaking weight management programmes, those undergoing chemo/radiotherapy and those on renal dialysis. Fifty two sets of patient data were collected in total. All patients underwent either group or one-to-one clinic sessions. The programme was of four weeks duration and patients were followed up for repeat measurements three months after the programme. Where populations fit a normal 'Gaussian' distribution parametric paired t-tests were chosen for statistical analysis. Where the population was found to be skewed, non- parametric Wilcoxon tests were used.

Results Following the programme overall HbA1c levels improved by 0.29% ($p=0.008$) with greater improvements occurring in those undertaking joint clinics ($p=0.037$) than groups ($p=0.111$). There was an overall weight loss of 0.5kg which did not reach statistical significance ($p=0.100$). However weight loss was greater in those attending group education ($p=0.04$) compared to those attending clinics ($p=0.438$). Quality of life scores improved by 11% overall ($p=0.000$) with group education being slightly more effective in achieving improvements ($p=0.000$) than group education ($p=0.001$). There was no change in symptoms of Hypoglycaemia awareness in the population as a whole ($p=0.052$) although as with HbA1c, those undergoing individual education had great improvements ($p=0.046$) compared to those in groups ($p=0.409$).

Conclusions The study has served to demonstrate the effectiveness of Aintree's '4-Step' programme in achieving key improvements in clinical and non-clinical aspects of patients' diabetes care. While the improvement in HbA1c is beneficial, it is unclear whether this is sustained over time. Longer term follow-up and refresher education at intervals may increase the likelihood of sustained clinical benefits. Whilst weight loss was shown to be minimal, the study importantly demonstrates that the '4-Step' programme does not lead to weight gain, an important finding when offering a programme enabling greater food freedom. Quality of Life improvements were highly significant with impressive improvements. However, future studies would benefit from including a more detailed analysis of the Quality of Life questionnaire. Whilst highlighting aspects which are most favourably influenced by the programme, this would also enable targeting of those aspects which demonstrate lower levels of satisfaction for future service provision. Hypoglycaemia Awareness did not improve, possibly due to the short study duration. Future evaluations may be better placed to measure frequency of hypoglycaemia for a more accurate assessment of the impact of the '4-Step' programme on hypoglycaemic events.

I hereby declare that work contained herewith is original and is entirely my own work (unless indicated otherwise). It has not been previously submitted in support of a Degree, qualification or other course.

Signed: **Dated:**

List of tables

Table 2.1 Reasons why people with Type 1 Diabetes who enjoy greater dietary freedom may gain or lose weight

Table 3.1 Patient demographics

Table 3.2 Measurements

Table 4.1 Mean clinical and psychological outcomes before and after '4-Step' programme

List of figures

Figure 2.0 Illustration of glycosylated haemoglobin (HbA1c)

Figure 4.0 Mean HbA1c at baseline and following '4-Step' programme in total population

Figure 4.1 Mean HbA1c at baseline and following '4-Step' programme in groups and clinics

Figure 4.2 Numbers of patients who lost, maintained and gained weight (n=52)

Figure 4.3 Mean weight (kg) at baseline and following '4-Step' programme in total population

Figure 4.4 Weight changes in those attending groups

Figure 4.5 Weight changes in those attending clinics

Figure 4.6 Mean Weight (kg) at baseline and following '4-Step' programme in groups and clinics

Figure 4.7 Mean Quality of life scores at baseline and following '4-Step'programme in total population

Figure 4.8 Mean Quality of Life scores at baseline and following '4-Step programme in groups and clinics

Figure 4.9 Mean Hypoglycaemia Awareness score at baseline and following '4-Step' programme in total population

Figure 4.10 Mean Hypoglycaemia awareness score at baseline and following '4-Step' programme in groups and clinics

Figure 4.11 Percentage changes in Hypoglycaemia awareness in groups

Figure 4.12 Percentage changes in Hypoglycaemia awareness in clinics

List of Contents

Title page	I
Acknowledgements	II
Ethical approval	III
Abstract	IV
Declaration	V
List of tables	VI
List of figures	VII

Chapters

1 Introduction
2 Literature review
3 Methodology
4 Results
5 Discussion
References

Appendices

Appendix 1: *Ethical approval acknowledgements*
Appendix 2: *'Problems Areas in Diabetes' Questionnaire*
Appendix 3: *'Symptoms of Hypoglycaemia Awareness' Questionnaire*
Appendix 4: *Histograms*
Appendix 5: *Data collection form*
Appendix 6: *SPSS Paired T-Test & Wilcoxon Signed Ranks Test analysis*

Chapter One

Introduction

Introduction

Diabetes self-management education is now widely recognised as a critical element of care for all people with diabetes and is considered necessary in order to improve patient outcomes. The need for structured education in diabetes care was highlighted by the publication of NICE guidance in 2003 which recommended that 'structured patient education is made available to all people with diabetes at the time of initial diagnosis and then as required on an on-going basis, based on a formal, regular assessment of need'. There is much evidence demonstrating that structured education among diabetes patients is effective in improving knowledge, blood glucose control, weight and psychological well-being (Department of Health & Diabetes UK, 2005). The National Service Framework for Diabetes Standard 3 (Department of Health, 2003), 'Empowering people with diabetes' states that 'structured education can improve knowledge, reduce blood glucose levels without increasing frequency of hypoglycaemia, reduce weight and improve psychological well-being'.

Personal empowerment of patients is being seen as increasingly important in the treatment of diabetes. In the White Paper entitled Our Healthier Nation: Choosing Health (Department of Health, 2004), emphasis was placed upon the importance of personal choice in achieving good health. According to the National Service Framework for Diabetes: Delivery Strategy (Department of Health, 2003), patient empowerment and a person-centred approach should be a key part of successful treatment, as there is much evidence to show that these improve both clinical outcomes and quality of life. Recommendations include the provision of support and structured education alongside medication and clinical care as required a main aim of which is to enable those with diabetes to self-manage their lifestyles and their diabetes.

In response to changing guidance, many local education initiatives across health authorities were developed offering a range of diabetes education models to all patients newly diagnosed with Type 1 or Type 2 diabetes. The face of diabetes care was changing and a systematic review published in Acta Diabetologia in 2008 entitled 'Analysis of the 2004-2007 literature on therapeutic patients education in diabetes: results and trends' which sought to assess the effectiveness of therapeutic patient education in diabetes over 3 years concluded that 'huge progress seems to have been achieved; health care teams in charge of the education of diabetics are increasingly trying to focus education on the

patient (patient centred education)' and this approach had resulted in more positive outcomes (Albano et al, 2008). This is in line with Bandura's (1997) teaching that the self-efficacy of the individual increases when he or she is empowered and that patient empowerment should form the basis for all diabetes structured education programmes.

Specific structured education programmes which teach carbohydrate counting and insulin dose adjustment have been gaining momentum in the international diabetes community for a number of years and it is also of note that the only specific programme recommended in the NICE guidance was one such programme, the Dose Adjustment for Normal Eating (DAFNE) programme which was outlined by NICE (2003) as being a suitable option for individuals with Type 1 diabetes, as 'one means of enabling people to self-manage this condition'. The programme is underpinned by the notion of patient empowerment and shared diabetes care and the evidence for improvements in these areas is strong.

The DAFNE programme and many similar regional models, teaches people with Type 1 diabetes how to correctly identify and count carbohydrates in the diet and correspondingly adjust their insulin dose to match the carbohydrate load eaten. This is in contrast to the patient administering a pre-determined number of units of insulin at each meal time and then aiming adjust carbohydrate intake accordingly. Although this approach remains appropriate for many patients, strict portion control is difficult to achieve for many, who aim to eat a 'similar sized meal' and take the prescribed insulin dose accordingly. Dietary guidance for these patients generally aims to assist with portion control, with focus on carbohydrate load and distribution over the course of the day. However due to the variability of food intake, glycaemic control can be challenging. The ability to offer carbohydrate counting and insulin dose adjustment has been made possible with the advancement of insulin therapies which enable the patient to more successfully match carbohydrate intake with insulin doses thereby mimicking physiological insulin production. Consequently, where insulin dose is calculated individually to match the amount of carbohydrate eaten it is shown than benefits can include improved glycaemic control without increased risk of severe hypoglycaemia and greatly improved quality of life and treatment satisfaction (DAFNE Study Group, 2002).

The publication of the landmark DAFNE Trial in 2002, which demonstrated clinically and statistically significant improvements in glycaemic control without exacerbation of

hypoglycaemia, weight loss and improved quality of life, paved the way for the development of many other such structured education models including BERTIE **(**Broomfield's Education Resources for Training in Insulin and Eating), (Everett et al, 2003), a course developed by Bournemouth Diabetes and Endocrine Centre which has been rolled out nationally by way of offering training courses and resources for centres wishing to develop their own programmes. Aintree's '4 Step' is one of many programmes which are developed and run locally and evaluated for effectiveness.

Aintree University Hospitals Diabetes Team based at Walton Hospital site is a consultant led multi-disciplinary team offering acute in-patient and out-patients diabetes care within the local community. The team is composed of seven consultant endocrinologists, one diabetes nurse consultant (DNC), five diabetes specialist nurses (DSN), one diabetes nurse educator (DNE), four podiatrists and a diabetes specialist dietician. The service offers diabetes care to all Type 1 Diabetes patients, complex Type 2 patients, young people aged 16-25 and gestational diabetes cases and in accordance with NICE guidance, structured education is offered to all patients newly diagnosed with Type 1 diabetes. Patients diagnosed with Type 2 diabetes are offered education in the community under the auspices of the PCT.

In November, 2007 in response to the identified benefits of carbohydrate counting education being demonstrated in clinical audits, the diabetes team identified a need for a cost effective method of delivering advanced carbohydrate counting. Staff undertook training with the BERTIE group and the DAFNE equivalent '4 Step' programme was developed by the team's specialist dietitian and specialist nurse which would be offered to all patients fulfilling the criteria with the aim of improving patients' quality of life and glycaemic control. Subsequently, with the revision of NICE Guidance on Insulin Pump Therapy in 2008, the team commenced an insulin pump therapy service which also required carbohydrate counting education as a pre-requisite for patients commencing insulin pump therapy. The '4 Step' programme is delivered at Walton Diabetes Centre both in a group education format and in a one to one joint clinic and is offered to patients undergoing insulin pump therapy and non-pump patients wishing for improved glycaemic control. Both group and one to one sessions are run by the diabetes specialist nurse and the specialist dietician.

Much published data exists demonstrating evaluation of regional and national DAFNE

and equivalent courses, which measure the effectiveness of and inform the quality of, these programmes. The evidence has consistently demonstrated improvements in clinical and psychosocial outcomes such as HbA1c, quality of life and awareness of hypoglycaemia. Although improvements in weight are not clearly demonstrated, it is important to know that these programmes do not result in weight gain which is important in programmes offering greater food freedom. The Diabetes UK Care Recommendation for education of people with diabetes (2003) recommends monitoring the effects of education programmes on HbA1c, BMI, quality of life and hypoglycaemia awareness by way of well-designed audit and service evaluation and it is these recommendations which form the basis of this service evaluation.

Rationale and hypotheses

Rationale 1: HbA1c is shown to improve following diabetes structured education teaching carbohydrate counting and insulin dose adjustment (DAFNE, 2002).

Hypothesis 1: There is a significant improvement in HbA1c in patients undertaking the '4-Step' programme.

Rationale 2: Weight is shown not to change significantly in patients following diabetes structured education teaching carbohydrate counting and insulin dose adjustment (Everett et al, 2008).

Hypothesis 2: There is neither weight gain or weight loss in patients undertaking the '4-Step' programme.

Rationale 3: Quality of life is shown to improve following diabetes structured education teaching carbohydrate counting and insulin dose adjustment (Everett et al, 2008).

Hypothesis 3: There is a significant improvement in quality of life in patients undertaking the '4-Step' programme.

Rationale 4: Hypoglycaemia awareness is shown to improve following diabetes structured education teaching carbohydrate counting and insulin dose adjustments (Samaan et al, 2006).

Hypothesis 4: There is a significant improvement in hypoglycaemia awareness in patients undertaking the '4-Step' programme.

Rationale 5: Group structured education is more effective than individual clinic education for lifestyle interventions (Norris et al, 2002).

Hypothesis 5: HbA1c, weight, quality of life and hypoglycaemia awareness will improve more in group settings than in clinics.

Chapter Two

Literature Review

2 Literature Review

2.1 Background

Diabetes Mellitus is a chronic, progressive disease that affects 1.3 million people in England and is thought to absorb an estimated 5 per cent of all NHS expenditure (DOH, 2004). Patients with diabetes are at increased risk of micro vascular complications, such as retinopathy, nephropathy and neuropathy as well as macro vascular complications such as myocardial infarction and stroke, with cardiovascular disease in fact being the leading cause of death in this patient group (Diabetes Control and Complications Trial, 1993). The implications of diabetes in terms of patient wellbeing and health service resources are far reaching and therefore high quality, effective patient care is imperative. Diabetes care has been evolving over a number of years as the scientific evidence base has changed, which along with improved medications and enhanced knowledge about methods of education and delivery of care, has resulted in the development of education programmes with the aim of improving patient outcomes. As previously discussed, Aintree University Hospital's '4 Step' programme was developed to teach carbohydrate counting and insulin dose adjustment with the aim of improving clinical and psychological outcomes. In accordance with recommendations, this project seeks to evaluate the impact of the '4 Step' programme on glycaemic control, weight, hypoglycaemia awareness and quality of life in all patients undertaking the programme.

2.2 General developments in diabetes structured education

On the basis of much emerging evidence, the National Service Framework for Diabetes Standard 3 (Department of Health, 2003), 'Empowering people with diabetes' was published signifying a change of direction for health care professionals (HCP's) in diabetes care, emphasising the use of structured education and diabetes self-management programmes, stating that 'structured education can improve knowledge, reduce blood glucose levels without increasing frequency of hypoglycaemia or weight and improve psychological well-being'. There followed a rise in diabetes education models which were designed to enable patient autonomy, self-management and shared care. A systematic review published in Acta Diabetologia in 2008 entitled 'Analysis of the 2004-2007 literature on therapeutic patient education in diabetes: results and trends' sought to assess the effectiveness of therapeutic patient education in diabetes over a four year period. Fifty four out of eighty studies demonstrated effectiveness of therapeutic patient education in terms of clinical, psychosocial and educational outcomes (Albano et al,

2008). The authors concluded that 'huge progress seems to have been achieved; health care teams in charge of the education of diabetics are increasingly trying to focus education on the patient (patient centred education)'. The authors also observed that whereas past evaluation protocols focused solely upon bio clinical criteria, more recently they were seeing the inclusion of psychosocial and educational criteria which they describe as "a significant change with the evaluation of therapeutic education now being multifactorial" (Albano et al, 2008). Patient education appeared to have switched from didactic presentations to interventions involving patient 'empowerment' with participation and collaboration (Norris et al, 2002). Although it could be said that the review focused on just four years of publications therefore limiting the generalizability of the findings, it is sufficient to indicate changes have taken place in the field of therapeutic patient education. This trend is seen nowhere more clearly than in the area of carbohydrate counting and insulin dose adjustment, otherwise known as intensive insulin therapy, with the establishment of numerous diabetes educational programmes both nationally and internationally. These seek to embrace a holistic approach to diabetes care and emphasise quality of life outcomes as well bio-clinical outcomes through the vehicle of diabetes self-management education.

2.3 The evolution of education providing carbohydrate counting and insulin dose adjustment

Historically, people with Type 1 diabetes were expected to follow rigid meal plans with precisely controlled and often restricted carbohydrate portions to match the fixed twice daily insulin regimens (Petrak et al, 1992). Patients would be given carbohydrate exchange lists of 10g items which they would aim to match to their insulin doses and naturally this would result in patients either restricting their carbohydrate intake or having to eat more than they otherwise would, which could have deleterious effects on health and weight. Furthermore, accurate insulin dose adjustments were hard to achieve because of inaccurate blood glucose testing systems and the unpredictable nature of available insulins. With the previously discussed increasing trend to recognize the importance of patient choice and quality of life, this approach has lost favour in recent years. Rather than eating fixed amounts of carbohydrate, patients on set daily doses of insulin are now educated to identify carbohydrates and focus on the load (amount) and distribution (spread throughout the day) rather than calculated portions. Education usually comprises teaching patients how to develop balanced meals and snacks with appropriate amounts of 'healthier' carbohydrate choices. The aim is for consistency in

day-to-day carbohydrate intake in terms of amount and source of carbohydrate; an approach which has been associated with lower levels of glycosylated haemoglobin (HbA_{1c}) (Wolver et al, 1999). HbA1c or glycosylated haemoglobin is the gold standard measure of overall diabetes control, representing the number of haemoglobin cells carrying a glucose molecule at a given time (see Figure 2).

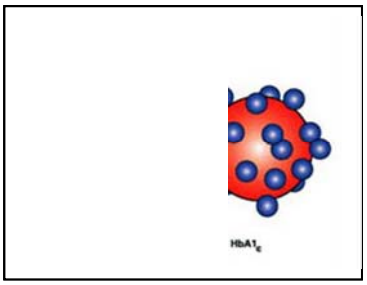


Figure 2 Illustration of glycosylated haemoglobin

The approach necessitates standardization of food portions which, although being less restrictive than the previous exchange system, results in dietary restrictions. If the restrictions are not adhered to it may result in worsening glycaemic control. However in spite of this, fixed insulin doses still remained the regime of choice for many patients, and this for a variety of sound clinical and social reasons.

The advent of more sophisticated insulin analogues with a better profile/action have in recent years enabled the advancement of more precise matching of insulin dose to carbohydrate intake by way of more flexible insulin regimes. Rapid-acting insulin analogues have a quick but short duration of action that more closely resembles the body's natural glycaemic response to different carbohydrate loads than older insulins (King, 2003). Carbohydrate counting and insulin dose adjustment programmes teach in-depth knowledge of carbohydrates and advanced counting methods with the aim of the patient taking personal responsibility for adjusting his/her own insulin dose according to the quantity of carbohydrate eaten at any given meal. Many of the programmes teaching this approach have found this not only has the benefit of conferring upon the patient the dietary freedoms enjoyed by people without diabetes, but can also lead to improved glycaemic control.

2.4 The importance of tight glycaemic control

The main clinical goal of diabetes treatment is to produce near-normal glycaemia (4-7mmol/l pre-prandial, <10mmol/l post-prandial) in order to prevent acute symptoms and chronic complications (Diabetes UK, 2003). Acute hypo/hyperglycaemia events increase the risk of diabetic ketoacidosis in Type 1 diabetes, hyperosmolar non-ketotic syndrome in Type 2 diabetes, glycosuria, and ketonuria. In the long term, good glycaemic control

reduces the risk of developing retinopathy, neuropathy, nephropathy and cardiovascular disease (Delahanty et al, 1993). Diabetes care should also involve aiming to maintain a healthy body weight and optimal quality of life.

The importance of glycaemic control in diabetes has been well established. Two landmark clinical trials have changed the face of diabetes care in recent years, providing best quality evidence for the benefits of glycaemic control. The first was the Diabetes Control and Complications Trial, (DCCT), a randomised, controlled clinical trial which

studied 1,441 volunteers with Type 1 diabetes at 29 medical centres in the US and Canada over a 10 year period between 1983 and 1993. The DCCT examined whether intensive treatment (aiming for tighter glucose control by way of multiple daily injections (MDI) of insulin), as opposed to traditional twice daily injections, could decrease the frequency and severity of complications. The results clearly demonstrated benefits of tight control in terms of micro vascular complications such as retinopathy, nephropathy and neuropathy. At 6 year follow up, tight blood glucose control (4-10 mmols) was found to reduce the onset of retinopathy by 76% in those without pre-existing primary retinopathy. In those with pre-existing mild to moderate retinopathy, progression was reduced by 54% (DCCT Research Group, 1993). The benefits of intensive therapy were significant after three years and the magnitude of risk reduction increased over time. Similarly, tight control resulted in a significant reduction in the development of nephropathy, demonstrated by a 34% ($p=0.004$) reduction in micro albuminuria in those with pre-existing nephropathy and a 56% reduction in those without. Micro albuminuria is the leaking of albumin into the urine indicating some degree of renal impairment and improved urinary albumin excretion is a positive outcome in terms of renal function. In patients with no pre-existing neuropathy, tight glycaemic control was found to reduce its onset by 69% ($p=0.006$) compared to conventional therapy.

However, intensifying insulin therapy to achieve tight glycaemic control was not found to be without problems as episodes of severe hypoglycaemia increased ($p<0.001$). Furthermore, intensive treatment was associated with a 33% increase in weight gain. Although much useful evidence was reported, the study fell short of identifying a suitable threshold for HbA1c (glycosylated haemoglobin), the gold standard blood glucose measure for diabetes. Recommendations were made for maintenance of blood glucose levels as close to the normal range as possible without increasing risk of hypoglycaemia. Administering multiple daily injections does incur an additional burden to the patient and prior to the DCCT there was no medical proof of any benefits to MDI compared with conventional therapy of twice daily insulin. Although the DCCT studied only a restricted

group of Type 1 diabetes patients, many clinicians began recommending tight control to patients with both Type 1 and Type 2 diabetes. HbA1c measures degree of glycosylated haemoglobin out of 100% over an 8 to 12 week period and is therefore a useful measure of blood coagulation and overall diabetes control. Even very small changes in HbA1c are considered clinically significant with their effects upon outcomes firmly established.

The (UKPDS) United Kingdom Prospective Diabetes Study was a large multi-centre, prospective, randomised controlled intervention trial which assessed 5100 patients newly diagnosed with Type 2 diabetes over a 20 year period to 1999 to assess the impact of tighter glycaemic control on future risk factors. Patients were recruited and initially treated with diet. The 95% who remained hyperglycaemic (fasting glucose >6mmols/L) were randomly allocated to different therapies to determine outcomes. These included continuation of diet only, inclusion of an oral hypoglycaemic agent (OHA) such as Gliclazide (an insulin stimulating drug), or injected insulin or both (Stratton et al, 2000). Results released in 1999 revealed similar benefits for the Type 2 diabetic population, with tighter glucose control resulting in a 25% reduction in micro vascular complications (95% CI) although reductions in myocardial infarction did not reach significance (Stratton et al, 2000). Risk of hypoglycaemia in those on a combination of insulin and sulphonylurea therapy showed a 5.6% increase as well as increased weight gain, although the p-values were not reported for this data. The UKPDS also provided strong evidence for the benefits of dietary advice for 3 months following diagnoses prior to initiating medication, demonstrating a significant reduction in fasting plasma glucose by 2.9mmol/l, HbA1c 1.9% and body weight by 3.7kg. Following publication of these key trials many medical centres started using a team approach to treating diabetes, consisting of doctors, specialist nurses and dietitians, and clinical targets changed, now aiming for progressively tighter glycaemic control. Diabetes UK recommended treatment which currently aims for the following:

- Blood pressure levels of 130/80 mm Hg or below
- HbA1c levels of 6.5 per cent
  or below
- Fasting blood glucose levels of 4-7 mmol/litre
- Aim for blood glucose levels before meals between 4 and 7mmol/litre

In light of the findings of the DCCT & UKPDS and the potential effects of intensive therapy increasing risk of hypoglycaemia, it is important to know that interventions teaching carbohydrate counting and insulin dose adjustment do so safely without

increasing episodes of hypoglycaemia. The DTTP (Diabetes Treatment & Teaching Programme), a prospective implementation study carried out across 96 diabetes centres in Germany sought to test the effects of such an educational programme on frequency and severity of hypoglycaemia. A total of 9,583 routine care patients were examined before and 1 year after the group education and the results clearly indicated that the programme provided benefits for patients at previous high risk of severe hypoglycaemia and severe ketoacidosis (Samaan et al, 2006). Regression to the mean was an important bias for the study which was not controlled. However, statistical simulations of baseline results were also carried out and demonstrated a reduction in hypoglycaemic events from 6.1 to 4.7 per patient which was still significant (Pennant et al, 2007). A further factor which may have affected bias was the sub-group analysis which was performed on those with two or more episodes of severe ketoacidosis and which due to a reduced sample size, should be interpreted with caution. However, these findings coupled with the positive outcomes of the DAFNE trial have resulted in a plethora of DAFNE style course springing up throughout the UK. The DAFNE study (2002) previously mentioned, importantly found that the carbohydrate counting intervention resulted in no differences in frequency of hypoglycaemia, which demonstrates safe reduction of blood glucose levels without exacerbation of hypoglycaemia.

2.5 Carbohydrate counting and insulin dose adjustment and effects on glycaemic control (HbA1c)

Carbohydrate counting is now synonymous with management of Type 1 diabetes (National Institute for Health and Clinical Excellence 2003) and the DAFNE (Dose Adjustment for Normal Eating with diabetes) programme was a forerunner of many such programmes established nationally and internationally, teaching carbohydrate counting and insulin dose adjustment for the purpose of gaining clinical and quality of life benefits. The evidence base for the DAFNE programme was published in 2002, with results from the UK based randomised controlled trial which involved two randomised groups of adults with Type 1 diabetes with moderate or poor glycaemic control defined as HbA1c 7.5–12%. The study measured HBA1c, frequency of hypoglycaemia, quality of life and effects on weight. Half entered the programme immediately and half delayed entering the programme for six months whilst still receiving their normal diabetes care. When the groups were compared at 6 months, the mean difference for HBA1c between groups was 1.0%, $P<0.0001$. At twelve months the difference in HBA1c had reduced to 0.5%, $P<0.001$ but was nevertheless significant with one quarter of those in the early intervention arm sustaining an HBA1c of 1.5% below their original value. Although the

results were encouraging it should be remembered that many factors influence glycaemic control and it is therefore difficult to attribute the change to any one factor alone. For example it is possible that the beneficial effect was simply related to an increased frequency of insulin injections in patients using this approach. Furthermore poor compliance with diet and/or diabetes medications are well recognized to be major contributing factors to poor diabetes control. Given that the high baseline HbA1c was 9.4 % which indicates irregular compliance, it may not be unreasonable to expect an improvement in the setting of a research trial particularly where this involved extensive diabetic education.

As demonstrated, tight glycaemic control therefore is paramount to modern diabetes care and it is pertinent that our study should assess the effect of our intervention on HbA1c which is the gold standard measure. However, it must be pointed out that whilst no-one will argue with the effects of self-management education upon glycaemic control, the evidence to show a sustained effect upon HbA1c is mixed. This was demonstrated in a meta-analysis by Norris et al (2002) assessing the effects of 31 RCTs which found that on average the intervention decreased glucose levels by 0.76% at immediate follow up, by 0.26% at 1-3 months follow up, and by 0.26% at 4 months follow up. However, it is known that RCT's are not always thought to be feasible in community based education interventions as they emphasis efficacy to the exclusion of other factors influencing effectiveness, which could in turn have influenced the results (Norris et al, 2002).

The original DAFNE trial did indeed demonstrate a 1% reduction in HbA1c at the 6 month baseline, although at one year this benefit had dropped to 0.5% indicating a reduced level of benefit over time. Follow up at 2 years indicated maintenance of the 0.5% benefit and further follow up published in Diabetic Medicine in 2007 by DAFNE (Speight et al, 2007), reported that re-testing the original feasibility study cohort demonstrated a mean improvement in HbA1c of 0.36% at 44 months post course. This is encouraging in that whilst some benefit is lost, there appear to be lasting benefits in HbA1c and therefore subsequent long term diabetes complications. Similar results are reported by other regional programmes across the UK which report reductions of 0.5% in HbA1c at 6 months. A programme called BBC (Basal Bolus Conversion Groups: Delivery of structured patient education) run by the Queen Alexandra Hospital, Portsmouth, using a sample size of 67 patients, detected a mean reduction of 0.6% in HbA1c at 3 months. A similar result was found by the CIGS (Carbohydrate and Insulin Structured Group Education Sessions) programme run by the Queen Alexandra Hospital

in Portsmouth. They used a sample size of 26 and recorded a 0.5% reduction in HbA1c at 3 and 6 months (Griffiths & Turner, 2008). However, the regional studies have not followed up patients beyond 6 months, and DAFNE remains the only study to evaluate long term results of these programmes upon HbA1c. Whilst HbA1c is the gold standard measurement of glycaemic control and is clinically very significant, clinical observation demonstrates that reducing glycaemic excursions, which may not always influence HbA1c, often results in improved patient wellbeing, reduced incidence of hypoglycaemia and correspondingly improved quality of life. Therefore, while HbA1c improvements are and should be our main clinical goal, where this is not achieved, it should not be assumed that no benefit to glycaemic control has occurred. However, HbA1c is monitored in all patients with diabetes to assess levels of overall control and it is known that three month follow is appropriate as a necessary time lapse for an accurate reflection of change in HbA1c. DCCT data showed that the most recent 30 days glycaemia contributes 50% to HbA1c and the previous 3-4 months contributes 10%. A time measure of greater than eight weeks is therefore considered necessary for HbA1c to accurately reflect changes in glycaemic control (DCCT, 1993). This service evaluation aims to measure the effects of the 4-Step programme on HbA1c at four months follow up.

2.6 Carbohydrate counting and insulin dose adjustment and hypoglycaemia awareness

Hypoglycaemia unawareness is defined as the onset of neuroglycopenia before the appearance of autonomic warning symptoms (De Galan et al, 2006). Neuroglycopenia occurs when the brain becomes glucose deprived and function is impaired. In the normal course of events, patients will detect and treat hypoglycaemia before neuroglycopenia occurs and the inability to detect and treat hypo symptoms in good time can be dangerous, leading to severe hypoglycaemia with potentially fatal outcomes (De Galan et al, 2006). Glucose counter regulation in patients with Type 1 diabetes is typically impaired with the loss of insulin capacity disrupting the first line defence against falling glucose levels, which in turn results in inadequate glucagon response. There is then a resulting lowering of the glycaemic threshold for these responses to lower levels of glycaemia (Meneilly et al, 1994) meaning patient awareness of the hypoglycaemic event will be impaired to some extent. Any episode of hypoglycaemia can provoke this problem resulting in a cycle of worsening counter regulation and eventually to hypoglycaemic unawareness.

It is known that “the most effective way of reducing risk of hypoglycaemia unawareness is to reduce risk of hypoglycaemia” (Fanelli et al, 1993) and therefore this must be the

goal of treatment whilst at the same time aiming for optimal glycaemic control (MacLeod, 2000). Clinical concerns may result in a reluctance to optimise insulin therapy, for fear of inducing hypoglycaemia (Hayes, M., 2008), which could adversely

affect long term outcomes for people with diabetes. Blood glucose monitoring, individualised targets and educational programmes are important in a bid to prevent and manage this problem and many training courses delivered with the aim of achieving tight blood glucose control are measuring the effects of the training upon hypoglycaemic awareness.

DAFNE style training is associated with significant improvement in HbA1c, reduction in severe hypoglycaemia and improvements in self-reported hypoglycaemia awareness (Samaan et al, 2006). The study assessed retrospective data on 9583 patients who had attended the courses over a 12 year period by way of sub-group analysis. Before attending the training, mean incidence of severe hypoglycaemia was 6.1 ± 9.6 events per patient per year and following training this was reduced to 1.4 ± 5.4 events. Before the training all participants of the subgroup had at least three episodes, 26% had ≥ six episodes and 8% had ≥ episodes of severe hypoglycaemia. After the training, 56% of patients had none, 20% had two, and 15% had three or more episodes. The adjusted mean differences of severe hypoglycaemia before and after the interventions was - 4.7 events per patient per year with a ($p<0.000$), a significant overall reduction which would be expected to impact favourably upon awareness (Samaan et al, 2006). This study will seek to assess the impact of the 4-Step programme upon hypoglycaemia awareness.

2.7 Carbohydrate counting and insulin dose adjustment and Weight

Weight maintenance is a pivotal part of diabetes management, with weight gain leading to increasing insulin resistance, increased insulin requirements and a consequent downward spiral of worsening control. Weight gain is a well-known side effect of insulin therapy and previous studies demonstrate weight increases of up to 21% in one year with some insulin regimes (Davies & Wylie-Rosett, 2008). It is important that education models which offer food freedom are not shown to lead to weight gain which could in turn worsen glycaemic control. There are a number of reasons why carbohydrate counting courses can impact upon weight and these are summarised in Table 2.1

Table 2.1: Reasons why people with Type 1 Diabetes who enjoy greater dietary freedom may gain or lose weight	
Gain weight	Lose weight
• Eating more or larger food servings • Eating food higher in calories than normal ie chocolate or cakes • Forgetting about healthy eating principles – concentrating on carbohydrates only • Efficient glucose storing with better insulin match • Higher total dose of insulin	• Less total insulin • Fewer snacks • Skipping meals or eating smaller portions • Eating to hunger rather than to treat hypoglycaemic events • Treat hypoglycaemic events appropriately • Feel well therefore do more exercise

Table 2.1: Reasons why people with type 1 diabetes who enjoy greater dietary freedom may gain or lose weight ***(Emma Jenkins, 2006)***

There is limited published research available assessing the effects of these courses upon weight/BMI. As previously reported the original DAFNE trial was reported as showing 'a fall of 1% in HbA1c and quality of life, without increasing hypoglycaemia or mean weight gain. A study published in 2008 evaluated two strategies for determining appropriate dosage of mealtime insulin and found weight gain was a problem in both groups. A simple algorithm that adjusted meal time insulin dose based on weekly average pre-meal glucose levels was compared with an algorithm based on carbohydrate counting as taught in the DAFNE style programmes. Interestingly, both groups achieved equivalent reductions in glycaemic control, although effects upon weight were different. Over the course of the 24 week study period both of the groups gained weight with the carbohydrate counting group gaining 2.3% compared with a 3.4% difference in the algorithm group. The 1% difference did not reach significance over the 6 month period as the study was not adequately powered to reach significance (Bergenstal et al, 2008). However, this level of weight gain over time could be significant and have an adverse effect (Davis & Wylie Rosett, 2008). In 2008 the Diabetes Education Network which was founded in 2003 to support diabetes teams in developing programmes, assessed results from 209 patients who had attended courses across seven UK centres and found no significant difference in weight from baseline to one year follow up (Everett, 2008). Due to the concerns around weight gain in diabetes management, it is now recognised as pertinent for local programmes to assess effects of weight alongside HbA1c and quality

of life benefits in order to ensure that the programmes do not cause weight gain. This study will therefore aim to identify the effects of the '4-step' programme upon body weight.

2.8 Carbohydrate counting and insulin dose adjustment and Quality of Life

Patients with diabetes face many challenges. These include changes in lifestyle and the possibility of developing debilitating and life-threatening complications which can induce stress and fear. Many have to cope with sexual dysfunction and in a study by De Berardis et al, (2002), 45.6% of diabetic patients with frequent erectile dysfunction reported severe depressive symptoms. In a cross-sectional case-control study in Canada, eating disorders were more prevalent in diabetic subjects (10%) than in non-diabetic controls (4%), ($p=0.001$) (Jones et al, 2000). According to a number of cross-sectional studies Type 1 diabetes is associated with a high prevalence of psychiatric disorders (Petrak et al, 2003). There is also increasing evidence of a link between psychiatric disorders and poorly controlled diabetes (Lustman et al, 2000) with patients caught in a trap of depression and worsening glycaemic control. In 2001 a meta-analysis by Anderson et al, assessing the prevalence of co-morbid depression in adults with diabetes, found that the presence of diabetes in fact doubles the odds of co-morbid depression in those studies which contained a control group of non-diabetic subjects (48% of studies). The review used odds ratios to assess the rate and likelihood of depression as a function of type of diabetes, sex, subject source, depression assessment method and study design. In the controlled studies the results did not differ by gender, type of diabetes, subject source or assessment method, although in the uncontrolled studies, the prevalence of comorbid depression was 28% higher in diabetic women than in diabetic men. Systematic reviews are known to be prone to publication bias which can limit generalizability, although depression was not the principle focus of many included studies. However some of the studies contained very small sample sizes and some were not population based which can influence the stability of the findings. Although the authors were unable to carry out a multivariate analysis controlling for all potential moderators, the odds ratios were uniformly similar in the tests suggesting that the two-fold increased likelihood of depression associated with diabetes is fairly robust and generalizable (Anderson et al, 2001).

Following the establishment of a link between depression and diabetes, a further relationship with glycaemic control was demonstrated in 2000 in a meta-analysis by Lustman and colleagues and published in Diabetes Care. Thirty one studies were divided into cross-sectional studies (n+26) and RCT's (n+5) and due to the RCTs being found to be heterogeneous they were not subjected to meta-analysis, leaving the 26 cross-sectional

studies to be examined. Depression was found to be significantly associated with hyperglycaemia ($p<0.001$). Although the effect size of 0.17 demonstrates that depression accounts for a small amount (3%) of the variance in blood glucose levels, this would be of significance in clinical practice. And as would be expected there was found to be no difference between Type 1 and Type 2 populations which showed similar effect sizes.

In recognition of the strong associations between diabetes and psychiatric co-morbidities, personal empowerment of patients is being seen in recent years as increasingly important in the treatment of diabetes in terms of improving quality of life. In the White Paper entitled Our Healthier Nation: Choosing Health (Department of Health, 2004) emphasis was placed upon the importance of personal choice in achieving good health. According to the National Service Framework for Diabetes: Delivery Strategy (Department of Health & Diabetes UK, 2003), "patient empowerment and a person-centred approach should be a key part of successful treatment, as there is much evidence to show that these improve both clinical outcomes and quality of life". Recommendations include the provision of support and structured education alongside medication and clinical care as required, of which a main aim is to enable those with diabetes to self-manage their lifestyles and their diabetes. Improving psychosocial outcomes and therefore quality of life are now widely accepted as key goals in diabetes and these are linked to patient centred education which emphasises patient autonomy and empowerment, shared decision making and shared care. Whereas, as previously discussed, the longer term sustained benefits of glycaemic control are in question, the evidence that self-management education improves quality of life and psychological wellbeing is well supported in the literature. A systematic review published in Psychology, Health & Medicine in 2007, described empowerment as 'helping patients discover and develop the inherent capacity to be responsible for one's own life. (Debono et al, 2007). The DAFNE (2002) Trial previously discussed, used a Diabetes Treatment Satisfaction Questionnaire to assess total treatment satisfaction. The mean difference in questionnaire scores between groups at 6 months was 8.75 ($p=0.001$), with the immediate group demonstrating greater satisfaction levels with diabetes treatment. Similarly, in 2008 the Diabetes Education Network mentioned previously, found quality of life scores from the

PAID (problem areas in diabetes) questionnaires improved significantly over one year from baseline ($p<0.001$).

Improvements in quality of life for the patient with diabetes are now considered paramount in diabetes care and all current studies indicate that carbohydrate counting interventions improve service satisfaction levels for the patient, offer a more positive diabetes experience for the patient, increase patient confidence and ultimately patient empowerment

2.9 Group vs Clinic – comparing educational models

As previously outlined, the NSF (2003) highlights the necessity to offer structured education to all patients with diabetes. The guidance also highlights the need to individualise education to meet different learning styles. Similarly, health professionals should identify the need to offer a flexible approach in order that all patients can access self-management education. The '4-Step' programme was designed with this in mind and offers patients a choice of individual and group education which are different in their approach. As demonstrated there is much evidence demonstrating that structured education among diabetes patients is effective in improving knowledge, blood glucose control, and psychological well-being (Department of Health & Diabetes UK, 2005) and there is some evidence to suggest that group education is a more effective format than one to one clinics (Norris et al, 2002). Whilst it is important to continue to offer a variety of educational formats, it could be useful to explore levels of effectiveness in both methods of delivery, with the aim of improving future service delivery.

In line with clinical audit guidelines, this study will seek to measure the effects of Aintree's 4-Step programme upon HbA1c, Weight, Quality of life and Hypoglycaemia Awareness. It will also assess the effectiveness of both groups and individual clinics.

Chapter Three

Methodology

3 Methodology

3.1 Design

This service evaluation was carried out at Walton Diabetes Centre, at Aintree University Hospital Trust in Liverpool, assessing a total of 52 patients attending the four week '4-Step' education programme for carbohydrate counting & insulin dose adjustment, to assess the effectiveness of the programme in terms of HbA1c, Weight, Quality of life and Hypoglycaemia awareness levels. The programme was offered in two formats, being group education and one to one joint clinics and patients were enrolled according to their convenience and preference.

3.2 Population & Subjects

The Aintree '4-Step' programme is a rolling programme and the data collection is an on-going process for monitoring effectiveness. Criteria for the '4-Step' programme includes all male and female adults with Type 1 Diabetes on multiple daily injections of insulin, aged 16 and over. Those excluded from data collection include those undergoing renal dialysis or chemotherapy/radiotherapy, those on weight management programmes and those receiving nutrition support, due to confounding effects upon weight and glycaemic control. For the service evaluation, data was collected from fifty two patients attending the programme over a period of approximately six months and analysed retrospectively. Gender and ages of participants are outlined below

Gender	Male	n=20
	Female	n=32
Age	Mean age	39 (23-61)

Table 3.1 Patient demographics

At visit one all patients were made aware of the on-going data collection for audit purposes and were given the opportunity to opt-out if they wished. In this case HbA1c and weight were still recorded as these are a necessary part of routine clinical care, although participation in questionnaires was not mandatory. The programme was four weeks duration and patients were followed up three months after completion of the programme. For those participating in data collection all measurements were repeated at the follow up visit three months after completion of the programme.

3.3 Procedures

The four week '4 Step' programme is delivered in two formats which are group and one to one clinics and patients have a choice of preference. The sessions are delivered by a diabetes specialist dietitian and a diabetes specialist nurse. The intervention includes one follow-up appointment at three months after completion of the programme. Prior to commencing the programme patients are seen by the specialist dietitian in an 'assessment clinic' in order to determine whether the referral is appropriate and explain the outline of the programme. All patients are given detailed information about the pros and cons of carbohydrate counting and insulin dose adjustment and the level of work and commitment involved. Patients are then offered a choice of either group education or one to one clinics and enrolled as appropriate. At this stage the service evaluation and data collection are discussed with the patient and verbal permission is obtained for the collection of data at the start of the programme and again at the follow up appointment three months after completion, with four months between measurements. The process is as follows.

The '4-Step' education sessions are structured as follows:

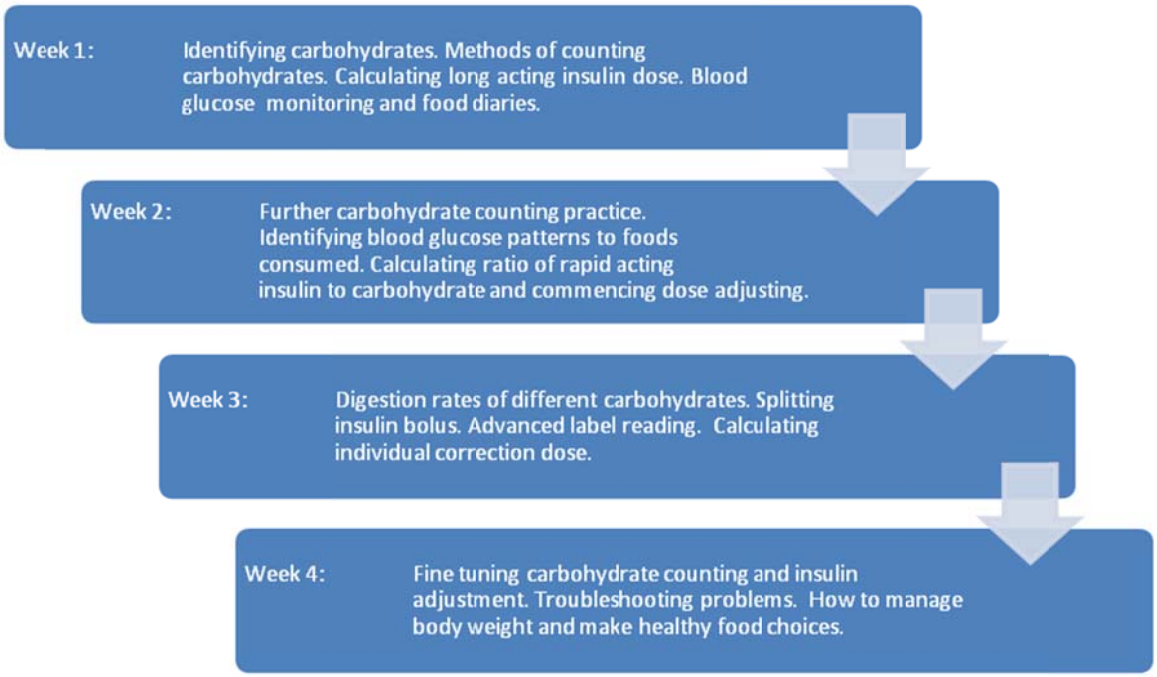
<u>Group education:</u>

- Maximum of eight patients per group
- Three hours per week for 4 weeks
- Total contact time is 12 hours

Clinic education:

- Individual patient education
- Forty minutes per week for 4 weeks
- Total contact time is 3 hours 40 minutes

Programme structure:



Group sessions are designed to include a variety of media and encourage patient participation and include talks, practical demonstrations, hands-on practical activities, group discussions and home work. A variety of media are included to allow for different learning styles and these include, powerpoint, flip chart, group activities such as weighing foods and reading labels, over-head projectors and individual workbooks. Patient participation is actively encouraged and the group size of 6 to 8 patients lends itself to an interactive approach. Clinic sessions are also interactive and use incorporate different learning styles, although in clinics there are greater time constraints.

3.4 Measurements

Measurements taken at baseline and repeated after four months	
HbA1c	Blood test documented on Medway and in case notes
Weight	Weight documented on Medway and in case notes
Quality of life	Problem Areas in Diabetes (PAID) questionnaire (Appendix 2)
Hypoglycaemia awareness	Hypoglycaemia Awareness (R-values) questionnaire (Appendix 3)

Table 3.2 Measurements

HbA1c is used to assess glycaemic control. It measures levels of exposure to glucose and subsequent protein glycosylation in percentage terms over a period of 8 to 12 weeks. (Jeffcoate, 2003). HbA1c is measured in all patients who attend the diabetes clinic, is taken on site according to normal clinic protocol and results are entered by the laboratory onto the 'Medway' computerised patient information system which is accessible to all clinical staff as well as onto the medical case note. Weight is also recorded at every clinic visit and entered into the medical case note.

Two questionnaires were used to assess quality of life and hypoglycaemia awareness. The 'Problem Areas in Diabetes' (PAID) questionnaire was used to assess quality of life with diabetes (Polonsky et al, 1995) initially and at three months follow up. Cross sectional questionnaires are objective methods used to collect data about people's experience and behaviours (Boynton & Greenhalgh, 2004) and are an accepted technique for assessment of healthcare treatments and patient satisfaction (Winocour et al, 2002). However, they can be limited by their sensitivity. For example if a generally high level of satisfaction is recorded it can be difficult to distinguish the factors that contribute to the satisfaction (Stanga et al, 2003) and in order to accurately assess patient opinion of quality of care, it is preferable for validated measures of patient satisfaction to be used. Continuous responses rated on a five to seven point Likert scale as found in the PAID questionnaire allow for discrimination between levels of satisfaction that cannot be achieved with closed questions which have categorical answers.

The Problem Areas in Diabetes (PAID) Scale is a fully validated self-reported measure of psychosocial adjustment specific to diabetes. It consists of a twenty item questionnaire with scores from 0-4 for each item and a highest possible score of 80 points per questionnaire (Appendix 2). High scores indicate more severe problems and the resource is used as a measure of diabetes distress (Polonsky et al, 1995). Patients' own

assessment of their diabetes experience is important. Dr. William Polonsky, a researcher in diabetes-related stress at the Joslin Diabetes Centre suggested that 'when assessing health-related quality of life, one should consider the patient's views of his own health and wellbeing in the areas of physical, psychological and social functioning'. A study published in 2003 measured the responsiveness (sensitivity to change over time) of the PAID tool by extracting data from seven diabetes intervention studies and concluded with strong support for its effectiveness (Welch et al, 2003). The tool was therefore chosen due to its comprehensive assessment of all these factors, as well as demonstrating high internal reliability and good item-to-total correlations.

The Hypoglycaemia Awareness Scale is a validated questionnaire used to help patients identify their levels of awareness using a series of eight questions. Patients score a series of eight questions with either an 'A' or 'R' response to each (see Appendix 3). Each answer carries an 'A' or 'R' score with a maximum of seven 'R' responses (0-7). A score above four 'R' responses indicates 'reduced hypoglycaemia awareness' (Clark et al, 1995). This tool is one of three methods which have been proposed to assess awareness of hypoglycaemia for clinical application. A cohort study sought to test the accuracy of the three methods in detecting reduced hypoglycaemia awareness. Eighty patients completed all three questionnaires whilst at the same time carrying out regular blood glucose monitoring and the Hypoglycaemia Awareness Scale (Clark et al, 1995) was found to have a strong level of accuracy in identifying impaired awareness ($p=0.001$) and was therefore recommended for use in routine clinical care (Geddes et al, 2007).

3.5 Data Management & Analysis

Statistical analysis

Statistical analysis was carried out using SPSS version 16.0 for windows (SPSS, Chicago, Ill., USA).

Descriptive statistics were used to explore the data initially followed by the use of appropriate graphs to identify trends or differences. The data is presented as mean, and standard deviation.

This was followed by the use of inferential statistics as a series of dependent (repeated) t-tests assuming the data had met the assumptions of normal distribution. These were reported by the letter 't'. If the data failed to meet this assumption, a non-parametric test,

Wilcoxon Signed Ranks test was used and reported by the letter ‘z’. Data was analysed for normal distribution using histograms (Appendix 4). All statistical analysis was assessed at the 0.05 level ($p=<0.05$, CI 95%).

Assessment of Weight and HbA1c in the total population (n=52), revealed a normal or ‘Gaussian’ distribution, meaning that the distribution of the measures in each group were even or ‘normal’ based upon sample size. Therefore paired sample t-tests were chosen.

Assessment of the ranked data in the Hypoglycaemia Awareness Questionnaires and Quality of life (PAID) questionnaires revealed non-normal distribution. Furthermore these represent an ordinal scale of measurement and therefore Wilcoxon Signed Ranks test was chosen for correctness.

Comparing groups with clinics required ‘splitting’ the population into smaller samples (n=30 and n=22) and histograms revealed skewness in the data (Appendix 4). Wilcoxon Signed Ranks test was used to reduce inaccuracy.

Chapter Four

Results

4 Results

4.1 Subject characteristics

For the service evaluation, data was collected from fifty two patients attending the programme over a period of approximately six months and analysed retrospectively (see data collection form Appendix 5).

Criteria for the '4-Step' programme included all male and female adults with Type 1 Diabetes on multiple daily injections of insulin, aged 16 and over. In order to reduce confounding factors patients with certain conditions were excluded from data collection. These included, patients receiving nutrition support, those on chemotherapy/radiotherapy, those on renal dialysis, those who were pregnant, or those on weight management programmes/medications.

Data was collected over a period of six months with all qualifying patients being given the option of opting out of data collection. By the end of six month, a total of fifty two patients had enrolled and all agreed to data collection. There were thirty two females and twenty males who participated in the programme, with a mean age of thirty nine and an age range of twenty six to sixty one. Thirty patients preferred group sessions and twenty two patients preferred clinic sessions.

All fifty two patients completed the programme and attended follow up. This is in part due to the high demand for the programme, coupled with the '4-Step' assessment clinic, the purpose of which is to explain the commitment required and offer patients a 'drop-out' option if required, prior to commencing the programme. This results in very low levels of non-attendance.

Results are displayed with each outcome measure in the total population, followed by the same outcome comparison between groups and clinics. Histograms can be found in Appendix 4, data collections in Appendix 5 and statistical output in Appendix 6.

4.2 Results

The primary aim of this study was to assess the effects of the '4-Step' programme on HbA1c, Weight, Quality of Life and Hypoglycaemia awareness before and after the '4-Step' programme (n=52). The secondary aim was to assess whether differences occurred in those undergoing 'group' education (n=30) as opposed to those undergoing 'clinic' education (n=22).

In line with the stated hypothesis, in the total population there were marked improvements in the mean values of the patients' HbA1c and Quality of life scores after the '4-Step' programme, and no significant change in weight. However, contrary to expected outcomes, there was no improvement in Hypoglycaemia awareness (see Table 4.1). Group and clinic data demonstrated that group education was more likely to improve psychosocial outcomes such as Quality of life and Weight and clinics were more likely to improve clinical outcomes such as HbA1c and Hypoglycaemia awareness.

Clinical Outcome	Clinical goal	Baseline	After Intervention	Change	P value
HbA1c (%)	Percentage reduction	9.33% ± 1.43	9.04% ± 1.33	0.29%	(p=0.008)
Weight (kilograms)	Weight reduction or maintenance	77.50 kg ± 2.14	77.02 kg ± 2.09	0.5 kg	(p=0.100)
Problem areas in diabetes (Score 0-80)	Reduction in score	Score 28 ± 18.81	Score 19 ± 14.62	-9	(p=0.000)
Hypoglycaemia awareness (Score 0-7)	Reduction in score	Score 1.58 ± 1.57	Score 1.33 ± 1.45	0.25	(p=0.052)

Table 4.1: Mean clinical and psychological outcomes before and after the '4-Step' programme (presented as mean ± SD) in total population

HbA1c in total population

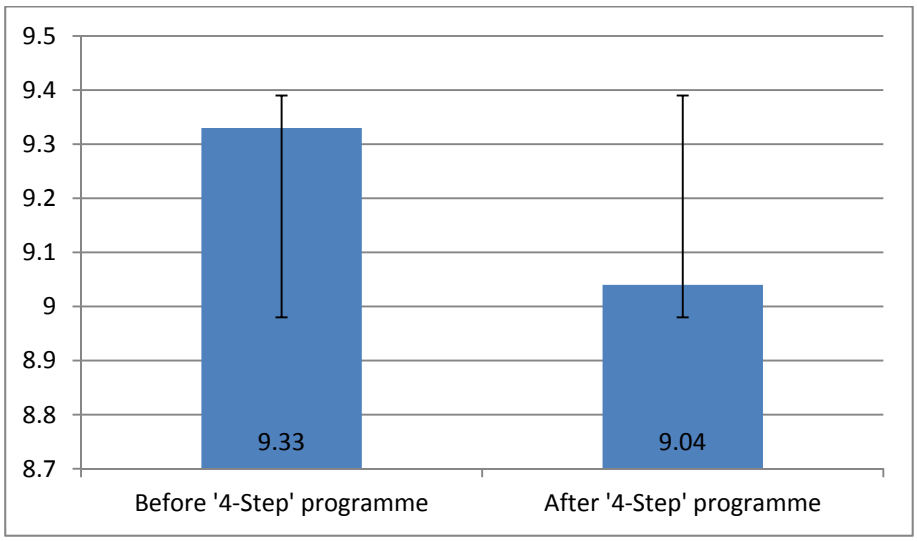


Figure 4.0 Mean HbA1c (as %) at baseline and following '4-Step' programme in total population

Positive improvements in HbA1c from baseline to four months follow up were observed in the total population (n=52). Mean HbA1c at baseline was 9.33% ± 1.43 and this dropped to 9.04% ± 1.33 following the '4-Step' programme (Figure 4.0).

The '4-Step' programme improved HbA1c levels by 0.29%. This was statistically significant (t=2.749, p=0.008).

HbA1c in groups and clinics

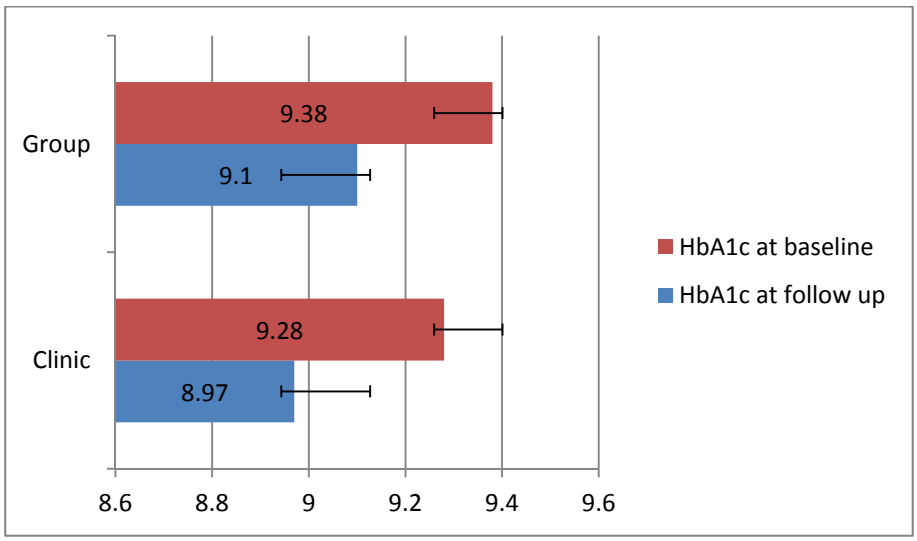


Figure 4.1 Mean HbA1c (as %) at baseline and following '4-Step' programme in groups and clinics

Group: Positive improvements in HbA1c from baseline to four months follow up were observed in those undertaking group education (n=30). Mean HbA1c at baseline was 9.38% ± 1.52 and this dropped to 9.10% ± 1.45 following the '4-Step' programme (Figure 4.1).

The '4-Step' programme improved HbA1c levels by 0.28% in those undergoing group education and this was not statistically significant (z=-1.592, p=0.111).

Clinic: Positive improvements in HbA1c from baseline to four months follow up were observed in those undertaking joint clinic education (n=22). Mean HbA1c at baseline was ± 1.32 and this dropped to 8.97% ± 1.16 following the '4-Step' programme (Figure 4.1).

The '4-Step' programme improved HbA1c levels by 0.31% in those undertaking joint clinic education and this was statistically significant (z=-2088, p=0.037).

Weight changes in total population

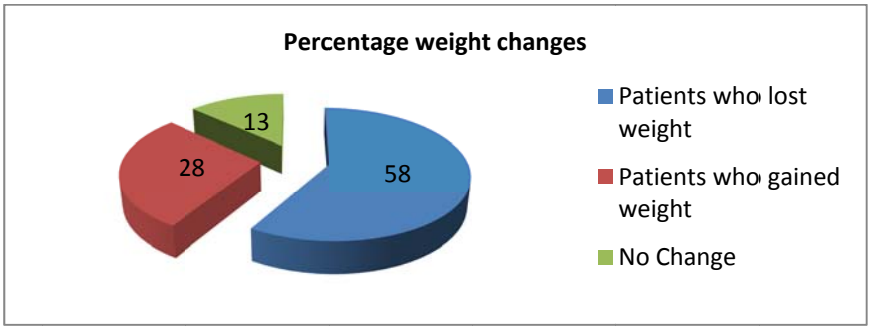


Figure 4.2 Numbers of patients who lost, maintained and gained weight (n=52)

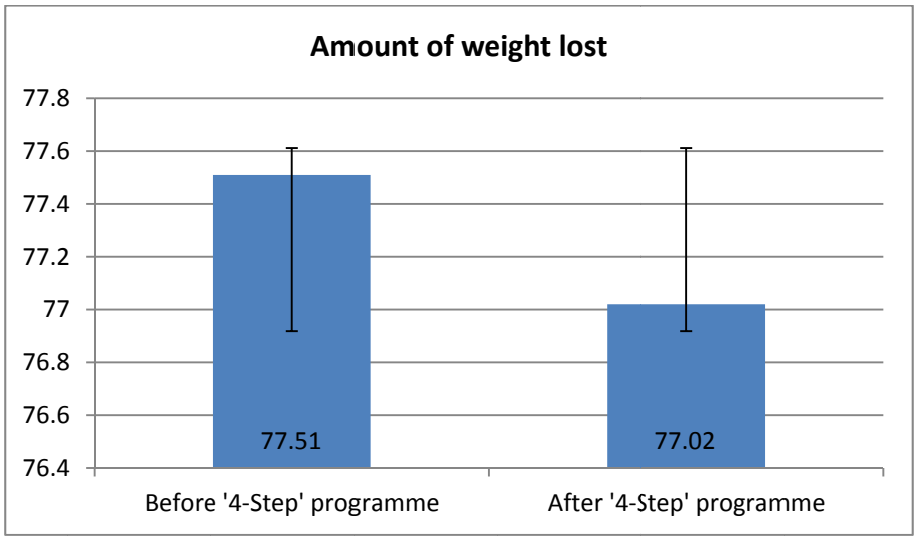


Figure 4.3 Mean weight (kg) at baseline and following '4-Step' programme in total population (n=52)

Total mean weight loss of 0.49 kg from baseline to four months follow up was observed in the total population (n=52). Mean weight at baseline was 77.51 kg ± 2.14 and this dropped to 77.02 kg ± 2.09 following the '4-Step' programme.

The '4-Step' programme resulted in 0.49 kg weight loss. This was not statistically significant (t=1.676, p=0.100).

Weight changes in groups and clinics

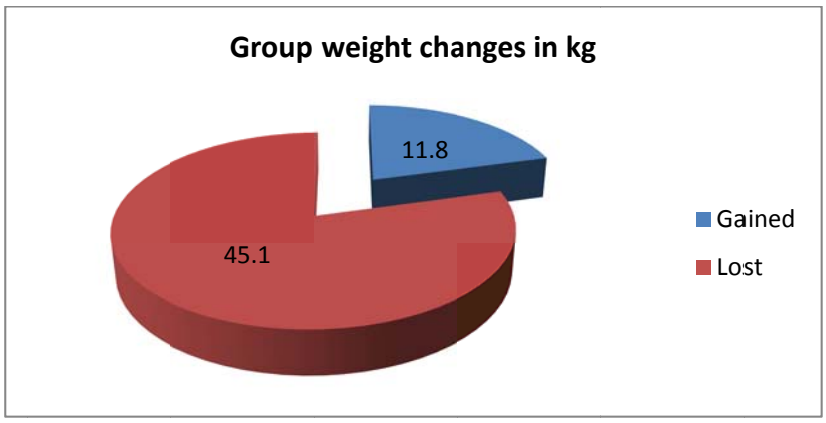


Figure 4.4 Weight changes in those attending groups

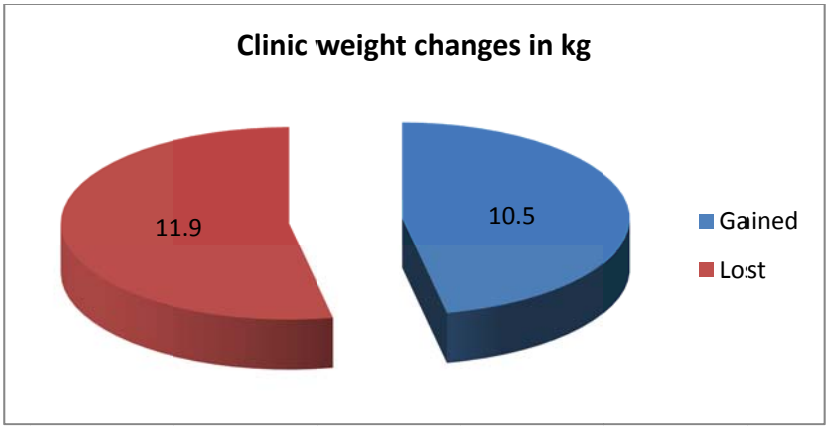


Figure 4.5 Weight changes in those attending clinics

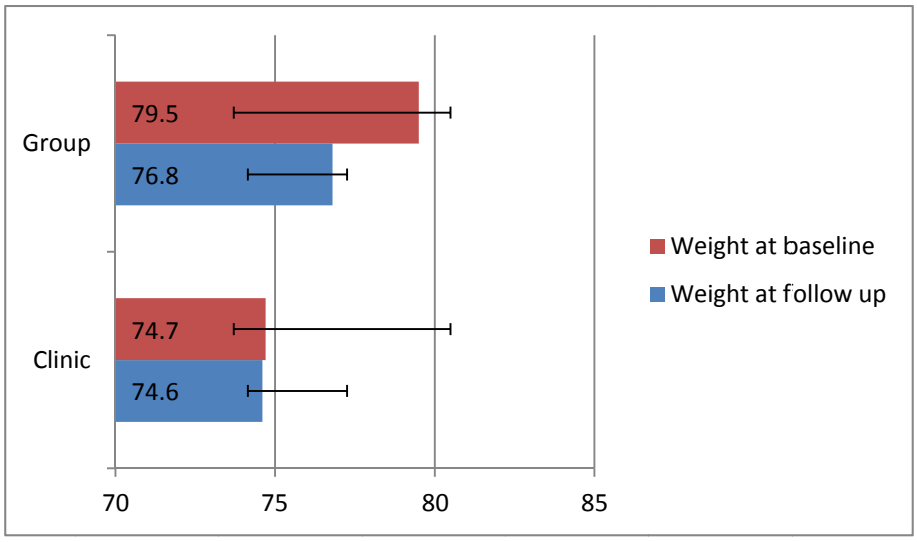


Figure 4.6 Mean Weight (kg) at baseline and following '4-Step' programme in groups and clinics

Weight changes in groups and clinics

Group Weight reduction was observed from baseline to four months follow up in those undertaking group education (n=30). Mean weight at baseline was 79.5 kg ± 13.02 and this dropped to 76.8 kg ± 12.80 following the '4-Step' programme (Figure 4.6).

The '4-Step' programme did result in weight loss in those undergoing group education and this was statistically significant (z=--2.012, p=0.043).

Clinic Weight reduction was not observed from baseline to four months follow up in those undertaking clinic education (n=22). Mean weight at baseline was 74.7 kg ± 12.34 and this dropped to 74.6 kg ± 12.30 following the '4-Step' programme (Figure 4.6).

The '4-Step' programme resulted in weight reduction in those undertaking joint clinic education and this was not statistically significant (z=-.776, p=0.438).

Quality of Life in total population

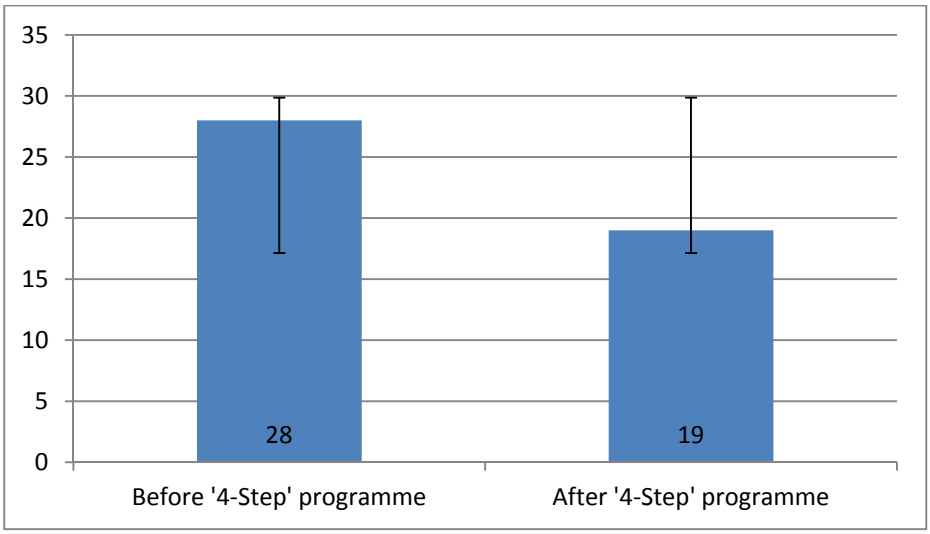


Figure 4.7 Mean Quality of life scores at baseline and following '4-Step' programme in total population

Positive improvements in Quality of Life from baseline to four months follow up were observed in the total population (n=52). Mean problems areas in diabetes (PAID) score at baseline was 28 ± 18.81 and this dropped to 19 ± 14.62 following the '4-Step' programme (Figure 4.7).

The '4-Step' programme improved problem areas in diabetes (PAID) scores by 9 points. This was statistically significant (z=-5.177, p=0.000).

Quality of Life in groups and clinics

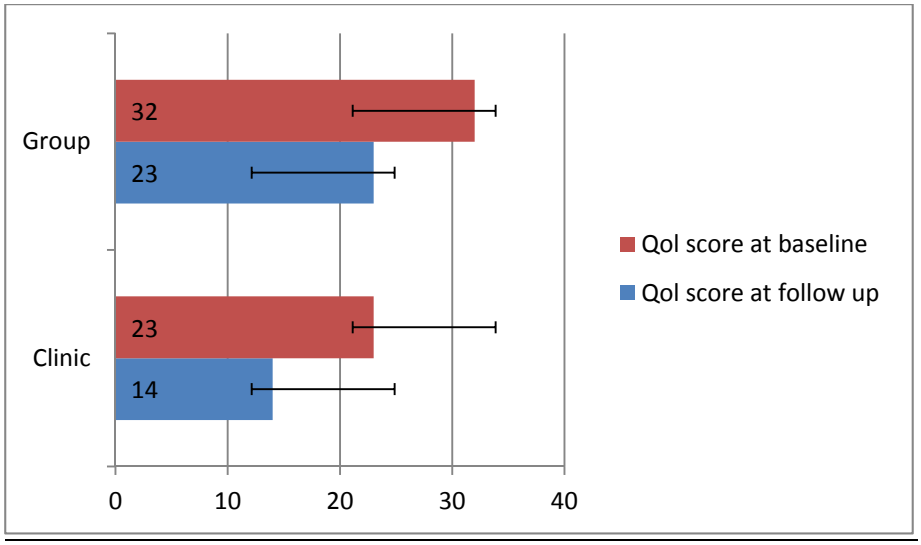


Figure 4.8 Mean Quality of Life scores at baseline and following the '4-Step' programme in groups and clinics

Group: Positive improvements in Quality of Life from baseline to four months follow up were observed in those undertaking group education (n=30). Mean problem areas in diabetes (PAID) scores at baseline was 32 ± 17.53 and this dropped to 23 ± 13.53 following the '4-Step' programme (Figure 4.8).

The '4-Step' programme improved Quality of Life in those undergoing group education and this was statistically significant (z=-4003, p=0.000).

Clinic: Positive improvements in Quality of Life from baseline to four months follow up were observed in those undertaking joint clinic education (n=22). Mean problem areas in diabetes (PAID) score at baseline was 23 ± 18.90 and this dropped to 14 ± 15.12 following the '4-Step' programme (Figure 4.8).

The '4-Step' programme improved Quality of Life in those undertaking joint clinic education and this was statistically significant (z=-3.201, p=0.001).

Hypoglycaemia Awareness in total population

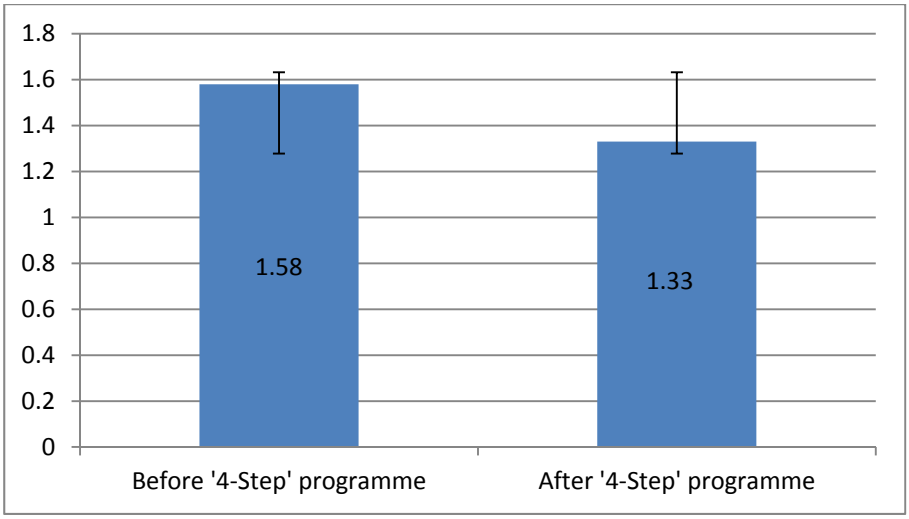


Figure 4.9 Mean Hypoglycaemia Awareness score at baseline and following '4-Step' programme in total population

Hypoglycaemia awareness scores dropped by 0.25 points from baseline to four months follow up in the total population (n=52). Mean score at baseline was 1.58 ± 1.57 and this dropped to 1.33 ± 1.45 following the '4-Step' programme (Figure 4.9).

The '4-Step' programme resulted in a reduction in hypoglycaemia awareness scores of 0.25 points and this was not statistically significant (z=-1.945, p=0.052).

Hypoglycaemia awareness in groups and clinics

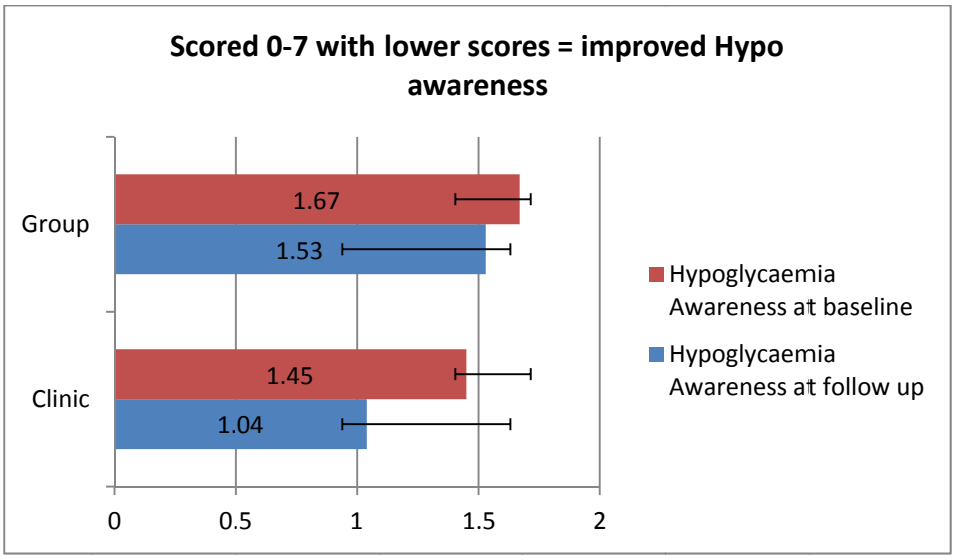


Figure 4.10 Mean Hypoglycaemia awareness score at baseline and following '4-Step' programme in groups and clinics

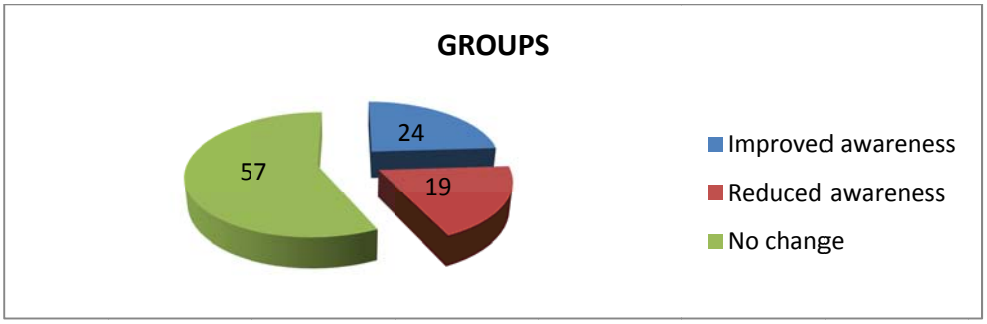


Figure 4.11 Percentage changes in Hypoglycaemia awareness in groups

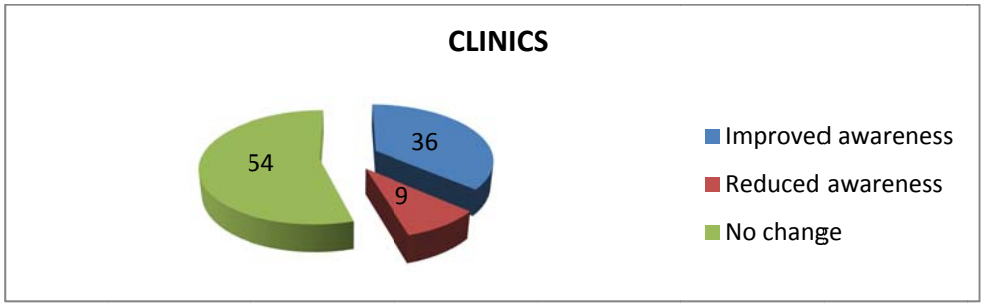


Figure 4.12 Percentage changes in Hypoglycaemia awareness in clinics

Hypoglycaemia Awareness in groups and clinics

Group Positive improvements were observed in Hypoglycaemia awareness scores from baseline to four months follow up in those undertaking group education (n=30). Mean score at baseline was 1.67 ± 1.68 and this dropped to 1.53 ± 1.71 following the '4-Step' programme (Figure 4.10).

The '4-Step' programme did improve Hypoglycaemia awareness in those undergoing group education although the result was not statistically significant (z=--0.825, p=0.409).

Clinic: Positive improvements Hypoglycaemia awareness scores from baseline to four months follow up were observed in those undertaking joint clinic education (n=22). Mean score at baseline was 1.45 ± 1.45 and this dropped to 1.04 ± 0.95 following the '4-Step' programme (Figure 4.10).

The '4-Step' programme improved Hypoglycaemia awareness in those undertaking joint clinic education and this was statistically significant (z=-1.998, p=0.046).

Chapter Five

Discussion

Discussion

5.1 Overview

Aintree Hospital's '4-Step' programme was developed to offer patients with Type 1 Diabetes structured patient education by training in carbohydrate counting and insulin dose adjustment. The aims of the programme include improving HbA1c, Quality of life and Hypoglycaemia awareness, without causing weight gain.

Data was collected from fifty two patients attending the programme over a period of approximately six months and analysed retrospectively. Those excluded from data collection included patients undertaking weight reducing programmes, those on chemo/radiotherapy, those undergoing renal dialysis and patients receiving nutrition support, due to the potential confounding influence upon weight gain and glycaemic control.

The programme was offered in two formats and following attendance at the assessment clinic, patients were offered a choice of either group education or individual clinics with each programme offering the same education in a different method of delivery. Initial data collection was carried out just prior to patients commencing the four week programme and repeated three months after completion of the programme, with a total of four months between measurements.

In line with National Service Framework recommendations (2003) that structured education programmes should be audited to assess for effectiveness and enable quality control, this study tested the effects of the '4-Step' programme in HbA1c, Weight, Quality of Life, and Hypoglycaemia awareness in the total sample of 52 patients. The study also looked for outcome differences in terms of group education and individual education in samples of 30 and 22 patients respectively.

5.2 Summary of major findings

The study demonstrated that in line with NSF Guideline (2003) Aintree Hospital's '4-Step' programme delivers real benefits to patients with Diabetes in terms of clinical and non-clinical outcomes and is an effective structured education tool. When comparing results in the total population (n=52), in line with our stated hypothesis, the study revealed that the '4 step' programme could significantly lower HbA1c levels (p=0.008)

and improve Quality of life (p=0.000), without increasing weight gain (p=0.100). However, contrary to our hypothesis, Hypoglycaemia awareness (p=0.052) did not

improve as a result of the programme (p=0.052). Interestingly, when comparing results in groups and individual clinics, patients in clinics were found to significantly improve HbA1c (p=0.037) and Hypoglycaemia awareness (p=0.046), although this was not reflected amongst patients in group sessions. Quality of life improved significantly in both groups (p=0.000) and clinics (p=0.001) and weight gain only benefitted those undergoing group education (p=0.043). The only aspect to change in both groups and clinics was Quality of life with equally significant improvements in both.

5.3 Discussion

HbA1c

The study demonstrated an overall reduction of 0.29% in HbA1c (p=0.008) which is in line with previously mentioned regional programmes (Griffiths & Turner, 2008) and our expected outcome that HbA1c would improve following the programme. The previously mentioned meta-analysis by Norris et al (2002) showed that average decrease in HbA1c one to three months after intervention was a similar 0.26%. This is in contrast with the UK based randomised controlled trial (DAFNE Study Group, 2002) which showed that patients enrolled in the DAFNE programme decreased their HbA1c values by 1% six months after the intervention (p=0.001,). However, at twelve months follow up this benefit had reduced to 0.5% (p=0.001). The duration of the '4-Step' programme against the DAFNE programme may in part explain the lower percentage decrease in HbA1c values in our study. The '4-Step' programme is taught over 3.5 to 12 hours depending upon group or individual format and the DAFNE programme is taught as a full time five day programme, teaching over 35 to 40 hours. This study demonstrates that significant changes can occur in a less cost intensive 'DAFNE equivalent' programme of shorter duration. However, the greater HbA1c reduction achieved by the DAFNE programme could be due to its more intensive structure and duration.

High baseline HbA1c values are not unusual in acute diabetes settings. Although they can highlight irregular compliance with diet and insulin this is by no means always the case. Patients can have varying levels of insulin resistance which will influence their response to carbohydrate counting. In this study, differences in HbA1c values may have been influenced by patients' individual approaches to carbohydrate counting education. Whilst many patients are conscientious, weighing and measuring food with great care, others preferred to 'guess' carbohydrate values. Some are careful to utilise additional injections

of insulin for larger snacks while others refuse additional injections. Whilst it is beyond the remit of this study to control or measure patient carbohydrate practices, this could of course influence results. It is important to mention that although the result in HbA1c % may seem small, even minor improvements in HbA1c after implementation of an intervention programme are considered by medical teams to be clinically significant (Young et al, 2007 & Pibernik-Okanovic et al, 2009). Indeed, studies have shown that even with minimal decreases in HbA1c values, patients report increased well-being and important psychological benefits (Nutbeam et al, 2000 & Bernheimer et al, 2002) and the DCCT (1993) linked small changes in HbA1c to long term microvascular and macrovascular benefits as well as improved psychological benefits. The medical team at Aintree Diabetes Centre fully understand the importance of structured education in empowering patients and helping them take control of their condition.

HbA1c – Group and Individual comparisons

When comparing HbA1c outcomes among patients undergoing groups and clinics, it is interesting that HbA1c did not significantly improve in those in groups ($p=0.111$) although there was an improvement in those in individual clinics ($p=0.037$), which contradicts Norris's suggestions that groups are more effective than clinics in terms of outcomes (Norris et al, 2002). The finding appears to suggest that an individual approach to education may result in improved understanding and/or better practices when compared to the group sessions. Whereas group education allows more social interaction and 'practice' using real foods, clinical observation shows that individual education as offered in joint clinics allows a more tailored approach, especially in facilitating patients' understanding of some of the more complex aspects of carbohydrate counting. The difference in HbA1c, although significant, was minimal and the finding does not negate the need for group education which may offer other benefits as well as satisfying the need for patient choice. However, the result may highlight difficulties for patients in a group situation in fully understanding the complexities of carbohydrate counting and insulin adjusting.

W*eight*

As stated, one of the aims of diabetes management is maintaining weight within an appropriate range. Recent studies have highlighted that one of the challenges of insulin regimens is weight gain (Bergenstal et al, 2008 & Davies & Wylie-Rosett, 2008). Due to the nature of the '4-Step' intervention, which allows greater food freedom, weight can be expected to increase or decrease depending upon a number of factors. One factor which Jenkins (2006) identifies as being contributory to patient's gaining weight was the

tendency to have larger food servings due to now having the ability to adjust insulin dose accordingly. Similarly, more high calorie snacks could be included as long as these are covered with additional insulin. She also pointed out that these patients concentrate on carbohydrates only and would forget healthy eating principles. Similarly, patients might also develop better glucose storing coupled with a better insulin match. Correspondingly, patients may lose weight due to the process of keeping food diaries and developing greater awareness of their diet. Patients who lose weight, according to Jenkins (2006) are those who have practised the knowledge they gained during the structured education programme. For instance, these patients now practise eating smaller portions of food or they begin to skip meals. They have also learned to appropriately treat hypoglycaemic events, use less total insulin and psychologically feel well (Jenkins, 2006).

Whilst weight loss would be desirable, the goal of this study was to ensure that teaching a programme which involves greater food freedom should not result in significant weight gain. Results were encouraging, with no significant change in weight at four months follow up ($p=0.100$) for the total group. This was in line with the finding of the Diabetes Education Network at one year follow up (Everett, 2008) which reported no weight change, and in line with our hypothesis that the programme would not lead to weight gain. However, whilst it could be assumed that there was no overall weight loss benefit, closer scrutiny of the data showed that the mean weight of patients before the '4 step' programme was 77.5 kg, which decreased to 77.02 kg three months after intervention resulting in a 0.48kg overall weight loss. In this study, fifty eight per cent of the population lost an average of 1.74 kg while twenty eight per cent gained an average of 1kg and thirteen per cent reported no weight change. Total weight lost was 52.3 kg and total weight gained was 28.0 kg and whilst the results failed to reach significance, it may be clinically significant and is reassuring that the trend is for weight loss rather than gain. It must be remembered that to patients any positive changes are beneficial, even if small. As stressed by Anderson et al (2010), "...the more goals patients attained, the more likely they were to improve or maintain their level of glycaemic control". Furthermore, weight is known to effect insulin resistance and even small amounts of weight loss are thought to improve glycaemic control. However, caution is needed in interpreting these results which differ from the study by Bergenstal et al (2008) which showed that over a twenty four week study period, all participants carbohydrate counting and insulin dose adjusting gained 2.4 kg compared to their baseline weights. Twenty four weeks is perhaps a more realistic time frame for weight loss changes and our short intervention may not reflect long term changes accurately.

Weight – Group and Individual comparisons

There was no significant difference in baseline weights and follow up weights for patients enrolled in individual sessions. However, patients in group sessions showed significant weight loss (p=0.043) after the intervention. It is difficult to explain why patients in group education sessions may have lost more weight than those in individual sessions. It may be due to the motivational qualities of a small group, where it is observed that people discuss diet, lifestyle and fitness regimes. Another explanation may be that unlike in clinic settings, patients in groups practice weighing and measuring foods which may increase portion awareness. However, identified study limitations may have caused bias and this is discussed further on.

Quality of life

Improvement in Quality of life was an important finding. Whilst improvement in HbA1c values are important in the clinical setting and are often considered the benchmark in determining the effectiveness of an education programme (Dinneen et al, 2009), it is becoming increasingly recognised that improvement in psychological well-being is a major health benefit which should also mark effectiveness of a teaching programme, standing equally alongside clinical outcomes. Statistical tests showed that Quality of life scores of the patients improved significantly in the total population (p=0.000) in line with our stated hypothesis. This study resulted in a 9 point change (p=0.000) in PAID scores, in line with the findings of the Diabetes Education Network where scores improved by 8.75 points and the DAFNE (2002) trial which also demonstrated significant improvements in paid scores (p=0.001).

As previously reported, Lustman et al (2000) linked poorly controlled diabetes to a high prevalence of psychiatric disorders. Further studies support this finding such as Anderson et al (2001) who found that the presence of diabetes could double the odds of co-morbid depression. While this study did not specifically investigate the levels of depression, the decrease in patients' Quality of life scores by nine points was highly significant, demonstrating that the '4 step' programme, even though of short duration, could significantly improve the well-being of patients. The positive change in Quality of life scores also demonstrates that the '4-Step' programme meets the National Service Framework for Diabetes Standard 3 (Department of Health, 2003), a very important guideline highlighting the need to increase patient autonomy in managing diabetes and thereby improving quality of life.

It may be that improvements in quality of life are linked to improvements in HbA1c as studies have shown that conservative changes to HbA1c values can result in patients' increased sense of well-being and self-esteem (Pibernik-Okanovic et al, 2009 & Dinneen et al, 2009). Patient feedback leads to the safe assumption that positive changes in quality of life can also be attributed to clinicians sharing greater knowledge and responsibility with the patient which in turn leads to increased patient autonomy in diabetes/lifestyle decisions and a more positive clinical experience. When evaluating the '4-Step' programme, comments received include "I feel in control of my diabetes for the first time", "why did no one teach me this years ago?" and "it's nice to make decision about adjusting my own insulin without having to ring the nurse all the time."

As mentioned previously, patient empowerment is a key goal in structured education outcomes and the results of this study suggest very significant improvements in patient empowerment and quality of life. Although it is clear that quality of life changes did occur which is a positive outcome of this study, it is difficult to make assumptions about the exact causes of the changes. Whereas the quality of life (PAID) questionnaire was assessed based upon a single score (0-80), closer analysis of the responses, which was beyond the remit of this study, could a useful way of determining the causes of change and thus would be a more useful tool for service development.

Quality of life – Group and Clinic comparison

Of those patients undergoing group sessions, seventy eight per cent demonstrated an improvement in quality of life ($p=0.000$) with thirteen per cent not showing any improvement. Of patients undergoing clinic education, seventy two per cent experienced a significant improvement in quality of life ($p= 0.001$) while twenty seven per cent did not show any improvement.

Both group and clinic sessions demonstrated highly significant changes in quality of life perhaps suggesting that the process of learning new skills to improve diabetes control and give greater autonomy is not dependent upon a particular learning format. This reinforces the belief that both group and individual education formats are useful vehicles for improving diabetes quality of life and should continue to be offered in line with maximising patient choice. In terms of effective use of resources, those attending group education average approximately 1.5 hours of clinical time per patient, whilst those attending individual sessions average 2.5 hours of clinical time. Groups are more

efficient in terms of use of clinicians' time and in view of the lack of additional benefits for those undergoing group education one could conclude that group education is the way forward. However, as previously stated the National Service Framework encourages health professionals to offer a wide variety of learning settings and styles which suit different learn needs.

Hypoglycaemia Awareness

On the hypoglycaemia awareness scale, a score of > 4 indicates reduced hypo awareness. Baseline hypoglycaemia awareness data of the patients in this study indicated a good level of awareness (mean= 1.57) and an expectation of this study had been to demonstrate a significant improvement in hypoglycaemia awareness after the '4-Step' programme as demonstrated by the Diabetes Education Network and some regional audits (Everett, 2008). However, although the scores improved slightly (mean 1.33), statistical tests failed to establish a significant improvement ($p=0.052$) in hypo awareness in the total population. It is notable that patients had relatively high hypoglycaemia awareness levels at the start of the intervention. While the improvement was minimal, the results of the study might be different if the sampled population had a lower awareness levels at baseline. It is unknown whether the sample was representative of the diabetes population in general who have long standing Type 1 diabetes as typical values of hypoglycaemia awareness are not quantified in the literature.

During the '4-Step' programme patients often report improvements in 'frequency' of hypoglycaemia as well as often being observed by the educators. Whilst it could reasonably be expected that the hypoglycaemia awareness data would reflect this change, indicating improved hypo sensitivity, unless frequency is measured statistically it fails to prove a real long term change, remaining instead a clinical observation. It is possible that frequency does improve and over time this would impact upon 'awareness' although this may not be evident during the short duration of the study, with a longer time period being needed to properly reflect changes in hypoglycaemia awareness. As previously suggested by McLeod (2000), "the best way of improving risk of hypoglycaemia unawareness is to improve risk of hypoglycaemia" as each episode of hypoglycaemia could potentially result in a lowering of the glycaemic threshold and an inadequate glucose response (Meneilly et al, 1994). Reduction in 'frequency' of hypoglycaemic events is immediately noticeable to the patient as is much valued by them, offering immediate benefits. Whilst this study measured hypoglycaemia awareness, many studies suggest frequency is of

greater clinical importance to both patients and health care practitioners (George et al, 2008, Hermanns et al, 2010, Mbaezue et al, 2010) and the DAFNE (2002) trial reported data for 'frequency' measurement rather than 'awareness'. It may therefore be pertinent to suggest that future evaluations of the '4-Step' programme especially if short-term, should measure frequency of hypoglycaemia rather than hypoglycaemia awareness. Furthermore, as with HbA1c data, a longer study period with follow up at three, six or twelve months may more accurately reflect changes in hypoglycaemia awareness.

Hypoglycaemia Awareness – Group and Clinic comparisons

Of patients undergoing group education, results revealed that whilst mean scores improved from 1.67 to 1.53 this failed to reach statistical significance (p=0.409). Twenty four per cent of the patients showed an improvement in hypoglycaemia awareness and awareness levels deteriorated in nine per cent of patients. Fifty seven per cent did not show any changes. Correspondingly, of those patients attending individual clinics hypoglycaemia awareness significantly improved (p=0.046) with thirty six per cent showing an improvement in awareness nineteen per cent experiencing reduced levels of awareness. Fifty four per cent did not show any changes.

As previously reported, this corresponds with that of differences in HbA1c between groups and clinics, with clinics reporting greater improvements in both HbA1c and hypoglycaemia awareness. Whilst there may be a suggestion that these findings are linked with the expectation that reductions in HbA1c would improve hypoglycaemia awareness, it seems premature to make these assumptions based upon this study. In order to satisfy this hypothesis, a study of longer duration with a larger sample size would be more conclusive, factoring in the identified study limitations.

Whilst the findings of this study suggest a discrepancy between group and clinic outcomes, with groups demonstrating better non-clinical benefits and clinics demonstrating better clinical benefits, assumptions should not be made without the benefit of further research. However, the study highlights factors which may influence outcomes according to mode of delivery and these are worth consideration when shaping the structure and content of the '4-Step' programme.

5.4 Study limitations

- A major limitation of this study is the absence of a control group which makes

interpretation of the results of the data limited. Future evaluations could focus on group and clinic outcomes in more detail, using larger sample sizes in order to draw more meaningful interpretation from the data.

- Group and individual sessions were assessed as secondary outcomes due to the limitations with the data. For example, needing to 'split' the data resulted in smaller sample sizes for comparison. Also the disparity in the numbers of patients who enrolled in group sessions from those who had individual sessions also limited the choice of statistical tests and the interpretation of the results. Differences in course content could also be a factor due to group sessions being longer and therefore more detailed. Furthermore, patients selected whether to attend group or clinic education and this could introduce bias. Due to these limitations, the group and clinic comparisons were described as secondary outcomes.

- Much of the data was skewed and therefore required non-parametric tests. Non parametric tests are known to be less sensitive and therefore may not have detected small differences in data analysis. Therefore, whilst non parametric tests are more accurate, they make lack the sensitivity of parametric tests and this could have affected overall results.

- The population was biased in favour of women with 32 females and 21 males meaning that the data may have been skewed. Research demonstrates that Type 1 diabetes in Europe is male dominant with a 3:2 male to female ratio which this study population does not accurately reflect. Data was collected within the restraints of limited clinical resources and a tight time limit imposed. It is hoped that future programme evaluations could increase the data collection time and recruit men to women on a 3:2 ratio making the sample more representative. This may also be useful to examine gender specific data for differences, which may in future help health educators to more specifically meet the needs of men and women and the issues pertinent to them.

5.5 Implications and applications for professional practice

- Unless data collection is over a longer period, future data collection should seek to measure hypoglycaemia frequency rather than awareness.

- In view of the improved clinical outcomes in the clinic setting, it may be beneficial to include some 'one-to-one' individual time into the group education sessions.

- It may be worth including six and twelve month follow up appointments to see if benefits are sustained or lost over time. This in turn could highlight the need for a '4-Step' refresher programme offered to patients at intervals during their diabetes journey.

- The programme may present an opportunity for weight management education which could include input from weight management dietitians including practical advice about portion sizes and meal balance.

- It is hoped that presentation of the findings of this study to the Diabetes Team at Aintree may result in increased resources being made available for the '4-Step' programme. Currently patients wait approximately 4 months before commencing their structured education programme. Both the specialist nurse and dietitian who run the course are each allocated two, half days per week. It is hoped that by demonstrating the effectiveness of the programme, additional resources would enable us to expand capacity in order to more effectively meet the demand such as:

    - Evening courses for people who work
    - Individualised courses according to age or gender. This could include young persons (16-25) sessions as young people have a very low attendance rate in general education programmes. An over sixties group may be helpful and separate gender groups.

5.5 Ideas for further research

- When comparing differences in groups and clinics, group education demonstrated greater improvements in Weight and Quality of life and joint clinics demonstrated greater improvements in HbA1c and Hypo awareness. Further research could focus upon these changes, to explore the reasons for the differences and seek to address them in further programmes.

- Longer term follow-up, perhaps at 6, 12 or 18 months may be helpful in terms of identifying whether or not HbA1c benefits are sustained over time.

- There is limited research upon the effects of diabetes structured education programmes on Weight/BMI. This study shows that this kind of programme has a positive effect on more than half of the participants and further research could include, looking more closely at the reasons why people gain or lose weight during the programme. This information could help shape service provision.

- The Problem Areas in Diabetes (PAID) questionnaire is a ranked series of twenty questions which were grouped together for statistical analysis. Results therefore only represented a general ideal on the improvement of the quality of life. Future service evaluations may benefit from splitting the questionnaire into sections with questions being grouped according to social relationships, patients perceptions of clinical care, and self-care and empowerment. This may lead to better interpretation of results and help educators to identify which aspects improved the most after the intervention programme.

- Monitoring 'frequency' of hypoglycaemia instead of 'awareness' may be more useful in future service evaluations. The short study duration may not have been sufficient to detect changes in awareness although changes in 'frequency' are detected much sooner. Hypoglycaemia awareness may be more accurately measured in studies of longer duration.

- Emerging evidence is suggesting that in future carbohydrate counting may benefit those with Type 2 diabetes and poor diabetes control. As a Diabetes Centre which deals with complex Type 2 patients Aintree is well placed to offer this education to people with Type 2 diabetes and compare outcomes with Type 1 patients.

5.6 Conclusions

This service evaluation used a combination of clinical tests and questionnaires to determine the effects of Aintree University Hospital's '4-Step' structured education programme on HbA1c, Weight, Quality of life and Hypoglycaemia awareness on fifty two patients undertaking the programme. Baseline and follow-up data is automatically collected on patients entering the programme for purposes of departmental clinical audit unless they fit the exclusion criteria and formed the basis of this study. The primary objectives of the study were to assess baseline and follow up measures in the total

population (n=52) and the secondary objectives were to assess differences between groups (n=30) and joint clinics (n=22).

The study has served to demonstrate the effectiveness of Aintree's '4-Step' programme in achieving key improvements in clinical and non-clinical aspects of patients' diabetes care. While the improvement in HbA1c is beneficial, it is unclear whether this is sustained over time. Longer term follow-up and refresher education at intervals may increase the likelihood of sustained clinical benefits. Whilst weight loss was shown to be minimal, the study importantly demonstrates that the '4-Step' programme does not lead to weight gain; a potential factor of programmes enabling greater food freedom. Quality of Life improvements were highly significant with impressive improvements. However, future studies would benefit from including a more detailed analysis of the Quality of Life questionnaire which, whilst highlighting aspects which are most favourably influenced by the programme, this would also enable targeting of those aspects which demonstrate lower levels of satisfaction for future service provision. Hypoglycaemia Awareness did not improve, possibly due to the short study duration. Future evaluations may be better placed to measure frequency of hypoglycaemia for a more accurate assessment of the impact of the '4-Step' programme on hypoglycaemic events.

The groups and joint clinics data was interesting, sometimes highlighting important changes which were not observed in the overall population. The study hypothesised that group education would demonstrate greater benefits than clinics. However whilst group education was found to most positively improve Quality of life and Weight loss, joint clinics most positively affected HbA1c and Hypo awareness. The need to 'split' the sample for purposes of comparing groups and clinics resulted in smaller sample sizes and therefore less accurate results and there were other limiting factors. However, the group and clinic comparisons provided interesting insight which could help shape future service provision and provide opportunities for further research.

It is important to evaluate health education interventions to ensure effectiveness in terms of expected patient benefits as well as inform service changes to increase efficiency and cost effectiveness. This study, whilst demonstrating that the '4-Step' programme delivers clinical and psycho-social benefits to patients, also provides invaluable insights which it is hoped can inform and stimulate more effective service provision to patients with Type 1 diabetes undertaking Aintree Hospital's '4-Step' programme.

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