

Commissioned Research Opportunity-led Research



Final Report

COM/4274/10

June 2011

1 Project Title

To evaluate the effectiveness of a structured education programme about diet and insulin management for adolescents with type 1 diabetes

6 Summary for Lay Audience (max 200 words)

This information will be used to communicate the results of your research to the public. Please summarise the findings of your research in layman's language.

Aim: to determine whether structured education can be used to improve glycaemic control, perceived quality of life, perceived empowerment and self-management strategies of adolescents at 1, 3, 6 and 12 months post intervention.

Methods: A randomised controlled trial was conducted with adolescents diagnosed with Type 1 diabetes for at least one year, from seven hospitals within Northern Ireland. Outcome measures included glycosylated haemoglobin (HbA1c), quality of life, empowerment and self-management strategies.

Results: 136 adolescents participated, 68 to the control group (CG), and 68 to structured education group (EG). There was no difference in HbA1c between groups post intervention despite the increased dietary freedom of the EG. Those within the EG reported significantly higher perception of control ($p \leq .005$). Impact on quality of life was significantly reduced for the EG at months 1 and 3 post intervention ($p \leq .05$, $p \leq .05$). Those within the EG reported improved dietary adherence ($p = .00$) when compared to the CG.

Conclusions: This study found that structured education reduced the impact of diabetes on quality of life and increased dietary adherence. These effects reduced over time suggesting the need for further support post education.

7 Summary of key research findings (max 500 words)

Please summarise your research findings against completed key milestones.

The clinical trial was funded initially by Diabetes UK. However, recruitment of the adolescents took longer than had been anticipated, further recruitment sites were required and thus the duration of the study needed to be extended. The opportunity-led research funding enabled the Research Fellow to continue until the 12 month follow-up data gathering was complete. The results presented here relate to the overall 12 month clinical trial results accrued from the entire study.

The key baseline characteristics of the sample are shown below.

Table 1: Baseline data

	Descriptive Statistics			
	Intervention		Control	
Gender	Male	29	Male	34
	Female	41	Female	31
	\bar{x}	(SD)	\bar{x}	(SD)
Age (years), mean (SD)	15.52	(1.85)	15.31	(1.68)
Duration (years), mean (SD)	6.46	(3.81)	6.74	(3.70)
Baseline HbA1c %, mean (SD)	8.73	(1.54)	9.04	(1.42)
Mean HbA1c %, mean (SD)	8.61	(1.25)	9.05	(1.56)
Weight, mean (SD)	63.19	(11.52)	63.08	(12.32)
Height, mean (SD)	1.66	(.10)	1.65	(.09)
BMI, mean (SD)	22.97	(3.45)	23.05	(4.22)

Table 1 presents the demographic profile and baseline data of all study participants by research group. Although the study was open to all adolescents between the ages of 13 and 19 years of age, the majority 76.1% (n = 103) were aged 16yrs or below. There was a wide variation in diabetes duration with some participants having been diagnosed for 1 year while others had lived with diabetes for up to 17 years. The average baseline HbA1c of the entire sample was 8.88% which is consistent with UK statistics. The majority of the sample,

75.2% (n = 100) had a Body Mass Index (BMI) of 25m² or less placing them within the accepted range for a healthy weight when compared with height, however, 24.8% (n = 33) had a BMI of above 25m² with 6.7% (n = 9) located within the obese or morbidly obese category.

Overall response rate for the study

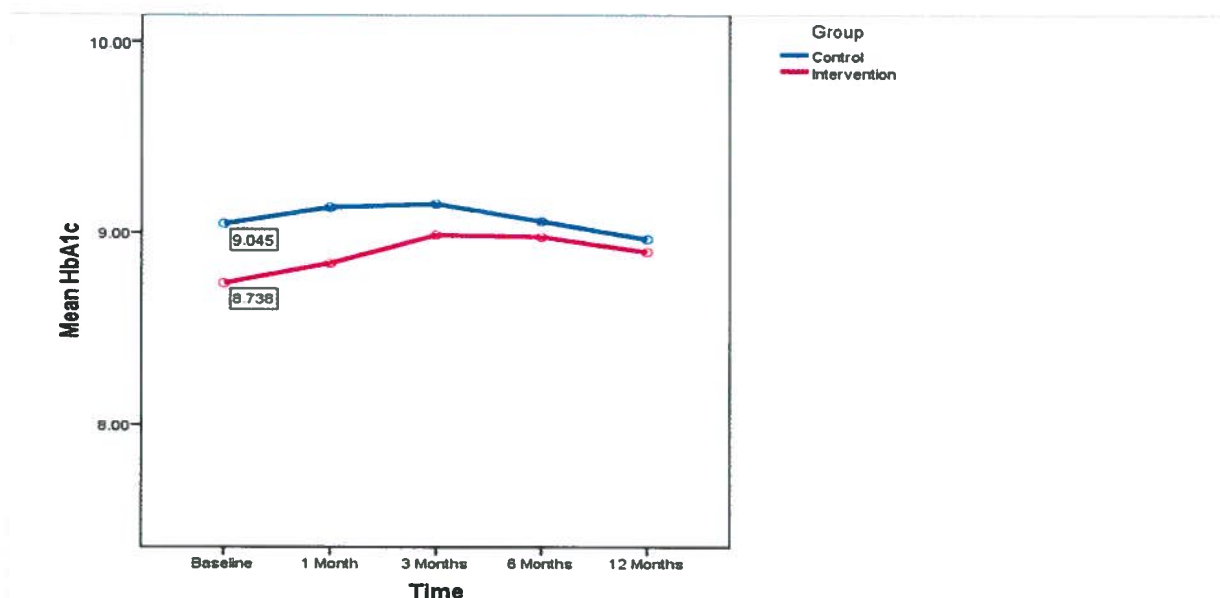
Table 2: Percentage response rate (n = 135)

Variable	1 Month	3 Months	6 Months	12 Months
HbA1c	95.6% (129)	94.8% (128)	81.5% (110)	52.2% (70)
Weight	95.6% (129)	94.1% (127)	70.4% (95)	56.3% (76)
Height	95.6% (129)	94.1% (127)	70.4% (95)	56.3% (76)
BMI	95.6% (129)	94.1% (127)	70.4% (95)	56.3% (76)
DNA's	94.8% (128)	95.6% (129)	73.3% (99)	57.7% (78)
Questionnaire	78.5% (106)	74.8% (101)	74.1% (100)	67.4% (91)

Table 2 outlines the data completeness for each clinical variable and the response rate for the study questionnaire. Despite a reducing response rate for return of questionnaires, follow up by post, text and at clinic appears to have been successful in obtaining a minimum response of 67.4% (n = 91). Clinical data were obtained from each participants medical notes, the reduction in available data at months 6 and 12 can be attributed to either DNA's or a lack of documented clinical data within an individuals' medical notes from their relevant clinic appointment.

Glycossylated haemoglobin

Figure 1 : Comparison of HbA1c over time



The mean score for HbA1c in the intervention group was slightly, but not significantly, lower than that of the control group at baseline. Despite an increasing mean value over the six-month study period (Figure 1) the mean score for the intervention group remained consistently below that of the control group in spite of the dietary freedom afforded to the intervention group by the programme.

Weight and height

The mean scores of both weight and height at the varying time-points for each group demonstrated a significant increase in both weight and height for both groups over time. This increase is not group dependant and can be attributed to normal growth of participants over the study duration.

Body Mass Index (BMI)

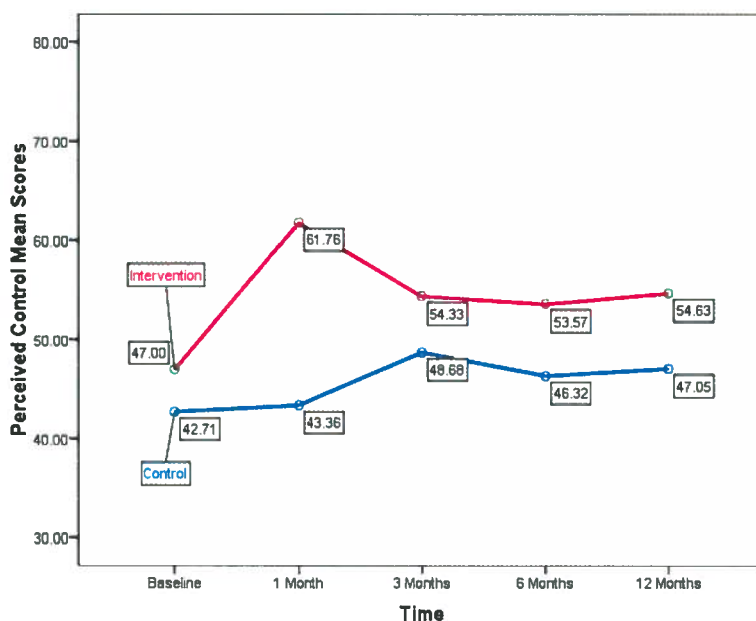
As anticipated, BMI rose in conjunction with both weight and height across time. This increase was not group dependant and may be said to reflect the normal growth of the adolescents within the study. At 12 months 6.7% of the entire sample had a BMI above 30, this percentage did not change over the study timeframe.

Perceived control of diabetes

There was no significant difference between mean scores of perceived diabetes control for intervention and control groups at baseline. There was a significant change over time within the intervention group ($p = .000$) but not within the control group ($p = .168$). Further analysis revealed a significant difference in the interaction effects between both the control and

intervention group ($p = .005$). This effect is also significant at group level ($p = .002$) and is shown in Figure 2. Within the plot, perceived control of diabetes rises significantly within the intervention group at month 1 when compared with those within the control group ($t = -4.69$; $df = 131$; $p = .000$). This increase was not sustained over time and is mediated at month 3 by increased scores among the control group. Although perceived diabetes control scores remain consistently higher for the intervention group, their level of significance was not sustained.

Figure 2: Perceived control of diabetes



Number of hyper and hypoglycaemic episodes per month

At 12 months there was no significant difference between the groups for either number of hyper or hypoglycaemic episodes.

Psychological outcomes

There was no significant difference between groups in the psychological variables measured within this research at baseline. Quality of life was measured and comprised three sub-scales: impact, worries and satisfaction.

Impact: There was a significant difference in impact of diabetes for the intervention group ($p = .006$) but not for the control group ($p = .095$) at 6 months, this difference was maintained within the intervention group at month 12 ($p = .008$).

Figure 3: Quality of life - impact of diabetes

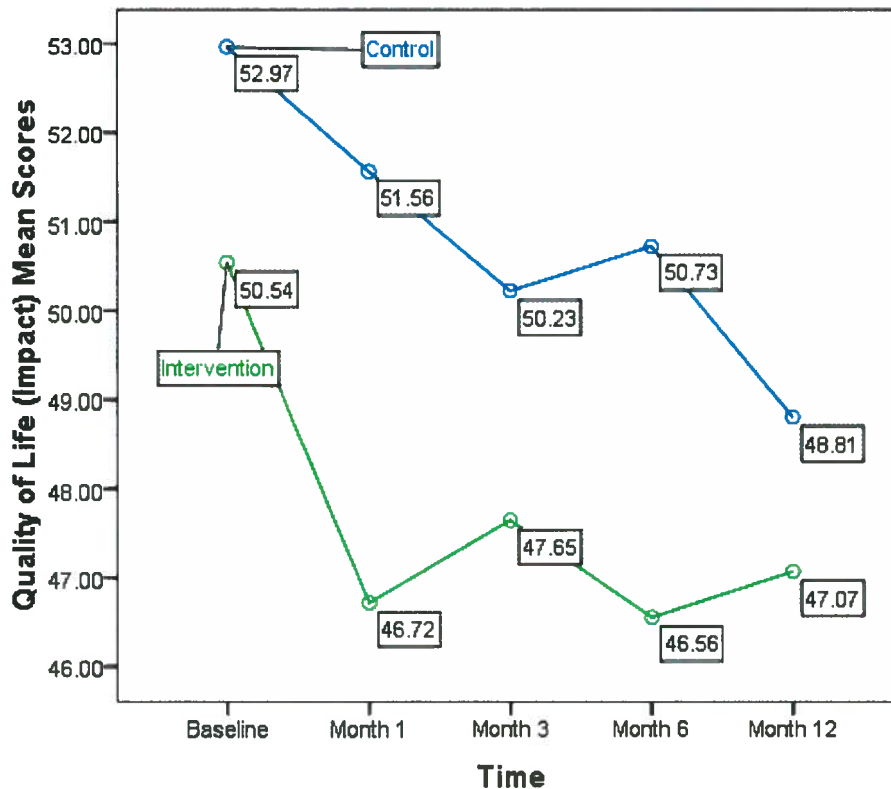


Figure 3 would suggest that the CHOICE diabetes programme has a significant effect on impact of quality of life at 1 month post intervention. This effect appears to be mediated by a drop in impact scores within the control group and rise in scores within the intervention group at month 3. However it is worth noting that although scores from the control group are not sustained, the intervention group scores drop to their lowest point at month 6 giving rise to another significant effect. This effect is once again mediated at month 12 by a further drop in impact scores within the control group. There was no significant difference between the groups at 12 months.

Worries: Despite the lower scores of the intervention group across each subsequent time point, no significant difference was detected between the two sample means.

Satisfaction: No difference was detected between groups at any time point.

Empowerment

The scores of the intervention group appear to increase very slightly over the study period but do not reach any level of significance when compared to the control group scores.

Level of understanding

There was no difference in levels of understanding about diabetes in either group at 12 months. Although levels of understanding fluctuated with an initial rise in the intervention group at months 1 and 3 there was a reduction in understanding 6 months post intervention and then both groups had increased mean scores from 6 to 12 months resulting in them being almost equal at the end of year 1.

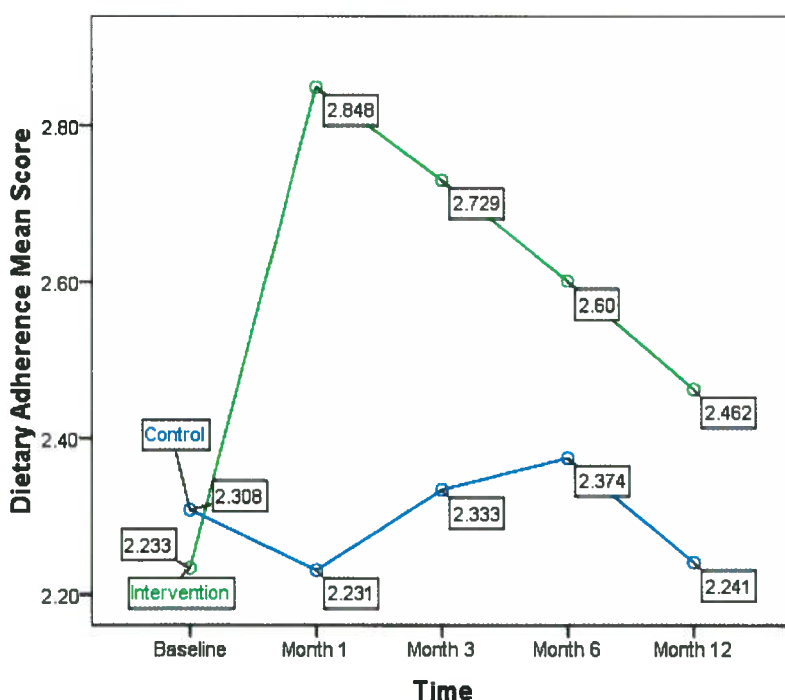
Control of problems and diabetes attitudes

There was no significant difference between the mean scores for control of problems or diabetes attitudes for either group at any time point within the study.

Dietary adherence scale

Those in the intervention group were more likely to adhere to their diet than those within the control group. Figure 4 describes this effect over 12 months by means of a line plot.

Figure 4: Dietary adherence



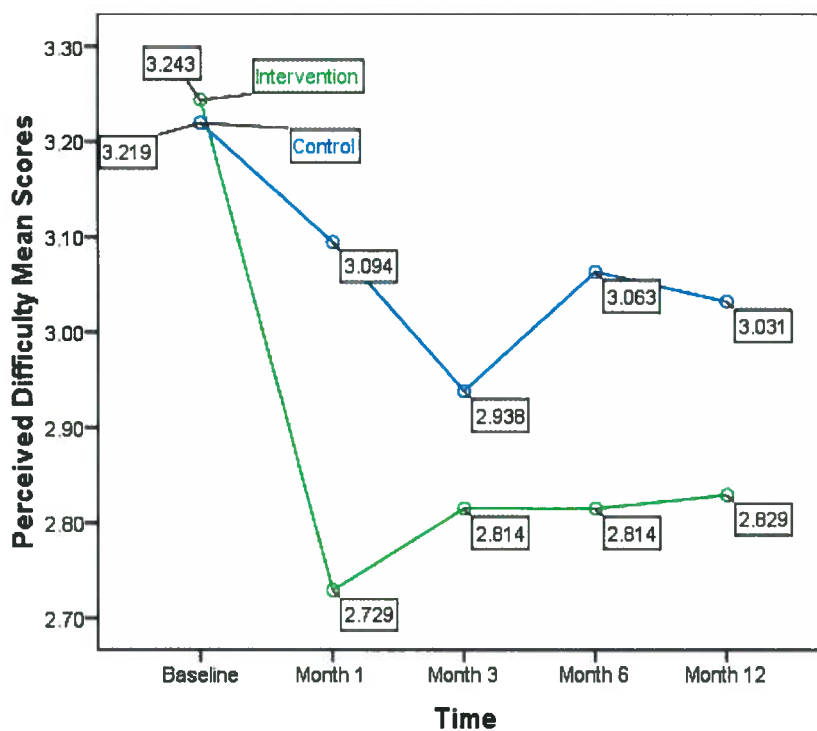
Restriction of diabetes

This variable referred to the amount of time adolescents' felt unable to undertake their normal activities (i.e. go to school, play with friends) due to their diabetes. No significant effect was found between the groups in respect of this variable across the duration of the study.

Perceived difficulty of diabetes

Adolescents' were asked to agree or disagree with the statement 'Having diabetes makes my life difficult'. Each adolescent recorded their opinion on a Likert scale where 1 equated to strongly disagree and 5 equated to strongly agree. Thus a higher score equates to increased difficulty. There was a significant decrease in perceived difficulty among those within the intervention group at 6 months post education ($P = .000$) and was maintained at 12 months post education. No significant difference was observed within the control group ($P = .145$).

Figure 9: Perceived difficulty of diabetes



Blood glucose monitoring

The number of blood glucose tests recorded by all participants within the study did not change to a significant degree at any stage across time.

Conclusion

This study found that structured education reduced the impact of diabetes on quality of life and increased dietary adherence. These effects reduced over time suggesting the need for further support post education. Issues of numeracy and literacy became apparent during the trial and need to be considered in future studies. Despite the increased dietary freedom no deterioration in HbA1c was noted between groups.

8 Problems encountered (max 500 words)

Please describe any difficulties encountered and how these were overcome.

These funds had been requested from the R&D Office as a consequence of problems relating to recruiting adolescents swiftly enough to complete the clinical trial on time. Once we had received these additional funds there were no further problems encountered with the completion of this research.

9 Benefits gained through receipt of this award (max 500 words)

Please describe the benefits gained.

This award was used to extend an existing grant from Diabetes UK to enable David Chaney to remain in post as a Research Fellow for a further 5 months. This time was used to complete the data gathering across 7 hospitals dispersed across NI. This proved to be a complicated project. The intervention (Structured Diabetes Education for adolescents with type 1 diabetes: the CHOICE programme) was run 14 times across NI, each person was followed up every 3 months for a year and then again at 24 months. The benefit of this award was that the research was completed, that the quality of the data was high, with relatively little missing data.

David Chaney used part of this work as a basis for his PhD. This award enabled him to complete on time and he was awarded the doctorate in December 2010.

Publications and presentations have been made and there are more to come. These submissions will be based on the data and experiences gained through the use of this award and thus they represent a further benefit from this funding.

A subsequent grant application was submitted to Diabetes UK in September 2011. If the previous research, funded by Diabetes UK, had not been successfully completed then it would not have been advisable to apply for further research funds.

10 Impact on Clinical Practice

Continued funding for HSC Research is dependent on satisfactory research outputs being achieved. Please describe how your research impacts on clinical practice and patient care. Where possible specific examples should be given. An indication of the expected time-line impact on patient care must be included. Please note this information may be shared with the public and/or other Government bodies (eg DHSSPS) so please ensure that the intended meaning would be clear to a non-specialist reader.

This research has enabled a robust evaluation of a structured education programme for adolescents to be completed. Prior to this study there was no other, evidence based programme available for this cohort of patients. Adolescents with type 1 diabetes face a lifetime of diabetes self-management therefore it is vital that they are equipped with the necessary knowledge and skills to do so. While we were unable to demonstrate a reduction in long term blood glucose (glycosylated haemoglobin) we did demonstrate other successes as a result of this research. These findings are currently being translated into clinical use. A CAWT (Co-operation and Working Together) project has adopted this educational programme and is using it as the basis of a service development to be offered to all adolescents in NI and to those in the border counties of Southern Ireland. This work is currently ongoing and will be evaluated.

The programme has been requested by clinical colleagues in Wales and in Bournemouth for use with adolescents. This programme was designed to be freely available to clinicians and was also prepared with a view to being applicable to routine use. Whilst further modifications may be required at a local level, this educational package can be made available to others wishing to enhance their provision to adolescents with type 1 diabetes.

11 Outputs to date from research project

Please note HSC R&D Division must receive copies of all reports or publications stemming from the research supported by this award. These may be attached to this report.

- i) Publications in peer reviewed journals (please include papers in press or in preparation)

Chaney, D, Coates, VE, Shevlin, M. (2010) Running a Complex Intervention – Lessons learned. *Journal of Diabetes Nursing*. 10(14):370 – 379.

Chaney, D, Coates, VE et al (2011) Diabetes Education: what do adolescents want? *Journal of Clinical Nursing*. Published on-line: 12 MAY 2011, DOI: 10.1111/j.1365-2702.2010.03692.x;

Chaney, D, Shevlin, M., Coates, VE. (2011) Alternative Factor Models of the Diabetes Quality of Life for Youths questionnaire. (About to be submitted to *Journal of Quality of Life*)

- ii) Other publications and reports

Coates, VE ,Chaney, D. (2011) Diabetes Education for Adolescents: Diabetes UK Final Research Report. University of Ulster, pp342.

iii) Presentations

A series of presentations have been made:-

Diabetes UK parents groups in Northern Ireland between 2008 and 2010, including Limavady, Belfast, Enniskillen and Londonderry.

Invited presentations have been delivered to professional groups:

Northern Ireland Diabetes Nurses Study Group (2008); Northern Ireland Diabetes Dietitians Study group (2008);

National Paediatric symposium for diabetes in Nottingham (September 2009); British Society for Paediatric Endocrinology & Diabetes (November 2009);

Diabetes UK Volunteer Conference (September 2010);

Workshop for diabetes specialist dietitians in Birmingham (April 2011).

Invited speaker and Conference presentations include:

National Paediatric symposium for Diabetes in Nottingham (September 2011) Presentation of study results;

Dealing with difficult teenagers (workshop) Annual Diabetes UK Conference (October 2010);

Chaney, D, Coates, VE, Shevlin, M. (2011) Evaluation of a Structured Diabetes Education Programme CHOICE. Diabetes UK April 2011 (Oral Presentation).

Poster presentations:

Chaney, D, Coates, VE, Shevlin, M, Carson, D, McDougall, A, Long, A. (2008) The Development of a Structured Diabetes Education Programme (The CHOICE Programme) for young people with Type 1 diabetes. *Diabetic Medicine*. 25 (Supplement 1). (Poster Abstract);

Chaney, D, Coates, VE, Shevlin, M. (2010) Running a complex educational intervention for adolescents with type 1 diabetes – lessons learned. *Diabetic Medicine*. 27 (Supplement 1): 117. (Poster Abstract).

iv) Other grants obtained, or grant applications made

Coates, V, Davies, M, Carey, M, Chaney, D, Davies, M, Thompson, K. Exploring patients lack of engagement with structured diabetes education in order to enhance future service provision. Proposal submitted to Diabetes UK under the “Overcoming barriers to good diabetes care and/or supported self-management” programme, September 2011.