

# Previous structured education attendance and the relationship with HbA<sub>1c</sub> and hypoglycaemia awareness in people living with type 1 diabetes mellitus using FreeStyle Libre: insights from the Association of British Clinical Diabetologists (ABCD) Nationwide Audit

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## Abstract

**Background:** Dose Adjustment For Normal Eating (DAFNE) is the gold standard National Institute for Health and Care Excellence (NICE) recommended structured education programme that promotes self-management in people living with type 1 diabetes (T1D). We have recently shown that FreeStyle Libre (FSL) is associated with improved haemoglobin A1c (HbA<sub>1c</sub>) and hypoglycaemia awareness.

**Aims:** To explore the effect of structured education including DAFNE on HbA<sub>1c</sub> and GOLD score when combined with FSL use.

**Methods:** The ABCD national audit data on FSL users were used to conduct this prospective longitudinal study. The Student's t test was used to compare the baseline and follow-up HbA<sub>1c</sub> and a change in the GOLD score for hypoglycaemia awareness. The baseline demographic and clinical characteristics of the study population were compared using ANOVA. Linear regression analysis identified predictors of change in HbA<sub>1c</sub> with FSL use.

**Results:** The study consisted of 14,880 people living with insulin-dependent diabetes mellitus (IDDM), 97% of whom had T1D, of which 50% were female, with a mean±SD baseline HbA<sub>1c</sub> of 70±18 mmol/mol and baseline body mass index (BMI) of 25.3±6.2 kg/m<sup>2</sup>. Follow-up data for HbA<sub>1c</sub> were available for 6,446 participants while data for GOLD score were available for 5,057 participants. The study population was divided into three groups: 6,701 people with no prior structured education (Group 1), 3,964 with other structured education (Group 2), and 4,215 had previously attended DAFNE structured education (Group 3). Groups 2 and 3 who had previously attended structured education had a lower initial HbA<sub>1c</sub> than those in Group 1 (p<0.0001). However, there was a significant but similar magnitude of the fall in HbA<sub>1c</sub> across all groups (−8.10 mmol/mol vs −6.61 mmol/mol vs −6.22 mmol/mol in Groups 1, 2 and 3, respectively), with p (ANOVA)=0.83. Similarly, the decline in GOLD score was comparable in Groups 1, 2 and 3 (−0.33 vs −0.30 vs −0.34, respectively), with p (ANOVA)=0.43. Linear regression analysis identified higher baseline HbA<sub>1c</sub> (β=0.585, p<0.0001), number of FSL scans over 14 days (β=−0.026, p=0.00135) and other structured education (β=−1.207, p=0.02483) as predictors of HbA<sub>1c</sub> reduction. Prior DAFNE training was not associated

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with improved HbA<sub>1c</sub> reduction in the linear regression model.

**Conclusions:** FSL use was associated with improvements in HbA<sub>1c</sub> and GOLD score. Although DAFNE is an evidence-based intervention to improve outcomes in those with T1D, DAFNE attendance prior to commencing FSL did not influence HbA<sub>1c</sub> or GOLD score outcomes when compared with FSL use alone. Other structured education was identified as a predictor of HbA<sub>1c</sub> reduction when combined with FSL use.

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**Key words:** type 1 diabetes mellitus, FreeStyle Libre monitoring, DAFNE structured education, structured education in diabetes, self-management in diabetes and improvement in HbA<sub>1c</sub>

## Introduction

Type 1 diabetes mellitus (T1D) is a challenging life-long condition requiring permanent insulin therapy, and suboptimal management can have catastrophic acute and chronic consequences. Regular multiple daily blood glucose measurements are required to inform insulin dosing with a view to achieving euglycaemia and thus reduce the risk of micro- and macrovascular complications.<sup>1,2</sup> Over the past few years, innovations in blood glucose monitoring have revolutionised care in people with T1D. FreeStyle Libre (FSL) monitoring is one such innovation, which became available on the UK National Health Services (NHS) drug tariff in November 2017 for people with T1D,<sup>3</sup> and can be described as intermittent or flash glucose monitoring. It has had a rapid uptake over the last few years and has now become standard of care for people with T1D receiving intensive insulin therapy.<sup>4,5</sup> By replacing self-monitoring of blood glucose (SMBG) using a glucometer, it eliminates lifestyle interference, inconvenience and discomfort/phobia from multiple daily finger pricks, which are limitations of SMBG.<sup>6,7</sup> FSL uses subcutaneous glucose-sensing technology to detect glucose levels in the interstitial fluid, automatically measuring glucose every minute while storing the readings at 15-minute intervals. To obtain a glucose reading, the Libre reader is held near the sensor and the device then displays glucose information over the preceding 8 hours, which includes current glucose and forecasts change in glucose levels thus allowing the operator to make necessary adjustments to diet and/or insulin dosing.<sup>8</sup> A lower cost, no calibration requirements (factory calibrated) and an infrequent sensor change (every 14 days) are seen as advantages over continuous glucose monitoring.<sup>1</sup> In a meta-analysis of clinical trials and real-world observational studies, Evans *et al* showed that, on commencing FSL, HbA<sub>1c</sub> fell within the first 2 months and was sustained for 12 months, concluding that the use of FSL in the management of T1D and type 2 diabetes (T2D), both in adults and children alike, led to significant and sustained improvement in glycaemic control.<sup>9</sup> Randomised controlled trials have demonstrated that FSL use is associated with a significant reduction in the incidence of hypoglycaemia in people with T1D and T2D.<sup>10,11</sup>

Dose Adjustment For Normal Eating (DAFNE) is a national structured education programme for adults with T1D (adapted from the German Diabetes Teaching and Treatment Programme), which is

taught over five days on an outpatient basis, Monday to Friday or one day a week for five consecutive weeks. It is a well-established, evidence-based and quality-assured programme, which promotes diabetes self-management with flexible insulin therapy and is delivered in over 70 centres across the UK and internationally in Ireland, Australia (Oz DAFNE), New Zealand, Kuwait and Singapore, serving as an important tool in the management of patients with T1D.<sup>12</sup>

In this study we explore the impact of attending a DAFNE or an alternate structured education programme prior to FSL initiation on glycaemic control and hypoglycaemia awareness.

## Methods

### Patient recruitment and data collection

The Association of British Clinical Diabetologists (ABCD) conducted a national audit on FSL use which began in November 2017.<sup>13</sup> Using data collected during this audit, we conducted a prospective longitudinal study. Data collected during routine clinical care were entered onto a secure online tool on the NHS IT network which allowed for anonymisation of the data. Baseline pre-FSL data included demographics, source of FSL funding, previous structured diabetes education completion, HbA<sub>1c</sub> values from the previous 12 months, GOLD score<sup>14</sup> (to assess hypoglycaemia awareness), severe hypoglycaemia, paramedic callouts and hospital admissions due to hypoglycaemia, hyperglycaemia and diabetic ketoacidosis (DKA) over the previous 12 months. The GOLD score is a seven-point questionnaire validated for identifying impaired awareness of hypoglycaemia (IAH); a GOLD score  $\geq 4$  determines IAH. We used this FSL user database for our analysis.

### Data analysis

The study population was divided into three groups based on their education category before commencing FSL. Group 1 had received no structured education, Group 2 had received other structured education while Group 3 attended the DAFNE structured education programme before FSL initiation. The Student's *t* test was used to compare the baseline and follow-up HbA<sub>1c</sub> and change in the GOLD score for hypoglycaemia awareness. The baseline demographic and clinical characteristics of the study population were compared using ANOVA. To identify the effect of structured education on HbA<sub>1c</sub> reduction in response to FSL use, change in the post-FSL HbA<sub>1c</sub> (pre-FSL HbA<sub>1c</sub> – post-FSL HbA<sub>1c</sub>) was modelled as an independent variable with an average of the pre-FSL HbA<sub>1c</sub>, age, sex, BMI, duration of diabetes, baseline BMI, number of FSL scans and structured diabetes education (entered as a dummy variable) as independent predictors. Data were collected at baseline and first follow-up visit following the initiation of FSL, which took place at a mean  $\pm$  SD of 7.2  $\pm$  6.3 months. Analysis was restricted to patients with complete information on the type of education, baseline and follow-up HbA<sub>1c</sub> and GOLD score.

### Ethical approval

The ABCD nationwide audit programme has Caldicott Guardian approval. The NHS encourages audit of clinical practice, and there are guidelines which were followed. Anonymisation of the

**Table 1.** Baseline demographic and clinical characteristics of the study population

	Group 1 (no prior structured education) (n=6,701)	Group 2 (other prior structured education) (n=3,964)	Group 3 (prior DAFNE structured education) (n=4,215)	P value*
Age (years)	40.6±18.3	33.5±19.7	45.2±14.9	<0.0001
Gender (% females)	2,999 (45%)	1,994 (50%)	2,383 (56%)	<0.0001
Baseline BMI (kg/m <sup>2</sup> )	25.4±6.3	24.3±6.4	26.2±6.2	<0.0001
Duration of diabetes (years)	16±49.6	11±56.7	21±45.4	<0.0001
Type 1 diabetes (%)	6,290 (94%)	3,882 (98%)	4,100 (97%)	<0.0001
Insulin pump (%)	847 (13%)	1,039 (26%)	1,156 (27%)	<0.0001
Mean pre-FSL HbA <sub>1c</sub> (mmol/mol)	72.3±20.8	68.4±16.9	69.3±16.1	<0.0001
Baseline GOLD score	2.7±1.8	2.5±1.6	2.7±1.7	<0.0001

Data are presented as mean±SD for continuous variables and N (%) for categorical variables.  
\*P values derived from Student's t test or  $\chi^2$  test.  
BMI, body mass index; FSL, FreeStyle Libre.

collected data was ensured at the point of uploading to the central database, and the contributing centres were required to collect data from routine clinical practice only.

## Results

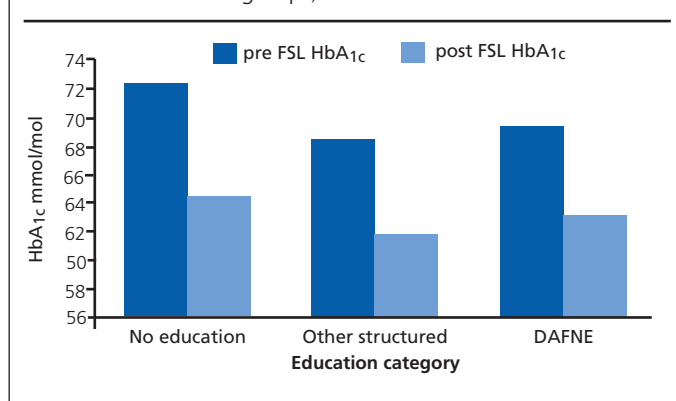
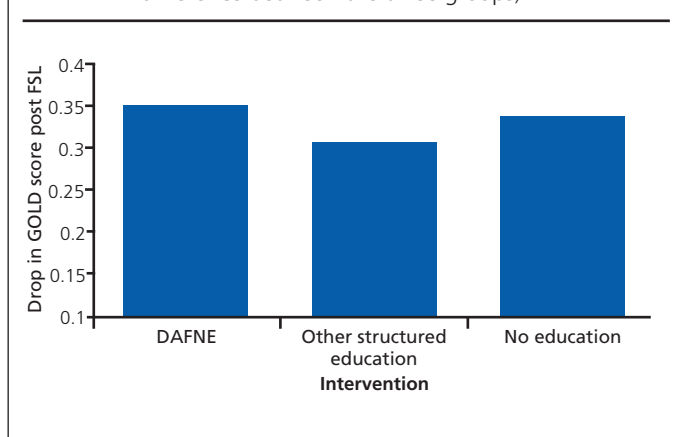
The study consisted of 14,880 people with insulin-dependent diabetes mellitus (IDDM) (97% of whom had T1D), of which 6,701 received no structured education (Group 1), 3,694 had other structured education (Group 2) and 4,215 attended the DAFNE programme (Group 3) before initiation of FSL. Follow-up data for HbA<sub>1c</sub> were available for 6,446 participants while data for GOLD score were available for 5,057 participants. In Group 1, FSL initiation resulted in a mean reduction in HbA<sub>1c</sub> of 5.28±18.84) mmol/mol compared with 5.05±11.44 mmol/mol in Groups 2 and 3 (p=0.56). In Group 1, the mean reduction in GOLD score after FSL initiation

**Table 2.** Factors associated with HbA<sub>1c</sub> response with use of FSL (n=6,446)

Variable	$\beta$	SE	P value
Age	0.019	0.012	0.13
Gender	0.118	0.437	0.78
Baseline BMI	-0.003	0.036	0.92
Duration of diabetes	0.006	0.003	0.06
Average pre-FSL HbA <sub>1c</sub>	0.585	0.013	<0.0001
Insulin pump	0.401	0.530	0.44
Number of FSL scans over 14 days (monitoring)	-0.026	0.008	0.001
Other structured education	-1.207	0.537	0.02
DAFNE	-0.603	0.524	0.24

BMI, body mass index; DAFNE, Dose Adjustment For Normal Eating; FSL, FreeStyle Libre.

was 0.33±1.57 compared with 0.32±1.50 in Groups 2 and 3 (p=0.92). The baseline demographic and clinical characteristics of the study population are shown in Table 1, which shows a statistically significant difference across all groups. DAFNE graduates were older with a longer duration of diabetes, were more likely to be female and on an insulin pump than the non-education group. There was a significant but similar reduction in HbA<sub>1c</sub> in all groups after FSL initiation. In the unadjusted univariate analysis, HbA<sub>1c</sub> fell by 8.10 mmol/mol in Group 1, 6.61 mmol/mol in Group 2 and 6.22 mmol/mol in Group 3 (Figure 1). The improvement in HbA<sub>1c</sub> was statistically not significant when compared between the groups (p (ANOVA)=0.83). Table 2 shows the association of linear regression analysis with change in HbA<sub>1c</sub> as a dependent variable. Predictors of HbA<sub>1c</sub> reduction were higher baseline HbA<sub>1c</sub> ( $\beta$ =0.585, p<0.0001), number of FSL scans over 14 days ( $\beta$ =−0.026, p=0.00135) and other structured education ( $\beta$ =−1.207, p=0.02483). Across the study population, with FSL use the GOLD score improved from 2.71±1.74 to 2.36±1.58 and was statistically significant (p<0.0001).

**Figure 1.** Reduction in HbA<sub>1c</sub> post-FreeStyle Libre (FSL) by education category (no education n=2,714; other structured education n=1,757; Dose Adjustment For Normal Eating (DAFNE) n=1,975); p (ANOVA)=0.83 (no significant difference between the three groups)**Figure 2.** Fall in GOLD score by education category (no education n=2,034; other structured education n=1,446; Dose Adjustment For Normal Eating (DAFNE) n=1,577); p (ANOVA)=0.43 (no significant difference between the three groups)

The decline in GOLD score following FSL initiation was comparable in all three groups and was shown to improve by 0.33 in group 1, 0.30 in group 2 and 0.34 in group 3.  $p$  (ANOVA) was applied to assess the mean fall in GOLD score among the groups and no significant difference was found ( $p$  (ANOVA)=0.43). Figure 2 shows the change in GOLD score after FSL initiation.

## Discussion

We report results of the largest real-world study investigating the interaction of previous structured education attendance and subsequent FSL initiation on glycaemic control in people living with T1D. We show that, although those who had previously attended any structured education had a lower initial HbA<sub>1c</sub> and were more likely to be on an insulin pump, previous structured education did not demonstrate a significant difference in change in HbA<sub>1c</sub> in response to FSL initiation. Interestingly, however, we show that other (non-DAFNE) structured education before FSL initiation was predictive of HbA<sub>1c</sub> reduction post FSL compared with those without structured education or those who had attended DAFNE. From our analysis, pre-FSL HbA<sub>1c</sub>, number of FSL scans over 14 days and other structured education were identified as predictors of HbA<sub>1c</sub> reduction.

Several studies have demonstrated improved glycaemic control with FSL use, which was reported to be greater in people with higher pre-FSL HbA<sub>1c</sub> levels and the number of FSL scans over 14 days.<sup>15–20</sup> In a large observational study, we have previously shown that FSL use is associated with improved glycaemic control and hypoglycaemia awareness among other clinically beneficial outcomes. However, on linear regression modelling, structured education was not a significant factor in the reduction of HbA<sub>1c</sub> ( $\beta$ =0.82,  $p$ =0.090).<sup>20</sup> In a prospective observational study of 900 individuals with T1D, Tyndall *et al* showed that FSL use was associated with a reduction in HbA<sub>1c</sub> of  $\geq 5$  mmol/mol in 48.1% of individuals. Interestingly, DAFNE attendance was amongst other variables (age, sex, diabetes duration, etc) which were not associated with a greater likelihood of achieving a 5 mmol/mol fall in HbA<sub>1c</sub> with FSL use.<sup>19</sup> These results support our findings of improvement in HbA<sub>1c</sub> with FSL use, which is independent of previous DAFNE education. Stimson *et al* explored the change in HbA<sub>1c</sub> and the rates of hospital admission following FSL monitoring in people with T1DM and reported a median fall in HbA<sub>1c</sub> of 1 mmol/mol over a median duration of 38 weeks while observing no change in overall hospital admissions.<sup>18</sup> In this study, DAFNE attendance was among the factors associated with a greater fall in HbA<sub>1c</sub>. However, as this was a univariate analysis and was not adjusted for other variables (baseline HbA<sub>1c</sub>, age, gender, etc), it should be interpreted with caution.

There are several possible reasons as to why DAFNE structured education prior to FSL use was not found to have an additional advantage in improving glycaemic control and hypoglycaemia awareness. The first is the timing of the completion of structured education. DAFNE courses have been running for 21 years, and many participants in the cohort may have completed DAFNE several years ago, possibly without recent re-enforcement of core DAFNE principles. Second, the HbA<sub>1c</sub> prior to FSL initiation was lower in the education groups (although this was controlled for in the mul-

tivariate analysis). Another possibility could be that DAFNE is not tailored to FSL use, although neither are other available structured education courses. Nevertheless, DAFNE is NICE recommended,<sup>21</sup> has been shown to improve glycaemic control<sup>22–26</sup> and hypoglycaemia awareness,<sup>24</sup> reduces severe hypoglycaemia episodes,<sup>24,27</sup> reduces diabetes-related distress,<sup>24,27</sup> improves the quality of life (QoL),<sup>22,25,27</sup> is cost-effective<sup>28</sup> and so remains integral to the management of T1D. A possible reason for a significant improvement in HbA<sub>1c</sub> in the other (non-DAFNE) structured education group could be an over-representation of the paediatric population in this subgroup. The paediatric population are more likely to have other structured education (as DAFNE is not available in this age group) and are also more likely to have a close follow-up and monitoring of their HbA<sub>1c</sub>. Therefore, a specific analysis of the children and young people (CYP) network programmes, such as SEREN, among others, might reveal a synergy with FSL use.

Very recently, Garden *et al* combined FSL initiation with a locally developed and accredited 1-day structured education programme (Cedric) for people with T1D and demonstrated improved glycaemic control in all the participants together with a reduction in the time spent in the hypoglycaemic range and number of hypoglycaemic episodes.<sup>29</sup> It is likely that the combination of the two intervention modalities resulted in a cumulative effect. A small sample size ( $n$ =213) and lack of a comparator arm (FSL alone) were limitations of this analysis. Nevertheless, these are encouraging results and support the findings of our analysis, where we have shown other structured education prior to FSL use to be a predictor of HbA<sub>1c</sub> reduction.

In the regression analysis, we show that other (non-DAFNE) structured education was associated with an approximate 1 mmol/mol ( $\beta$ =1.16) fall in HbA<sub>1c</sub> after adjustments for all covariates. We have previously shown that, in the whole population, FSL use resulted in a 5.2 mmol/mol fall in HbA<sub>1c</sub>,<sup>20</sup> and therefore it could be argued that FSL is valuable irrespective of previous education status.

There are numerous reasons as to why FSL use alone led to a significant HbA<sub>1c</sub> reduction and improvement of hypoglycaemia awareness, one of which is the alleviation of previously described limitations to conventional SMBG.<sup>6,7</sup> Using state of the art technology, FSL provides on-demand, real-time record and trend of the glucose level, placing the users in a position of strength as they can make prompt adjustments to insulin doses in relation to diet/activity, which facilitates time spent in the glucose target range.<sup>1</sup> Furthermore, it has been observed that FSL users were more likely to administer prandial insulin 15–20 min before a meal,<sup>15,17</sup> a practice that has been shown to improve postprandial glucose control.<sup>30,31</sup>

It is also worth noting that, on commencing FSL monitoring, people are provided with a brief face-to-face tutorial surrounding its use and provided access to online educational resources including the Diabetes Technology Network (DTN) (<https://abcd.care/dtn-education/flash-glucose-monitoring>). It is likely that these measures maximise the benefits from FSL monitoring for people with T1D.

In terms of limitations, as this was an observational study, causality cannot be inferred and the effect of structured education programmes prior to initiation of FSL can be more effectively stud-





## Key messages

- Introduction of FreeStyle Libre monitoring improves glycaemic control irrespective of prior completion of structured education
- Higher baseline HbA<sub>1c</sub>, number of FreeStyle Libre scans over 14 days and other (non-DAFNE) structured education were predictors of HbA<sub>1c</sub> reduction

ied with a randomised controlled trial. Furthermore, we did not have information about the exact nature of the other (non-DAFNE) structured education programmes, which can vary in different hospitals across the UK. However, we provide the largest real-world data to date investigating the effect of structured education prior to FSL on glycaemic control.

Considering the results presented from our analysis, we show that FSL monitoring improves glycaemic control irrespective of previous structured education status. It is likely related to the increase in glucose monitoring frequency, a conclusion supported by the results of our analysis and several previous studies where the number of FSL scans over 14 days was a predictor of improvement in HbA<sub>1c</sub>.<sup>15–20</sup> Perhaps attendance at a targeted, intensive and flexible education programme combined with FSL initiation may be a helpful approach in securing optimum benefit in terms of glycaemic control in people living with T1D who are started on FSL. However, well-designed randomised controlled trials will be needed to establish this conclusively.

## Conclusion

In this large cohort of people with IDDM (97% T1D), those who had completed structured education before FSL initiation had lower HbA<sub>1c</sub> values than those who had not. However, the subsequent change in HbA<sub>1c</sub> and GOLD score associated with FSL use did not differ between those who had completed education and those who had not. In addition to this, our multivariate analysis showed that other (non-DAFNE) structured education was a predictor of HbA<sub>1c</sub> reduction even after adjusting for glucose monitoring (number of FSL scans over 14 days) and other co-variables. Our findings add to the growing evidence of the effectiveness and utility of FSL monitoring; however, large-scale randomised controlled trials are needed to conclusively underline the clinical efficacy of FSL monitoring in clinical practice.

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**Conflict of interest** EGW serves on the advisory panel for Abbott Diabetes Care, Dexcom and Eli Lilly and Company; has received research support from Diabetes UK; and is on the speakers' bureau for Abbott Diabetes Care, Dexcom, Eli Lilly and Company, Insulet Corporation, Novo Nordisk and Sanofi. PC had recommended fees from Abbott, Dexcom, Medtronic, Novo Nordisk, Lilly, Sanofi and Insulet. CW has a spouse/partner serving on the ad-

visory panel for Celgene and on the speakers' bureau for LEO Pharma and Novartis. REJR serves on the advisory panel for Novo Nordisk A/S and is on the speakers' bureau for BioQuest. TS serves on the speakers' bureau for Novo Nordisk Foundation and reports a relationship with Bristol-Myers Squibb, Eli Lilly and Company, and Sanofi. The other authors have no conflicts of interest in relation to this article.

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