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Group follow-up compared to individual clinic visits after structured education for type 1 diabetes: a cluster randomised controlled trial

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Abstract

Aim To compare the effectiveness of group follow-up with individual follow-up after participation in the Dose Adjustment for Normal Eating (DAFNE) structured education programme.

Methods Cluster randomised controlled trial involving 437 adults with type 1 diabetes attending hospital diabetes clinics in Ireland. All participants received DAFNE at baseline. Intervention arm participants received 2 group education sessions post-DAFNE and did not attend clinics. Control arm participants received 2 one-to-one clinic visits post-DAFNE.

Results We observed no significant difference in the primary outcome (change in HbA_{1c}) at 18 months follow-up (mean difference 0.14%; 95% CI -0.33 to 0.61; p=0.47). Secondary outcomes, including rates of severe hypoglycaemia, anxiety, depression, the burden of living with diabetes and quality of life did not differ between groups. Mean level of HbA_{1c} for the entire sample (regardless of treatment arm) did not change between baseline and 18 month follow–up (p=0.09), but rates of severe hypoglycaemia, diabetes related hospital attendance, levels of anxiety, depression, the burden of living with diabetes, quality of life and treatment satisfaction all significantly improved.

Conclusions Our data suggest that group follow-up as the sole means of follow-up after structured education for individuals with type 1 diabetes is as effective as a return to one-to-one clinic visits.

Keywords: Type 1 diabetes; Structured education; Patient education; Follow-up.

1. Introduction

Structured education programmes (SEPs) were first introduced in mainland Europe [1, 2] and, based on positive outcomes, have now become popular in the UK and Ireland as a means of delivering self-management education to individuals living with diabetes [3-6]. The approach involves trained educators delivering a programme of education based on a curriculum, shared decision making and patient-centred care to groups of individuals living with the condition [7, 8].

The Dose Adjustment for Normal Eating (or DAFNE) programme is one such high quality programme for individuals with type 1 diabetes [9, 10] and is based on a programme originally developed in Germany [1]. An initial evaluation of DAFNE in the UK demonstrated improvement in $HbA_{1c,}$ improvement in perceived quality of life and no increase in rates of severe hypoglycaemia in a cohort of individuals with poorly controlled type 1 diabetes [11]. The programme is currently delivered by over 77 diabetes teams in the UK and Ireland. A very similar programme called OzDAFNE is being delivered in Australia. Audit data from these "real world" settings suggest that improvement in HbA_{1c} is less impressive than that seen in the initial trial although improvement in psychosocial outcomes is maintained [12-14]. How best to provide follow-up support to individuals who have received a structured diabetes education programme in order to maintain the benefit of education has become an important unanswered question [15].

We hypothesised that by continuing to provide "booster" sessions of group education at 6 and 12 months we could maintain or further improve outcomes following DAFNE training. We designed a cluster randomised trial to compare group follow-up (delivered instead of clinic visits) with one-to-one clinic follow-up.

2. Subjects, materials and methods

The Irish DAFNE Study protocol outlining the methods of the study has been reported previously [16]. Ethical approval was received from Research Ethics Committees in each of the participating centres in the Republic of Ireland and through the Office for Research Ethics Committees in Northern Ireland.

2.1 Participants (Centres and Individuals)

There are 46 clinics delivering outpatient diabetes care on the island of Ireland (35 in the Republic and 11 in Northern Ireland). At the time that the Irish DAFNE Study was designed 7 of these centres were delivering (or had plans to deliver) the DAFNE programme. Six of these centres agreed to participate in the study and were cluster randomised to become intervention or control arm centres. Randomisation (by a computer generated numbers list) was undertaken by an independent statistician. We opted for a cluster design because we felt that educators and doctors would be at risk of contamination of the control arm if they were expected to deliver both methods of follow-up in an individual centre. The process of becoming a DAFNE centre involves 43 hours of training for a DAFNE doctor and 105 hours of training for each of the (at least 2) DAFNE educators [9]. Centres then become part of the DAFNE Collaborative and agree to participate in ongoing internal and external peer review to ensure the quality of delivery of the education programme.

Study participants were recruited from waiting lists of individuals who had expressed an interest in receiving DAFNE training in participating centres. Recruitment commenced in October 2006 and finished in February 2009. Inclusion criteria were broad and included a diagnosis of type 1 diabetes of at least 12 months duration, the ability to read and speak English, a willingness to engage in regular self-monitoring of blood glucose and a HbA_{1c} level below 13 percent at recruitment. The protocol did not specify a lower limit of HbA_{1c} for eligibility. Participants had to be using a basal/bolus insulin regimen or be willing to convert to such a regimen prior to participation. Patients were excluded if they had advanced diabetes complications, were pregnant or planning pregnancy in the next 2 years, were currently using an insulin pump to manage their diabetes or had significant co-morbidities likely to interfere with study participation.

2.2 Intervention

The content and organization of the education delivered to patients within the DAFNE week has been described in detail elsewhere [9]. It encourages a liberal approach to diet but emphasises matching of quick-

acting insulin to food and separation of basal and meal-related insulin. After completing the DAFNE course, participants in control arm centres were invited back to outpatient clinics at 6 and 12 months where they received one-to-one visits with a doctor, nurse and/or dietician. Follow-up care in intervention arm centres did not include any one-to-one visits. Instead participants returned in their original group and received "booster" education sessions, lasting about 3 hours, at 6 and 12 months post-DAFNE. If an individual was unable to attend for follow-up in their original group an alternative date (with a different group) was offered. A structured curriculum was developed to facilitate group follow-up sessions and incorporated individual insulin dose adjustments where necessary. The curriculum set out learning objectives across a range of topics that were then "offered" to participants based on perceived needs identified by themselves; this ensured a patient-centred approach [8] that is recommended in SEPs [15]. Goal setting and action planning was emphasised as was review of patients' blood sugar records ("DAFNE diaries"). Educators in intervention arm centres received formal training in the delivery of this follow-up curriculum.

The approach to quality assurance (QA) within the DAFNE Collaborative has been described previously [9] and involves a process of internal and external peer review of education sessions by trained peer reviewers. All centres in the Irish study participate in this process of QA ensuring that the "package" of education delivered by educators is similar across centres. To ensure that group follow-up was being delivered appropriately we incorporated an external quality assurance (peer) review of the delivery of a 6 month group follow-up session in each of the 3 intervention arm centres in addition to the existing routine QA. This was undertaken by an experienced UK-based peer reviewer.

2.3 Outcomes and Measurement

The primary outcome was the change in HbA_{1c} from baseline to 18 months post DAFNE training. HbA_{1c} was measured centrally in a laboratory with a track record of supporting large multi-centre studies. The method used was a DCCT-aligned HPLC assay (ADAMS-A_{1c} HA-8160). We did not collect data on the number of changes to insulin doses during follow-up visits. Secondary outcomes included weight, blood pressure, lipid levels and rates of severe hypoglycaemia. Baseline measurements were taken in the week prior to DAFNE training. Follow-up measurements were taken prior to the follow-up visits at 6, 12 and 18 months post-DAFNE. Severe hypoglycaemia was self-reported and defined as an episode of hypoglycaemia requiring the assistance of another person for treatment. Patients were asked (at baseline) how many such episodes they had in the past 12 months. During follow-up visits patients were asked how many episodes they had since their last review. A number of psychosocial measures were included as secondary outcomes. These assessed diabetes-specific quality of life and treatment satisfaction (using the Diabetes-Specific Quality of Life Scale; DSQOLS) [17], anxiety and depression (using the Hospital Anxiety and Depression Scale; HADS-A and HADS-D) [18] and diabetes-related distress (using the Problem Areas in Diabetes Scale; PAID) [19]. A health economic questionnaire was devised and completed at baseline and during follow-up. Self-reported rates of hospitalisation were documented in that questionnaire and are included in the current report. All other health economic data will be reported separately.

2.4 Sample Size Estimation

We used a sample size calculator designed for cluster randomised trials [20]. We based the sample size calculation on an anticipated mean HbA_{1c} difference between the 2 arms of the study of 0.5 percent (4 mmol/ mol) from month 6 onwards [11]. Based on a standard deviation of HbA_{1c} of 1.2 and an intra-class correlation co-efficient (ICC) of 0.05 we estimated that 336 patients from 6 clusters would be required to detect a 0.5 percent (4 mmol/ mol) difference in HbA_{1c} with 90 percent power. The UK study on which the above sample size was based excluded patients with a baseline HbA_{1c} of less than 7.5 percent (59 mmol/ mol). We believed that patients with lower HbA_{1c} would still derive benefit from DAFNE training and we elected to include these patients. Based on pre-study audit data from Irish centres we estimated that approximately 20 percent of participants would have a baseline HbA_{1c} below 7.5 percent (59 mmol/ mol). To maintain the power of our study to detect a clinically important difference we increased our total sample size to 420 patients. Allowing for dropouts we aimed to recruit a total of 450 patients across the 6 participating centres.

2.5 Statistical Analysis

Summary statistics and graphical techniques were used to summarize baseline characteristics and to investigate factors related to the presence of missing data. An intention to treat analysis was performed where missing values in the response variables were accounted for using linear mixed models [21] and using multiple imputation based on chained equations [22, 23]. A per protocol analysis was performed using data from those participants who attended both the 6 and 12 month follow-up visits. Two *a-priori* sub group analyses looked at treatment responses among participants with baseline HbA_{1c} above and below 7.5 percent (59 mmol/ mol). Changes in outcomes over time (the effect of DAFNE) are presented for all study participants regardless of intervention or control arm assignment.

A linear mixed model for longitudinal data was used for all continuous primary and secondary responses [21] in order to account for cluster specific baseline adjustments [24] and for the correlation within subject across time. The response at baseline was included as a covariate in order to adjust for differences in subjects at baseline and the possibility that the change in a subject's response was related to their initial value. Variable selection techniques were used to determine the most parsimonious set of patient characteristic explanatory variables for inclusion in each model. The need for higher order interactions between all the explanatory variables and treatment was investigated. The ICC was calculated for each response variable from the estimated variance components due to cluster from the final fitted model for each response variable.

As a large proportion of participants had zero severe hypoglycaemic episodes recorded (i.e. over dispersion) a Quasi Poisson linear mixed model for count data was fitted when modelling the change in the number of severe hypoglycaemic episodes over time [21]. An alternative approach used was to compare, using a logistic mixed model, the proportion of subjects in the treatment and control arm demonstrating a change in the number of severe hypoglycaemic episodes over time conditioning on whether a subject had recorded zero or one or more episodes at baseline.

Appropriate model checking, based on residual plots, was performed for all mixed models and the significance level for all analyses was set at the 5% level. All analyses were carried out using Minitab 16 and R (2.10).

3. Results

3.1 Baseline characteristics

Figure 1 shows the flow of centres and participants through the study. One of the 7 eligible centres declined to participate. The vast majority of individuals approached on DAFNE waiting lists were eligible and consented (442/499; 89%). The baseline characteristics of those who participated are described in Table 1. The cohort comprised 54% females. Participants were (on average) 41 years old, slightly overweight, normotensive and living with diabetes for 16 years. They were mainly using analogue-based insulins and had a baseline average HbA_{1c} of 8.3% or 67 mmol/ mol (SD 1.3% or 11 mmol/ mol) with 29% having a HbA_{1c} below 7.5% (59 mmol/ mol). Episodes of ketoacidosis in the preceding year were very uncommon, reported by only 9 (2% of) individuals. Episodes of severe hypoglycaemia were more commonly reported; 104 of 433 respondents (24%). Approximately one in five were smokers and a similar proportion reported being aware of complications from their diabetes. Most participants were employed and 48% had completed 3rd level education. The scores on baseline psychosocial questionnaires indicated that around one quarter of the sample had levels of anxiety and just under one fifth had levels of depression which would be considered 'clinical cases' on the HADS. Almost 40 percent of individuals reported feeling burdened by their diabetes on the PAID scale

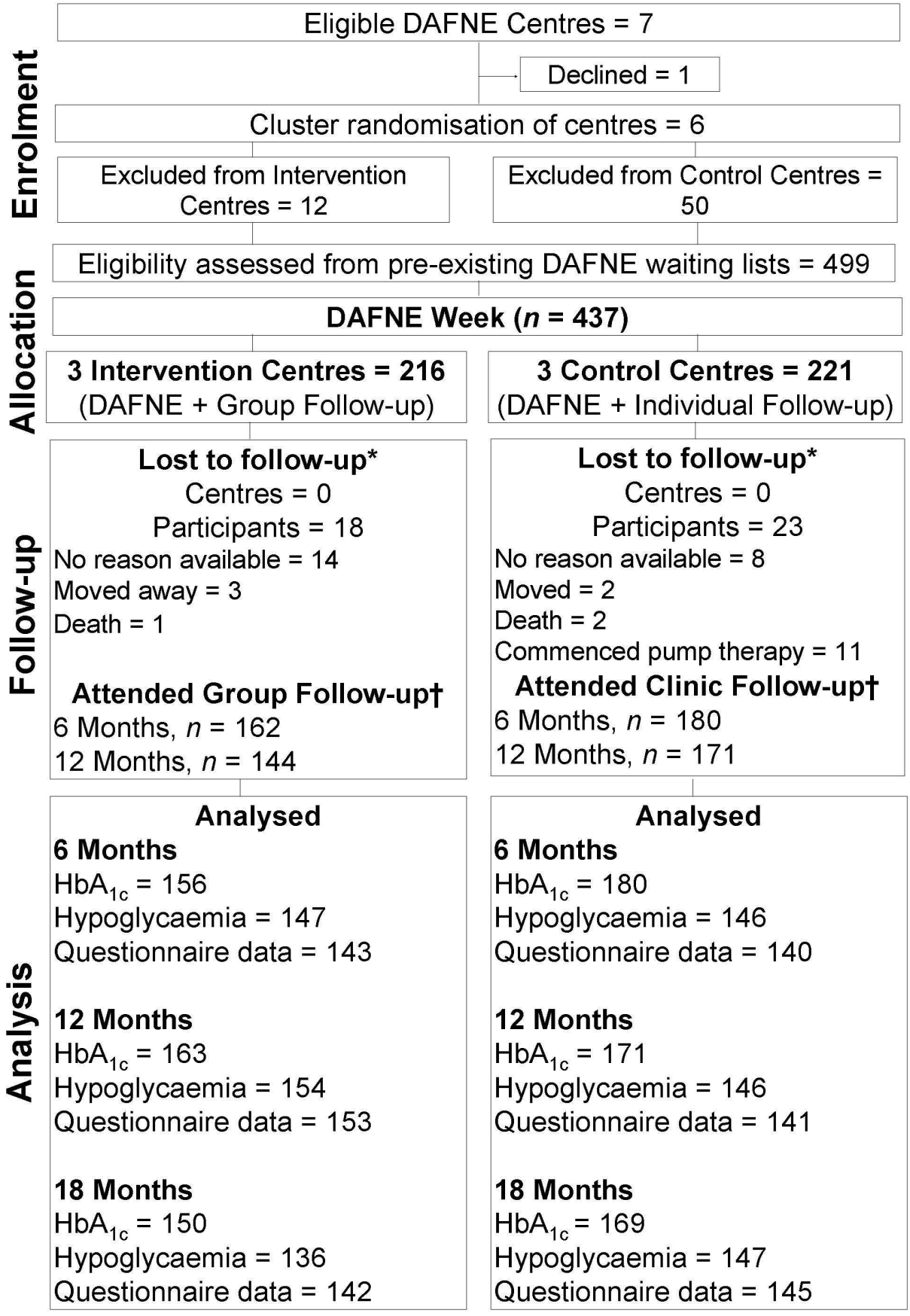

Figure 1 CONSORT Flowchart of the Irish DAFNE Study

Table 1 Baseline characteristics of participating individuals

	Intervention		Control		Total	
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**
Age (years)	40.1	12.0	41.5	11.4	40.8	11.7
Years since diagnosis	15.5	10.4	16.3	11.2	15.9	10.8
Baseline BMI (kg/m^2)	25.8	4.0	26.3	4.3	26.0	4.1
Systolic BP (mmHg)	124.8 (9 missing)	17.3	125.1 (25 missing)	20.6	124.9	18.9
Diastolic BP (mmHg)	74.0 (9 missing)	9.9	74.2 (25 missing)	12.0	74.1	10.9
Baseline HbA_{1c} (%)	8.4	1.4	8.2	1.3	8.3	1.3
Baseline HbA_{1c} (mmol/ mol)	68	9.8	66	9.1	67	9.1
	Number	**%**	**Number**	**%**	**Number**	**%**
Number	216	49.4%	221	50.6%	437	100%
Gender						
- Female	108	50%	127	57.5%	235	53.8%
- Male	108	50%	94	42.5%	202	46.2%
Married	130/ 200	65%	106/ 178	59.6%	236/ 378	62.4%
Education						
- Completed 3rd level	82/197	41.6%	96/174	55.2%	178/371	48.0%
Occupation						
- Employed	141/201	70.1%	136/178	76.4%	277/379	73.1%
- Retired	5	2.5%	6	3.4%	11	2.9%
- Other	55	27.5%	36	20.2%	91	24.0%
Smokers	42/ 202	20.8%	37/ 180	20.6%	79/ 382	20.7%
Self-reported diabetic complications*	53/ 215	24.7%	40/ 219	18.3%	93/ 434	21.4%
Ketoacidosis in previous year	4/ 215	1.9%	5/ 220	2.3%	9/ 435	2.1%
Baseline PAID $\geq$ 33	86/ 207	41.6%	80/ 216	37.0%	166/ 423	39.2%
Baseline HADS Anxiety > 8	57/212	26.9%	44/215	20.5%	101/427	23.7%
Baseline HADS Depression > 8	37/211	17.6%	34/215	15.8%	71/426	16.7%

* Numbers represent participants who reported at least one or more of the following complications; myocardial infarction, coronary revascularisation, peripheral revascularisation, cerebrovascular accident, painful neuropathy, foot ulcer, amputation of the toe, amputation more than a toe, retinopathy, proliferative, laser treatment, registered partially blind, registered blind, microalbuminuria, proteinuria, dialysis or transplantation.

3.2 Primary Outcome

Intervention versus control arm: the effect of group follow-up

There was no difference in mean HbA_{1c} levels between intervention and control arm participants at baseline (Table 2). After 18 months of follow-up the mean difference in HbA_{1c} between intervention and control

arms was 0.14 percent (95% CI -0.33 to 0.61; p=0.47, Figure 2 and Table 2). The per protocol and intention-to-treat analysis based on multiple imputation revealed similar results. For this reason only data from the analysis based on mixed models are included in Table 2. In the *a priori* sub-group analyses involving individuals with baseline HbA_{1c} above and less than or equal to 7.5% (59 mmol/ mol) no effect of group follow-up on HbA_{1c} in either sub-group (p=0.66 and p=0.55 respectively) was observed.

Change in HbA_{1c} over time: the effect of DAFNE

Following DAFNE training and during 18 months of follow-up no significant change in HbA_{1c} was observed in either intervention or control arm participants (Figure 2 and Table 2). Individuals with a baseline HbA_{1c} above 7.5 percent (59 mmol/ mol) showed a statistically significant decrease in HbA_{1c} across time (mean difference -0.16 percent, 95% CI -0.27 to -0.06; p<0.001). Individuals with a baseline HbA_{1c} less than or equal to 7.5 percent (59 mmol/ mol) showed a statistically significant increase in HbA_{1c} across time (mean difference 0.61 percent, 95% CI 0.48 to 0.74; p<0.001).

3.3 Secondary Outcomes

Intervention versus control arm: the effect of group follow-up

At baseline, 24% (*n* = 104) of the cohort reported experiencing one or more episodes of severe hypoglycaemia in the previous year (19% in the intervention arm and 29% in the control arm). When data for severe hypoglycaemia were analysed as rates (i.e., episodes per patient per year) and when rates were compared between the intervention and control arms no significant difference was observed (rate ratio 0.47, 95% CI 0.03 to 6.57, p = 0.56). Likewise when the reduction (from baseline to 18 months) in the proportion of individuals experiencing one or more episodes of severe hypoglycaemia was compared between arms no difference was observed (see figure 2).

We observed no effect of group follow-up over individual follow-up for a range of secondary outcomes including weight and measures of psychosocial wellbeing or distress. These data are presented in table 3 and the psychosocial data are represented graphically in figure 2 (additional information is available as supplementary tables on the journal's website).

Change in outcomes over time: the effect of DAFNE

There was evidence of a reduction in the rate of severe hypoglycaemia at 18 months compared to baseline (rate ratio 0.42, 95% CI 0.33 to 0.55, p < 0.001). Among individuals who reported no episodes of severe hypoglycaemia at baseline the commonest outcome (reported by 90% of individuals) was no change in the number of severe hypoglycaemic episodes following DAFNE training (95% CI 84 to 94%). Only 10% reported an increase (95% CI 6 to 16%). Among individuals who reported one or more episodes of severe hypoglycaemia at baseline 93% reported a decrease following DAFNE training (95% CI 82 to 98%), 4% reported an increase (95% CI (0.005 to 13%)) and 6% reported no change (95% CI 1 to 17%). This analysis (based on proportions) is represented graphically in Figure 2.

Weight did not differ between groups at baseline and decreased slightly (but not significantly) in both groups during follow-up. Likewise no significant change was seen over time in blood pressure or lipid levels. The combined rate of hospitalisation was 5% at baseline; this reduced significantly to 2% at 18 months (p = 0.01).

Figure 2 shows the change from baseline in the intervention and control arms for the main psychosocial measures used in the study. These data are presented for the 18 month follow-up time period compared to baseline in Table 3. A similar pattern was observed for all measures, i.e., an improvement from baseline without any significant difference between groups.

Table 2 Comparison of HbA_{1c} between intervention and control arms at baseline and follow-up

		Baseline		At 18 months Follow-up		Adjusted Treatment Effect (between treatment arms)			Adjusted difference over time (between baseline and 18 months follow-up)			ICC
		Mean (SD)		Mean (SD)		Estimate (difference in mean)	p-value	95% CI	Estimate	p-value	95% CI	
		Intervention	Control	Intervention	Control							
HbA_{1c} (%)	Total	8.4 (1.4)	8.3 (1.3)	8.4 (1.3)	8.1 (1.1)	0.14	0.47	(-0.33, 0.61)	0.08	0.09	(-0.01, 0.16)	0.003
	High	9.0 (1.4)	8.8 (1.1)	8.8 (1.2)	8.5 (1.0)	0.14	0.66	(-0.45, 0.73)	-0.16	<0.001	(-0.27, -0.06)	0.059
	Low	6.8 (0.4)	6.8 (0.5)	7.5 (0.9)	7.4 (0.9)	0.08	0.55	(-0.25, 0.40)	0.61	<0.001	(0.48, 0.75)	<0.001

ICC refers to the Interclass Correlation Coefficient. High refers to baseline HbA_{1c} above 7.5% or 59mmol/ mol. Low refers to baseline HbA_{1c} equal to or below 7.5% or 59mmol/ mol.

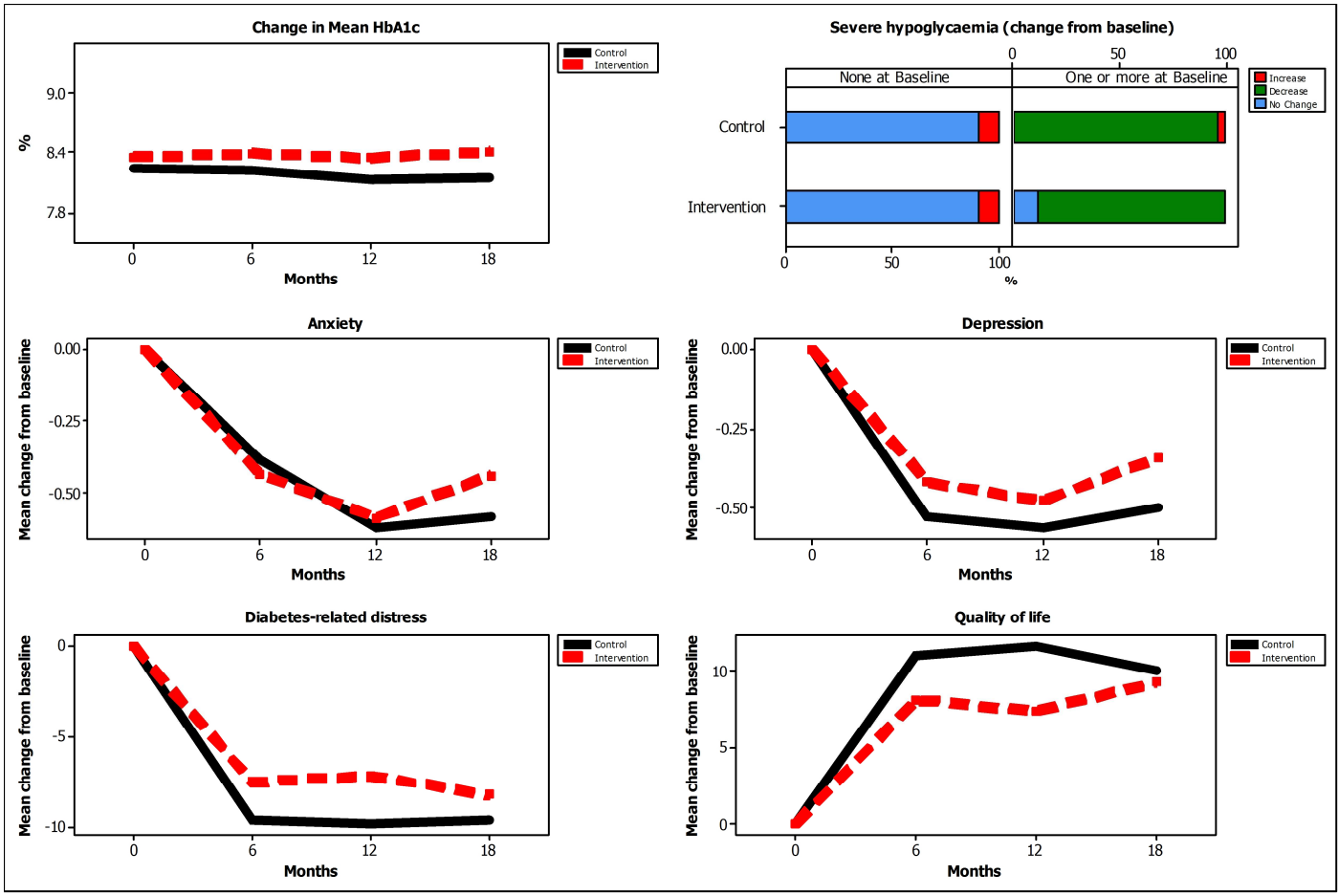

Figure 2 Primary and secondary outcomes

Table 3 Comparison of secondary outcomes between intervention and control arms at baseline and follow-up

		Baseline		At 18 months Follow-up		Adjusted Treatment Effect (between treatment arms)			Adjusted difference over time (between baseline and 18 months follow-up)			ICC
		Mean (SD)		Mean (SD)		Estimate	p-value	95% CI	Estimate	p-value	95% CI	ICC
		Intervention	Control	Intervention	Control							
Weight (kg)		210 76.9 (16.1)	217 77.0 (14.3)	137 76.4 (16.3)	140 75.8 (13.3)	0.10	0.83	-1.1, 1.3	-0.21	0.40	-0.7, 0.3	< 0.001
HADS (Hospital Anxiety and Depression Scale)	Anxiety	212 5.3 (3.8)	215 4.9 (3.4)	143 4.7 (3.8)	147 4.1 (3.3)	0.26	0.32	-0.3, 0.8	-0.53	<0.001	-0.8, -0.2	<0.001
	Depression	211 4.6 (3.5)	215 4.5 (3.1)	143 4.1 (3.3)	147 3.8 (3.1)	0.25	0.28	-0.2, 0.7	-0.44	<0.001	-0.7, -0.2	<0.001
Problem Area in Diabetes (diabetes-related distress)		207 30.0 (18.9)	216 29.8 (18.2)	144 21.6 (17.9)	144 18.9 (16.0)	2.58	0.10	-0.2, 5.3	-9.13	<0.001	-10.6, -7.6	0.001
Diabetes -Specific Quality of Life Scale	Treatment Satisfaction	140 55.4 (4.0)	159 55.6 (4.8)	78 58.7 (6.0)	84 57.3 (5.0)	-0.2	0.64	-1.3, 0.9	2.61	<0.001	1.8, 3.4	<0.001
	Quality of Life	200 64.9 (17.8)	192 64.4 (18.6)	140 72.6 (18.2)	143 76.1 (15.6)	-3.25	0.06	-6.8, 0.3	9.23	<0.001	7.6, 10.9	<0.001

4. Discussion

Our study was designed to compare two different methods of follow-up of individuals with type 1 diabetes who had completed the DAFNE structured education programme. Our results show no additional benefit from group follow-up compared to individual clinic visits. Over an 18 month period we found that DAFNE impacted favourably on rates of severe hypoglycaemia and hospitalisation and led to improvement in several measures of psychosocial wellbeing and distress. DAFNE was not associated with any improvement in HbA_{1c} although almost 30 percent of the cohort had a baseline HbA_{1c} below 7.5% (59 mmol/mol).

Among the strengths of our study are its size (which makes it unlikely that we missed a true effect of group follow-up), the cluster design (which protected against contamination of the control arm), the broad inclusion criteria (we did not exclude individuals with baseline HbA_{1c} in target) and the pragmatic setting (busy hospital clinics in 2 different health services). Our findings address an important question regarding the optimal method of follow-up of DAFNE graduates but also raise important questions regarding how individuals with "good" glycaemic control use the skills they are taught in a structured education programme. Limitations of our study include missing data (resulting from non-attendance at follow-up) and lack of blinding of the intervention (an unavoidable problem with all educational interventions). While our overall rate of loss to follow-up was as predicted, the problem with missing data was greater than expected and it is likely due to the challenges and practicalities of conducting a randomised controlled trial in busy clinical settings. However, it was broadly similar between the 2 arms of the study and (we believe) reflects the pragmatic nature of the trial. We were able to account for missing data (by imputation) in the analysis.

A potential reason why group follow-up was not superior to individual follow-up relates to the timing of delivery of the sessions. We chose 6 and 12 month visits for pragmatic reasons (these times reflect usual follow-up frequency). Our qualitative data suggest that DAFNE graduates find the period around 6 months especially difficult to maintain the DAFNE approach [25]. It is possible that more intensive follow-up early on would be more beneficial. Alternatively group follow-up in addition to (as opposed to instead of) individual clinic visits may be the preferred model for delivering care. This view is also supported by data from our qualitative research (K Murphy and D Casey, personal communication) and by emerging data from the paediatric diabetes literature [26].

Very few studies have formally assessed group follow-up of individuals with diabetes. Trento and colleagues reported a 3 year randomised controlled trial of group care compared to one-to-one clinic visits for individuals with type 1 diabetes [27]. The study randomised 62 patients and delivered 15 group care sessions over 3 years. They reported improvement in knowledge, health behaviours and quality of life but no change in HbA_{1c}. The intervention did not emphasise carbohydrate counting skills. They subsequently reported, in a brief communication, that when education in carbohydrate counting was included, levels of HbA_{1c} improved [28]. Evaluation of group-based care in type 2 diabetes suggests that it can take up to 2 years for improvement in HbA_{1c} to be realised with this approach [29]. Smith and colleagues reported that 9 peer support sessions delivered over 2 years to individuals with type 2 diabetes in general practice did not demonstrate any improvement in HbA_{1c} [30]. Likewise "group medical clinics" delivered in the Veterans Administration health service in the US were associated with improvement in blood pressure but not glycaemic control [31]. Sperl-Hillen and colleagues compared individual and group education and found improved

outcomes in those who received individual education [32]. Although extrapolating evidence from studies in type 2 diabetes to individuals with type 1 diabetes needs to be done cautiously, nevertheless, taken together these data suggest that the "dose" and duration of group follow-up may need to be greater than what we delivered to see benefit in terms of metabolic control.

Why did we not observe a greater effect of DAFNE training on HbA_{1c}? Almost one third of individuals recruited into our study had levels of HbA_{1c} that would be considered optimal at baseline. At the same time the burden of living with diabetes (reflected in our PAID scores) was high. It is conceivable that, when offered a "menu of benefit" through structured education, individual patients prioritise improvement in psychosocial wellbeing, reduction in rates of severe hypoglycaemia or hospitalisation over improvement in HbA_{1c}. Another potential explanation for our lack of improvement in HbA_{1c} over time relates to the "environment" in which the person with type 1 diabetes undertakes self-management. Metabolic control following structured education appears to improve considerably in Germany [1], less so in the UK [11] and less again in Ireland. The health services in these 3 countries are quite different from each other. It is conceivable that certain societal factors are contributing to these differences in metabolic outcomes. We believe the question of how different health services impact on an individual's ability to optimally self-manage is worthy of further investigation.

The HbA_{1c} is both a blessing and a curse to diabetes care. From the clinician's standpoint (the blessing) it reflects an integrated measure of glycaemic control over time, and is often viewed as the pre-eminent outcome in diabetes trials [33]. From the patient's standpoint (the curse) when readings are not in a "good" range it can be used as a stick with which to criticize the patient. Young adults in a UK diabetes centre have described how their non-attendance at clinic is due in large part to fear of reprimand related to elevated HbA_{1c} levels [34]. Colagiuri and colleagues recently suggested that a hierarchy of outcomes must be influenced before diabetes education can impact upon metabolic control [35]. These outcomes include knowledge, self-management, self-efficacy and psychological adjustment. The HbA_{1c} data from our study suggest little impact of education on glycaemic control. The psychosocial and qualitative data we collected highlight improvement in quality of life and a change in the relationship between the patient and the diabetes team. This is in contrast to the findings of a recently published health technology assessment in which a purely psychological intervention delivered to individuals with very high baseline HbA_{1c} led to improvement in metabolic control with no impact on psychosocial outcomes [36]. More research is needed to try to unravel the complex relationships between the individual, their baseline state of psychological and metabolic health and the impact of interventions (including structured education and group follow-up) on outcomes.

5. Conclusion

We have shown that group follow-up, as the sole means of follow-up after structured education for individuals with type 1 diabetes, is as effective as one-to-one clinic visits. We plan to publish an accompanying cost-effectiveness study of this trial, which will shed more light on the relative merits of the two approaches. To ensure maximum benefit from participation in DAFNE (and similar programmes), future research should explore alternative methods of engaging patients to maintain successful behaviour change in the longer term.

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