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A cluster randomized controlled non-inferiority trial of 5-day Dose Adjustment for Normal Eating (DAFNE) training delivered over 1 week versus 5-day DAFNE training delivered over 5 weeks: the DAFNE 5 x 1-day trial

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What's new?

- Structured education for people with Type 1 diabetes is provided in many different formats, but very few randomized controlled trials examining the biomedical, psychological and cost-effectiveness of these formats have been performed. Course format may limit accessibility for some people.

- Data from our randomized controlled trial shows that there were no major differences in outcomes between 5-week and 1-week Dose Adjustment for Normal Eating courses.

- As participants highly valued both course formats, and some found it easier to attend one type than the other, we have been persuaded to provide both 5-week and 1-week courses in the future.

Abstract

Aims To compare, in a randomized controlled non-inferiority trial, the outcomes of the traditional format for Dose Adjustment for Normal Eating structured education courses; that is, one delivered over 5 consecutive days (1-week course) with a variant of this format delivered 1 day a week for 5 consecutive weeks (5-week course).

Methods Adults with Type 1 diabetes, from seven UK Dose Adjustment For Normal Eating training centres, were individually randomized, stratified by centre, to receive either a 1-week or 5-week course. A qualitative study was embedded within the trial to explore patients' experiences.

Results In total, 213 patients were randomized and 160 completed the study procedures. In the per protocol analysis, the difference in HbA1c levels (95% CI) between the arms at 6 months was 0.4 mmol/mol (-2.4, 3.1) or 0.03% (-0.22, 0.28) and -0.9 mmol/mol (-3.9, 2.2) or -0.08% (-0.36, 0.20) at 12 months. All confidence limits were within the non-inferiority margin of ±5.5 mmol/mol (0.5%) for HbA1c%. For those patients with a baseline HbA1c of ≥ 58 mmol/mol (≥7.5%) the mean change (95% CI) in HbA1c was -2.2 mmol/mol (-4.0, -0.4) or -0.20% (-0.37, -0.04) at 6 months (*P*=0.016), and -2.0 mmol/mol (-4.1, 0.04) or -0.18% (-0.37 to 0.004) at 12 months (*P*=0.055). Episodes of severe hypoglycaemia were decreased by 82% [relative risk 0.18 (95% CI 0.03 to 0.936); *P*=0.042], psychosocial outcomes improved significantly, and the difference between arms was not significant. Qualitative interviews showed that patients overwhelmingly favoured the format of course that they attended.

Conclusions In summary, 5-week and 1-week Dose Adjustment for Normal Eating courses are equivalent in terms of biomedical and psychosocial outcomes, and we were persuaded that both course formats should be made available in routine care.

(Clinical Trials Registry no: NCT01069393)

Introduction

The Dose Adjustment for Normal Eating (DAFNE) course aims to improve HbA1c levels, whilst also reducing the occurrence of hypoglycaemia and increasing dietary freedom [1]. After the publication of the original trial, DAFNE training has been successfully rolled out to 76 centres and self-management skills have been taught to >31 000 people with Type 1 diabetes across the UK, as well as in centres abroad. Other centres have also adopted similar forms of structured education, albeit of varying duration, content and quality [2]. Ongoing internal and external quality assurance is an integral part of the DAFNE programme (and is listed as a required element of training in a Department of Health report [3]), but is rarely provided systematically by those running other courses.

Despite national acknowledgement that structured skills training is a key element of diabetes care, access to it is not universal [4]. The possible limitations of providing DAFNE training only over 5 consecutive days from Monday to Friday has been raised [5]. It has been suggested that delivering courses on 1 day a week over a longer period may improve access for those in full-time work, whilst still improving glycaemic control, but a trial in which structured education was delivered for 2.5 days spread over 6 weeks failed to show improvement in biomedical outcomes [5]. Single centres running longer courses have reported similar outcomes to those of the DAFNE trial [6], but these findings are observational, uncontrolled and prone to bias.

Different modes of course delivery may result in contrasting outcomes. It is conceivable, for instance, that a 1-week course may facilitate the incorporation of self-management skills via more intense bonding and peer support amongst course participants [7]. Alternatively, a 5-week course may lead to better integration of self-management skills into everyday life, by enabling participants to practice key behaviours over longer periods between course dates. To evaluate the biomedical impact of an alternative mode of course delivery, and to explore ways to improve accessibility, we conducted a randomized controlled trial to compare outcomes after 5-day DAFNE courses delivered over 1 week (1-week course) with those from courses delivered over 1 day a week for 5 consecutive weeks (5-week course).

The DAFNE 5×1-day randomized controlled trial was designed to meet the following objectives: (1) to compare the effectiveness of DAFNE delivered over 1 week vs 5 weeks, in terms of both biomedical and quality-of-life outcomes; (2) to compare the cost-effectiveness of the two formats; (3) to understand and interpret any differences and similarities in biomedical and psychological outcomes; (4) to ascertain patient preference for one format over the other (qualitative sub-study reported separately [8]; and (5) to provide recommendations for future delivery of DAFNE courses.

Patients and methods

The trial protocol has been reported previously [9]. Briefly, this multicentre randomized controlled trial involved seven UK DAFNE centres. Participants were recruited via waiting lists and, in some centres, by information evening meetings, and were informed of a pair of course dates (a 1-week or a 5-week course) for which they would need to be available. After obtaining written consent, participants were randomized to attend either a 1-week course (control arm delivered Monday to Friday) or a 5-week course (intervention arm delivered 1 day a week over 5 consecutive weeks). To reduce bias, both course formats were delivered by the same two DAFNE educators in each centre.

The content of the 5-week curriculum was identical to that of the standard 1-week DAFNE in terms of skills training and educational subject matter, with only minor adaptations [9]. A full economic analysis was undertaken, for which the methods are detailed in the protocol paper [9] and the results of which are reported in a separate paper [10]. Qualitative interviews were also undertaken with participants who attended the 5-week and 1-week courses, within 2 weeks of course completion, to establish their likes/dislikes of the course they had just attended and their views about whether, and why, future DAFNE courses should be offered in a 5-week and/or 1-week format [8].

The inclusion criteria were: diagnosis of Type 1 diabetes for at least 6 months; age 18–80 years; not having previously attended a DAFNE course; HbA1c level <108 mmol/mol (12%); willingness to undertake intensive insulin therapy, with multiple self-monitoring tests of

blood glucose; willingness to undertake carbohydrate counting and insulin self-adjustment; and no strong views about attending a 1-week or 5-week course. The exclusion criteria were: severe diabetic complications; inability to communicate in English; strong preference for a 1-week or 5-week course; or inability to give informed consent.

The sample size was calculated to test non-inferiority between the two different course delivery formats. Based on a non-inferiority margin in HbA1c level of 5.5 mmol/mol (0.5%), a standard deviation of 16.5 mmol/mol (1.5%), seven to eight participants per course, an 80% power at a one-sided 5% significance level and an intracluster correlation coefficient of 0.05, it was calculated that 150 participants were required to complete the trial. Assuming a 10% drop-out rate this meant randomizing 166 participants. Each centre was originally required to run four courses; that is, two pairs of 1-week and 5-week courses. As the trial progressed, however, the drop-out rate was higher than anticipated between the time of randomization and course attendance, so one centre ran an extra pair of courses.

After baseline data collection, randomization of participants was performed individually using a random block size, stratified by centre and a blinded web-based remote randomization system. The allocation sequence was generated using a computer program RANDLOG (University of Southampton, Southampton, UK).

Data on HbA1c levels, lipid profiles, weight, severe hypoglycaemic episodes, hospital admissions and psychosocial questionnaires were collected at baseline, and 6 and 12 months after course completion. Based on findings from qualitative interviews after the courses a number of additional questions about self-management behaviours were built into a 12-month questionnaire, which also enquired about course format preference. The psychosocial questionnaires included measures to assess diabetes distress, mood and quality of life. HbA1c levels were measured at Diabetes Control and Complications Trial (DCCT)-aligned local laboratories (as per DCCT trial [11]). The primary outcome was change in HbA1c from levels at baseline to those at 6 and 12 months. Secondary outcomes were: change in HbA1c where the baseline HbA1c was ≥58 mmol/mol (7.5%; this was because some patients choose to undergo DAFNE training in order to increase dietary freedom, or to decrease episodes of hypoglycaemia as opposed to reducing HbA1c level), number of

episodes of severe hypoglycaemia (defined as needing assistance of a third party to recover), changes in lipid profile /estimated glomerular filtration rate, and differences in psychosocial outcomes [9].

Statistical analysis

We used a linear model of HbA1c at 12 months for the primary analysis, with baseline HbA1c as a covariate, using generalized estimating equations to control for clustering within courses. The intracluster correlation coefficient was estimated using the method of moments. A negative binomial model was used for the number of severe hypoglycaemic episodes during 12 months, which has more power than a dichotomy of having/not experiencing an episode, again using generalized estimating equations to account for clustering. A per-protocol analysis was the main analysis, as appropriate for a non-inferiority study [12]. An intent-to-treat analysis was also undertaken. When analysing psychosocial measures, missing data were imputed using the mean for domains for which > 50% of questions were answered. The full-analysis set for the intent-to-treat analysis included all patients for whom baseline data were collected.

Ethical considerations

Written informed consent was obtained from all participants. Ethical approval was obtained from the Derbyshire Research Ethics Committee (09/H0401/91). The study sponsor was Sheffield Teaching Hospitals NHS Foundation Trust and all components of the trial were approved by the local Research and Development departments of all participating centres.

Results

Figure 1 shows the CONSORT diagram [14]. A total of 217 patients were assessed for eligibility, and 213 were randomized to either a 1-week or a 5-week course, between May 2010 and May 2011. Of these, 180 patients commenced the course, and 160 completed study procedures (89%). The mean age of those randomized was 41.6 years and the mean duration of diabetes was 18.5 years. The remainder of the baseline summary statistics are summarized in Table 1, and baseline psychosocial questionnaire scores are shown in Table 2.

Outcomes: HbA1c (primary and secondary)

Across the entire cohort, the improvements in HbA1c were small. For those patients with a baseline HbA1c of ≥58 mmol/mol (≥7.5%) the mean (95% CI) change in HbA1c was -2.2 mmol/mol (-4.0, -0.4) or -0.2% (-0.37, -0.04) at 6 months (*P*=0.016), and -2.0 mmol/mol (-4.1, 0.04) or -0.18% (-0.37, 0.004) at 12 months (*P*=0.055; Table 3). The primary outcome of the mean change in HbA1c between the two arms at 6 and 12 months was not significantly different. Non-inferiority would be established if the 95% two-sided CI for the difference between the 5-week and 1-week course was entirely above the non-inferiority margin (i.e. entirely above -0.5). For both the per-protocol and intent-to-treat analyses of the primary endpoint and the secondary outcome of change in HbA1c level from baseline to those at 6 and 12 months for patients whose baseline HbA1c was >58 mmol/mol (>7.5%), the 95% CIs were within the non-inferiority margins (Table 4). The point estimate of the intracluster correlation for HbA1c between courses at 12 months was -0.02 (95% CI -0.10 to 0.12) which suggests little variation in outcome between courses and that the generalized estimated equations analysis would be similar to one which did not account for clustering.

Secondary outcomes

Biomedical outcomes

The number of episodes of severe hypoglycaemia was reduced in the 12 months after DAFNE training compared with the 12 months before. The estimated relative risk for after vs before DAFNE training was 0.18 (95% CI 0.03 to 0.936; *P*=0.042). This shows that patients have an 82% reduced risk of severe hypoglycaemia after vs before DAFNE training. The interaction between treatment arm for before vs after DAFNE training was not significant (*P*=0.939); thus, the decrease in risk was the same in both treatment arms. There were some small differences in other biomedical outcomes between the two arms. In the 5-week arm the mean (95% CI) decrease in weight was higher than in the 1-week arm [-1.61 kg (-2.79, -0.44) vs -0.07 kg (-1.49, 1.35)] and was associated with bigger decreases in BMI [-0.54 kg/m2 (-0.95, -0.14) vs 0.01 kg/m2 (-0.48, 0.50)], diastolic blood pressure [-2.7 mmHg (-5.6, 0.2) vs 0.5 mmHg (-2.7, 3.6) mmHg] and triglycerides [-0.12 mmol/l (-0.31, 0.07) vs 0.30 mmol/l (0.00, 0.65)] in the 5-week vs the 1-week arm.

Psychosocial outcomes

For all psychosocial outcomes, scores improved significantly 6 months after DAFNE training, the improvement was maintained at 12 months, and the 5-week intervention was non-inferior to the 1-week intervention. For example, for the Problem Areas in Diabetes [15] questionnaire, which measures diabetes distress and in which lower scores indicate less distress, the mean score decreased from baseline by averages of 9.5 points at 6 months and 10.2 points at 12 months, with no significant difference between the arms. Similar improvements were achieved and maintained across a range of other scales with no difference between treatment arms, i.e. the Hospital and Anxiety Depression scale [16], the Confidence in Diabetes Scale [17], the Diabetes-Specific Quality of Life (all subscales) [18], the Hypoglycaemia Fear Survey Worry Subscale [19], and the EuroQol questionnaire, the EQ-5D State of Health scale (Table 5) [20].

Qualitative sub-study

Some findings from the qualitative sub-study have been previously reported [8]; briefly, a comparison of 5-week and 1-week course participants' interviews did not show any differences in their experiences and diabetes self-management practices after their courses. Positive experiences of the course were reported by both groups, with virtually all patients perceiving advantages to, and preferring the format of, the course that they had just attended. The 12-month follow-up questionnaire reinforced these findings, showing that 85% of respondents thought that the format of course that they attended would be better than the alternative format.

Discussion

The results of this randomized controlled trial show that attending DAFNE structured training 1 day a week over 5 consecutive weeks is as effective as attending a standard DAFNE course delivered over 5 consecutive days. Although we only aimed to show that the 5-week course was non-inferior to the 1-week course, we can conclude that the two formats are equivalent because the CIs for the difference are bounded by both -5.5 mmol/mol and +5.5mmol/mol (-0.5% and +0.5%). The mean change in HbA1c level from that at baseline vs those at 6 and 12 months was similar, and this was also true for patients with a baseline HbA1c of ≥58 mmol/mol (≥7.5%). Across the whole cohort, the relative risk of severe hypoglycaemia decreased by 82%, and this occurred independently of treatment arm. In the original DAFNE trial [1] no significant difference in the rate of severe hypoglycaemia was observed, but a reduction has been reported in a later observational study of an evaluated roll-out of DAFNE graduates [21], and in another report showing reductions in costs of emergency treatment after DAFNE training [22].

For the cohort as a whole, the improvement in HbA1c was modest; for those with baseline HbA1c ≥58 mmol/mol (≥7.5%), it was -2.2 mmol/mol (-0.2%) at 6 months (P=0.016) and -2.0 mmol/mol (-0.18%) at 12 months (P=0.055). These values are greater than the change for the entire cohort, possibly because of regression to the mean; however, these changes were

smaller than those achieved in the original DAFNE trial, which reported a change in the group who received DAFNE of -11 mmol/mol (-1.0%) at 6 months, and -5.5 mmol/mol (-0.5%) at 12 months [1]. The original DAFNE trial only recruited patients with an HbA1c level ≥58 mmol/mol (≥7.5%) and so we can make a valid comparison. In the original DAFNE trial the mean HbA1c level for those who received the intervention was 79 mmol/mol (9.4%) which is greater than the level of 74 mmol/mol (9.0%) in the present restricted cohort, suggesting a greater possibility of regression to the mean in the original trial. However, HbA1c among the control group in the original trial went from 78 mmol/mol (9.3%) at baseline to 79 mol/mol (9.4%) after 6 months, which implies that we cannot attribute any of the change in the DAFNE group to regression to the mean. In addition, the success of the original DAFNE trial may have contributed to a change in culture so that more adults with Type 1 diabetes are now encouraged to use a basal-bolus regime (as opposed to a twice-daily mix); and many patients now have some experience of carbohydrate counting even without formal DAFNE training [23]. The cohort in the present randomized controlled trial may therefore already have been more skilled in dose adjustment and carbohydrate counting, thus reducing the potential for improvement in HbA1c levels. It is noteworthy that another recent controlled trial of the DAFNE intervention also did not show much improvement in HbA1c [24], whilst observational data from two different cohorts have recently shown improvements in HbA1c of 3 mmol/mol (0.3%) at 12 months [22,25].

We also assessed psychosocial outcomes, confirming the findings of other DAFNE studies [21,24–26] by showing marked improvements at 6 months and maintenance at 12 months, with no differences between participants in the 5-week vs the 1-week arm.

One key objective of the qualitative research was to ascertain patients' likes and dislikes of their courses and their views about which format should be offered in the future [8]. As reported elsewhere, before attending their courses, half the participants had no preference and those who did often cited logistical reasons for why one format would be better for them than the other [8]. After the course, however, participants overwhelmingly preferred the format they had just received, citing perceived educational, clinical and behavioural benefits to justify their post-course preferences [8]. While this raises important questions about the usefulness of patient consultation exercises, a subject debated in a separate

paper [8], these findings do suggest that both course formats are liked by participants. This is reflected by the fact that, once participants commenced a course, the number of drop-outs was low (Fig. 1), with only one participant in the 1-week arm and seven participants in the 5-week arm dropping out. The reasons for drop-out were generally life events, for example, illness, bereavement, illness of a relative or snow, which are more likely to occur over a 5-week than a 1-week period.

We have undertaken a detailed health economic analysis to compare the cost-effectiveness of the two different delivery formats of the course, the results of which are detailed in a separate paper [10], but indicate few differences.

In conclusion, we have shown that there were no major differences in biomedical and psychosocial outcomes or in cost-effectiveness [10] between the 5-week and 1-week DAFNE courses. As participants valued both course formats highly, and some found it easier to attend one type than the other, we have been persuaded to provide both 5-week and 1-week courses in the future.

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Competing interests

None declared.

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FIGURE 1 CONSORT diagram: participant flow through the Dose Adjustment for Normal Eating 5×1-day randomized controlled trial.

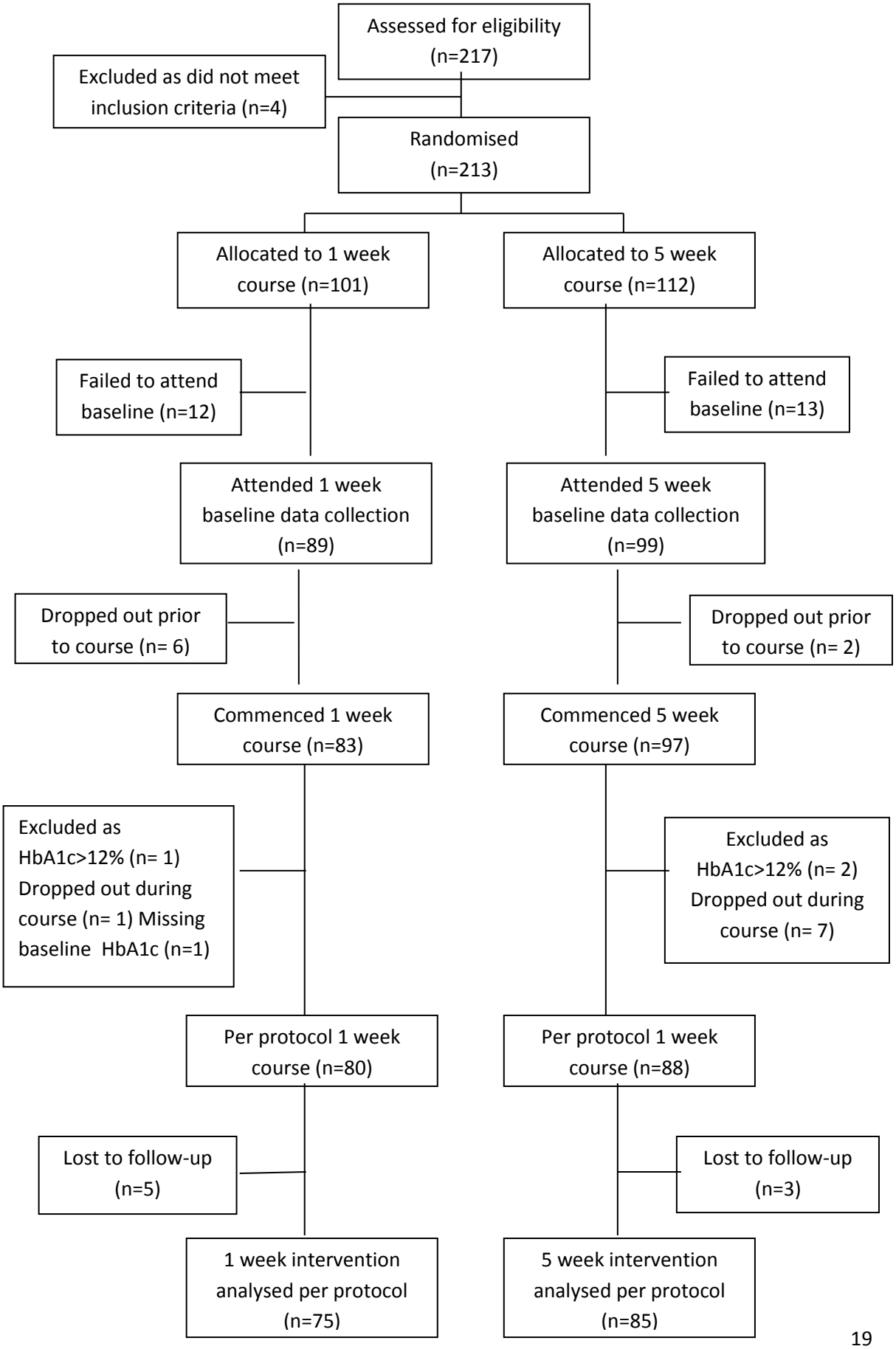

Table 1 Baseline summary statistics of participants

	Treatment arm									
	1-week course (N = 80)					**5-week course (N = 88)**				
Gender: male, n (%)	39 (48.8)					56 (63.6)				
Ethnicity, n (%) White Other	 77 (96.3) 3 (3.8)					 83 (94.3) 5 (5.7)				
	N	**Mean**	**SD**	**Min.**	**Max.**	**N**	**Mean**	**SD**	**Min.**	**Max.**
Age, years	80	40.7	13.2	19.0	73.0	88	42.4	12.9	19.0	72.0
Age at diagnosis, Years	79	20.1	12.8	2.0	65.0	88	26.1	14.8	2.0	65.0
Diabetes duration, Years	79	20.9	13.7	0.0	51.0	88	16.3	12.0	0.0	48.0
Weight, kg	76	78.3	15.7	51.0	135.4	88	78.3	15.3	54.5	127.5
Height, cm	77	170.2	8.5	152.0	190.5	87	171.6	8.7	152.5	190.0
BMI, kg/m²	76	27.0	4.6	19.0	39.0	87	26.5	4.6	19.8	44.7
Systolic blood pressure, mmHg	76	132.0	18.7	103.0	224.0	86	127.4	18.2	90.0	198.0
Diastolic blood pressure, mmHg	71	75.3	9.8	55.0	100.0	86	74.0	10.2	44.0	100.0
HbA1c mmol/mol %	80	 70.3 8.59	 1.1 1.97	 46 6.4	 101 11.4	88	 67.5 8.33	 14.8 1.35	 33 5.2	 102 11.5
Total cholesterol, mmol/l	76	4.6	0.9	2.8	7.7	84	4.3	0.7	2.5	6.5
Triglycerides, mmol/l	55	1.2	0.6	0.4	3.4	66	1.3	1.0	0.4	5.5
HDL, mmol/l	65	1.6	0.5	0.6	3.2	80	1.5	0.4	0.8	2.9
eGFR<60 ml/min/1.73m², n(%)	5 (6.3)					1 (1.1)				
eGFR>60 ml/min/1.73m², n(%)	71 (88.8)					73 (83.0)				

eGFR, estimated glomerular filtration rate

Table 2 Baseline summary statistics of psychosocial measures

Questionnaire	Treatment Arm									
	1-week course					5-week course				
	N	Mean	SD	Min.	Max.	N	Mean	SD	Min.	Max.
Problem Areas in Diabetes	80	27.44	20.39	1.25	82.50	85	27.82	20.05	1.24	100.00
Hospital and Anxiety Depression Scale: Anxiety	80	6.86	4.11	0.00	18.00	85	7.08	4.08	0.00	18.00
Hospital and Anxiety Depression Scale: Depression	80	4.05	3.56	0.00	14.00	85	4.46	3.44	0.00	18.00
Confidence in Diabetes Score	69	82.29	10.47	47.00	100.00	84	82.67	10.90	54.00	100.00
Diabetes-Specific Quality of Life, total	80	31.45	19.05	1.05	91.93	85	30.40	17.28	0.00	98.60
Hypoglycaemia Fear Survey Worry Score	73	28.51	8.66	13.00	49.00	87	30.25	12.78	13.00	65.00
EQ-5D, single index	79	85.12	23.62	-1.60	100.00	79	82.34	23.58	12.40	100.00
EQ-5D, State of Health	80	69.93	16.58	22.00	99.00	84	69.81	18.67	20.00	100.00

Table 3 Mean change in HbA1c level across the entire 5x1 cohort

	N	Unadjusted mean change	95% CI	P
HbA1c level				
6 months mmol/mol %	166	 -0.8 (69.4 to 68.5) -0.08 (8.50 to 8.42)	 -2.3, 0.7 -0.21, 0.06	0.277
12 months mmol/mol %	167	 -0.7 (68.9 to 68.2) -0.07 (8.46 to 8.39)	 -2.4, 0.9 -0.22, 0.08	0.382
Baseline HBA1c ≥ 58 mmol/mol (7.5%)				
6 months mmol/mol %	127	 -2.2 (74.7 to 72.5) -0.20 (8.99 to 8.78)	 -4.0, -0.4 -0.37 to -0.04	0.016
12 months mmol/mol %	126	 -2.0 (74.4 to 72.4) -0.18 (8.96 to 8.78)	 -4.1, 0.04 -0.37, 0.004	0.055

Table 4 Per-protocol and intent-to-treat analysis of change in HbA1c level

	1-week course		5-week course		
	N	**Mean change† (95% CI)**	**N**	**Mean change† (95% CI)**	**Model summary coefficient* (95% CI)**
Per-protocol analysis					
Whole Population					
6 months	70		84		
mmol/mol		-1.0 (-3.3, 1.3)		-0.9 (-3.0, 1.3)	0.4 (-2.4, 3.1)
%		-0.09 (-0.30, 0.12)		-0.08 (-0.27, 0.11)	0.03 (-0.22, 0.28)
12 months	72		84		
mmol/mol		-1.5 (-4.1, 1.1)		0.0 (-2.4, 2.4)	-0.9 (-3.9, 2.2)
%		-0.14 (-0.37, 0.10)		0.00 (-0.22, 0.22)	-0.08 (-0.36, 0.20)
Baseline HBA1c ≥ 58 mmol/mol (7.5%)					
6 months	59		58		
mmol/mol		-1.8 (-4.4, 0.9)		-2.7 (-5.4, 0.03)	0.4 (-2.6, 3.4)
%		-0.16 (-0.41, 0.08)		-0.25 (-0.50, 0.00)	0.04 (-0.24, 0.31)
12 months	61		56		
mmol/mol		-2.3 (-5.2, 0.7)		-1.6 (-4.9, 1.7)	-1.2 (-5.0, 2.7)
%		-0.21 (-0.48, 0.06)		-0.14 (-0.44, 0.16)	-0.11 (-0.46, 0.25)
Intent-to-treat analysis					
Whole Population					
6 months	75		91		
mmol/mol		-1.0 (-3.2, 1.2)		-0.7 (-2.8, 1.4)	0.4 (-2.2, 3.0)
%		-0.09 (-0.20, 0.11)		-0.07 (-0.26, 0.13)	0.03 (-0.21, 0.27)

12 months mmol/mol %	77	 -1.8 (-4.2, 0.7) -0.16 (-0.38, 0.06)	90	 0.2 (-2.1, 2.4) 0.01 (-0.19, 0.22)	 -1.4 (-4.2, 1.4) -0.13 (-0.39, 0.13)
Baseline HBA1c ≥ 58 mmol/mol (7.5%)					
6 months mmol/mol %	64	 -1.7 (-4.2, 0.8) -0.15 (-0.38, 0.07)	63	 -2.7 (-5.4, -0.1) -0.25 (-0.50, -0.01)	 0.7 (-2.1, 3.5) 0.06 (-0.19, 0.32)
12 months mmol/mol %	66	 -2.5 (-5.3, 0.2) -0.23 (-0.48, 0.02)	60	 -1.4 (-4.6, 1.7) -0.13 (-0.42, 0.16)	 -1.6 (-5.2, 2.1) -0.14 (0.47, 0.19)

† Unadjusted mean change

* Difference between treatment groups, adjusted for baseline value and cluster effect. A positive value indicates that the 5-week course has a better change. Non-inferiority is established if the 95% two-sided CI for the difference between the 5-week course and 1-week course is entirely above the non-inferiority margin (i.e. entirely above -0.5).

Table 5 Psychosocial outcomes

Questionnaire		1-week course		5-week course		
	Months post course	N	Mean change† (95% CI)	N	Mean change† (95% CI)	Model summary coefficient* (95% CI)
Problem Areas in Diabetes	6	63	-10.04 (-14.41, -5.66)	72	-9.11 (-12.11, -6.11)	-2.21 (-7.27, 2.86)
	12	62	-8.78 (-13.30, -4.27)	74	-11.30 (-14.30, -8.30)	3.18 (-1.31, 7.66)
Hospital and Anxiety Depression scale: anxiety	6	63	-0.65 (-1.38, 0.08)	71	-0.86 (-1.58, -0.14)	0.08 (-0.96, 1.12)
	12	62	-1.11 (-1.98, -0.24)	75	-1.88 (-2.75, -1.02)	0.71 (-0.44, 1.85)
Hospital and Anxiety Depression scale: depression	6	63	-0.87 (-1.61, -0.13)	71	-0.88 (-1.34, -0.43)	-0.10 (-1.05, 0.86)
	12	62	-0.93 (-1.66, -0.20)	74	-1.23 (-1.85, -0.60)	0.15 (-0.71, 1.01)
Confidence in Diabetes Scale	6	56	7.36 (4.50, 10.22)	71	5.41 (3.31, 7.51)	-1.11 (-3.60, 1.39)
	12	54	5.16 (2.13, 8.19)	73	5.66 (3.45, 7.87)	0.88 (-1.98, 3.75)
Diabetes-Specific Quality of Life, total	6	63	-10.07 (-14.09, -6.04)	72	-8.24 (-10.97, -5.52)	-2.04 (-6.13, -2.06)
	12	62	-10.75 (-14.44, -7.06)	75	-10.45 (-13.34, -7.57)	0.27 (-3.42, 3.96)
Hypoglycaemia Fear Survey Worry Score	6	58	-0.80 (-2.35, 0.75)	73	-3.50 (-5.71, -1.29)	2.01 (0.59, 3.43)
	12	56	-2.63 (-4.92, -0.33)	76	-4.01 (-6.39, -1.63)	0.33 (-2.21, 2.86)
EQ-5D, single index	6	61	0.47 (-3.20, 4.14)	64	4.25 (-0.58, 9.09)	2.59 (-3.51, 8.69)
	12	61	-0.91 (-3.84, 2.02)	69	3.26 (-0.60, 7.12)	3.66 (-1.09, 8.41)
EQ-5D, State of Health	6	62	5.26 (0.85, 9.97)	71	5.08 (0.82, 9.35)	0.33 (-4.90, 5.56)
	12	62	4.40 (0.18, 8.63)	74	6.20 (2.28, 10.13)	2.64 (-1.75, 7.02)

† Unadjusted mean change

* Difference between treatment groups, adjusted for baseline value and cluster effect. A positive value indicates that the 5-week course has a better change, all 95% Cis include zero, so the outcomes of the 5-week course are not significantly different from the outcomes of the 1-week course.