Contents available at Sciverse ScienceDirect

Diabetes Research and Clinical Practice

journal homepage: www.elsevier.com/locate/diabres

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

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ARTICLE INFO

Article history:
Received 2 August 2012
Received in revised form
11 December 2012
Accepted 14 January 2013
Published on line 8 February 2013

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

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.

☆ Trial registration: Current Controlled Trials ISRCTN79759174.

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http://dx.doi.org/10.1016/j.diabres.2013.01.017

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 h of training for a DAFNE doctor and 105 h 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 an 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 h, 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 months 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.