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Can peer educators influence healthy eating in people with diabetes?

Results of a randomised controlled trial

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ABSTRACT

Aims:

To assess whether the Expert Patient Programme (EPP), adapted for people with type 2 diabetes, can be used to promote healthy eating to improve diabetic control.

Methods

Adults with type 2 diabetes (n=317) were randomised to receive either a diabetes specific EPP (n=162) or individual one off appointments with a dietitian (control group) (n=155). The diabetes specific EPP followed the standard NHS programme although all participants in the group had diabetes only, rather than a mix of chronic conditions. Participants attended a group session for two hours once a week for six weeks. In addition, a final seventh week two hour session was included that was specific to issues concerning diabetes. Outcomes were assessed at baseline, 6 and 12 months.

Results

There were no statistically significant differences between the control and the intervention group in any of the clinical outcomes measured. There was no significant difference between the groups in any dietary outcome. There was a higher starch intake in the EPP group, although this did not reach statistical significance (effect size for starch adjusted for baseline values 8.8g; 95%CI: -1.3 to 18.9). There was some loss of participants between baseline measurement and randomisation, although this did not appear to have had an important impact on baseline balance.

Conclusions

In this study of people with type 2 diabetes, the EPP approach was not effective in changing measures of diabetes control or diet.

Key words (5)

Expert patient; type 2 diabetes; diet; randomised controlled trial.

Introduction

With an aging population and increasing prevalence of obesity, the prevalence rates of type 2 diabetes is expected to continue to rise. In addition, the number of people with diabetes is 1.6 times greater in areas where there are high levels of poverty and where there are higher proportions of people of South Asian origin[1]. As the incidence of diabetes in the population rises, the need has emerged for effective methods of helping people with diabetes improve their management of the disease and improve their long-term health prospects.

In common with people suffering from other long term problems, who are managed in the community (for example by themselves and their GP), less than 50% of people with diabetes follow their treatment correctly. Less than 10% of adults with diabetes manage to follow all the steps required to achieve good diabetic control[2]. People with diabetes often do not know enough about their condition, and few have been helped to help themselves[2]. The concept of self-management has emerged as one promising route to improved health and well-being for those with chronic illness, in particular in the format of the Expert Patient Program (EPP), in which participants learn skills such as problem solving and relaxation from peer educators who themselves have a chronic condition (i.e. lay people who are trained to give advice to other people; the term lay tutor and peer educator are interchangeable)[3,4]. A review of research studies focusing on self-management found that such approaches could improve people's health in the short-term[5]. For example, disabled people have been trained to provide health messages to others with disabilities - the success of this project is partly due to the understanding between them about their situation[5,6]. In the UK, the "Challenging Arthritis" programme has led the way in successful peer education as has the "Living with Long Term Illness" project[7]. Consequently, in 2002 the Department of Health (DH) introduced generic self-management courses nationally, in the form of the Expert Patients Programme (EPP)[8]. The standard EPP consists of six, weekly sessions, each lasting around two hours. Whether the EPP can lead to improvement in diet of people with diabetes, through better self-management, is not known. In order to provide a more focussed course, an additional diabetes-specific session was added to the EPP in this study at week seven, developed by the University of Leeds but delivered by the peer educators.

The aim of this study was to train people with diabetes to deliver the EPP to other people with diabetes. This analysis aims to answer the key question: can peer educators promote healthy eating to improve control in people with type 2 diabetes?

Participants and Methods

Participants

Participants with type 2 diabetes were recruited from GP practices in the Burnley, Pendle and Rossendale area of Lancashire, following ethical approval from East Lancashire Local Research Ethics Committee. There were two phases to recruitment. First, participants were approached to become “peer educators”. These were people with diabetes, living in the community, who were willing to be trained in chronic disease self-management and to deliver group sessions on chronic disease self-management to other people with diabetes. Five people volunteered to become peer tutors. Of these, four attended a residential training course for this purpose, provided by the NHS EPP within East Lancashire. One participant withdrew due to unavoidable delays in setting up the residential course. Subsequently, two tutors who had been trained withdrew through ill health and were replaced by an additional two tutors; therefore four tutors were available to run courses for the trial. In addition, a senior trainer who had worked for the NHS EPP supported the project for a total of six months (and was paid to do so). It was a requirement of the EPP programme to have a more experienced tutor work with less experienced tutors. The senior trainer worked alongside volunteer peer tutors to deliver the programme, thereby providing five lay tutors in total. All tutors in this study were given additional training to deliver the diabetes specific elements of the course (week 7).

Participants for the intervention phase were also recruited from GP practices in the Burnley, Pendle and Rossendale area between October 2003 and October 2004. Eligibility criteria were adults with type 2 diabetes (defined as onset over 30 years, not on insulin within the first year); registered with GP practices selected from socially deprived catchment areas (using Jarman scores).

Following informed consent, potential participants were randomised into either the intervention or the control arm of the study before being invited for baseline measurements at the start of the intervention. The decision to randomise prior to baseline measures was a pragmatic one, designed to reduce the burden on control participants who would otherwise have to attend an additional appointment for the collection of baseline measures. Initially the gap between randomisation and baseline measures was minimal. However, as recruitment progressed delays were encountered that were out of the control of the research project team, which led to a greater delay between randomisation and collection of baseline measures. This resulted in some drop out between randomisation and collection of baseline

measures with subsequent potential effect on baseline balance between intervention and control groups.

Intervention

The EPP is being delivered by the NHS using a highly structured and standardised delivery format to people with a range of chronic health problems. Our intervention used this programme. It differed from the standard NHS practice in that each group included only people with diabetes. One extra session relating to aspects of diabetes was also added. Subjects attended a two hour session, once a week, for seven weeks. The first six sessions covered aspects of learning to cope with a long term health problem, and improved eating, relaxation and exercise patterns. A new seventh session was also delivered, specifically about diabetes. This session covered the following: identifying common problems for people with diabetes; monitoring diabetes; self-managing diabetes in terms of food intake, physical activity, blood glucose and blood pressure; goal setting.

Comparison

The control group received 'standard care', comprising an individual appointment with a dietitian, lasting approximately 15-30 minutes, depending on the duration of time since the patient was diagnosed with diabetes. At this session, the dietitian provided standard dietary advice, as would be delivered within the NHS setting.

Outcomes

The primary clinical outcome under study was a change in HbA1c, as a marker of diabetes control. Subjects were followed up at six months and 12 months following the EPP course. Group follow up sessions were arranged for the EPP group and individual follow up was arranged for the control group. Extensive measures were put in place to maximise response to the 12 month follow up, including two reminders to the initial follow up postal contact; telephone contact (at which minimal data were collected if participants would not return questionnaires, or attend a face-to-face appointment) and a medical note search (for which additional ethical approval was received). In addition, gift vouchers were provided to participants who returned the questionnaires (at a value of £5 per questionnaire returned). Subjects who did not attend the 12 month follow up were contacted by post with questionnaires and asked for permission to obtain clinical data from GP notes search.

Other outcomes of clinical relevance were weight, body mass index (BMI), waist circumference, lipid profile and blood pressure. Dietary changes were measured through the completion of repeated 3-day food diaries and questionnaires. Psychological measures were collected through questionnaires. These were the short-form Diabetes Empowerment Scale (DES), adapted for use in UK populations[9] and the Audit of Diabetes-Dependent Quality of Life (ADDQoL)[10]. The DES has three subscales: managing the psychosocial aspects of diabetes (9 statements), assessing dissatisfaction and readiness to change (9 statements) and setting and achieving diabetes goals (10 statements). Scores for each subscale range from a minimum of 1 to a maximum of 5, with 5 showing the greatest empowerment. The 18 questions in the ADDQoL were related to the freedom to eat and drink and enjoyment of food with diabetes. The combined score for impact on life ranged from -9 (maximum negative impact of diabetes) to +9 (maximum positive impact of diabetes).

Sample size

The sample size for the study was based on 90% power to detect a standardised difference of 0.4 in any of the main outcome measures. This required 135 subjects in each group (270 in total). This sample size would give adequate power to detect a difference between the groups of 2% in mean percentage of energy from fat (eg. 37% v. 35%), or a difference of 200kcal per day in total calorie intake or a difference of 3/4 of a portion of fruit and vegetables per day (400g per week). To allow for the effect of losses to follow-up we aimed to randomise an additional 10% of participants (300 in total).

Statistical analysis

Analyses were performed using Statistical Package for the Social Sciences (SPSS for Windows, version 11.5; SPSS, Chicago, IL). Independent sample t-tests (or non-parametric tests where appropriate) and chi-squared tests were used to investigate differences in baseline characteristics and response rates between the two groups. However, a poor response rate was seen in the intervention group, which meant that the original balance obtained through randomisation could not be guaranteed and a full intention-to-treat analysis (ITT) could not be performed. Therefore, analysis of covariance was performed, adjusting for baseline values. Sensitivity analyses were also performed to explore the effect of obtaining data from the medical note search, attendance at four or more sessions of the EPP and attendance at the diabetes-specific session of the EPP (week seven).

Results

Response rates

Progress through the study is given in figure 1. We targeted 1726 subjects as potential participants in the study. Of these, 319 subjects consented to take part in the study. Following randomisation, baseline measurements were available from 112 EPP and 127 control subjects (total 239 subjects). However, at six months there was a considerable drop out rate among the EPP group, with six month follow up dietary data from 61 (55%) of the EPP participants. Follow up of the control group at six months was much higher with 98 (77%) providing some data.

Attendance rates for the EPP group at baseline found that for 110 subjects for whom data was available, 18 attended only one session and 22 attended all seven sessions; 63 subjects attended the final diabetes specific session.

Attempts to improve follow up at 12 months were successful. At 12 months, clinical data (HbA1c) was available on 86 (77%) of the intervention participants and 118 (93%) control participants, with dietary data available on 74 (66%) of intervention participants and 101 (80%) of control participants. Although less than originally intended, this maintained almost 80% power for the same effect size as the study was originally powered for, and easily achieves more than 80% power for standardised differences of 0.5. Twelve month data were collected on some participants for whom there were no baseline measures (23 control and 21 intervention participants with 12 month but no baseline HbA1c). Baseline and 12 month clinical measures were available on 63 (56%) intervention and 91 (72%) control participants, with dietary data on 74 (66%) intervention and 103 (81%) control participants. For 12 month data, where baseline values were not always present, but response rates were higher, unadjusted figures are presented.

Figure 1 around here

Characteristics of participants at baseline

The mean age of participants at baseline in the EPP group was 65.4 years (SD 11.6) and in the control group was 66.2 years (SD 11.5). Of the EPP participants at baseline, 43% were female and 57% were male and of the control subjects, 40% were female and 60% were male. Over 95% of each group characterised themselves as of white European origin. In terms of employment, 8% of the EPP and 15% of the control group classified themselves as working full-time; 65% of the EPP and 63% of the control group were classified as retired. For education, 21% of the EPP and 20% of the control group had a degree level education. Similar percentages in each group (36% of the EPP and 37% of the control group) were living on their own. These results suggest that the groups were largely comparable at baseline.

Since drop out was an issue we also present baseline results for participants at 12 months, there were some small differences, particularly for the EPP group compared to the full baseline sample. Mean age was 65.8 years (SD 11.0) in the EPP group and 66.6 years (SD 11.0) in the control group. Of the 12 month participants in the EPP group 38% were female and 62% were male, while in the control group, 42% were females and 58% were males. Over 95% of each group characterised themselves as of white European origin. In terms of employment, 10% of the EPP and 14% of the control group classified themselves as working full-time, 62% of the EPP and 65% of the control group were classified as retired, 20% of the EPP and 23% of the control group had a degree level education and 29% of the EPP and 34% of the control group lived on their own.

Changes in primary clinical outcomes at 12 months

The key variables at baseline, six and 12 months for all participants are given in table 1. In subjects for whom there were both baseline and 12 months data, there was no significant difference in any clinical or dietary measure, with the exception of a borderline significant difference in unadjusted values for starch, which disappeared after adjusting for baseline values (see table 2). Using all 12 month data collected (including the medical note search), there was also no significant difference on any primary

clinical or lifestyle outcome. There was no significant difference in any dietary outcome, apart from a borderline difference in starch intake (EPP-control difference = 11.2g; 95% CI 0.2, 22.2; $p < 0.05$). Qualitative exploration of the sources of starch from food diaries failed to find any particular differences in food sources of starch between the groups.

Tables 1, 2 around here

Sensitivity analyses

Participants for whom 12 month data were extracted from clinical notes only (i.e. non-responders to the 12 month follow up session who consented to having their GP notes searched for relevant information), were compared with participants who provided data at 12 months follow up. There were no significant differences for any clinical measure between the two groups. Comparison was also made between individuals who attended four or more EPP sessions and controls and individuals who attended the diabetes-specific session (week seven of the course) and controls. Again, there were no significant differences between the groups in clinical or dietary measures. There were also no significant differences in psychological measures (data not presented).

Discussion

This study failed to show any significant difference in outcome between intervention and control subjects at 12 months. However, a high drop out, particularly from the intervention group, may have compromised the results of the trial. The sensitivity analyses performed also failed to elicit any differences between groups.

A major weakness of this research was the drop-out between randomisation and baseline measurement. The possible effect of this was to reduce the benefit of randomisation leading to potential selection bias and possible imbalance in baseline covariates. Nevertheless, imbalance was slight at worst, and results, adjusting for baseline covariates, were broadly the same as for unadjusted.

This problem was caused by unexpected delays in setting up the EPP which were beyond the control of the research project team. These included delays in implementation of the scheme at national and local level, including the development of generic course materials, setting up of training for tutors, lack of availability of senior trainers and changes in procedures associated with EPP delivery, which required all lay tutors to be supervised while delivering their first course.

A further problem was the relatively low response rate to follow up. However, the medical note search did go some way to address the differences in response rate between intervention and control participants. The lack of any intervention effect is disappointing, given the significant investment (at least £18 million) in the EPP by the NHS. However, it is interesting to note that these results are similar to those found in a small trial (n=83) comparing peer advisors with health professionals who delivered a self-management training programme to people with type 2 diabetes. This study concluded that because there was no difference in outcomes between the peer advisors and health professionals that this showed the success of the peer advisors. In fact, there was no difference in either group between baseline and follow up in measures of diabetic control (HbA1C) implying that neither group was successful in improving outcomes[11].

The mean glycated haemoglobin at baseline was 7.3-7.5%. This is lower than in other studies which have recruited participants with poor diabetes control and who may therefore be more likely to experience a positive outcome[12]. Diet was recorded using a 3-day food diary. The food diary technique is often considered to be a gold standard, although it can be prone to under-reporting. Energy intakes reported in our study are similar to those found in the low income diet and nutrition survey[13], which were estimated to be about 80% of the estimated average requirements.

Although, in this study peer educators do not appear to have been effective in promoting healthy eating and improving diabetic control, other group-based, education programmes have been successful[14]. The X-PERT programme, which is health professional led, was found at 14 month follow up to improve glycaemic control, body mass index, reduced requirement for diabetes medication and increased consumption of fruit and vegetables[15]. That project had excellent attendance rates[16]. This suggests people may be more committed to a programme if it is led by health professionals. A

recent review of therapeutic patient education for people with diabetes found that most education was undertaken by a multiprofessional team according to best practice guidance[17].

It is possible that the intervention, i.e. the EPP was not appropriate for the population under study. The evidence base for the EPP primarily derives from the US, where a different system of health care is in place. Self management is a more familiar concept there than in the UK, and this may raise issues around its transferability[18]. People who agreed to take part in this study were not representative of the local population, for example, there were fewer people of South Asian origin (5%) taking part than occur in Burnley, Pendle and Rossendale (10%). However, this would not affect the outcome of the study only its potential generalisability.

To explore our findings in more detail, we undertook qualitative interviews with participants from the intervention and control groups, along with tutors and trainers involved in delivering the EPP. The results of that qualitative study will be reported in detail elsewhere. In brief, there was considerable expression of disappointment regarding this course, although there were some participants who felt they had benefited. Positive aspects were around exchanging ideas with others who had diabetes and the diabetes specific week seven material. Nevertheless, these benefits do not appear to have translated into measurable improvements in health, and few changes in knowledge, attitude or behaviour could be attributed to the course. Most participants who had attended any session of the EPP course expressed a wish that there had been a higher proportion of diabetes-specific information and less instruction in techniques of self-management. A frequently expressed view was that concrete, relevant information applicable to their situation as people with diabetes would be more helpful than self-management skills that are broadly applicable in any situation. Participants who dropped out early in the course felt the most strongly about this.

The lack of impact of EPP in this trial may be due in part to a lack of receptivity to its basic concepts in a local culture where many see self-management as no more than the common sense they already possess. Future EPP courses may benefit from screening participants to determine potential likelihood of benefiting from the course. The other clear recommendation emerging from this study, however, is for a brief, intensive, disease-specific course such as the XPERT Programme, containing both medical

information and self-management techniques, to be offered to all diabetes patients within the first two months of diagnosis.

This trial was conducted in the early stages of delivery of the EPP, now that the programme has become more established, repeating this evaluation may yield a different result. It could be that softer outcomes, associated with other factors such as improved self-esteem or greater confidence may show greater differences between the two groups. While no differences were seen between groups in the psychological measures that were collected, these were mainly diabetes-specific outcomes and more generic measures may show greater differences. The generic EPP is now running in a number of areas of the country. A UK-wide evaluation of the pilot phase of the national EPP programme has been conducted by the National Primary Care Research and Development Centre (NPCRDC). A randomised controlled trial of the standard EPP course found moderate gains in self-efficacy for people attending courses. They note that caution should be applied to this finding since those results are only pertinent to people who volunteer to go on such a course and not those with long-term conditions more generally[19]. Diet, as measured in that study by one item, was not different between the EPP and the waiting list control groups.

In conclusion, this randomised controlled trial of an EPP targeted for people with diabetes found that the EPP approach was not effective in changing measures of diabetes control or diet.

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Declaration of competing interests: nothing to declare.

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References

- [1] Evans JMM, Newton RW, Ruta DA, MacDonald TM, Morris AD. Socio-economic status, obesity and prevalence of Type 1 and Type 2 diabetes mellitus. *Diabetic Medicine* 2000; **17**(6):478-480.

- [2] World Health Organisation. Therapeutic patient education. 1998. Copenhagen, WHO.
- [3] Lorig KR, Mazonson PD, Holman HR. Evidence Suggesting That Health-Education for Self-Management in Patients with Chronic Arthritis Has Sustained Health Benefits While Reducing Health-Care Costs. *Arthritis and Rheumatism* 1993; **36**(4):439-446.
- [4] Lorig KR, Sobel DS, Stewart AL et al. Evidence suggesting that a chronic disease self-management program can improve health status while reducing hospitalization - A randomized trial. *Medical Care* 1999; **37**(1):5-14.
- [5] NHS Centre for Reviews and Dissemination. Complications of diabetes: Renal disease and promotion of self-management. *Effective Health Care Bulletin* 2000; **6**(1):2000.
- [6] Griffin SJ, Kinmonth AL, Skinner C, Kelly J. Educational and psychosocial interventions for adults with diabetes. 1999. London, British Diabetic Association.
- [7] Barlow JH, Wright CC. Knowledge in patients with rheumatoid arthritis: A longer term follow-up of a randomized controlled study of patient education leaflets. *British Journal of Rheumatology* 1998; **37**(4):373-376.
- [8] Expert Patient Programme. <http://www.expertpatients.co.uk/public/default.aspx> . 19-11-2008.
- [9] Anderson RM, Funnell MM, Fitzgerald JT, Marriott DJ. The Diabetes Empowerment Scale: a measure of psychosocial self-efficacy. *Diabetes Care* 2000; **23**:739-743.
- [10] Bradley C, Todd CGT, Symonds E et al. The development of an individualised questionnaire measure of perceived impact of diabetes on quality of life. *Qualitative Life Research* 1999; **8**:79-91.

- [11] Baksi AK, Al-Mrayat M, Hogan D et al. Peer advisers compared with specialist health professionals in delivering a training programme on self-management to people with diabetes: a randomized controlled trial. *Diabetic Medicine* 2008; **25**:1076-1082.
- [12] Norris SL, Engelgau MM, Narayan KMV. Effectiveness of self management training in type 2 diabetes - A systematic review of randomized controlled trials. *Diabetes Care* 2001; **24**(3):561-587.
- [13] Nelson M, Erens B, Bates B., Church S., Boshier T. Low income diet and nutrition survey. 2007. London, The Stationery Office.
- [14] Deakin T, McShane CE, Cade JE, Williams RD. Group based training for self-management strategies in people with type 2 diabetes mellitus. *Cochrane Database Syst Rev*. *Cochrane Database Systematic Review* 2005; Apr 18;CD003417(2).
- [15] Deakin TA, Cade JE, Williams R, Greenwood DC. Structured patient education: the Diabetes X-PERT Programme makes a difference. *Diabetic Medicine* 2006; **23**:944-954.
- [16] Deakin TA, Cade JE, Williams DRR, Greenwood DC. EXpert Patient Education versus routine treatment (X-PERT): process evaluation. *Diabetologia* 2002; **45**:317.
- [17] Albano MG, Crozet C, d'Ivernois JF. Analysis of the 2004-2007 literature on therapeutic patient education in diabetes: results and trends. *Acta Diabetologica* 2008; **45**(4):211-219.
- [18] Griffiths C, Taylor S, Feder G, et.al. Self management education by lay leaders for people with chronic conditions [Protocol]. *Cochrane Library* 2004.

[19] NPCRDC National Evaluation team. The National Evaluation of the Pilot Phase of the Expert Patients Programme: Final Report. 2006. Manchester, NPCRDC.

Figure 1: Participant Flow

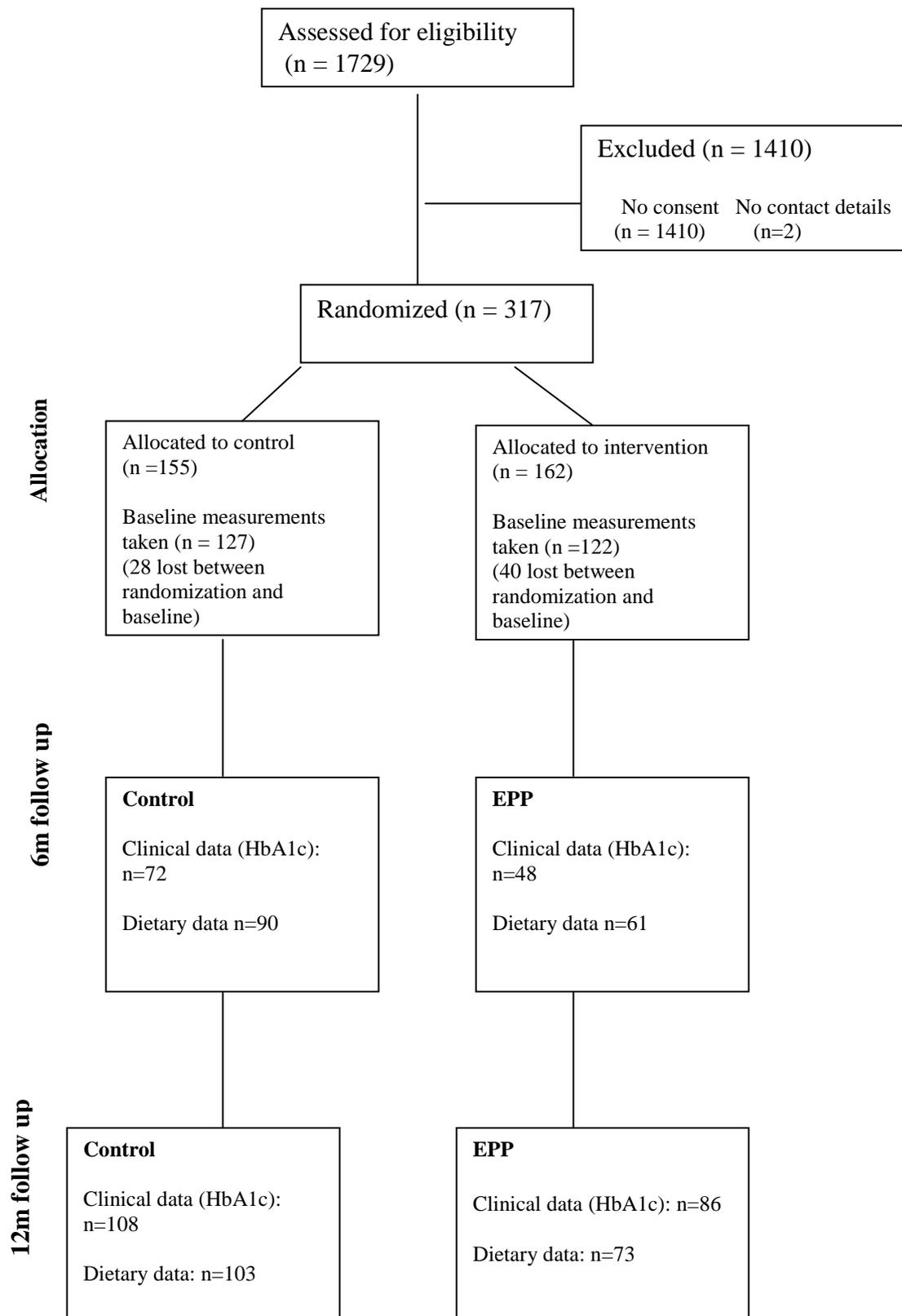


Table I. Comparison of key variables: baseline, 6 and 12 months (all participants)

	Control						EPP					
	Baseline		6 months		12 months		Baseline		6 months		12 months	
	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n
Anthropometry												
Weight (kg)	86.2 (17.6)	133	85.3 (16.3)	107	85.5 (16.8)	123	84.9 (19.3)	118	82.2 (17.2)	76	84.7 (18.7)	96
BMI (kg/m ²)	30.8 (5.6)	133	30.4 (5.0)	107	30.6 (5.2)	119	30.7 (6.0)	117	29.8 (5.5)	74	30.4 (5.7)	93
Blood												
HBA _{1c} (%)	7.5 (1.4)	118	7.5 (1.4)	91	7.6 (1.3)	108	7.3 (1.3)	89	7.5 (1.2)	73	7.6 (1.2)	86
Cholesterol (mmol/l)	4.6 (1.1)	121	4.4 (1.0)	93	4.3 (1.1)	106	5.0 (1.1)	90	4.6 (1.0)	69	4.5 (1.0)	87
Chol/HDL ratio	4.5 (1.1)	115	4.1 (1.0)	88	3.8 (1.0)	101	4.7 (1.4)	90	4.5 (1.3)	61	4.2 (1.1)	83
Systolic BP (mm Hg)	152 (21)	133	148 (20)	115	152 (21)	125	154 (24)	115	147 (20)	87	149 (21)	98
Diastolic BP (mm Hg)	82 (12)	133	81 (12)	115	80 (15)	125	83 (12)	90	79 (11)	86	80 (13)	98
Diet												
Energy (kcal)	1728 (473)	122	1542 (883)	90	1563 (473)	103	1886 (444)	102	1829 (706)	61	1668 (443)	73
Fat (g)	63.9 (24.5)	122	67.8 (39.7)	90	57.1 (24.9)	103	70 (22.8)	102	65.4 (28.5)	61	58.1 (19.8)	73
Saturated fat (g)	22.0 (9.1)	122	24.3 (15.0)	90	20.0 (9.8)	103	24.5 (10.1)	102	22.4 (10.2)	61	20.4 (8.9)	73
CHO (g)	210.6 (60.5)	122	219.8 (87.8)	90	196.5 (68.0)	103	227.3 (53.8)	102	225.1 (82.5)	61	211.1 (56.8)	73
Protein (g)	83.6 (21.8)	122	94.7 (41.3)	90	76.0 (20.0)	103	89.0 (21.8)	102	84.1 (22.8)	61	77.2 (18.3)	73
NSP (Englyst g)	16.1 (5.9)	122	17.0 (8.4)	90	15.0 (5.6)	103	16.2 (5.7)	102	16.7 (6.6)	61	15.8 (5.1)	73

Table II Unadjusted means and effect sizes adjusted for baseline values, for key clinical and dietary variables at 12 months.

	Control	EPP	Difference in means adjusting for baseline	95% CI	P
	Mean	Mean			
Clinical measures	(n=120 ¹)	(n=93 ²)			
Weight (kg)	85.9	84.2	-0.3	-1.4, 0.8	0.6
BMI (kg/m ²)	30.6	30.4	-0.04	-0.4, 0.3	0.8
HbA1c (%)	7.6	7.6	0.04	-0.3, 0.4	0.8
Cholesterol (mmol)	4.3	4.4	0.02	-0.2, 0.3	0.9
Systolic BP (mmHg)	152	149	-3.8	-8.7, 1.1	0.1
Diastolic BP (mmHg)	80.6	79.9	-1.0	-4.4, 2.4	0.6
Dietary measures					
	(n=87)	(n=64)			
Energy (Kcal)	1545	1648	21.7	-108.7, 152.1	0.7
Fat (g)	56.0	55.9	-2.7	-9.0, 3.7	0.4
Protein (g)	75.3	77.8	0.4	-5.4, 6.2	0.9
CHO (g)	194.5	209.2	4.1	-15.0, 23.2	0.7
Starch (g)	107.6	130.4	8.8	-1.3, 18.9	0.09
Englyst fibre (g)	14.8	15.6	0.8	-0.7, 2.3	0.3
Fruit and vegetable intake (g)	364.2	368.7	19.4	-39.2, 78.1	0.5

¹ weight, BMI n=118; HbA1c n=95; cholesterol n=97

² weight n=94; HbA1c n=65; cholesterol n=67