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Accepted: 8 December 2007

## Effectiveness of the diabetes education and self management for ongoing and newly diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes: cluster randomised controlled trial

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### EDITORIAL by Dinneen

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BMJ 2008;336:491-5

doi:10.1136/bmj.39474.922025.BE

### ABSTRACT

**Objective** To evaluate the effectiveness of a structured group education programme on biomedical, psychosocial, and lifestyle measures in people with newly diagnosed type 2 diabetes.

**Design** Multicentre cluster randomised controlled trial in primary care with randomisation at practice level.

**Setting** 207 general practices in 13 primary care sites in the United Kingdom.

**Participants** 824 adults (55% men, mean age 59.5 years).

**Intervention** A structured group education programme for six hours delivered in the community by two trained healthcare professional educators compared with usual care.

**Main outcome measures** Haemoglobin A<sub>1c</sub> levels, blood pressure, weight, blood lipid levels, smoking status, physical activity, quality of life, beliefs about illness, depression, and emotional impact of diabetes at baseline and up to 12 months.

**Main results** Haemoglobin A<sub>1c</sub> levels at 12 months had decreased by 1.49% in the intervention group compared with 1.21% in the control group. After adjusting for baseline and cluster, the difference was not significant: 0.05% (95% confidence interval -0.10% to 0.20%). The intervention group showed a greater weight loss: -2.98 kg (95% confidence interval -3.54 to -2.41) compared with 1.86 kg (-2.44 to -1.28), P=0.027 at 12 months. The odds of not smoking were 3.56 (95% confidence interval 1.11 to 11.45), P=0.033 higher in the intervention group at 12 months. The intervention group showed significantly greater changes in illness belief scores (P=0.001); directions of change were positive indicating greater understanding of diabetes. The intervention group had a

lower depression score at 12 months: mean difference was -0.50 (95% confidence interval -0.96 to -0.04); P=0.032. A positive association was found between change in perceived personal responsibility and weight loss at 12 months ( $\beta=0.12$ ; P=0.008).

**Conclusion** A structured group education programme for patients with newly diagnosed type 2 diabetes resulted in greater improvements in weight loss and smoking cessation and positive improvements in beliefs about illness but no difference in haemoglobin A<sub>1c</sub> levels up to 12 months after diagnosis.

**Trial registration** Current Controlled Trials ISRCTN17844016.

### INTRODUCTION

Several programmes have been developed in Europe<sup>1,2</sup> and North America<sup>3</sup> to educate patients about diabetes. The National Institute for Health and Clinical Excellence (NICE), however, found little evidence in the United Kingdom for the effectiveness of any educational approach in such patients,<sup>4</sup> a view reinforced in several reviews.<sup>5,6</sup> Evidence shows that education programmes with a theoretical basis and using cognitive reframing can improve outcomes.<sup>7,8</sup> Few programmes have been developed in a primary care setting and none has been designed specifically for patients from diagnosis.

We carried out a randomised controlled trial of the diabetes education and self management for ongoing and newly diagnosed (DESMOND) structured education programme. The preliminary phases of the trial are described elsewhere.<sup>9</sup> We evaluated the

effectiveness of the programme on biomedical, psychosocial, and lifestyle measures in people with newly diagnosed type 2 diabetes.

## METHODS

The trial was carried out in 13 primary care sites across England and Scotland. Randomisation was at practice level, with stratification by training status and contract with the primary care organisation.

Adults with type 2 diabetes were referred within four weeks of diagnosis, with those in the intervention arm attending a structured group education programme within 12 weeks of diagnosis (see [bmj.com](http://bmj.com) for exclusions). None of the practices provided structured education that had been described and evaluated. Most offered access to some kind of diabetes education. Control practices were resourced to enable them to provide contact time with healthcare professionals equivalent to that of the intervention group.

The intervention was devised as a group education programme, with a comprehensive curriculum, to be delivered in the community and integrated into routine care. Trained healthcare professionals delivered the programme, lasting six hours. Learning was elicited rather than taught. Most of the curriculum focused on lifestyle factors. We measured haemoglobin A<sub>1c</sub> levels, blood pressure, and body weight at baseline and at 4, 8, and 12 months; blood lipid profile and waist circumference were measured at baseline and at eight and 12 months. We obtained data on smoking status (summary of diabetes self care activities questionnaire<sup>10</sup>), physical activity (international physical activity questionnaire<sup>11</sup>), and quality of life (World Health Organization's quality of life instrument WHOQOL-BREF<sup>12</sup>). We assessed people's perception that they understood their diabetes (coherence), perception of the duration of their illness (timeline), and perception of their ability to affect the course of their diabetes (personal control) with the illness perceptions questionnaire—revised.<sup>13</sup> We assessed perceived seriousness and perceived impact of diabetes (diabetes illness representations questionnaire<sup>14</sup>), emotional distress specific to diabetes (problem areas in diabetes scale<sup>15</sup>), and depression (hospital anxiety and depression scale<sup>16</sup>).

## Statistical analysis

Statistical analysis was carried out on an intention to treat basis. We summarised continuous variables using means, standard deviations, medians, and ranges, and categorical variables using counts and percentages. Missing outcomes were not replaced and we derived an average over time of continuous outcomes. To adjust for a potential clustering effect we used robust generalised estimating equations<sup>17</sup> with exchangeable correlation structure. For binary outcomes we used a logit link with a binomial distribution for the outcome, and for continuous outcomes we used an identity link with a normal distribution. For ordinal outcomes we used an ordinal regression model with proportional odds

assumption, adjusted for clusters.<sup>18</sup> Adjustments were not made for multiple testing. All the results from planned analyses are reported and small P values are interpreted taking into account the overall pattern of the results. Statistical significance was set at 5%.

## RESULTS

Overall, 207 general practices (105 control, 102 intervention) were recruited from 13 sites in England and Scotland. Practice list sizes ranged from 847 to 34 324. From 1 October 2004 to 31 January 2006, 162 practices (77 control, 85 intervention) actively referred participants. In the intervention arm the mean number of participants attending a programme was 5 (range 3–11).

Of 1109 patients referred, 824 consented to take part (see [bmj.com](http://bmj.com)). The overall consent rate was 74% and lower in the intervention arm (70% *v* 79%). The mean (standard deviation) age was significantly higher in the consented group (60.3 years (12.2) *v* 56.5 years (13.0);  $P < 0.001$ ).

The mean (standard deviation) levels of haemoglobin A<sub>1c</sub> were significantly higher in the intervention group than in the control group: 8.3% (2.2) *v* 7.9% (2.0); see [bmj.com](http://bmj.com). The mean change in haemoglobin A<sub>1c</sub> levels from baseline to 12 months was higher in the intervention group: -1.49% (95% confidence intervals -1.69% to -1.29%) compared with -1.21% (-1.40% to -1.02%; see [bmj.com](http://bmj.com)). Adjustment for baseline and cluster effect, however, indicated that the difference was not significant ( $P = 0.52$ ). Further analyses of haemoglobin A<sub>1c</sub> levels with an additional adjustment for oral hypoglycaemic agents showed no significant difference between the two groups ( $P = 0.64$  at 12 months). Both groups showed a loss in body weight over the 12 months; the mean change was greater in the intervention group: -2.98 kg (-3.54 to -2.41) compared with -1.86 kg (-2.44 to -1.28). The differences in weight, after adjusting for baseline and cluster effect, were significant at four and 12 months ( $P = 0.024$  and  $P = 0.027$ ). The intervention group showed a significant reduction in triglyceride levels at eight months ( $P = 0.008$ ). Both groups showed improvements in the remaining biomedical measures over the 12 months; however the differences between the groups were not significant.

Although the risk estimate for cardiovascular disease from the United Kingdom prospective diabetes study<sup>19</sup> was not a specified end point it was calculated at baseline and 12 months for participants with complete data for the required variables (146 in control group, 180 in intervention group). The median 10 year risk estimate of coronary heart disease or stroke at baseline was 17.7% (interquartile range 11.6%–29.1%) for the control group and 18.9% (11.2%–31.8%) for the intervention group. The equivalent risks at 12 months in the control and intervention groups were 13.6% (7.6%–20.2%) and 10.9% (6.7%–19.1%;  $P < 0.002$ ). The intervention group showed a greater reduction in smoking status at all time points (see [bmj.com](http://bmj.com)). At 12 months the

odds of not smoking in the intervention group was 3.56 (95% confidence interval 1.11 to 11.45) higher than that of the control group, after adjusting for baseline and cluster effect. The results for smoking status were significant at eight and 12 months (both  $P=0.033$ ). The intervention group showed a greater increase in physical activity at all time points, which was significant at four months ( $P=0.046$ , see [bmj.com](#)).

education. Adjusted analyses showed that differences between the groups in four illness belief scores (coherence, timeline, personal responsibility, and seriousness) were all highly significant ( $P<0.001$ , see [bmj.com](#)). The directions of change were positive showing that the intervention group had greater understanding of their illness and its seriousness. The intervention group also showed a better perception of the duration of their diabetes and of their ability to affect the course of their disease, as indicated by the increase in these scores at 12 months (see [bmj.com](#)).

Symptoms indicative of depression were reported by 16% of women and 8% of men at baseline, values that compare with normative data from the UK.<sup>20</sup> Depression scores were lower in the intervention group than in the control group at all time points, and the difference was significant at 12 months ( $P=0.032$ , see [bmj.com](#)). The groups did not differ significantly for emotional impact of diabetes at eight and 12 months ( $P=0.97$  and  $P=0.91$ , see [bmj.com](#)) or the scores for six dimensions of quality of life. The results of the analyses are available at [www.leicestershire.diabetes.org.uk](http://www.leicestershire.diabetes.org.uk). After controlling for weight at baseline, sex, and age, the change in perceived responsibility correlated with weight loss at four and 12 months.

## DISCUSSION

A group structured education programme focused on behaviour change can successfully engage those with newly diagnosed type 2 diabetes in starting effective lifestyle changes sustainable over 12 months from diagnosis. Although clinically significant improvements were found in haemoglobin A<sub>1c</sub> levels, lipid profile, body weight, and blood pressure in both groups, after adjusting for cluster and baseline values, we found no statistically significant differences, apart from greater reductions in triglyceride levels at eight months and in body weight at four and 12 months in the intervention group. The modest (1.1 kg) but statistically significant difference in weight loss, and significantly greater reduction in those reporting smoking in the intervention group, were sustained to 12 months. Self reported physical activity was greater in the intervention group at four months but not at eight and 12 months. There was a greater improvement in the risk score for coronary heart disease at 12 months, with significantly more participants in the intervention group having a 10 year risk score of less than 15%.

Key health beliefs differed significantly, with the intervention group showing greater improvement in

beliefs about diabetes related illness. Depression scores decreased significantly at 12 months in the intervention group but no difference was found in diabetes specific emotional distress.

Across the whole cohort, after adjusting for body weight at baseline, a significant association was found between change in perceived personal responsibility and weight loss at four and 12 months. Although this analysis does not establish causality, data from the pilot study<sup>9</sup> indicate that changes in these illness beliefs are evident immediately after the intervention and therefore precede changes in weight loss.

## Strengths and limitations of the study

education. Intervention and control participants were well matched for variables except for haemoglobin A<sub>1c</sub> levels and sex. Such anomalies are not uncommon in pragmatic cluster randomised controlled trials. The introduction of the quality and outcomes framework may have incentivised treatment to target, particularly for haemoglobin A<sub>1c</sub>.<sup>21</sup> The lack of difference in quality of life between the groups may result from a lack of sensitivity in the tool used.

education. The study has several strengths. It has widespread generalisability as the sample size was large and representative of patients with newly diagnosed type 2 diabetes. The intervention was pragmatically designed for implementation in a primary care setting. The trial had a robust cluster design to reduce contamination between practices, with high recruitment and retention rates of participants. Finally, we applied few exclusion criteria and used validated generic and disease specific questionnaires.

The UK now has some of the best data in the world for process in diabetes care,<sup>21</sup> with over 90% of patients with diabetes having biomedical variables recorded and translated into good outcomes in achieving targets for haemoglobin A<sub>1c</sub> levels, blood pressure, and lipid levels. Shortly after diagnosis, when medical outcomes are being aggressively and effectively targeted, it becomes harder to show the additional benefits of providing structured education.

The structured group education approach encourages people to choose their own risk factors for action. As this intervention is offered early in the course of type 2 diabetes, it is not surprising that people focused on factors such as weight loss, physical activity, and smoking rather than biomedical variables that may already be at target levels. Overall mean levels for the cohort at 12 months were 6.7% for haemoglobin A<sub>1c</sub>, 4.4 mmol/l for cholesterol, 134 mm Hg for systolic blood pressure, and 77 mm Hg for diastolic blood pressure. These levels are well below those advocated by the quality and outcomes framework.

## Putting the study in context

One study reported on weight loss in adults using data from 22 studies with a follow-up of 1-5 years.<sup>22</sup> The

**WHAT IS ALREADY KNOWN ON THIS TOPIC**

The diabetes national service framework promotes structured education for all from diagnosis of diabetes

However, until now, there has been no scientific evaluation and no programmes demonstrably meeting all the quality criteria

**WHAT THIS STUDY ADDS**

A structured group education programme for patients with newly diagnosed type 2 diabetes was associated with benefits in illness beliefs, weight loss, physical activity, smoking status, and depression but not in haemoglobin A<sub>1c</sub> levels

Most of the changes were sustained over 12 months without further reinforcement

pooled weight loss for any intervention compared with usual care was 1.7 kg. Thus weight loss strategies including dietary, physical activity, or behavioural interventions produced improvements in weight between the groups, similar to our results. For changes in self reported smoking status, a recent meta-analysis of psychosocial interventions for smoking cessation<sup>23</sup> showed overall a positive effect of the intervention on abstinence after 6-12 months, with an odds ratio of 1.66. In comparison, our study reported an odds ratio of 3.56 (95% confidence interval 1.11 to 11.45).

Since the last NICE review of structured education in people with type 2 diabetes,<sup>4</sup> two key studies have been published. The Turin study<sup>24</sup> reported on a group education intervention in people with established diabetes (about nine years). Although the study was relatively small (n=120) and done in one specialist centre, at five years biomedical outcomes, knowledge about diabetes, and quality of life differed significantly between the control and intervention groups. The findings have informed the rethink organisation to improve education and outcomes study,<sup>25</sup> which is being done across several sites. The second study<sup>26</sup> was carried out in one primary care trust, with the programme delivered by one educator to people with established diabetes (n=314). At 14 months there was a reduction in haemoglobin A<sub>1c</sub> levels and significant improvements in knowledge about diabetes, physical activity levels, and satisfaction with treatment, with no difference in quality of life.

It is difficult to compare our results directly because of the different populations and because our study concerned multiple sites and educators. The study was robustly done according to an evaluation framework accepted as providing scientific rigour for complex interventions.<sup>27</sup>

We found significant reductions in haemoglobin A<sub>1c</sub> levels in both arms of our study. Although the intervention group had a higher baseline and an absolute decrease at 12 months that was 0.4% greater

than the control group, both groups had haemoglobin A<sub>1c</sub> levels well below 7.0%.

**Implications**

The results provide evidence that structured education meeting national service framework and NICE quality standards can provide added benefit to medical optimisation. Additional benefits shown in our intervention group were improvements in weight loss, self reported smoking status, and physical activity levels, and a change in illness beliefs that was associated with these behavioural changes. Depression in people with diabetes is associated with poor glycaemic control<sup>28</sup>; however, our intervention led to a decrease in depression scores.

In summary, the DESMOND structured group education programme encapsulates a patient centred approach to diabetes care. Taking place at a time when the quality and outcomes framework targets aggressively promote medical therapies to reach glycaemic targets, it is perhaps not surprising that levels of haemoglobin A<sub>1c</sub> were not significantly different between the groups. Pharmacological treatments cannot, however, tackle markers of successful long term control such as beliefs about illness and attitudes to diabetes, which influence behaviour and lifestyle change and sustain motivation. We found that group structured education that focused on behaviour change can successfully engage patients in starting effective lifestyle changes sustainable over 12 months from diagnosis.

**Contributors:** See bmj.com.

**Funding:** This study was funded by Diabetes UK. The project office administration was funded by an unrestricted educational grant from Novo Nordisk. The researchers were independent of any of the study funders. The study sponsor was the University Hospitals of Leicester NHS Trust. The research team and the principle investigator were employees of the sponsor during the period of the study.

**Competing interests:** None declared.

**Ethical approval:** This study was approved by the Huntingdon local research ethics committee.

**Provenance and peer review:** Not commissioned; externally peer reviewed.

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Accepted: 18 December 2007

## A memorable patient

### “We’d better do it under local”

She had been discharged from our breast cancer clinic almost 10 years earlier. There was no reason for her to think she might have relapsed when the bowel investigations at another hospital were normal. Because she had complained about her “waterworks,” she was referred to their local urologists for cystoscopy, but, just in case, the gastroenterologist had also arranged for computed tomography. She was due her cystoscopy after her CT scan but before being reviewed by the gastroenterologist, and she was therefore seen in the urology preassessment clinic by a junior doctor.

Unprompted, he began: “I’ve got this report, let me read it to you. ‘Multiple metastases are present throughout both lungs as well as throughout the skeleton. The metastases are predominantly sclerotic, although extensive destruction around the right SI joint is noted. The sclerotic metastases are most likely due to breast carcinoma, and I understand she has had a previous lumpectomy. A deposit is present in the spleen. A small left pleural effusion is noted. Liver clear.’ I don’t think we’d better do a general anaesthetic cystoscopy then, we’d better do it under local.”

“Don’t you expect me to be upset?” she asked.

“Yes,” he replied, “but there’ll be a meeting tomorrow between the gastroenterologists and the oncologists to discuss your cancer.” He then explained the cystoscopy to her.

The nurse was no more enlightening, as she was “just a urology nurse.” Despite the “meeting tomorrow,” it was a further two weeks before she saw the gastroenterologist again and was referred back to us.

She told me she felt strangely detached from the whole experience, which was just as well. Indeed, her lack of anger with the staff was most striking.

“You see, my partner died of oesophageal cancer eight years ago. I have no dependants and nothing particularly to live for. How long have I got? A month?”

We talked about her life, and I discovered she had been on a hospital management committee, as my father had. She therefore had a good understanding of how hospitals work and was still grateful for much of the care she had received. Perhaps her knowledge had also helped her cope with the extraordinarily unhelpful consultation she had received.

There must still be many unsatisfactory “bad news” interviews up and down the country. Much effort is going into training medical students in communication, but the current national communication skills training programme for senior doctors is underfunded. It is clear that there is still a major need for this.

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