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Research: Educational and Psychological Issues

Increasing capacity to deliver diabetes self-management education: results of the DESMOND lay educator non-randomized controlled equivalence trial

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Abstract

Aim To develop and test a format of delivery of diabetes self-management education by paired professional and lay educators.

Methods We conducted an equivalence trial with non-randomized participant allocation to a Diabetes Education and Self Management for Ongoing and Newly Diagnosed Type 2 diabetes (DESMOND) course, delivered in the standard format by two trained healthcare professional educators (to the control group) or by one trained lay educator and one professional educator (to the intervention group). A total of 260 people with Type 2 diabetes diagnosed within the previous 12 months were referred for self-management education as part of routine care and attended either a control or intervention format DESMOND course. The primary outcome measure was change in illness coherence score (derived from the Diabetes Illness Perception Questionnaire-Revised) between baseline and 4 months after attending education sessions. Secondary outcome measures included change in HbA_{1c} level. The trial was conducted in four primary care organizations across England and Scotland.

Results The 95% CI for the between-group difference in positive change in coherence scores was within the pre-set limits of equivalence (difference = 0.22, 95% CI 1.07 to 1.52). Equivalent changes related to secondary outcome measures were also observed, including equivalent reductions in HbA_{1c} levels.

Conclusion Diabetes education delivered jointly by a trained lay person and a healthcare professional educator with the same educator role can provide equivalent patient benefits. This could provide a method that increases capacity, maintains quality and is cost-effective, while increasing access to self-management education.

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Introduction

Structured self-management education programmes have been recommended in global and national guidelines for the management of Type 2 diabetes [1–3]. Such education should be designed to enable people with diabetes to initiate and sustain successful self-management of their disease, by providing them with the necessary skills and knowledge to empower them to make informed choices. Diabetes education is designed to influence the beliefs that people have about their condition, which have been shown to be robust predictors of health outcomes [4]. In the UK, diabetes-specific programmes such as the Diabetes Education and Self Management for Ongoing and Newly Diagnosed Type 2 diabetes (DESMOND) course [5] and X-PERT [6] have shown that structured self-management education can improve biomedical, psychological and lifestyle outcomes for people with Type 2 diabetes. Cost savings [7] and cost-effectiveness [8] have also been demonstrated for diabetes education, and longer-term follow-up has indicated that improvements in some health beliefs can be sustained over 36 months [9]. Delivering high-quality structured diabetes

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What's new?

- We evaluated a novel format of delivering education to patients with Type 2 diabetes, involving a lay educator and a healthcare professional educator, with the paired educators taking an equal role.
- We demonstrated that education sessions delivered in this new format can provide psychosocial and health outcome benefits that are equivalent to those obtained from sessions delivered by two healthcare professional educators.
- Equivalent benefits included positive change in terms of participants' understanding of their condition, derived from the Diabetes Illness Perception Questionnaire-Revised, and also reduction in HbA_{1c} levels.

education is, however, dependent on factors such as funding, organization of services and availability of appropriately trained healthcare providers. UK data have highlighted the limitations of current access to appropriate education, suggesting that in 2009–2010, only 10% of those recently diagnosed with diabetes in the previous 12 months received structured education [10].

One strategy for increasing capacity to deliver patient education is the use of educators who are not healthcare professionals. The Expert Patients Programme for people with chronic conditions is delivered by lay people who are also peers in terms of living with a chronic condition. Evaluation of the generic programme for people with any chronic condition has suggested positive outcomes [11], but evidence regarding the benefits of diabetes-specific versions has been mixed. Studies in the USA have suggested positive outcomes for people with Type 2 diabetes attending diabetes-specific versions [12,13], but in the UK a randomized controlled trial of an adapted version of the programme failed to demonstrate any statistically significant impact on measures of diabetes control [14]. In addition to the pioneering work of the Expert Patients Programme, a range of lay-led patient self-management education and support initiatives has been described. In the UK, Baksi *et al.* [15] compared patient outcomes after education that was delivered by either a healthcare professional or a trained peer advisor and found that, with effective training, lay people could impart knowledge to their peers as effectively as healthcare professionals. A similar study conducted in Argentina reported similar positive outcomes [16]. The use of lay people to deliver education has been particularly favoured as a method of seeking to address the needs of harder-to-reach groups, including people from specific ethnic backgrounds [17–19] or from other vulnerable or marginalized groups, such as people with serious mental illness [20] or those living in farming communities [21]. To our knowledge, no study has explored the potential of lay people to work alongside healthcare professionals as educators with an equal role in terms of delivering self-management education. The present DESMOND lay educator study was designed to address this gap.

The trial took place within the context of the DESMOND programme [5]. The DESMOND programme is an interactive group self-management education programme for people with Type 2 diabetes, delivered either during 1 day or two half-days. It is underpinned by a patient-centred philosophy [22] and is currently widely adopted in the UK. DESMOND programmes are delivered by two trained registered healthcare professional educators who follow a recognized training, mentorship and accreditation pathway [23].

Patients and methods

The study was conducted between 2008 and 2011 and consisted of two phases: a development phase involving the recruitment, selection and training of lay educators (Fig. 1), [24,25], and the formal trial phase. This paper focuses on the latter.

Design of main trial

The study was an equivalence trial, designed to test the hypothesis that, with appropriate selection, training and support, lay educators paired with healthcare professional partners (new model of DESMOND education delivery, designated as the intervention group) could deliver structured diabetes education with the same degree of interaction fidelity, quality and efficacy as the normal partnership of two healthcare professionals (standard model of DESMOND education delivery, designated as the control group). Both educators would have an equal role in delivering the education. Delivery was in four primary care organizations across England and Scotland. The trial was registered with the ISRCTN (ISRCTN99350009). The study was approved by the Leicestershire, Northamptonshire and Rutland Research Ethics Committee 1 (09/H0406/87).

Outcome measures

Primary and secondary outcome measures were based on changes between baseline and 4 months after attending education. The primary outcome measure was change in illness coherence score, derived using a validated tool, the Diabetes Illness Perception Questionnaire-Revised. The score measures the extent to which an individual's illness representations provide a coherent understanding of their condition, with higher scores indicating greater coherence [26]. The choice of coherence as a primary outcome measure was guided by the results of the original DESMOND trial in which a change in this score predicted statistically significant weight loss [5].

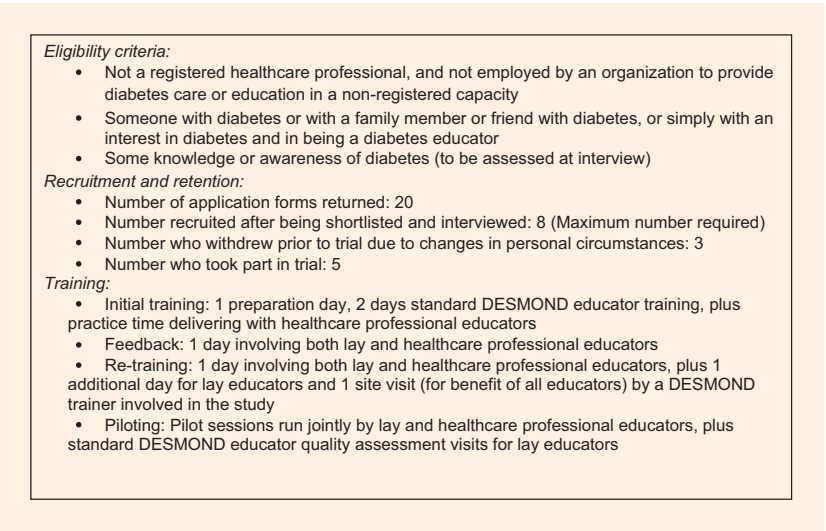

FIGURE 1 Recruitment and training of lay educators.

Secondary outcome measures included the Diabetes Illness Perception Questionnaire-Revised personal control score, which measures an individual's perception of the extent to which they are able to affect the course of their diabetes (with higher scores indicating a greater level of perceived control) [26], depression score (using the Hospital Anxiety and Depression Scale [27]) and the economic impact of using lay educators, assessed using the EuroQol 5 Dimension (EQ5D) [28]. The economic evaluation is not included in this paper and will be presented separately. Biomedical and anthropometric outcome measures included HbA_{1c}, lipids, blood pressure, weight and waist circumference.

Satisfaction with the delivery of education sessions was assessed immediately after attending the programme, using a modified version of the Medical Interview Satisfaction Scale-21 [29].

Eligibility

Patients aged > 18 years, who had been diagnosed in the previous 12 months with Type 2 diabetes, were eligible to participate. Participants were excluded if they had Type 1 diabetes, were taking insulin, were unable to give informed consent, had severe and enduring mental health problems, were unable to take part in a group programme, were not primarily responsible for their own care or were unable to participate in education groups conducted in English.

Referral and recruitment of participants

Patient referral was conducted in accordance with established local procedures in each site. Patients routinely referred for DESMOND education [5] were provided with information about the trial, and those expressing an interest received a study information pack. The local DESMOND coordinator confirmed eligibility and offered participants the first available study course, regardless of whether the two educators scheduled to deliver the session included one trained lay person. If the participant was unable to attend they were offered the next available date. Participants were aware that the courses would be run by either two healthcare professionals or one healthcare professional and one trained lay person, but coordinators were instructed not to inform participants about the type of course they would be attending. Any decision not to attend the first session offered was therefore based on convenience rather than on who would be delivering the education. In this way, patients were blinded as to whether a lay educator was involved up to the point of attendance; after this point, however, lack of awareness of the lay or professional status of the educators could not be guaranteed.

Education delivery and quality control

All study centres were requested to deliver a total of eight DESMOND courses over a 12-month period, alternating courses between intervention and control group format in terms of the paired educators. For both types of course (intervention and control formats), delivery was shared between the two educators, with each delivering ~50% of the content. This is in accordance with usual practice. The healthcare professional educators taking part in the study were generally consistent throughout the trial, and were accredited to deliver the programme. The lay educators followed the established continuing professional development pathway and were formally assessed within the timeframe specified for healthcare professional educators as part of the DESMOND National Programme procedures.

Collection of baseline and follow-up data

Baseline biomedical and anthropometric data collected by the primary care team, as part of routine care, were sent to the local study coordinating team. Participants were sent a questionnaire booklet before the course, to complete and bring with them on the day. Written, informed consent was taken by the educators before delivery of the course, and before completed questionnaires were collected. The same data were collected at 4 months. Participants were mailed up to 3 weeks before the follow-up date and asked to arrange an appointment with their nurse or general practitioner for collection of study data and to complete and return a follow-up questionnaire booklet.

Sample size and analysis

It was calculated that a total of 240 participants, 120 in each arm, would be needed to obtain 95% limits of equivalence of ± 2.5 points for the change in coherence score. This estimate assumed a value of 3.92 for the standard deviation of the change in the score from baseline [5]. An estimated 20% loss to follow-up was also assumed. As no relevant data could be identified from the literature for setting the limits of equivalence, these had been determined in advance through consultation with the psychologist working on the study. Since no data were available regarding the expected degree of clustering of the change in coherence score between courses, for reasons of caution, an intra-class correlation coefficient of 0.05 was assumed. With an estimated average of six subjects per course, this yielded a design effect of 1.25 in the calculation.

Continuous variables are presented as means (SD) or median and interquartile ranges, and categorical variables are given as counts and percentages. As group allocation was not based on formal randomization, the baseline datasets for the two study groups were assessed for comparability using *t*-tests, chi-squared tests or Wilcoxon tests. All outcomes, apart from the satisfaction score, used change from baseline as the dependent variable. To adjust for course cluster we used robust generalized estimating equations with an exchangeable correlation structure, with an identity link with a normal distribution. The limits of equivalence for the two modes of delivery were assessed as a 95% CI for the mean difference in patient outcomes. The analysis was not adjusted for confounders, as the two groups were well matched at baseline. Statistical significance was set at 5% and the analysis was carried out using STATA software (version 10.0).

Results

A total of 42 DESMOND courses were run, attended by 260 participants. This was a slightly higher number than was required by the power calculation because of the practical requirement to run courses with viable group numbers. The 22 intervention group courses were attended by 122 participants and 138 people attended the 20 control group courses. The mean (range) numbers of participants attending were 5.5 (2–10) and 6.9 (4–12) for the intervention and control group courses, respectively. Table 1 shows the baseline characteristics of the two groups; the mean age of the cohort was 61.1 years with 60.4% being male. The groups were well matched across all biomedical characteristics and also in terms of scores for coherence, control and depressive symptoms.

Coherence scores show improvement at 4 months in both intervention and control group participants (mean change in scores of 4.28 and 4.06 respectively). When comparing changes in scores between the two study groups, there was no statistically significant difference (difference = 0.22, 95% CI -1.07 to 1.52; P=0.74). The 95% CI is within the predefined limits of equivalence, confirming equivalence in relation to our primary outcome measure (Table 2). Similar results were seen for changes in personal control and depression scores. No statistically significant between-group differences were seen for changes in any of the biomedical outcomes, with equivalent reductions in blood pressure, HbA_{1c}, cholesterol, triglycerides, weight, BMI and waist circumference observed in the two groups. Figure 2 shows HbA_{1c} at baseline and 4 months, by study group. A reduction in HbA_{1c} was seen in both groups (intervention group 0.87%, control group 0.98%).

There was also no significant difference between the two groups in any of the satisfaction scores (distress, communication, rapport, compliance) [29] (P = 0.62, 0.85, 0.11, 0.57, respectively). Although educator competency was not formally assessed as an outcome measure, lay educators attained accreditation within similar time frames to healthcare professional educators trained at or about the same time, suggesting equivalence in levels of competency.

Discussion

The present study shows that diabetes self-management education delivered by a trained lay educator and a healthcare professional partner can provide psychological and biomedical benefits to patients that are equivalent to those obtained by attending education delivered by two healthcare professionals. Patient benefits of attending a structured group education session were observed in both arms of the trial.

Strengths, limitations and challenges

This was a multicentre study, making the findings more robust and generalizable. Previous evaluations have often been limited by the absence of a control group [17,20,21], or have to date been able to report pilot data only [30]; our findings are based on well-matched intervention and control groups and we included a range of patient outcome measures

Table 1 Baseline data for intervention and control groups

	Control group			Intervention group			
	N*	Mean (SD)/median [IQR]	*n* (%)	N*	Mean (SD)/median [IQR]	*n* (%)	*P*
Number of participants	138			122			
Age, years	138	60.5 (11.7)		122	61.8 (11.5)		0.36
Sex, male	138		89 (64.5)	122		68 (55.7)	0.15
Systolic blood pressure, mmHg	136	135.7 (16.4)		118	137.8 (15.6)		0.28
Diastolic blood pressure, mmHg	135	80.1 (9.6)		118	79.7 (9.9)		0.71
HbA_{1c}, mmol/mol	129	60 (18)		144	58 (16)		0.23
HbA_{1c},%	129	7.7 (1.7)		114	7.4 (1.5)		0.23
Total cholesterol, mmol/l	136	5.0 (1.2)		119	5.0 (1.2)		0.79
HDL, mmol/l	125	1.1 (0.3)		107	1.1 (0.2)		0.37
LDL, mmol/l	52	3.1 (0.8)		45	3.1 (1.1)		0.97
Triglycerides, mmol/l	52	1.9 (0.8)		47	2.2 (1.1)		0.24
Weight, kg	112	95.1 (20.6)		100	94.1 (19.5)		0.71
BMI, kg/m^2	89	32.2 (7.9)		87	33.3 (6.6)		0.31
Waist circumference, cm	97	105.4 (13.3)		86	108.6 (15.0)		0.13
Current/ex-smoker	91	20 (22.0)		74	19 (25.7)		0.58
Coherence score*	131	15 [12–19]		112	14 [11–17]		0.19
Personal control score*	131	24 [23–27]		114	24 [22–26]		0.19
HADS score*	135	2 [1–5]		113	3 [1–6]		0.17

IQR, interquartile range; HADS, Hospital Anxiety and Depression Scale.
*Number of cases with valid data available. Unless indicated, continuous data were compared using *t*-tests. Categorical data were compared using chi-squared tests. Data given as median [interquartile range] differences between groups were tested using Wilcoxon's test.

Table 2 Change in outcomes at 4 months

	Control group Change (95% CI)	Intervention group Change (95% CI)	Difference between groups* Coefficient (95% CI)	*P*
Coherence score	4.06 (3.28 to 4.84)	4.28 (3.39 to 5.16)	0.22 (−1.07 to 1.52)	0.74
Personal control score	1.48 (0.86 to 2.10)	1.14 (0.50 to 1.78)	−0.32 (−1.13 to 0.49)	0.44
HADS	−0.19 (−0.60 to 0.22)	−0.38 (−0.80 to 0.03)	−0.18 (−0.72 to 0.36)	0.51
Systolic blood pressure, mmHg	−2.75 (−6.99 to 1.50)	−5.18 (−8.73 to −1.63)	−2.44 (−8.08 to 3.21)	0.40
Diastolic blood pressure, mmHg	−2.88 (−5.17 to −0.60)	−3.27 (−5.58 to −0.96)	−0.39 (−3.69 to 2.91)	0.82
HbA_{1c}, mmol/mol	−9.42 (−12.35 to −6.48)	−8.98 (−12.61 to −5.35)	0.60 (−3.52, 4.71)	0.78
HbA_{1c},%	−0.86 (−1.13 to −0.59)	−0.82 (−1.15 to −0.49)	0.05 (−0.32 to 0.43)	0.78
Total cholesterol, mmol/l	−0.54 (−0.74 to −0.34)	−0.51 (−0.70 to −0.31)	0.05 (−0.28 to 0.38)	0.77
HDL, mmol/l	0.02 (−0.01 to 0.06)	0.02 (−0.01 to 0.06)	−0.004 (−0.06 to 0.05)	0.89
LDL, mmol/l	−0.65 (−0.92 to −0.38)	−0.50 (−0.82 to −0.17)	0.17 (−0.28 to 0.61)	0.47
Triglycerides, mmol/l	−0.33 (−0.55 to −0.11)	−0.20 (−0.59 to 0.19)	0.14 (−0.29 to 0.56)	0.53
Weight, kg	−3.31 (−4.70 to −1.91)	−3.28 (−4.70 to −1.86)	0.04 (−2.23 to 2.31)	0.97
BMI, kg/m^2	−1.17 (−1.71 to 0.63)	−0.68 (−1.38 to 0.01)	0.49 (−0.39 to 1.36)	0.28
Waist circumference, cm	−2.89 (−4.54 to −1.23)	−4.09 (−6.25 to −1.93)	−1.27 (−3.56 to 1.02)	0.28

*Adjusted for course only.

based on psychological and biomedical benefits and also satisfaction. In addition to these strengths, the present study adds to the previous literature in a number of ways. A lay and professional partnership model was investigated in our study. This format differed from the one studied by Baksi *et al.* [15], which compared the outcomes of an educational intervention that was delivered either by one healthcare professional or by a single trained lay person [15]. Additionally, in that study, a healthcare professional was present during the sessions delivered by lay educators, with a specific role of intervening if inaccurate information was given [15]; this format would negate potential resource savings. In the study by Gagliardino *et al.* [16], the lay educators delivered an adapted version of the education programme delivered by professional educators and also provided supplementary follow-up support, whereas the same content was delivered in the two arms of our study. In some studies the role of the lay people was focused mainly on patient support [17,18,20,21,31], whereas in the present study, supplementary training was provided specifically to enhance diabetes knowledge, and lay people undertook the same educator role as healthcare professionals.

The design of the present study had some limitations. Guaranteed blinding of participants was not possible after

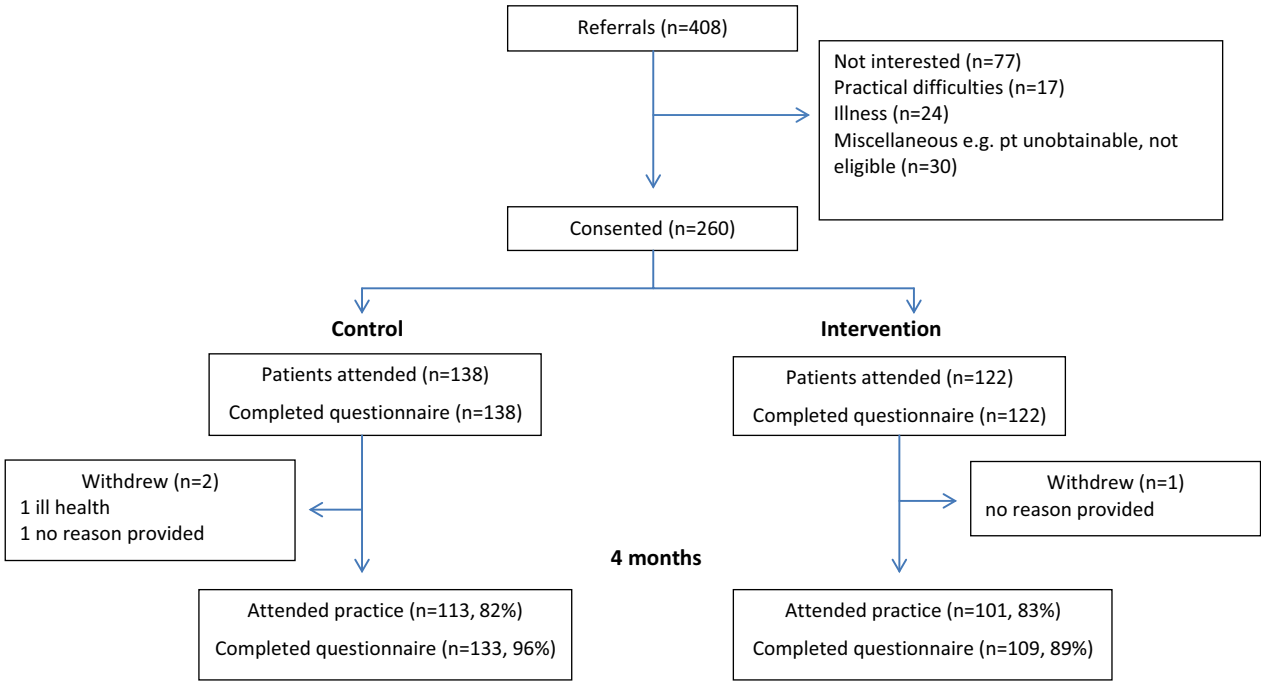

FIGURE 2 Change in HbA_{1c} in participants in the intervention and control groups. Numbers show the mean (95% CI) HbA_{1c} at baseline and 4 months by group.

the point of attendance at their allocated session. Additionally, due to anticipated limited numbers of eligible patients at each centre, group allocation was based on the next available session rather than formal randomization. It is acknowledged that the absence of strict randomization is an important limitation of the study, as it raises the possibility of bias, the extent of which cannot be accurately determined. In considering the impact of bias, however, it should be borne in mind that participants did not choose which type of session they attended based on educators facilitating. Moreover, the two groups were well matched at baseline and the referral and course selection process mirrored the way in which this occurs in a 'real-world' context. Although the 4-month follow-up period may be considered short, we have previously shown that some positive changes observed 4 months after attending DESMOND education may be sustained after 3 years [9].

Implications for practice

The present findings have potentially important implications for those providing care to people with Type 2 diabetes, as we have shown that it is possible to increase capacity by using lay educators without diminishing quality. As previously stated, a detailed economic evaluation is not within the scope of the present paper, but we have estimated that in the case of organizations providing the DESMOND programme, employing lay educators would lead to a reduction in costs of a minimum of 27% per education programme delivered (based on current UK NHS salary scales). In the present study, we tested a model of education delivery where a lay educator was paired with a healthcare professional educator, but good levels of competence achieved by the lay educators who took part in the main trial suggest that using two trained and experienced lay educators may be an option in the future. This format would have the potential for further increasing capacity and cost-effectiveness by freeing up healthcare professional time; however, this would need additional testing and evaluation. Although the present study was based on delivering a specific structured group education programme (the DESMOND programme), it has identified important considerations relevant to all such programmes in diabetes, and the learning is transferable to other long-term conditions.

Other lay educator initiatives have specified that the lay educators should themselves have diabetes or a strong family connection to the condition [14–16,20,21,30,31]. In the present study, although four of our five lay educators either had diabetes (Type 1 or Type 2), or a family connection, this was not specified as a prerequisite for the role [24] and the lay educator without this background was able to fulfil the required role competently. This would suggest that peers with diabetes or a close connection are a very appropriate group to target when recruiting lay people, but that others should not necessarily be excluded.

In conclusion, the present DESMOND lay educator study has confirmed that self-management education is beneficial to patients and it has shown that it is possible to recruit, select, train and accredit lay people to deliver diabetes group structured education competently and effectively. In addition

to potentially reducing costs, the use of lay educators could increase access to structured education. Our study has generated learning transferable to structured education in other long-term conditions and has highlighted the potential for harnessing an untapped pool of talent and skill that exists in lay people who wish to make a formal contribution to supporting people to live successfully with chronic conditions such as Type 2 diabetes.

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Competing interests

The guarantor, M.E.C., acknowledges a grant from Diabetes UK and is National Director of the DESMOND Programme, an NHS initiative in Type 2 diabetes structured education, hosted by the Leicester Diabetes Centre at UHL NHS Trust, of which she is an employee. R.H. is an active supporter of Diabetes UK, the funders. There are no other potential conflicts of interest to report.

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