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Long-term effects of self-management education for patients with Type 2 diabetes taking maximal oral hypoglycaemic therapy: a randomized trial in primary care

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Abstract

Aims Education is an essential part of the management of patients with Type 2 diabetes, but the long-term effects are unclear and not well investigated in primary care.

Methods Fifty-four patients (39–75 years) treated with maximal dosages of oral hypoglycaemic agents, needing to start insulin ($HbA_{1c} \geq 7.0\%$), were randomly allocated to a 6-month educational programme by a diabetes nurse (DN group) or usual care (UC group). Main outcome measures were HbA_{1c}, number of patients with $HbA_{1c} < 7.0\%$, and number of patients treated with insulin 18 months after baseline.

Results Six weeks after the intervention HbA_{1c} levels had improved from 8.2 (1.1) to 7.2 (1.3) in the DN group, and from 8.8 (1.5) to 8.4 (1.7) in the UC group. Adjusted for baseline values, at 6 weeks HbA_{1c} improved 0.7% (95% confidence interval 0.1, 1.4) more in DN than in UC. Of the patients in DN, 60% reached $HbA_{1c} < 7.0\%$ compared with 17% in UC ($P < 0.01$). However, at 18 months there were no significant differences for HbA_{1c}, number of patients with $HbA_{1c} < 7.0\%$, or number treated with insulin.

Conclusions Education was effective in improving glycaemic control and in delaying the need for insulin therapy in patients treated with maximal oral hypoglycaemic therapy. The reduced effect after 1 year was probably due to the discontinuation of the educational programme. Short-term education should not be offered without regular reinforcements integrated into standard diabetes care.

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Keywords glycaemic control, randomized controlled trial, self-management control

Introduction

In current guidelines self-management education is considered an essential part of the approach of patients with Type 2 diabetes [1]. Educational programmes should focus on general knowledge of diabetes, adherence to medication, lifestyle changes, and if possible self-monitoring of blood glucose [2]. One of the fundamental goals is to optimize glycaemic control, in order to prevent acute and chronic complications and to improve quality of life [3].

However, while there is unanimity about the importance of education, its effectiveness is still debated [4]. Recently, two systematic reviews of randomized controlled trials of the

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efficacy of self-management education in adults with Type 2 diabetes reported significant effects on glycaemic control shortly after the last patient–educator contact, but this effect tended to diminish with longer follow-up [5,6]. These reviews, however, included only a few studies with a follow-up of more than 6 months. So the effects of education in the medium and long-term seem to be poor, and in any case not well established. Finally, most of the studies reviewed were conducted in secondary care, which hampers the generalizability of the results to patients treated in primary care.

Therefore we studied the efficacy in the short and long-term of a 6-month educational programme in Type 2 diabetes patients treated in primary care. We included those treated with maximal dosages of oral hypoglycaemic agents but still inadequately controlled ($HbA_{1c} \geq 7.0\%$), to assess the net effect of education.

Methods

Design

Patients were randomly assigned to an individual educational programme by a diabetes nurse (DN group), or to usual care by their general practitioner (GP) (UC group). Randomization was done by a telephone call to an independent trial centre, which used a computer-generated random assignment with blocks of eight at a time. The intervention period lasted 6 months. The medical ethics committee of the University Medical Centre of Utrecht approved the study. All patients gave written informed consent.

Patients and practices

Patients were recruited from 57 general practices (78 GPs) in and around the city of Utrecht, the Netherlands. The CONSORT flow chart (Fig. 1) shows the recruitment process. An assessment of 1810 patients' medical records by two research assistants was followed by a completion of the database [7]. Subsequently, in patients under age 76 years and with $HbA_{1c} \geq 7.0\%$, oral medication was optimized [8]. After this optimization, 76 patients had $HbA_{1c} \geq 7.0\%$ while taking the maximum feasible dosages of two different oral hypoglycaemic agents, mostly sulphonylurea and metformin. These patients were eligible for the present study. Exclusion criteria were: severe comorbidity (defined as having an illness that surpasses the impact of diabetes); insufficient understanding of spoken Dutch to follow instructions; or requirement for insulin therapy in the short term on account of severe hyperglycaemic symptoms. After 18 exclusions, and four withdrawals after randomization, the final study population included 54 patients.

Educational programme

The educational programme was developed in collaboration with the Dutch Foundation of Diabetes Nurses. It could be classified as a collaborative, 'mixed' educational intervention [5], and was provided by two skilled diabetes nurses in one-to-one sessions. It focused on: general information on diabetes; reinforcing compliance with actual medication; importance of physical exercise and losing body weight; and nutritional advice. All patients were also taught how to control their blood glucose at home on a regular basis, for which they were given a blood glucose meter (Glucotouch; Lifescan Benelux, Beerse, Belgium) and necessary materials (reagent strips, lancets). During the 6-month period, six sessions were given, at intervals of 3–6 weeks. The sessions were intended to take between 15 and 45 min, resulting in a total contact time of approximately 2.5 h. A brief outline of the programme is shown in Table 1. After the last session patients returned to usual care.

Usual care

Patients in the UC group remained under the care of their GP, and were managed according the current Dutch guideline on Type 2 diabetes [9]. This guideline recommends 3-monthly reviews, focusing on diabetic symptoms and measurement of fasting blood glucose, with education being given during normal medical appointments. During the 6-month intervention period the GP was asked not to refer the patient to a diabetes nurse. Furthermore, the GP was instructed not to alter the medication, unless a patient developed severe hyperglycaemic symptoms.

Outcome measures

HbA_{1c} % was measured at randomization, 7.5 months after randomization (6 weeks after the last session of the programme), and again 18 months after randomization, by turbidimetric inhibition immunoassay (Hitachi 917; Roche Diagnostics, Basel, Switzerland; normal range 4–6%). As part of the educational programme, in the DN group HbA_{1c} was also measured after the third session. Body weight was measured at randomization, and 6 months after randomization. One year after the last session the GPs were asked if patients had started with insulin treatment.

Statistical analysis

The primary outcome measure was the difference in HbA_{1c} between the two intervention groups. To detect a difference of at least 0.8%, which we assessed as clinically useful for this category of patients, 26 patients were needed in each group (SD 1.0, α 0.05, power 80%). Data are expressed as means and SD unless indicated otherwise. Analyses were based on intention to treat, with the last value carried forward for missing data. Ineligible patients mistakenly randomized, and patients who withdrew before the start of the intervention, were excluded from analysis [10].

Comparison between the two groups for HbA_{1c} and body weight was performed by analysis of covariance (ANCOVA), adjusting for baseline values [11]. In addition, logistic regression was applied to assess the difference in proportion of patients who reached $HbA_{1c} < 7.0\%$, and who were treated with insulin.

Additionally, stepwise multiple linear regression analysis was used to assess the potential confounding effect on HbA_{1c} level reached at 6 weeks after the intervention by age, sex, body mass index, duration of diabetes, and educational level.

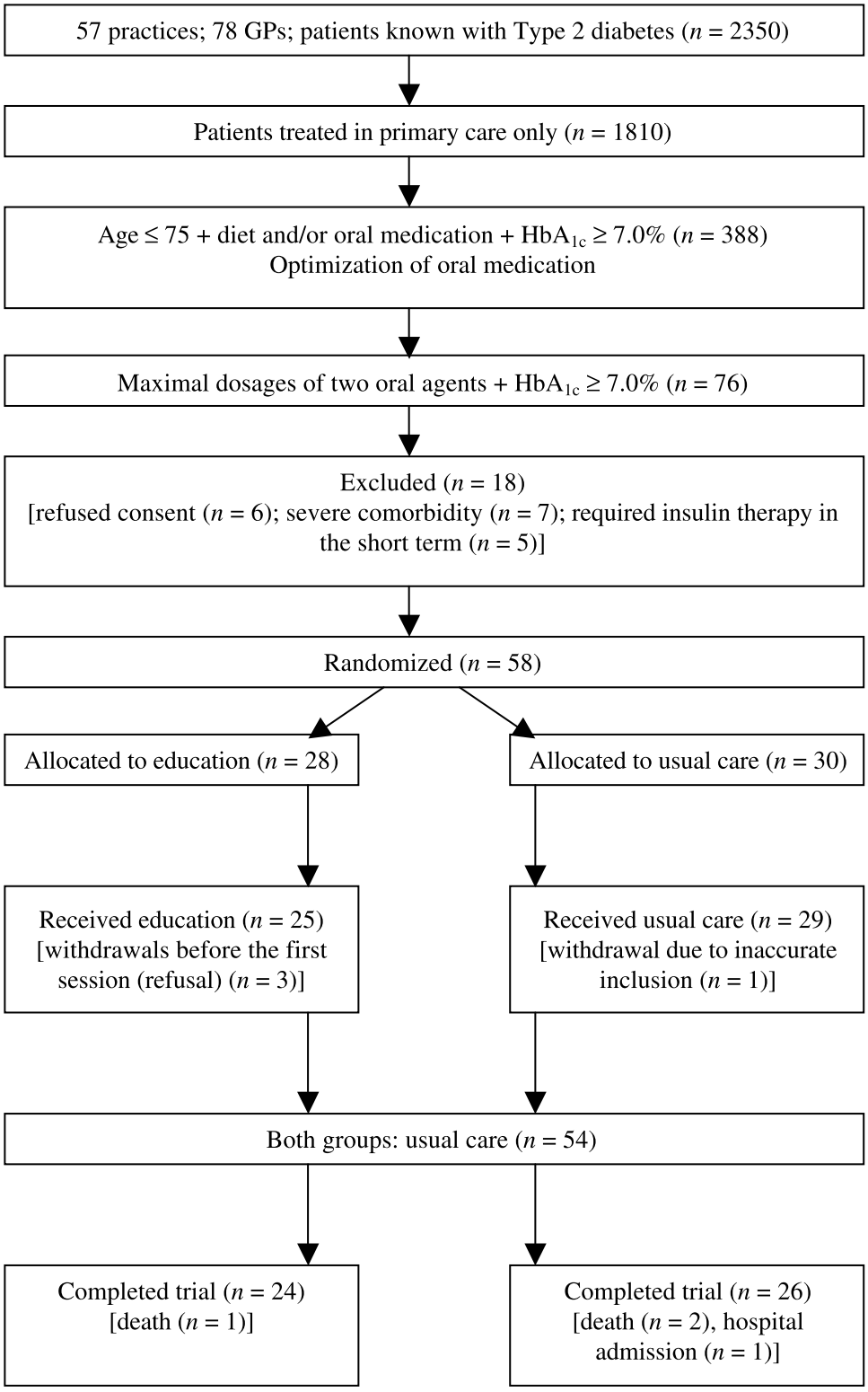

Figure 1 Trial profile.

Results

The baseline characteristics of the participants, and of the original population from which they were drawn, are shown in Table 2. In the original population 22% of the patients was treated with diet only, 66% with oral hypoglycaemic agents, and 12% with insulin. Characteristics of excluded patients were comparable to those of the study group (data not shown).

Table 1 Brief summary of the educational programme

Session	Week	Duration (min)	Backgrounds	Medication	Physical exercise	Nutritional advice	Self-monitoring of blood glucose
1	0	45	Outline of diabetes	Compliance	Actual status		How to perform a self-test
			Rationale of treatment	Time of taking drugs	Why of importance		How to record results in a diary
				Adverse effects	Measurement of body weight		
					Tailored advice and goal setting		
2	3	30	Normal values for blood glucose and HbA_{1c} Goal setting	Compliance	Evaluation and questions		Evaluation
							How to perform and interpret self-tests throughout the day
3	8	15	Questions	Compliance	Progress	Review of actual calorie intake	Evaluation of self-tests
					Evaluation of potential barriers	Ever visited a dietician? (if no: initiate referral)	How to code the meter
							Referral for HbA_{1c} test
4	14	15	Signs and symptoms of hypo- and hyperglycaemia?	Questions	Evaluation	Evaluation of potential barriers	Evaluation of HbA_{1c} test
							Evaluation of self-tests
5	20	15	Questions	Questions	Evaluation	Repetition	Evaluation of self-tests
6	26	15	Questions	Questions	Evaluation	Repetition, evaluation and questions	Evaluation of self-tests
					Measurement of body weight		

In the DN group all 25 patients completed the six sessions with the diabetes nurse, and during the programme there were no changes of medication for diabetes, nor any referrals for insulin therapy. In the UC group, however, two patients (one man, age 42; one woman, age 50) were referred to secondary care before the end of the intervention period, because of symptomatic hyperglycaemia and comorbidity. The other 27 patients in the UC group had no change in antidiabetic medication.

The HbA_{1c} levels in both groups are shown in Fig. 2. HbA_{1c} changed from 8.2 (1.1) to 7.2 (1.3) in the DN group, and from 8.8 (1.5) to 8.4 (1.7) in the UC group. Adjusted for baseline values, mean HbA_{1c} % in the DN group fell by 0.7 more than in the UC group [95% confidence interval (CI) 0.1, 1.4; $P = 0.025$]. After adjustment for sex and duration of diabetes, the mean difference in HbA_{1c} % was 0.6 (95% CI 0.03, 1.2; $P = 0.039$). Further adjustment for other variables did not change the result. In the DN group 60% of the patients achieved HbA_{1c} levels < 7.0%, compared with 17% in the UC group (odds ratio 6.6; 95% CI 1.8, 24.5; $P = 0.004$). Finally, adjusted for baseline values, mean body weight in the DN group fell by 2.0 kg more than in the UC group (95% CI 0.4, 3.6; $P = 0.013$).

One year after the last session of the programme, data were available for 50 patients, three (one in the DN group and two in the UC group) having died, and one in the UC group having been hospitalized (Fig. 1). Adjusted for baseline, the difference between the mean change in HbA_{1c} in the two groups was 0.2% in favour of the DN group, not statistically significant (95% CI –0.7, +0.4; P = NS). Of the patients in the original DN group, 17% still had HbA_{1c} levels < 7.0%, vs. 15% in the UC group (NS). Six patients (25%) of the DN group were receiving insulin therapy, vs. 10 patients (38%) of the UC group (NS).

Discussion

This randomized study involved patients in general practice, needing insulin therapy. Follow-up data were obtained 18 months after baseline, greater than most diabetes education studies [6]. Moreover, in addition, the net effect of education was studied since medication was not changed in both groups during 6 months.

The characteristics of the original population of diabetes patients were comparable to other recent investigations in general practices in the Netherlands, although glycaemic control seemed slightly better [12,13]. However, we assessed glycaemic control in a selection of the entire DM population of these practices, since patients treated by a diabetologist were excluded. The study group clearly differed from the original population: they were younger (age 60.5 vs. 65.3), had poorer glycaemic control (HbA_{1c} % 8.5 vs. 7.1), and all had maximum oral medication.

The study demonstrates that in the short term structured individual education by a diabetes nurse led to a significant,

Table 2 Characteristics at baseline of the original population, the final study group, and both intervention groups

	Original population	Final study group	Diabetes nurse group	Usual care group
Number of patients	1810	54	25	29
Age (years)	65.3 (10.4)	60.5 (13.3)	62.6 (9.0)	58.7 (11.4)
Sex (male %)	44	48	52	44
Educational level (%)				
Low	59	65	66	64
Middle	31	26	28	24
High	10	9	8	10
Duration of diabetes (years)	4.6 (5.6)	7.5 (4.4)	7.3 (5.0)	7.6 (3.8)
Body mass index (kg/m^2)	28.7 (5.2)	30.0 (5.0)	30.2 (4.4)	29.8 (5.5)
HbA_{1c} (%)	7.1 (1.7)	8.5 (1.4)	8.2 (1.1)	8.8 (1.5)

Results are means (SD) or percentages.

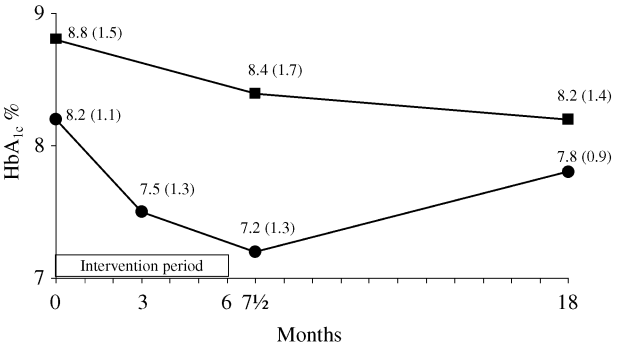

Figure 2 Mean HbA_{1c} values (SD) at baseline (0), and 3 (DN only), 7.5 and 18 months after randomization. ■, Usual care group (UC); ●, Education group (DN); white bar, 6-month intervention period.

and clinically relevant improvement in HbA_{1c} level, with an average change of –0.7% at 6 weeks after intervention. In addition, 60% of the patients in the DN group, vs. only 17% in the UC group, reached HbA_{1c} levels < 7.0%, an important indicator of the need for insulin [3,9].

One year after the last session of the educational programme, however, most of the effects were lost. Thus, the long-term results of an educational programme without structured follow-up were disappointing.

The decline in HbA_{1c} was accompanied by a considerable decrease of body weight in the DN group. This finding underlines the importance of weight management in patients with Type 2 diabetes, and it seems to rebut the widespread belief that people with diabetes cannot lose weight [14].

It is noteworthy that glycaemic control in the control group gradually improved during the study (Fig. 2). This might be a regression-to-the-mean effect [15]. Moreover, since this was an unblinded study and randomization was done on a patient level, in the control group patients as well as doctors have become increasingly aware of the issue of tighter control and started acting upon it. This may have diminished the effect of the intervention. Further improvement of HbA_{1c} in the control group after the intervention could be the result of the switch to insulin therapy in 38% of the patients.

In this study the intervention was delivered by two skilled nurses with long experience in the field of diabetes, while in routine daily practice, educators are likely to be less experienced and thus probably less effective. This aspect of the study might limit its generalizability.

If we compare our results with the outcomes of a systematic review by Norris *et al.* [6], which assessed the efficacy of 31 randomized controlled trials of self-management education on glycaemic control, some differences and some similarities stand out. Compared with the review's average decrease of HbA_{1c} of 0.3% at 1–3 months of follow-up, our result is encouraging. This does demonstrate that an educational intervention focused on blood glucose control using 2.5 h contact time was able to facilitate a relevant improvement in the short term [6,16]. However, probably a more comprehensive programme is needed to judge the effectiveness on other important issues, such as other cardiovascular risk factors, psychosocial well-being, and quality of life. The deterioration after 18 months was comparable to that found by Norris, who included only two studies with follow-up longer than 6 months [17,18]. It was probably due to the discontinuation of the educational programme, rather than worsening of diabetes over time [19]. The question remains whether the educational materials or the method of working of the diabetes nurses was (most) responsible. Nevertheless, the course was short and the educational materials were simple and cheap. Indeed, the nurses were experienced and for that reason we did not train them. One might argue that less experienced nurses should be trained before this intervention, and this might limit the generalizability of our results. This type of educational intervention is widely promoted in diabetes guidelines, without specifying possible subgroups of patients who might have the greatest benefit. Our results are encouraging for patients taking maximal oral medication who should start with insulin therapy. We expect that around two or three patients per practice (of 2500 patients) would need such an intervention each

year. Our results stress the limited value of short-term educational programmes in diabetes care, and we are doubtful if education in this form should be offered without regular reinforcements integrated in standard diabetes care. Further research is needed to show whether such reinforcements can achieve sustained improvements in glycaemic control, and what time intervals are most cost-effective [4,5].

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