

Effects of self-management training in Type 2 diabetes: a randomized, prospective trial

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Abstract

Aims The efficacy of three education programmes for Type 2 diabetic patients was tested in a randomized trial. A didactic-oriented training programme (treatment A) was compared with a self-management-oriented programme delivered in group sessions (treatment B). The latter programme was compared with a more individualized approach (treatment C).

Methods One hundred and eighty-one Type 2 diabetic patients (age 55.6 ± 6.3 years, diabetes duration 6.6 ± 6.2 years, HbA_{1c} $7.8 \pm 1.6\%$, female 49.7%) took part. Efficacy was assessed 3 months (t1) after baseline (t0) and at a follow-up 15 months (t2) after baseline.

Results The fall in HbA_{1c} in treatment B at t1 was sustained at t2 (t0 $8.1 \pm 1.8\%$, t1 $7.3 \pm 1.7\%$, t2 $7.4 \pm 1.9\%$). In treatment A, HbA_{1c} was unchanged throughout (t0 $7.6 \pm 1.5\%$, t1 $7.5 \pm 1.3\%$, t2 $7.7 \pm 1.7\%$; treatment A vs. treatment B; $P < 0.05$). With the more individualized approach of treatment C, there was a fall in HbA_{1c} at t1, but this was not sustained at t2 (t0 $7.8 \pm 1.6\%$, t1 $7.1 \pm 1.3\%$, t2 $7.6 \pm 1.6\%$; treatment B vs. treatment C; $P = 0.73$). There were also significant benefits in treatment B subjects compared with treatment A in further medical (body mass index and fasting blood glucose), psychological (control, irritability and hunger dependency of eating behaviour, and trait anxiety) and behavioural (exercise) variables. There were no significant benefits of the more individualized treatment C compared with group treatment B. No significant differences were found regarding triglyceride levels, high-density lipoprotein, diabetes-related knowledge, negative well-being, urine or blood glucose levels or foot care.

Conclusion Self-management training had a significantly higher medium-term efficacy than didactic diabetes education. The group sessions were more effective than a more individualized approach.

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Keywords diabetes education, glycaemic control, group intervention, self-management, Type 2 diabetes

Abbreviations BMI, body mass index; FBG, fasting blood glucose; HbA_{1c}, glycated haemoglobin A_{1c}

Introduction

Diabetes education has become an integral part of diabetes treatment in many countries [1–7]. It is especially important in the treatment of non-insulin-dependent diabetic patients, since these patients are challenged by complex modifications of their

eating behaviour and physical exercise. Recently there has been a shift from primarily didactic interventions that focus on the acquisition of knowledge and skills about diabetes towards more self-management-oriented interventions [6,8]. This trend has consequences for the concept and duration of modern diabetes education programmes. Whereas education programmes that focus primarily on the transfer of knowledge and skills are of rather short duration, a more self-management-oriented approach that also addresses emotional, motivational and

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cognitive barriers to effective diabetes therapy requires a longer programme. In the latter type of diabetes education, time is needed to take into account individual lifestyle patterns and goals for diabetes treatment. This has been demonstrated by a meta-analysis of the efficacy of diabetes patient education; the meta-analysis provided information about intervention methods and number of episodes [9]. The average number of episodes that addressed motivational or cognitive barriers by teaching problem-solving skills or using cognitive reframing techniques was 16.5 (median 14.5) compared with 7.4 (median 6.0) episodes in diabetes education programmes which did not use these techniques. Furthermore, the average number of episodes when treatment goals were negotiated with the patient was 12.8 (median 12) compared with 5.5 (median 6) events when goal setting was dictated [9].

However, although (i) the idea of enhancing patients' self-management abilities and addressing barriers to diabetes therapy is theoretically more appealing, and (ii) there is some evidence from meta-regression analysis that cognitive reframing techniques that address emotional and cognitive barriers to diabetes self-management have a beneficial effect on glycaemic control [10], direct comparisons of modern diabetes education programmes with traditional and primarily knowledge- and skill-oriented diabetes education concepts would make the argument for these concepts even stronger [8].

The first objective of this study was to examine the effect of a self-management-oriented group programme which allowed patients to negotiate their treatment goals; helped patients self-monitor their eating and exercise behaviour; supported patients in analysing emotional, cognitive and motivational barriers to behaviour change by conducting a behaviour analysis; and assisted patients in performing their self-selected changes in eating, exercise and self-care behaviour [11,12]. Because it is unethical not to offer diabetes education, we compared this self-management-oriented group programme with a traditional education programme which focused solely on diabetes knowledge and treatment skills [13].

Another matter of debate is the issue of the setting in which emotional, cognitive and behavioural barriers to diabetes treatment should be addressed. Some studies have demonstrated beneficial effects of self-management programmes conducted in individual settings [3,10,14–18]. Others have shown beneficial effects from group sessions, effects which might be related to beneficial therapeutic group effects [19–23].

The second objective of this study was to examine the effect of a more individualized approach to diabetes education. It seems rational that such an approach is better able to address individual barriers to diabetes treatment than a group approach. Therefore, we developed a more individualized approach that used a self-management-oriented group programme in which decisive parts (e.g. analysis of individual dietary and exercise patterns, agreement regarding dietary changes and physical activities) were delivered in an individual setting, whereas the more knowledge-oriented parts (glucose control, blood pressure control) were delivered in a group setting. This second

objective was to determine the effect of the more individualized approach compared with a group approach on the outcome variables listed above.

Methods

Design

This prospective, randomized trial compared three different treatment programmes, which differed in content and setting. The first (treatment A) was a didactic-oriented intervention focusing on the acquisition of knowledge, skills and information about the correct treatment of diabetes. This course lasted for four lessons (90 min each) and was conducted in a group setting [24]. This programme has been well assessed and since the late 1980s has been commonly used for diabetes education in Germany [25]. The second programme (treatment B) was based on a self-management/empowerment approach and focused on emotional, cognitive and motivational processes of behaviour change. It was designed to help patients promote lifestyle modifications in daily life, particularly changes in eating behaviour and physical exercise [26]. Treatment B was performed as a group programme with 12 lessons of 90 min each.

The third programme (treatment C) had the same content as treatment B and likewise consisted of 12 lessons. Six of these 12 lessons were conducted in an individual setting and the other six in a group setting.

All programmes were conducted by four health psychologists (two male and two female), who received training in conducting the treatments. To avoid performance bias, each psychologist conducted each treatment twice. The average number of patients treated in each group by each staff member was similar (A, 16.0 ± 2.2 ; B, 15.8 ± 2.2 ; C, 16.0 ± 2.9 ; $P = 0.98$).

Sample recruitment

Eligibility criteria were as follows: Type 2 diabetes mellitus, age 40–65 years, no insulin treatment, stimulated C-peptide > 0.8 nmol/l, body mass index (BMI) > 26.7 kg/m², no acute psychiatric illness (as diagnosed by the primary care physician) and able to read and speak German.

This study was approved by the local Ethics Committee. All patients included in the baseline examination gave written, informed consent.

In the recruitment area in and around the city of Würzburg, Germany (total population 456 320), all physicians (general practitioners, family doctors, internists) were invited to refer patients to the study. In addition, Type 2 diabetic patients were invited to participate in the study through newspaper articles and radio messages. Four hundred and eighteen patients were referred by their doctors or referred themselves; 82 physicians referred patients. Figure 1 shows the flow of patients through each stage of the trial.

A power calculation suggested a total of 192 patients was needed. One hundred and ninety three patients fulfilled the inclusion criteria and were randomly allocated sequentially to the three treatments by the Department of Biometry of the University of Heidelberg. Block randomization was used, with a minimum of 15 and a maximum of 33 patients being assigned together to

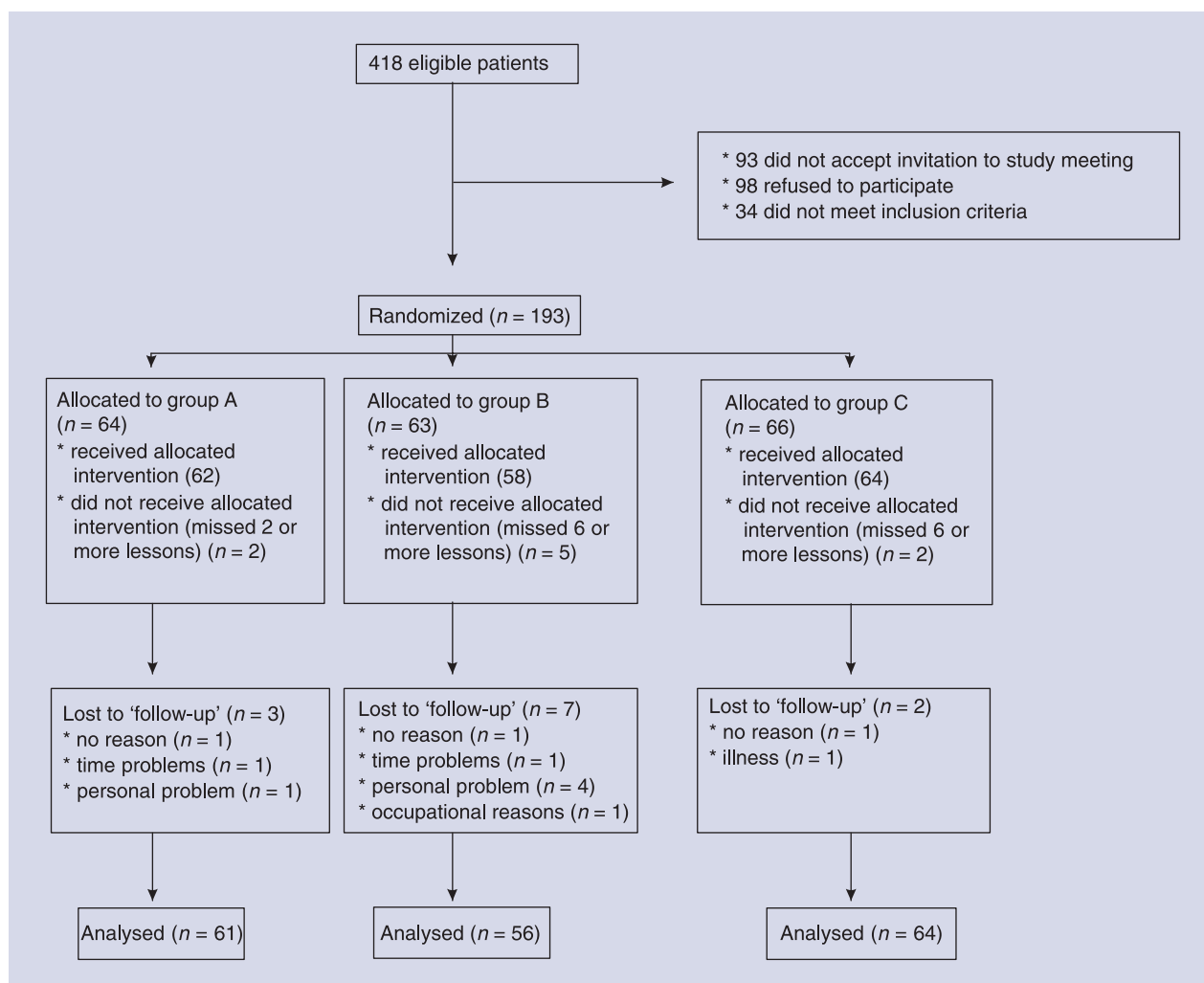


FIGURE 1 Diagram of patient flow.

one of the three treatment groups. The average size of the three groups was similar (group A 8.0 ± 1.4 patients, group B 7.8 ± 1.7 patients and group C 8.0 ± 2.0 patients; $P = 0.98$, median in all groups was eight patients). The range of group size was between six and 11 persons.

The primary efficacy variable was measured in 181 patients. Twelve patients were lost to follow-up (6.6%) for the following reasons: acute, life-threatening illness ($n = 1$); personal problems ($n = 6$); time problems ($n = 2$); left region because of occupational reasons ($n = 1$); no reason given ($n = 2$). The baseline characteristics of those who dropped out were similar to those who remained in the study.

Relevant demographic and clinical characteristics are shown in Table 1. There were no significant differences in baseline characteristics between the groups.

Measures

Glycated haemoglobin was determined by the affinity chromatography method. The mean normal value for non-diabetic persons was $4.8 \pm 0.4\%$ (range 4.0–5.6%). Since HbA_{1c} values

with a normal range between 4.1 and 6.1% are commonly used to assess glycaemic control, the glycated haemoglobin values were linearly transformed to HbA_{1c} values with an upper normal range of 6.1% according to a linear regression formula provided by Wilson *et al.* [27].

Weight was measured by a gauged balance by staff members blinded to the treatment group of the subjects.

Diabetes knowledge was assessed by a knowledge test specifically designed for non-insulin-treated Type 2 diabetic patients [28]. The maximum score was 14, indicating optimal diabetes knowledge. A German version of the Three Factor Eating Questionnaire, with the three scales 'cognitive restraint of eating' (score range 0–21), 'inhibition' (score range 0–16) and 'hunger' (score range 0–14), was used to measure psychological determinants of eating [29,30]. The German version of the Trait-version of the State-Trait-Anxiety Inventory (score range 20–80) originally developed by Spielberger *et al.* [31] was used to assess anxiety symptoms [32]. Negative well-being was assessed by a Psychological Strain Questionnaire (German 'Befindlichkeits-Sakala') which measured psychological strain [33]. A minimum score of 0 indicates optimal psychological well-being, whereas

Table 1 Characteristics of the participating subjects

Variable	Treatment A <i>n</i> = 61	Treatment B <i>n</i> = 56	Treatment C <i>n</i> = 64	<i>P</i> *
Age (years)	55.2 ± 5.6	56.6 ± 6.7	55.4 ± 6.5	0.43
% female	54.1	46.4	48.4	0.69
Years of education	9.4 ± 1.0	9.4 ± 1.0	9.2 ± 1.2	0.31
Disease duration (years)	6.2 ± 5.6	6.4 ± 6.1	7.2 ± 6.5	0.45
Prevalence of late complications				
% photocoagulation	6.8	7.4	9.4	0.86
% reduced sensitivity in ankle†	28.8	33.3	31.2	0.87
% coronary heart disease‡	5.1	7.4	9.0	0.20
% stroke	3.4	9.3	0.0	0.06
% peripheral vascular disease§	8.5	9.3	6.2	0.82
% hypertension¶	52.5	55.6	50	0.83

*Results of ANOVA or χ^2 Test.
†Vibration test, tuning fork < 5/8.
‡Significant congestive heart disease, previous heart infarction or positive coronary angiography.
§Ratio systemic blood pressure/blood pressure in leg < 0.9.
¶Antihypertensive drug therapy.

a maximum score of 56 indicates poor psychological well-being.

Self-care behaviour was assessed by a questionnaire which asked the participants how regularly they performed blood or urine glucose self-tests, foot care or regular exercise (0 = never, 1 = at least one or two times a month, 2 = once a week, 3 = two or three times a week, 4 = daily).

All patients brought their prescribed medication to the baseline (t0) and final (t2) examinations. The type and prescribed dose of oral glucose-lowering agents were recorded by a trained medical assistant.

Measurement points

The first examination took place at baseline (t0). Immediate treatments effects were measured 3 months after the start of the treatments (t1) and stabilization of these effects was assessed 15 months after baseline (t2).

During the course of the study, the responsibility for ongoing medical treatment remained with the patient's own physician. Regardless of the treatment group to which each subject was randomly assigned, these physicians were given a standardized information form about the results of both the physical examination and laboratory tests. They were asked also to continue being responsible for the type and dose of glucose-lowering drug therapy.

Statistical analysis

The hypotheses were tested by ANCOVA. To control for baseline differences between groups, the between-treatment factor was controlled for baseline differences by including baseline scores as covariate.

Dependent variables were the above-mentioned medical, psychosocial and behavioural variables. If there was a significant effect for the treatment factor, post hoc tests (Scheffé test) were performed to localize the treatment effect according to the

main hypotheses (treatment A < treatment B and treatment B < treatment C).

In addition, we report the within factor 'time' of variance analyses with the three repeated measures of the dependent variable to determine the immediate treatment effect and the stability of the effects during follow-up in each group. To localize the effect during either treatment or follow-up, comparisons were made between t0 and t1 (immediate treatment effect) and between t1 and t2 (maintenance, relapse, or further improvement during follow-up). Only patients who were lost to follow-up at t2 were excluded from the analysis. To control for possible selection bias, an intention-to-treat analysis was performed using the 'carrying last observation forward method' for individuals who were lost to follow-up.

The only primary variable was glycaemic control; thus, there was no adaptation of the α -error level. For the secondary variables, an α -error level of 0.05 was regarded as appropriate because an adaptation of the α -error level towards a lower level would have necessarily increased the β -error. Given the primarily exploratory purpose of the analysis of the secondary variables, such an adaptation would have been seen as disadvantageous.

For statistical analysis, Systat 10.2 software (Systat Software Inc., Point Richmond, CA, USA) was used.

Results

There was no change in HbA_{1c} throughout the study in treatment group A (Fig. 2). There was a significant improvement in HbA_{1c} of 0.7% in treatment group B at time t1, which was sustained at t2. In subjects in treatment group C, there was an initial significant improvement in HbA_{1c} of 0.7% at t1, but this improvement was not sustained at t2. There was a significant 'treatment effect' for HbA_{1c} ($P = 0.013$). HbA_{1c} was significantly lower in group B compared with group A ($P = 0.017$). HbA_{1c} in group C was also lower than in group A at t1, but not

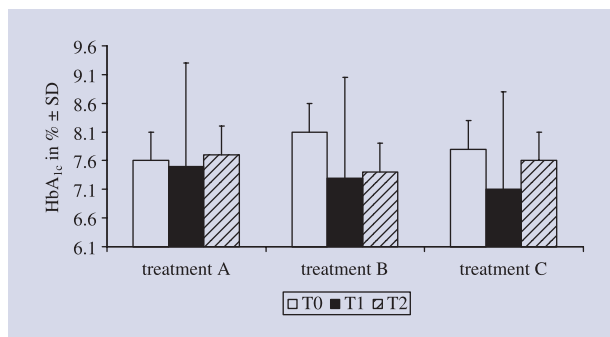


FIGURE 2 Effect of treatments on HbA_{1c}.

at t2. At t2, HbA_{1c} in treatment C was higher than in treatment B ($P = 0.729$). Thus, contrary to our hypothesis, the individualized approach of treatment C had no superior effect on glycaemic control compared with treatment B.

An additional intention-to-treat analysis yielded a similar effect for treatment ($P = 0.028$).

Table 2 shows the results of all secondary variables. There was a significant treatment factor effect between groups for BMI and fasting blood glucose (FBG). FBG fell significantly from t0 to t1 in all three groups. However, in group A, FBG rose thereafter, so that it was significantly higher at t2 than at t0 or t1. In group B, FBG at t2 was significantly lower than at t0 and t1. In group C, FBG at t2 was significantly higher than at t1 and similar to that at t0. BMI in group A was significantly lower at t1 than at t0, but values at t2 were similar to those at t0. In groups B and C, BMI was lower at t1 and t2 than at t0.

Most of the psychological variables were influenced by the treatments. Knowledge was improved equally in all three groups. Determinants of eating, as measured by the Three Factor Eating Questionnaire, changed significantly during the three treatments. 'Cognitive restraint of eating' increased, whereas negative factors for weight loss, such as 'inhibition' and 'hunger', decreased. There were significant 'treatment effects' for all three variables. The improvements in these variables were significantly greater in treatments B and C than in treatment A. The more individualized treatment C, however, again showed no advantage when compared with treatment B. For 'cognitive restraint of eating' and 'inhibition', the scores for these variables increased significantly in groups B and C from t1 to t2, but at the end of follow-up (t2) they remained lower than at t0. Scores for cognitive restraint of eating and hunger also improved in group C at t1, and although scores for both were higher at t2 compared with t1, they remained lower than at t0.

There was a significant 'treatment effect' for the trait anxiety. Treatment B showed a significant improvement compared with treatment A. Contrary to our second hypothesis, there was no significant advantage of treatment C compared with treatment B. The fall in anxiety scores in groups B and C occurred between t0 and t1, but was sustained at t2. Negative well-being improved in all three groups; thus, there was no significant effect between the groups.

There were comparable improvements in urine and blood glucose monitoring and foot care in all three treatment groups. However, regular exercise was significantly more stimulated among treatment B and treatment C subjects, compared with treatment A subjects. Treatment C had a poorer effect on exercise than treatment B.

Glucose-lowering medication

Six patients commenced insulin therapy during the trial (group A, $n = 3$; group B, $n = 2$; group C, $n = 1$; $\chi^2 = 1.1$, $P = 0.57$). The prescribed doses of glibenclamide, metformin and acarbose and the proportion of patients taking these medications were similar in the three treatment groups. In an ANCOVA using the drug dose at t2 as a covariate, the effect of treatment group on glycaemic control remained significant (ANCOVA; $F[2,175] = 4.5$; $P = 0.013$). If the analysis of treatment effects on HbA_{1c} was controlled for use of oral glucose lowering agents (yes/no), there were almost identical results (ANCOVA; $F[2,175] = 4.49$, $P = 0.012$). Thus, there was no indication that differences in glucose-lowering medication accounted for the significant group effect on glycaemic control.

Adherence rate

To determine adherence rates to the treatments, attendance at lessons was recorded. Patients missed only between 7.6% and 9.5% of their lessons (group A, $7.6 \pm 1.3\%$; group B, $9.4 \pm 1.3\%$; group C, $8.5 \pm 1.3\%$; $P = 0.77$). Thus, there was a high adherence rate, comparable in all treatments.

Intention-to-treat analysis

We performed an intention-to-treat analysis carrying last observation forward for individuals who were lost to follow-up. The results of the intention-to-treat analysis are shown in Table 2. The primary end-point of glycaemic control was robust against the lost to follow-up cases; the same outcome was true for most of the secondary efficacy variables. Compared with the previous analysis, treatment effects for cholesterol and triglycerides as well as blood glucose and urine glucose self-control became significant in the intention-to-treat analysis, whereas the treatment effect for the scale 'inhibition' failed to reach significance.

Discussion

In support of our first hypothesis, a self-management-oriented group intervention is significantly more effective than a traditional diabetes education programme in improving glycaemic control. Although deterioration in glycaemic control could be expected with increasing duration of Type 2 diabetes [34], HbA_{1c} fell significantly as a result of treatment B. In treatment A, glycaemic control deteriorated slightly. A net reduction of 0.7% HbA_{1c} at 12 months' follow-up in treatment B is more

Table 2 Effects of treatment factors (results of ANCOVA controlled for baseline values exploratory within effects in treatment groups). Number in parentheses are results of intention to treat analyses.

Treatment	T0	T1	T2	Within factor 'time'	'Treatment factor' ^a
Secondary variables					
<i>Medical variables</i>					
Body mass index (kg/m ²)					
All	32.2 ± 3.7 (32.3 ± 3.9)	31.1 ± 3.7 (31.3 ± 3.9)	31.5 ± 3.9 (31.6 ± 4.0)	< 0.001*†† (< 0.001*††)	0.038 (0.028 ^c)
A	32.1 ± 3.9 (32.1 ± 3.6)	31.3 ± 3.7 (31.5 ± 3.7)	31.6 ± 3.9 (31.6 ± 3.8)	< 0.001*	
B	31.8 ± 3.3 (32.2 ± 3.9)	30.5 ± 3.4 (31.2 ± 4.1)	30.9 ± 3.6 (31.4 ± 4.2)	< 0.001*††	
C	32.6 ± 4.2 (32.6 ± 4.1)	31.3 ± 4.1 (31.3 ± 4.1)	31.9 ± 4.2 (31.8 ± 4.1)	< 0.001*††	
Fasting blood glucose (mmol/l)					
All	9.0 ± 2.6 (9.1 ± 2.7)	7.6 ± 2.4 (7.6 ± 2.4)	9.0 ± 2.7 (9.0 ± 2.7)	< 0.001*†† (< 0.001*††)	0.001 ^{b,c} (0.004 ^{b,c})
A	8.6 ± 2.1 (8.8 ± 2.2)	8.0 ± 2.3 (8.1 ± 2.3)	9.6 ± 3.0 (9.6 ± 3.0)	< 0.001*††	
B	9.5 ± 2.8 (9.6 ± 2.8)	7.3 ± 2.6 (7.5 ± 2.6)	8.7 ± 2.8 (8.7 ± 2.8)	< 0.001*††	
C	8.9 ± 2.9 (8.8 ± 2.9)	7.4 ± 2.2 (7.4 ± 2.2)	8.8 ± 2.4 (8.8 ± 2.4)	< 0.001*†	
Cholesterol (mmol/l)					
All	6.0 ± 1.2 (6.0 ± 1.2)	5.8 ± 1.0 (5.8 ± 1.0)	5.9 ± 1.0 (5.9 ± 1.0)	0.013 (0.035)	0.054 (0.039 ^b)
A	6.0 ± 1.1 (6.0 ± 1.1)	6.1 ± 1.0 (6.1 ± 1.0)	5.9 ± 1.0 (5.9 ± 1.0)	0.330	
B	6.0 ± 1.2 (6.0 ± 1.2)	5.6 ± 1.0 (5.6 ± 1.0)	5.8 ± 1.1 (5.8 ± 1.1)	0.008*†	
C	6.1 ± 1.3 (6.2 ± 1.4)	5.8 ± 1.0 (5.8 ± 1.0)	5.9 ± 0.9 (5.9 ± 0.9)	0.054	
High-density lipoprotein (mmol/l)					
All	1.2 ± 0.4 (1.2 ± 0.4)	1.2 ± 0.3 (1.2 ± 0.3)	1.2 ± 0.3 (1.2 ± 0.3)	0.021 (0.028)	0.542 (0.658)
A	1.2 ± 0.4 (1.2 ± 0.3)	1.2 ± 0.4 (1.2 ± 0.4)	1.2 ± 0.4 (1.2 ± 0.4)	0.113	
B	1.3 ± 0.6 (1.3 ± 0.6)	1.2 ± 0.3 (1.2 ± 0.3)	1.2 ± 0.3 (1.2 ± 0.3)	0.288	
C	1.2 ± 0.3 (1.2 ± 0.3)	1.2 ± 0.3 (1.2 ± 0.3)	1.1 ± 0.3 (1.1 ± 0.3)	0.106	
Triglycerides (mmol/l)					
All	2.4 ± 1.3 (2.3 ± 1.3)	2.3 ± 1.4 (2.1 ± 1.3)	2.3 ± 1.8 (2.3 ± 1.8)	0.029 (0.047)	0.067 (0.049 ^b)
A	2.4 ± 1.4 (2.4 ± 1.4)	2.3 ± 1.5 (2.3 ± 1.5)	2.6 ± 1.7 (2.6 ± 1.7)	0.178	
B	2.3 ± 1.4 (2.2 ± 1.3)	1.9 ± 1.4 (1.9 ± 1.3)	2.0 ± 1.1 (2.0 ± 1.1)	0.057	
C	2.4 ± 1.2 (2.4 ± 1.2)	2.1 ± 1.2 (2.1 ± 1.2)	2.3 ± 2.2 (2.3 ± 2.1)	0.315	
<i>Psychosocial variables</i>					
Diabetes knowledge score					
All	6.6 ± 3.3 (6.6 ± 3.3)	8.9 ± 2.8 (8.8 ± 2.9)	8.4 ± 2.9 (8.3 ± 2.9)	< 0.001*†† (< 0.001*††)	0.641 (0.432)
A	7.3 ± 3.4 (7.4 ± 3.4)	9.1 ± 3.1 (9.0 ± 3.2)	8.6 ± 3.3 (8.7 ± 3.3)	< 0.001*†	
B	6.6 ± 3.4 (6.4 ± 3.3)	8.9 ± 2.7 (8.6 ± 3.0)	8.4 ± 2.9 (8.2 ± 2.9)	< 0.001*††	
C	5.9 ± 3.1 (5.9 ± 3.1)	8.8 ± 2.6 (8.7 ± 2.6)	8.2 ± 2.7 (8.1 ± 2.6)	< 0.001*††	
Trait-anxiety					
All	39.9 ± 10.3 (40.0 ± 10.6)	37.2 ± 10.0 (38.3 ± 11.4)	38.0 ± 10.4 (38.4 ± 11.0)	< 0.001*† (< 0.001*†)	0.012 ^b (0.039 ^b)
A	39.4 ± 9.1 (39.3 ± 9.4)	39.0 ± 10.8 (39.2 ± 11.0)	39.0 ± 10.5 (39.6 ± 11.3)	0.628	
B	40.4 ± 10.8 (40.7 ± 11.2)	35.4 ± 8.6 (37.7 ± 11.5)	37.0 ± 9.5 (37.7 ± 10.4)	< 0.001*†	
C	39.8 ± 10.9 (39.9 ± 11.1)	37.0 ± 10.2 (38.1 ± 11.9)	38.0 ± 11.2 (37.9 ± 11.4)	0.041*	
Negative well-being					
All	14.6 ± 11.0 (14.8 ± 11.6)	11.4 ± 11.1 (12.5 ± 12.7)	12.2 ± 12.1 (12.4 ± 12.6)	< 0.001*† (< 0.001*†)	0.329 (0.679)
A	15.5 ± 11.6 (15.9 ± 12.5)	14.3 ± 12.4 (14.8 ± 13.8)	12.6 ± 13.1 (12.9 ± 13.4)	0.068	
B	13.4 ± 10.0 (13.7 ± 10.9)	9.4 ± 8.8 (10.9 ± 12.0)	11.2 ± 11.5 (11.6 ± 12.7)	0.006*	
C	14.8 ± 11.3 (14.9 ± 11.5)	10.6 ± 11.2 (11.8 ± 12.2)	12.8 ± 11.8 (12.6 ± 12.0)	0.035*	
Three Factor Eating Questionnaire: 'Cognitive restraint of eating'					
All	11.9 ± 4.5 (12.0 ± 4.5)	15.5 ± 3.7 (15.0 ± 4.2)	14.6 ± 4.4 (14.7 ± 4.4)	< 0.001*† (< 0.001*†)	< 0.001 ^{b,c} (0.018 ^b)
A	11.7 ± 4.2 (6.6 ± 3.3)	14.1 ± 4.3 (6.6 ± 3.3)	13.8 ± 4.7 (6.6 ± 3.3)	< 0.001*†	
B	12.1 ± 4.6 (6.6 ± 3.3)	16.7 ± 2.7 (6.6 ± 3.3)	15.4 ± 4.0 (6.6 ± 3.3)	< 0.001*††	
C	12.0 ± 4.8 (6.6 ± 3.3)	15.8 ± 3.5 (6.6 ± 3.3)	14.6 ± 4.5 (6.6 ± 3.3)	< 0.001*††	
Three Factor Eating Questionnaire: 'Inhibition'					
All	6.6 ± 3.4 (6.5 ± 3.4)	5.2 ± 3.1 (5.4 ± 3.3)	5.6 ± 3.3 (5.6 ± 3.3)	< 0.001*† (< 0.001*†)	0.008 ^b (0.113)
A	7.2 ± 3.3 (7.2 ± 3.4)	6.6 ± 3.4 (6.7 ± 3.5)	6.2 ± 3.7 (6.1 ± 3.7)	0.007*†	
B	6.1 ± 3.4 (6.1 ± 3.4)	3.9 ± 2.4 (4.4 ± 3.1)	5.1 ± 2.9 (5.2 ± 3.0)	< 0.001*††	
C	6.5 ± 3.4 (6.3 ± 3.4)	4.9 ± 2.7 (5.1 ± 3.0)	5.5 ± 3.0 (5.4 ± 3.0)	< 0.001*†	
Three Factor Eating Questionnaire: 'Hunger'					
All	5.6 ± 3.4 (5.5 ± 3.5)	4.0 ± 3.0 (4.1 ± 3.2)	4.5 ± 3.3 (4.4 ± 3.3)	< 0.001*† (< 0.001*†)	0.005 ^{b,c} (0.050)
A	5.8 ± 3.5 (5.7 ± 3.6)	5.3 ± 3.5 (5.2 ± 3.6)	4.8 ± 3.2 (4.6 ± 3.2)	0.024†	
B	5.3 ± 3.3 (5.2 ± 3.3)	3.4 ± 2.4 (3.8 ± 2.8)	3.9 ± 3.4 (4.0 ± 3.3)	< 0.001*†	
C	5.6 ± 3.5 (5.5 ± 3.5)	3.2 ± 2.7 (3.4 ± 2.9)	4.6 ± 3.4 (4.5 ± 3.4)	< 0.001*††	

Table 2 Continued

Treatment	T0	T1	T2	Within factor 'time'	'Treatment factor' ^a
<i>Behavioural variables</i>					
Urine or blood glucose self test					
All	0.4 ± 0.8 (0.6 ± 1.0)	1.9 ± 0.9 (1.6 ± 1.1)	1.4 ± 0.7 (1.5 ± 0.9)	< 0.001*†‡ (< 0.001*†‡)	0.085 (0.046 ^c)
A	0.3 ± 1.0 (0.6 ± 1.0)	1.9 ± 1.0 (1.8 ± 1.1)	1.5 ± 0.7 (1.6 ± 0.9)	< 0.001*†‡	
B	0.5 ± 1.0 (0.7 ± 1.1)	2.0 ± 0.7 (1.5 ± 1.1)	1.5 ± 0.8 (1.6 ± 1.0)	< 0.001*†‡	
C	0.3 ± 0.7 (0.5 ± 1.0)	1.8 ± 0.9 (1.5 ± 1.1)	1.2 ± 0.5 (1.3 ± 0.7)	< 0.001*†‡	
Foot care					
All	0.7 ± 1.0 (0.8 ± 1.0)	1.5 ± 0.8 (1.4 ± 0.9)	1.3 ± 0.9 (1.3 ± 0.9)	< 0.001*†‡ (< 0.001*†‡)	0.072 (0.475)
A	0.7 ± 0.8 (0.7 ± 0.9)	1.3 ± 0.7 (1.3 ± 0.8)	1.2 ± 0.8 (1.2 ± 0.8)	< 0.001*†‡	
B	0.9 ± 1.1 (1.0 ± 1.1)	1.7 ± 0.8 (1.5 ± 1.0)	1.5 ± 0.9 (1.5 ± 0.9)	< 0.001*†‡	
C	0.7 ± 1.0 (0.6 ± 1.0)	1.5 ± 0.8 (1.4 ± 0.9)	1.2 ± 0.9 (1.2 ± 0.9)	< 0.001*†‡	
Exercise					
All	1.0 ± 1.0 (0.9 ± 1.0)	1.5 ± 0.9 (1.3 ± 1.1)	1.3 ± 1.0 (1.3 ± 1.0)	< 0.001*†‡ (< 0.001*†‡)	< 0.001 ^{b,c} (0.001 ^{b,c})
A	1.1 ± 0.9 (1.0 ± 0.9)	1.3 ± 0.9 (1.1 ± 1.0)	1.1 ± 0.9 (1.1 ± 0.9)	< 0.001*†‡	
B	0.9 ± 1.0 (0.8 ± 1.0)	1.6 ± 0.9 (1.3 ± 1.1)	1.4 ± 1.0 (1.4 ± 1.0)	< 0.001*†‡	
C	0.9 ± 1.0 (0.9 ± 1.0)	1.9 ± 0.9 (1.6 ± 1.1)	1.3 ± 1.0 (1.3 ± 1.0)	< 0.001*†‡	

^aBetween effect 'treatment' controlled for baseline of ANCOVA represents time-treatment interaction of ANOVA.

Contrasts within effect 'time': *t0/t1 $P < 0.05$; †t1/t2 $P < 0.05$; ‡t0/t2 $P < 0.05$; contrasts between effect 'treatment': ^btreatment A vs. treatment B $P < 0.05$; ^ctreatment A vs. treatment C.

than could be expected from the meta-analysis of Norris *et al.* [5], who reported a net reduction of 0.24% at 6 months' follow-up. The fall in HbA_{1c} was independent of oral glucose-lowering drugs. The significantly greater effects were also seen for additional medical, psychological and behavioural variables. Changes in body weight indicate a beneficial effect of treatment B on risk factors other than glycaemic control.

Effects on medical variables were mirrored in a change of the psychological determinants of eating behaviour such as enhanced 'cognitive restraint of eating', lower 'inhibition' and 'hunger'. In addition, the amount of exercise increased in treatment B compared with treatment A. Furthermore, anxiety symptoms improved significantly in treatment B subjects, indicating that a more self-management-oriented diabetes education programme is also beneficial for mental health. Perhaps improved self-management abilities contributed to subjects' perception of a greater ability to control diabetes, a perception which reduced anxiety symptoms.

Psychological well-being improved in all three treatments, suggesting that a more effective approach to facilitating lifestyle changes does not impair quality of life aspects.

The didactic intervention group (treatment A) focused on the transfer of knowledge and also stressed the importance of foot care and urine glucose self-monitoring [25]. This focus might have been responsible for the equivalent efficacy of the three treatments for these variables.

Our second hypothesis was that individual self-management training programmes would be more effective than group programmes. However, our results refute this. Although glycaemic control and most other medical, psychological and behavioural variables improved more or to the same extent in the individualized setting than in the group setting during the

treatment period, the deterioration during follow-up was greater in the individualized setting. Thus, group effects may help in the maintenance of successful changes in behaviour and attitudes. It seems that there is no beneficial effect of a more individualized approach in training Type 2 diabetic patients and group education is certainly more cost effective [35]. Further research should clarify which group processes are responsible for the observed beneficial effects.

We have tried to ensure our study is robust. Randomization, as well as widespread announcement of the study in the recruitment area, may have helped to reduce selection bias [3,36].

Since the responsibility for medical treatment remained with the patients' own physicians and 82 different physicians referred patients to the study, it is unlikely that differences in treatment with oral glucose-lowering drugs influenced the outcome. When the effect of a possible pharmaceutical cointervention was controlled by an ANCOVA, the beneficial effects of group self-management education remained significant. Since the drop-out rate was small, attrition bias was minimized [5,36].

Another weakness of efficacy studies of diabetes education programmes stems from the relatively short follow-up intervals. Because most studies have either no follow-ups or follow-up intervals of ≤ 6 months, it is difficult to assess the stability of the achieved treatment effects [3,8]. With a follow-up period of 12 months, this study allows the examination of a medium-term effect of diabetes education. It has also been suggested that analysis of self-management programmes has focused too narrowly on the assessment of medical variables. A broader assessment of the efficacy of education programmes, taking into account psychological and behavioural variables, has been demanded for more than a decade [3,4]. This study determined

the effects of the three diabetes education programmes on a broader spectrum of medical, psychological and behavioural outcome variables.

A comparison of the analysis in which patients lost to follow-up were excluded with an intention-to-treat analysis showed broadly similar results.

There remain, however, some methodological limitations to our study. Whereas in drug studies the results of randomization can easily be concealed from patients and medical care providers, a double-blind study cannot be performed to determine the efficacy of diabetes education. When interpreting the results of our study, one should also consider that there was no control group (i.e. a group with no diabetes education). This shortcoming makes it difficult to distinguish the specific treatment effects from the general effect of diabetes education. The significant within-subject effects indicate that diabetes education *per se* is effective. Moreover, there is evidence from meta-analyses that diabetes education is effective [3,5,9]; therefore, the use of a control group without such education would have been unethical [13]. Thus, it is possible that the overall efficacy of diabetes education is underestimated [8].

Treatment group C attended a mixture of group and individual sessions, so that there was some overlap with the group-only approach in treatment B. Thus, we cannot make a statement about the efficacy of a fully individualized approach to diabetes education.

Treatment B consisted of 12 lessons, whereas the traditional knowledge-oriented programme (treatment A) consisted of four lessons. It clearly cannot be ruled out that the different lengths of treatments A and B contributed to the observed results. A meta-regression by Norris suggested that the number of contact hours has an influence on the improvement of glycaemic control. In Norris's analysis, every hour of contact time reduced HbA_{1c} by 0.04% [5]. A conservative assumption would suggest that approximately one-third of the HbA_{1c} improvement in group B compared with group A was a result merely of the longer duration of the former programme. However, a meta-regression by Ellis *et al.* [9] could not replicate this finding. They found that face-to-face intervention, teaching methods and integrating exercise were more beneficial for glycaemic control than the length of intervention. However, since some dependent variables, such as duration of an education programme, and more sophisticated techniques (e.g. cognitive reframing techniques) might be correlated [9], our study suggests that there might not be a simple linear relationship between duration and intensity of a programme and improvement of glycaemic control; the most intense treatment, C, in which patients participated in six group lessons and six one-to-one lessons about individual eating and exercise behaviours, did not yield the most beneficial outcome. More research is needed to address the question of the relationship between length and intensity of education programmes and efficacy.

However, treatment A has been implemented widely in several European countries as a standard tool for diabetes education [37]; furthermore, it serves as a model educational programme

for Latin America [38]. The finding of our randomized, prospective study that this popular programme did not demonstrate a beneficial effect on glycaemic control compared with a longer lasting self-management-oriented programme may be of considerable interest for clinical diabetes care.

In summary, this randomized, prospective trial proves the efficacy of a self-management-oriented approach delivered in a group setting. Through randomization, a follow-up period of 12 months and control of the effects of pharmacological cointervention, this study enhances the body of knowledge about the efficacy of self-management interventions and has addressed some problems raised in a recent meta-analysis about the effects of didactic interventions in diabetic patients [3].

Competing interests

Lilly GmbH, Germany and GlaxoSmithKline GmbH & Co., Germany supported further education related to group treatment for diabetologists, diabetes educators and general physicians. N.H. and B.K. received reimbursement for organizing and performing this further education.

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