A 5-Year Randomized Controlled Study of Learning, Problem Solving Ability, and Quality of Life Modifications in People With Type 2 Diabetes Managed by Group Care

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OBJECTIVE — To study time course changes in knowledge, problem solving ability, and quality of life in patients with type 2 diabetes managed by group compared with individual care and education.

RESEARCH DESIGN AND METHODS — We conducted a 5-year randomized controlled clinical trial of continuing systemic education delivered by group versus individual diabetes care in a hospital-based secondary care diabetes unit. There were 120 patients with non–insulin-treated type 2 diabetes enrolled and randomly allocated to group or individual care. Eight did not start and 28 did not complete the study. The main outcome measures were knowledge of diabetes, problem solving ability, quality of life, HbA_{1c}, BMI, and HDL cholesterol.

RESULTS — Knowledge of diabetes and problem solving ability improved from year 1 with group care and worsened among control subjects ($P < 0.001$ for both). Quality of life improved from year 2 with group care but worsened with individual care ($P < 0.001$). HbA_{1c} level progressively increased over 5 years among control subjects (+1.7%, 95% CI 1.1–2.2) but not group care patients (+0.1%, −0.5 to 0.4), in whom BMI decreased (−1.4, −2.0 to −0.7) and HDL cholesterol increased (+0.14 mmol/l, 0.07–0.22).

CONCLUSIONS — Adults with type 2 diabetes can acquire specific knowledge and conscious behaviors if exposed to educational procedures and settings tailored to their needs. Traditional one-to-one care, although delivered according to optimized criteria, is associated with progressive deterioration of knowledge, problem solving ability, and quality of life. Better cognitive and psychosocial results are associated with more favorable clinical outcomes.

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Patient education facilitates self-management of diabetes (1) and has evolved to become a cornerstone of quality oriented diabetes care (1–3). Education should be a systematic, patient-centered process (4) to acquire and retain the knowledge and skills necessary to live as satisfactory a life as possible with a disease (5). Patients with chronic diseases are often adults for whom a specific andragogic, rather than pedagogic, approach is required (6). In particular, specific teaching models are necessary to induce appropriate health behaviors. Adults differ from school-age individuals because they have their own life experience, maturity, independence, self-direction, and a desire to contribute. They need to know why they learn something and will learn it more readily if it relates to everyday life (5,6). However, teaching methods and programs are often not tailored to, and are sometimes at conflict with, patients' needs and learning abilities (7), which may result in failure to adopt correct and durable health behaviors (8,9). In addition, objectives, teaching techniques, and learning processes applied to diabetes education are seldom described in the literature (8,10,11).

We developed a model to manage type 2 diabetes through a systemic group education approach that resulted in sustained body weight reduction, increased HDL cholesterol, and stabilization of HbA_{1c} (12,13). In contrast, control patients managed by traditional one-to-one clinical and education sessions experienced progressive worsening of metabolic control in accordance with the results of previous trials of intensified care (14). Furthermore, group care improved knowledge of diabetes, problem solving ability, and quality of life (12,13). In this article, we describe the time course modifications of these cognitive and psychosocial variables over a 5-year follow-up in these patients and in a matched control population.

RESEARCH DESIGN AND METHODS

— There were 120 patients with non–insulin-treated type 2 diabetes who gave informed consent to participate in a randomized controlled clinical trial of group versus individual diabetes care. Eight did not fulfil the inclusion criteria, and of the remainder, 56 were divided into six education groups

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Abbreviations: CdR, problem solving ability (*Condotte di Riferimento*); DQOL, diabetes quality of life; DQOL/Mod, modified DQOL; GISED, Education Study Group of the Italian Society for Diabetes.

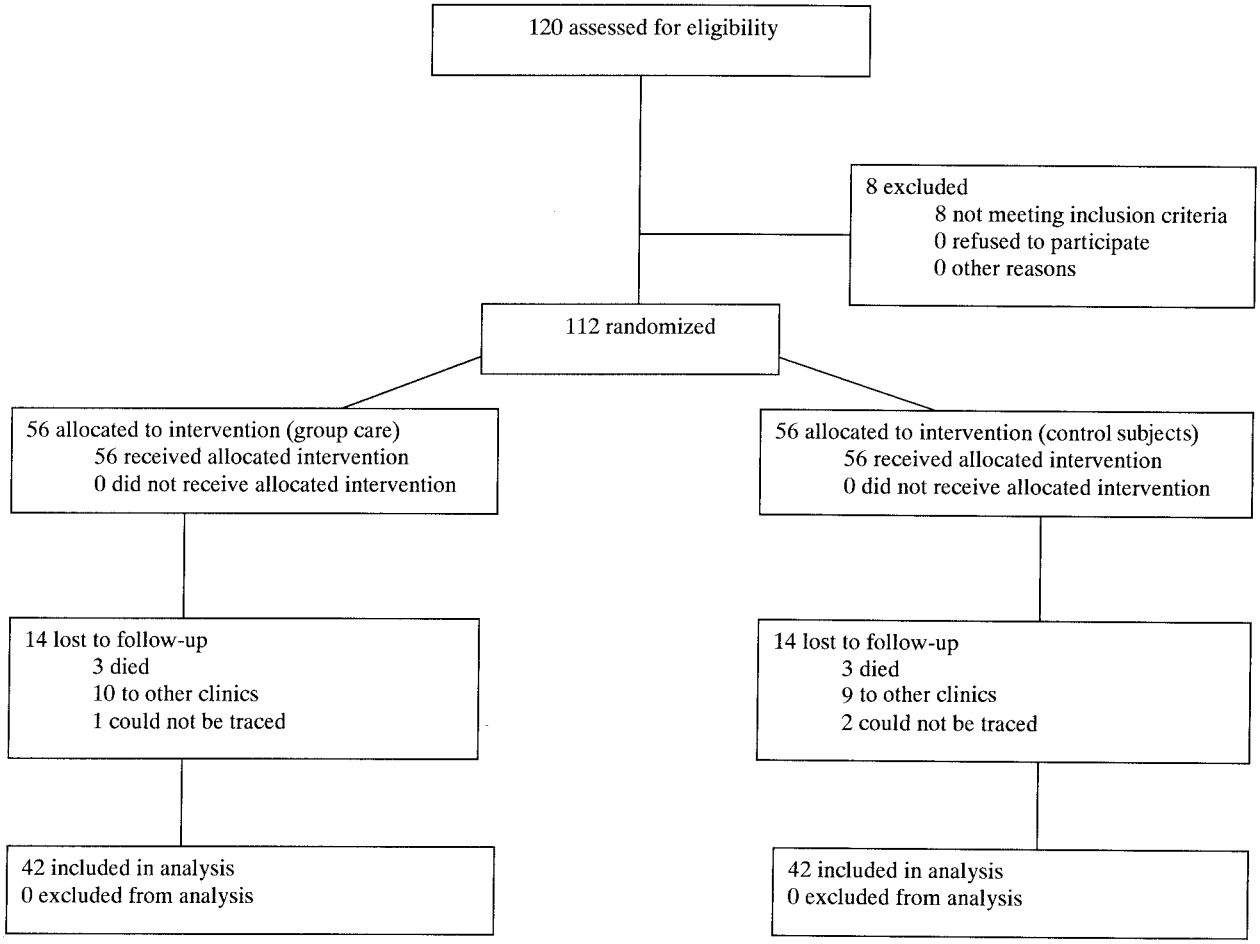

Fig. 1—*Participant flow.*

while the other 56 continued with traditional one-to-one consultations and education sessions. Group sessions were held every 3 months, with one or two physicians and an educator (M.Tr.) acting as facilitators. None of the patients moved from one treatment to the other during the study period. Of those who did not complete follow-up, 6 patients died (3 in group care and 3 control subjects), 19 moved to other clinics (10 in group care and 9 control subjects), and 3 could not be traced (1 in group care and 2 control subjects) (Fig. 1). Of the patients who completed follow-up, those in group care included 20 men aged 60 ± 8 years with a known duration of diabetes of 8.8 ± 5.8 years. Corresponding values for control subjects were 22 men aged 61 ± 8 years with a known duration of diabetes of 10.1 ± 7.8 years. Schooling and occupation were similar to those reported for the 4-year follow-up (13). Dropouts and patients who continued follow-up did not differ for any of the variables measured at baseline.

Details of the clinical and educational approaches adopted for group and individual care were given previously (12,13). Group care was based on a systemic education approach (10,11,15). Planning included educational diagnosis (5), definition of learning goals, development of procedures (including the facilitators' attitudes toward the patients), program definition, and overall assessment of intervention efficacy in terms of specific knowledge, problem solving ability, quality of life, and clinical outcomes (9,12,13). The curriculum was intentionally kept to a minimum of essential concepts (16) to be transmitted by hands-on activities, group work, problem-solving exercises, real-life simulations, and role playing. The program included the burden of overweight, choosing food and planning meals, physical exercise, checking and improving metabolic control, smoking cessation, correct assumption of medication, and preventing complications. This curriculum, initially divided in four sessions, was repeated in years 1 and 2, then spread over seven sessions in years 3 and 4 and started again in year 5 to allow more in-depth discussion and learning.

Formal teaching and medical or scientific jargon were avoided as much as possible. To stimulate observation, technical and cognitive skills, and conscious choices, simple support material was developed, e.g., food models or graduated containers. To induce positive group dynamics (13,15), the patients were encouraged to report on personal experience and stimulated to describe, interpret, discuss, and compare real-life situations (6,17). Reports of unknowingly wrong behavior were not criticized but used as a source of positive learning. Facilitators tried to stimulate learning by proposing problems that stimulated the patients' solving ra-

ther than mnemonic abilities (17,18). Throughout the sessions, we constantly tried to obtain feedback on how much of the topic being covered had been retained by the patients (18). To minimize anxiety and consequently resorting to avoidance strategies in the patients, complications and relevant risk factors were addressed later, after the sessions on weight and eating control had presumably induced some degree of mastery on the patients' reactions and behaviors (19).

At baseline and after 1, 2, 3, 4, and 5 years, three questionnaires were administered to measure:

1) Knowledge of diabetes using a 38-item questionnaire (modified to simplify some terms) developed by the Education Study Group of the Italian Society for Diabetes (GISED) (20). The areas explored included general definitions and academic notions about diabetes (e.g., symptoms, carbohydrates, insulin and insulin resistance, glycemia, glycosuria, ketone bodies, treatment of diabetes, oral agents, and calories) and practical knowledge (food exchanges, fiber, exercise, HbA_{1c}, hypoglycemia, monitoring, self-management, and foot care). Correct answers scored one point and wrong answers scored no points.

2) Problem solving ability (*Condotte di Riferimento*) (CdR) (12,13) with a purpose-built 16-item questionnaire that assessed diabetes-related problem solving knowledge rather than compliance or adherence behaviors. Questions posed hypothetical situations using the "What would you do if. . ." format to test whether the subjects could identify underlying health problems and react correctly. The CdR questionnaire covered eating beliefs and habits, physical activity, therapy (mostly hypoglycemia and appropriate consumption of prescribed drugs), and complications (mostly prevention through regularly consulting with the health care team, exercise, and foot care). Correct answers scored one point and wrong answers scored no points.

3) Quality of life using a modified version of the diabetes quality of life (DQOL) questionnaire (21) that had been translated into Italian and revalidated (22). The questionnaire was modified by leaving out six questions (items 1–3 and 5–7 rom the "Worry: Social/Vocational" section) that, in the original version, were only pertinent to young, insulin-dependent subjects. The modified (DQOL/Mod) questionnaire included 39 items; answers were along a 5-point Likert scale from 1 (very satisfied) to 5 (very dissatisfied). The "Satisfaction" section included 14 items and explored the patients' psychological well-being. The 20-item "Impact" test primarily assessed the practical consequences of diabetes on everyday life. Finally, the 5-item "Worry: Social/Vocational" section investigated diabetes-related anxiety, with special reference to clinical conditions.

All questionnaires were checked for internal consistency by Cronbach's α-coefficient (23) and internal validity by cluster analysis (24). Patients with literacy problems were helped to complete the questionnaires.

Statistical analysis

Results within treatment groups are means ± SD. Differences between baseline and year 5 values within treatment groups are means and 95% CI. Changes in cognitive, psychosocial, and clinical variables from year 1 to 5 between the two groups were tested by ANCOVA and adjusted for baseline differences in the two groups.

A multivariate regression model was fitted using the calculated increase/decrease from year 1 to 5 for each cognitive and psychosocial variable (GISED, CdR, DQOL/Mod), as well as each clinical variable, as dependent variables. Group care (coded 0/1), baseline values of the dependent variable, age, length of attendance, duration of diabetes (coded in years), and schooling (coded in a five-level ordinal scale and introduced in the model as dummy variables) were used as independent variables.

RESULTS — The values of cognitive, psychosocial, and clinical variables measured at baseline and year 5 are listed in Table 1.

Descriptive analysis suggests that knowledge of diabetes kept increasing throughout the observation period among the patients randomized to group care from year 1, more rapidly so over the first 2 years ($P < 0.001$ for both). On the contrary, patients followed by traditional one-to-one care tended to gradually reduce their knowledge ($P < 0.005$). Points that were mostly not modified by either intervention included those that were more technical and theory based. Patients in group care improved their scores on the practical and some of the more academic questions.

Answers to the CdR questionnaire followed a similar pattern, suggesting that problem solving ability had already improved after the first year ($P < 0.005$) and was still rising at year 5 ($P < 0.001$). The areas that improved were assuming treatment properly, recognizing symptoms of poor control, preventing acute and chronic complications, weight control, food choices, and smoking cessation. Problem solving ability correlated with the baseline level of schooling, specifically indicating that low levels of schooling are significantly correlated with a lower score in this variable. However, control patients exhibited slow, gradual worsening of their problem solving ability from year 3 onwards ($P < 0.005$).

It took 2 years for quality of life to improve in the patients managed by group care ($P < 0.001$); however, after year 2 this variable worsened among control subjects ($P < 0.001$). Changes in the satisfaction, impact, and worry subareas followed a pattern similar to that of the parental scale.

BMI, HDL cholesterol, triglyceride, and creatinine improved over 5 years in the patients in group care (Table 1), but not in a way significantly different from control subjects. HbA_{1c} remained stable in the patients in group care but increased among control subjects, showing a significant difference between the two groups ($P < 0.001$).

In multivariate analysis, group care per se was the major factor associated with improved knowledge, problem solving ability, and quality of life, entered as dependent variables ($P < 0.001$ for all). The effect of group care was independent of schooling, age, duration of diabetes, and length of attendance in our clinic. Knowledge seemed to act as a determinant of CdR scores in the group care patients, whereas no such relationship held within the individual care control subjects. On the other hand, neither variable influenced the DQOL/Mod questionnaire score in either group, suggesting that the effect of what is learned about diabetes and how it is put into effect is not sufficient to improve quality of life. Finally, modifications of the clinical variables did not correlate with knowledge, problem solving ability, or quality of life as assessed by the three questionnaires. The

Table 1—*Biochemical and clinical variables at baseline and year 5 in patients followed by group care* (n = 42) *and in control subjects* (n = 42).

	Baseline	5 years	Increase/decrease	*P**
Knowledge of diabetes (GISED score)				
Group care	15.5 ± 7.9	27.9 ± 5.7	12.4 (9.7 to 15.2)	<0.001
Control subjects	21.4 ± 7.2	18.0 ± 8.5	−3.4 (−1.1 to −5.7)	
Problem solving ability (CdR score)				
Group care	11.4 ± 2.6	17.1 ± 2.4	5.7 (4.6 to 6.8)	<0.001
Control subjects	12.3 ± 4.2	10 ± 3.8	−2.3 (−1.1 to −3.4)	
Quality of life (DQOL/Mod score)				
Group care	67.4 ± 19.0	43.7 ± 7.2	−23.7 (−30.0 to −17.3)	<0.001
Control subjects	70.0 ± 21.4	89.2 ± 30.1	19.2 (8.4 to 29.9)	
Body weight (kg)				
Group care	79.6 ± 13.7	76.1 ± 12.9	−3.5 (−5.2 to −1.8)	0.015
Control subjects	77.5 ± 16.0	77.3 ± 16	−0.24 (−1.9 to 1.5)	
BMI (kg/m^2)				
Group care	30.0 ± 4.7	28.6 ± 4.1	−1.4 (−2.0 to −0.7)	0.067
Control subjects	27.7 ± 4.6	27.6 ± 4.4	−0.10 (−0.7 to 0.5)	
Fasting blood glucose				
Group care				
mmol/l	9.8 ± 2.6	9.4 ± 2.3	−0.4 (−1.52 to 0.70)	NS
mg/dl	177 ± 49	170 ± 42	−7.3 (−27.4 to 12.7)	
Control subjects				
mmol/l	9.9 ± 3.2	10.2 ± 2.9	0.3 (−0.99 to 1.51)	
mg/dl	179 ± 57	184 ± 52	4.7 (−17.9 to 27.3)	
HbA_{1c} (percentage of total Hb) [3.9–5.1]				
Group care	7.4 ± 1.4	7.3 ± 1.0	−0.1 (−0.5 to 0.4)	<0.001
Control subjects	7.4 ± 1.4	9.0 ± 1.6	1.7 (1.1 to 2.2)	
Creatinine				
Group care				
μmol/l [44.2–114.9]	91.94 ± 14.14	75.14 ± 25.63	−16.79 (−25.63 to −10.60)	NS
mg/dl [0.5–1.3]	1.04 ± 0.16	0.85 ± 0.29	−0.19 (−0.29 to −0.12)	
Control subjects				
μmol/l [44.2–114.9]	91.05 ± 14.14	78.67 ± 47.73	−12.37 (−26.52 to 2.65)	
mg/dl [0.5–1.3]	1.03 ± 0.17	0.89 ± 0.54	−0.14 (−0.3 to 0.03)	
Total cholesterol				
Group care				
mmol/l [2.59–6.21]	5.84 ± 1.11	5.50 ± 1.06	−0.32 (−0.68 to 0.03)	NS
mg/dl [100–240]	225 ± 42	213 ± 41	−12.6 (−26.3 to 1.0)	
Control subjects				
mmol/l [2.59–6.21]	5.46 ± 0.93	5.27 ± 1.13	−0.43 (−0.54 to 0.10)	
mg/dl [100–240]	212 ± 35	204 ± 44	−8.5 (−21.2 to 4.2)	
HDL cholesterol				
Group care				
mmol/l [0.90–1.68]	1.27 ± 0.31	1.39 ± 0.33	0.14 (0.07 to 0.22)	NS
mg/dl [35–65]	49 ± 12	54 ± 13	5.7 (2.7 to 8.7)	
Control subjects				
mmol/l [0.90–1.68]	1.32 ± 0.31	1.42 ± 0.31	0.10 (−0.02 to 0.23)	
mg/dl [35–65]	51 ± 12	55 ± 12	3.9 (−0.9 to 8.8)	
Triglyceride				
Group care				
mmol/l [0.56–1.98]	2.54 (0.66–11.49)	2.17 ± 2.30	−0.48 (−1.15 to 0.20)	NS
mg/dl [50–175]	235 ± 205	193 ± 204	−42.3 (−102.0 to 17.9)	
Control subjects				
mmol/l [0.56–1.98]	1.81 (0.51–5.22)	1.52 ± 0.75	−0.28 (−0.60 to 0.03)	
mg/dl [50–175]	160 ± 88	135 ± 67	−25.5 (−53.9 to 2.9)	

Data are means ± SD or means (95% CI); values in square brackets refer to the normal reference ranges in the laboratory. *Difference between group care and control subjects.

difference in HbA_{1c} between patients in group and individual care remained associated with treatment modality after adjusting for changes in BMI.

CONCLUSIONS — This is the first 5-year intervention study reporting on the time course modifications of learning, problem solving ability, and quality of life in patients with a chronic disease, type 2 diabetes, managed by a program specifically designed to continuously deliver health education with care. The results of this study suggest that, in contrast with reports of their declining cognitive function (25), diabetic adults are able to acquire new knowledge and conscious behaviors, independent of schooling and age, if exposed to procedures and settings specifically tailored to their needs and characteristics. To the contrary, patients followed by the traditional one-to-one approach experienced progressive deterioration of knowledge, problem solving ability, and quality of life.

Improving diabetes knowledge scores among patients in group care shows that the information delivered was successfully retained over 5 years. Presumably, improved knowledge was a result of the particular teaching approach, patient/provider relationship, and permanent educational reinforcements (6,26) that were built into the group care model (12,13). Improvement in problem solving ability was strongly correlated with increasing knowledge about diabetes. Indeed, group care aimed at modifying the existing reference system, thus providing guidance in eating, exercise, and healthy practices in general. We aimed at modifying lifestyle in the patients by increasing awareness of risks, problems, and solutions that may arise in the course of life with diabetes, rather than inducing passive behavioral changes. It is worth mentioning that in our analysis, problem solving ability showed a relationship with the level of schooling, specifically suggesting that low levels of schooling are significantly correlated with a lower score in this variable. Problem solving ability seems therefore to be a result not only of greater knowledge, but also of a more complex, "educated" lifestyle.

According to Knowles's andragogy theory (4), adults will learn new notions if *1*) the teacher takes into account their personal experience and responsibility in making autonomous decisions, *2*) they help people cope with real-life situations, and *3*) they respond to internal motivations. On the contrary, adults will resist new concepts if they clash with established habits and experience.

Quality of life was the variable that showed more resistance to change. This is perhaps not surprising because quality of life is linked to self-perception and relationships with society at large. Multivariate analysis confirmed that changes in quality of life were independent of acquired knowledge, problem solving ability, or clinical improvements and depended only on the treatment modality. Possibly, group dynamics and peer identification may improve self-perception and self-esteem, reduce disease-related anxiety, and ultimately induce a feeling of well-being in spite of diabetes.

Not only were the three questionnaires validated for internal coherence and consistency, but a ceiling effect was not observed for any of the measured variables, indicating that the questionnaires had been well calibrated to detect variations within the range to be observed.

Group care prevented deterioration of glycemic control, as observed among patients in individual care, rather than lower HbA_{1c} levels. This should be considered a very positive outcome of this approach because previous trials, such as the U.K. Prospective Diabetes Study (14), had shown that metabolic control tends to worsen progressively in type 2 diabetes despite intensive hypoglycemic intervention. Multivariate analysis suggests that the difference in HbA_{1c} depended only in part on the decrease in BMI observed in the patients followed by group care. The possibility that the latter had received more intensive pharmacological treatment is ruled out by the observation, detailed previously (13), that dosages of hypoglycemic agents had to be increased in the patients in individual care but remained unchanged, or decreased, among those in group care. Improving CdR scores and levels of HDL cholesterol, on the other hand, suggest that positive changes in eating and exercise behaviors, although not measured directly in this study, might have been induced by group care and contributed to stabilizing metabolic control. On the other hand, that patients in individual care had been treated according to optimized standards is supported by the observation that their HbA_{1c} levels remained below those reported in the U.K. Prospective Diabetes Study for a similar known duration of diabetes (14).

It is often repeated in the literature that new models should be developed to empower patients and build strategies that enable them to cope with chronic diseases. We suggest that managing type 2 diabetes by systemic education-based group care may represent one such model. We showed previously (12,13) that individual visits can be substituted by interactive group consultations as a feasible, cost-effective form of outpatient diabetes care. Whether appropriate adaptations of the teaching program could make this model useful for other chronic conditions remains to be ascertained by similar randomized controlled clinical trials.

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