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Lifestyle intervention by group care prevents deterioration of Type II diabetes: a 4-year randomized controlled clinical trial

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Abstract

Aims/hypothesis. Metabolic control worsens progressively in Type II (non-insulin-dependent) diabetes mellitus despite intensified pharmacological treatment and lifestyle intervention, when these are implemented on a one-to-one basis. We compared traditional individual diabetes care with a model in which routine follow-up is managed by interactive group visits while individual consultations are reserved for emerging medical problems and yearly checks for complications.
Methods. A randomized controlled clinical trial of 56 patients with non-insulin-treated Type II diabetes managed by systemic group education and 56 control patients managed by individual consultations and education.
Results. Observation times were 51.2±2.1 months for group care and 51.2±1.8 for control subjects. Glycated haemoglobin increased in the control group but not in the group of patients ($p<0.001$), in whom BMI decreased ($p<0.001$) and HDL-cholesterol increased ($p<0.001$). Quality of life, knowledge of diabetes and health behaviours improved with group care ($p<0.001$, all) and worsened among the control patients ($p=0.004$ to $p<0.001$). Dosage of hypoglycaemic agents decreased ($p<0.001$) and retinopathy progressed less ($p<0.009$) among the group care patients than the control subjects. Diastolic blood pressure ($p<0.001$) and relative cardiovascular risk ($p<0.05$) decreased from baseline in group patients and control patients alike. Over the study period, group care required 196 min and 756.54 US $ per patient, compared with 150 min and 665.77 US $ for the control patients, resulting in an additional 2.12 US $ spent per point gained in the quality of life score.
Conclusion/interpretation. Group care by systemic education is feasible in an ordinary diabetes clinic and cost-effective in preventing the deterioration of metabolic control and quality of life in Type II diabetes without increasing pharmacological treatment. [Diabetologia (2002) 45:1231–1239]

Keywords Type II diabetes, overweight, disease management, hypoglycaemic agents, diabetic retinopathy, health education, group visits, quality of life, health behaviours, cost-effectiveness.

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Abbreviations: CdR, (Condotte di Riferimento) Health behaviours questionnaire; DQOL/Mod, Diabetes Quality of Life questionnaire (Modified); GISED, (Gruppo Italiano di Studio Educazione e Diabete) knowledge questionnaire; INHS, Italian National Health Service; QoL, Quality of Life

Prevention of vascular complications in Type II (non-insulin-dependent) diabetes mellitus requires correction of hyperglycaemia, overweight, hypertension and dyslipidaemia [1, 2]. Directions on eating habits, smoking and exercise are usually reinforced by pharmacological intervention. On its own, lifestyle intervention reduces progression from impaired glucose tolerance to Type II diabetes [3] and can improve metabolic control [1, 4] and prevent microvascular outcomes [2] in established Type II diabetes. However, intensified treatment with hypoglycaemic agents in-

creases weight [1, 2, 5], reversing one main effect of lifestyle intervention. Furthermore, progressive rise of glycated haemoglobin suggests that metabolic control can inevitably deteriorate in the natural history of Type II diabetes [1].

Lifestyle intervention was implemented individually in previous studies [1, 2, 3, 4, 5], presumably on the assumption that a one-to-one approach to patients is the preferable, time-honoured clinical option. However, scarcity of time and resources prevent ordinary clinics from adopting the optimal standards of individual care delivered during dedicated trials. We have developed a clinical approach [6, 7] in which diabetes care is routinely delivered as group sessions built upon a systemic education programme [8, 9] whereas individual care is reserved to emerging problems, yearly checks for complications or patients' explicit requests. The working hypothesis was that longer interaction of patients among themselves and with health care providers within a group setting would modify lifestyle favourably. Dealing electively with emerging problems, on the other hand, would make diabetes care less repetitive and more professionally rewarding for the team. We report on the clinical, educational, quality of life (QoL) and cost-analysis outcomes of a 4-year trial of this group education-centred approach compared with traditional one-to-one visits.

Subjects and methods

We randomly selected from our database 120 patients who met the following inclusion criteria: Type II diabetic patients treated by diet alone or with oral agents (age <80 and ≥1 year attendance in our clinic). Of these patients eight either declined to participate or had to start insulin. After randomization by random table numbers, 56 patients were assigned to six groups of nine to ten patients, while 56 control subjects continued individual consultations. All patients gave their informed consent to the study, which conformed with the principles of the Declaration of Helsinki [10].

The systemic approach [8, 9] to group care, including procedures, programme and evaluation of efficacy [11] has been described [6, 7]. Educational sessions were held every 3 months, with one to two physicians and an educationist (MTr) acting as facilitators. The programme included: the burden of overweight, choosing food, meal planning, physical exercise, checking and improving metabolic control, smoke cessation, assuming medication and preventing complications. This curriculum, divided into four sessions, was repeated in years 1–2 and then spread over seven sessions in years 3–4 to avoid excessive repetition and allow more in-depth discussion and learning. Patients requiring individual attention (i.e. those undergoing annual screening for complications and/or presenting clinical or biochemical abnormalities) and any who requested it, were offered individual care soon after the group session.

The control patients were scheduled for 3-monthly visits, or as frequently as necessary, in the general diabetes clinic by the same physicians in charge of the group sessions, who were blinded to their status in the study to avoid performance bias. Knowledge on diabetes self-care was checked annually and one-to-one educational reinforcement offered accordingly by the same educationist involved in group activities, with special reference to eating habits, home monitoring of blood glucose, if practised, and preventing complications.

Primary outcomes included measurements of body weight, fasting blood glucose, HbA_{1c}, blood lipids, knowledge of diabetes, health behaviour and QoL. Secondary outcomes included assessment of diabetic retinopathy, hypoglycaemic medication, microalbuminuria, systolic and diastolic blood pressure, Framingham score for cardio-vascular risk [12], anti-hypertensive and lipid-lowering medication. Body weight, fasting blood sugar (glucose-oxidase) and HbA_{1c} (HPLC) were measured every 3 months. Yearly screening for complications included assays of blood urea nitrogen, serum creatinine concentrations, total and HDL cholesterol, triglyceride, microalbuminuria-to-creatininuria ratio and fundus examination. Blood pressure was measured by a mercury sphygmomanometer after 5 min of lying.

Knowledge of diabetes was measured by a 38-item questionnaire developed by the Education Study Group of the Italian Society for Diabetes (GISED) [13]. Correct answers scored 1 and wrong answers scored 0. Health behaviours were measured with a purpose-built 16-item questionnaire ("Condotte di Riferimento" = CdR) [6, 7] proposing real-life situations in the "What would you do if ..." format to test whether patients could identify underlying problems and react appropriately. Correct answers scored 1 and wrong ones scored 0. QoL was measured using the DQOL questionnaire [14] translated into Italian [15] and modified by omitting six questions addressed to young insulin-dependent subjects. The modified version (DQOL/Mod) included 39 items and was re-validated [7]. Answers were along a 5-point Likert scale, from 1 (very satisfied) to 5 (very dissatisfied). Questionnaire validation included internal consistency, by Cronbach's alpha coefficient [16], and internal validity by cluster analysis [17]. Patients with literacy problems were helped by a health operator.

Diabetic retinopathy was assessed by indirect and direct ophthalmoscopy by a trained physician (MP) and color fundus photography of two 45° fields on 35 mm film (Elite Chrome 100 ASA, Eastman Kodak, Rochester, N.Y., USA), according to EURODIAB [18] and European Screening Guidelines [19] procedures. Rare microaneurysms and/or microhaemorrhages and/or isolated cotton wool spots at least one disc in diameter away from the fovea defined mild retinopathy. Lesions closer to the macula, and/or more advanced presentations defined more severe retinopathy. Ophthalmoscopy records and color slides were assessed separately by the same physician, blinded to the treatment option, and the worst diagnosis for the worst eye was taken into account.

Hypoglycaemic treatment was assessed both as class of medication (diet alone, oral agents, insulin) at the beginning and at the end of study and overall dosage modifications prescribed according to clinical judgement. Decrease or increase of final dosage compared to baseline is shown as the algebraic sum of interventions in which medication was reduced (– sign) or increased (+ sign). Changing from diet alone to oral agents, adding insulin to the latter and switching from oral agents to insulin ranked as one increase. Anti-hypertensive medication was quantified as the number of different classes of drugs administered, and lipid-active medication as the prescription of fibrates or statins.

Cardiovascular risk was assessed by a prediction model from the Framingham Heart Study [12] and expressed as relative risk obtained dividing the subjects' absolute risk by the average comparative risk in a Framingham population sample matched by age and sex. Risk factors considered in the model included: age, sex, systolic and diastolic blood pressure, total and HDL cholesterol, smoking and diabetes.

Differential costs between treatments were calculated with a micro-economic approach from a quasi-societal point of view [20]. Two types of direct costs were calculated: those paid by the Italian National Health Service (INHS) for staff and educational material and expenditures incurred by patients and their caregivers, if any. INHS costs included clinical procedures and pharmacological treatment normalized to an average duration of 1547 days, assuming full compliance. Since costs of blood and urine tests were similar for test and control patients, and mortgage rates for premises and equipment were negligible, they were not included. Patients' expenditures to attend clinics were calculated as transportation costs between home and hospital plus opportunity-cost value of time. Information on transportation times and costs, absence or presence of accompanying persons and subjective evaluation of opportunity-cost was collected using a nine-item questionnaire [21]. Timing of clinic procedures was measured during 12 group sessions, including preparation of case notes before and individual consultations at the end of the session, and five clusters of individual visits. INHS staff costs were related to 1999. Costs were originally calculated in Italian lira and converted into US dollars with an exchange rate of 0.46985 US $ to 1000 ITL, representing the weighted average of official rates during 1996 to 2000 [22]. Cost-effectiveness was calculated as the ratio between differential total direct costs and differential DQOL/Mod scores, taken as a surrogate end-point.

Statistical methods. Analysis was by intention-to-treat. Unless otherwise specified, results are expressed either as means ±1 SD, if the variable is approximately normally distributed, or mean and range if skewed or non-continuous. The Statistical Package for Social Sciences (SPSS, Chicago, Ill., USA) was used for calculations and to check the validity of questionnaires. Firstly, differences between baseline and 4-year values within groups were checked by paired Student's *t* test or Wilcoxon rank-sum test. A *p* value of less than 0.05 was taken as statistically significant, corrected to a *p* value of less than 0.005 to take into account multiple comparisons (following the Bonferroni approach), without increasing excessively the risk to incur in a beta error. Subsequently, significant increases or decreases were used as dependent variables in a general linear model where age, duration of diabetes, education and being followed by group visits or individual care were taken as independent variables.

Results

Patients' data at baseline are shown in Table 1. Despite randomization, the control patients had higher education and better knowledge of diabetes (GISED scores: 20.4±7.8 vs 14.9±7.9; $p<0.005$). Out of 56 patients on group care, 3 died and 8 moved to other clinics. Two patients who, for personal reasons, had left the groups after year 1 re-entered them at year 3. Of the 56 control subjects, 2 died, 17 had moved and 2 were lost to follow-up. The 17 who moved were recalled at year 4 and 10 accepted to return for check-up and to complete the questionnaires. In total, data from 45 patients on group care (27 men) and 45 control patients (34 men) were available for analysis at year 4. There were no differences between drop-outs and patients who continued follow-up for any of the variables measured at baseline. Total observation period was 51.1±2.1 months for group care and 51.2±1.8 months for the control group. Group patients received on average 15.8 sessions (range 13–17) and the control patients had 12.5 (6–17) individual visits ($p<0.001$).

HbA_{1c} remained stable between baseline and year 4 in group patients but worsened among the control group

Table 1. Data of patients at baseline

	Group care patients (*n*=56)	Control patients (*n*=56)	Significance
Sex (men/women)	27/29	34/22	NS
Age (years)	62.0 (35–80)	61.0 (43–78)	NS
Education[a]	N=15, P=31, M=5, H=3, U=0	N=2, P=41, M=11, H=1, U=2	Significant[b]
Occupation[c]	H=14, R=24, W=4, B=7, O=7	H=10, R=27, W=2, B=8, O=9	NS
Known duration of diabetes (years)	9.4 (1–23)	9.8 (1–39)	NS
Attendance in clinic before study (years)	4.8 (1–11)	4.8 (1–9)	NS
Family history of diabetes mellitus	37	31	NS
Self-monitoring blood glucose	12	16	NS
Smoking			
currently	10	15	NS
never	32	27	
stopped	14	14	
Hypoglycaemic treatment			
diet only	6	10	
oral hypoglycaemic agents (OHA)	50	46	NS

[a] *N* No formal education, *P* Primary school, *M* Middle school, *H* High school, *U* University degree

[b] Patients followed by group consultations had less education than those on one-to-one care (N vs P vs all others: $p<0.01$; N vs all others: $p<0.005$)

[c] *H* housewife, *R* retired, *W* white collar worker, *B* blue collar worker, *O* other

Results are expressed as means ± 1 SD, median and (range) or absolute numbers, as applicable

Table 2 Biochemical and clinical variables at baseline and year 4

	Group care patients			Control patients		
	Baseline	4 years	Difference	Baseline	4 years	Difference
Body weight (kg)	77.8±13.6	75.2±13.0	–2.6[b]	77.8±15.0	76.9±16.1	–0.9
BMI (kg/m^2)	29.8±4.5	28.7±4.0	–1.0[b]	27.9±4.5	27.6±4.7	–0.3
Fasting blood glucose, mmol/l and (mg/dl)	9.8±2.6 (176±47)	9.3±2.6 (168±46)	–0.5 (–9)	10.2±3.2 (184±57)	11.0±4.6 (199±83)	+0.8 (+15)
HbA_{1c} (percent of total Hb)[c] [3.9–5.1]	7.4±1.4	7.0±1.1	–0.3	7.4±1.4	8.6±2.1	+1.3[b]
Systolic blood pressure (mmHg)	160±26	154±21	–5.9	151±19	149±15	–1.9
Diastolic blood pressure (mmHg)	95±11	88±7	–7.1[b]	92±10	86±9	–6.3[b]
Creatinine, µmol/l [44.2–114.9] and (mg/dl) [0.5–1.3]	91.94 ±14.14 (1.04±0.16)	86.63 ±15.91 (0.98±0.18)	–5.31 (–0.06)	91.05 ±14.14 (1.03±0.16)	97.24±25.64 (1.10±0.29)	+6.19 (+0.07)
Urea nitrogen, mmol/l [3.6–17.8] and (mg/dl) [10–50]	14.42±4.82 (40.4±13.5)	13.67±3.82 (38.3±10.7)	–0.75 (–2.1)	13.56±3.57 (38.0±10.0)	15.74±5.78 (44.1±16.2)	+2.18[a] (+6.0)[a]
Microalbuminuria (alb:creatinine ratio)	31.79 (0.3–889)	6.26 (0.35–60.12)	–25,52	4.96 (0.3–59.81)	6.15 (0.6–67.3)	+1.18
Total cholesterol, mmol/l [2.59–6.21] and (mg/dl) [100–240]	5.84±1.11 (226±43)	5.77±1.34 (223±52)	–0.07 (–3)	5.46±0.93 (211±36)	5.59±1.29 (216±50)	+0.13 (+5)
HDL cholesterol, mmol/l [0.90–1.68] and (mg/dl) [35–65]	1.27±0.31 (49±12)	1.42±0.31 (55±12)	+0.15 (+6)[b]	1.32±0.31 (51±12)	1.37±0.28 (53±11)	+0.05 (+2)
Triglyceride mmol/l (range) [0.56–1.98] and mg/dl (range) [50–175]	2.54 (0.66–11.49) 225 (59–1018)	2.11 (0.45–10.93) [187 (40–968)	–0.43 (–37)	1.81 (0.51–5.22) 160 (45–462)	1.64 (0.43–3.47) 145 (38–307)	–0.17 (–15)

Figures in square brackets refer to normal reference range in the laboratory

[a] $p<0.05$

[b] $p<0.001$

[c] The difference between baseline and 4 year values is significantly different between the two groups after adjusting for age, duration of diabetes and education

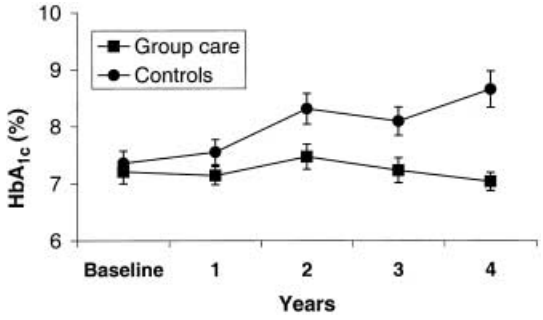

Fig. 1. HbA_{1c} in patients on group care (*squares*) and controls (*circles*) from baseline to year 4. Values are shown as means ± SEM. Differences reach statistical significance at years 2 (p=0.015), 3 (p=0.013) and 4 (p=0.000)

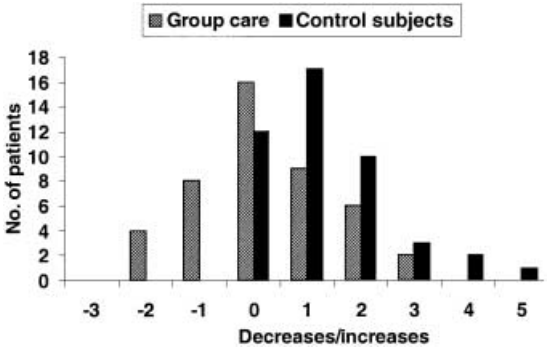

Fig. 2. Changes of hypoglycaemic medication during the 4 years in group care and control patients. *Bars* indicate numbers of patients in whom dosages of hypoglycaemic agents were changed, on multiple occasions during the study, resulting in net reduction (– sign) or increase (+ sign) of medication. Increases in dosage also include changes from diet to oral agents and from oral agents to insulin. The difference between group care and control patients is significant (p<0.001) if one compares increases vs decreases in the two groups

(p<0.001) (Fig. 1). Body weight (p<0.001) and BMI (p<0.001) decreased and HDL cholesterol increased (p<0.001) in group patients but not in the control patients. Blood urea nitrogen increased among the control patients (p=0.038). Blood pressure decreased in both group and control patients but the difference was significant only for diastolic values (p<0.001) (Table 2).

Fitting the general linear model, in which the above differences between baseline and 4-year values were used as dependent variables, only HbA_{1c} and urea remained different between group care and the control patients after adjusting for age, duration of diabetes and education. Further adjustment of HbA_{1c} for BMI, to test the hypothesis that weight reduction had contributed to stabilize HbA_{1c} in group patients, showed that this difference, though partially correlated with BMI, remained an independent effect of intervention.

The scores of GISED, CdR and DQOL/Mod questionnaires improved with group care (p<0.001, all) but worsened among the control patients (p=0.004 for GISED; p<0.001for CdR and DQOL/Mod) (Table 3). These differences remained significant after adjusting for age, duration of disease and education.

Diabetic retinopathy remained stable or changed from mild to non-detectable among patients followed by group care but worsened among the control patients (p<0.009, Table 4).

Hypoglycaemic treatment at year 4 included diet only (2 group and 2 control patients), oral agents (38 and 37, respectively), oral agents and insulin (4 and 3) and insulin alone (1 and 3). Dosage of hypoglycaemic agents during the 4 years decreased among group patients and increased among the control patients (p<0.001, Fig. 2). Use of antihypertensive and lipid-active medication showed a tendency to increase over the 4 years in both group and control patients.

Because of diabetes, the absolute cardiovascular risk at baseline in the patients of this study (group care 24.4±10.0, control subjects 26.1±13.0; NS) was higher than the average risk of matched reference Framingham populations (15.3±5.4 and 16.7±6.9, respectively), resulting in relative risks of 1.7±0.6 and 1.6±0.6, respectively. The absolute risk did not change over 4 years in either group (24.6±8.9) or control patients (25.8±12.0), mostly because lower blood pressure had counterbalanced the effect of ageing. On the contrary, since the average risk had become higher in the reference populations (17.1±6.1 and 18.5±6.8, respectively), the relative cardiovascular risk was reduced by 0.2 in group care

Table 3. Knowledge of diabetes, health behaviours and quality of life at baseline and year 4

	Group care patients			Control patients		
	Baseline	4 years	Difference	Baseline	4 years	Difference
Knowledge of diabetes (GISED score)[c]	14.9±7.9	27.1±6.6	+12.2[b]	20.4±7.8	17.2±8.7	–3.2[a]
Health behaviours (CdR score)[c]	11.0±2.7	16.5±2.9	+5.4[b]	12.3±4.2	10.2±3.9	–2.1[b]
Quality of life (DQOL/Mod score)[c]	67.6±19.0	44.0±7.5	–23.6[b]	70.5±21.7	89.8±28.1	+19.2[b]

[a] p<0.05
[b] p<0.001
[c] The difference between baseline and four year values remains significantly different (p<0.009) between the two groups after adjusting for age, duration of diabetes and schooling

Table 4. Progression of diabetic retinopathy

GROUP CARE (*n*=45)	Retinopathy at year 4		
Retinopathy at baseline	More severe (*n*=0)	Mild (*n*=10)	None (*n*=35)
Mild (*n*=12)	–	6	6
None (*n*=33)	–	4	29
CONTROLS (*n*=42)	Retinopathy at year 4		
Retinopathy at baseline	More severe (*n*=3)	Mild (*n*=20)	None (*n*=19)
Mild (*n*=14)	3	10	1
None (*n*=28)	–	10	18

Numbers of patients in group care and control patients for whom data were available at the beginning and end of the study, with reference to status of retinopathy at baseline (vertical) and year 4 (horizontal). The difference is significant p=0.009 comparing the number of patients improved vs those who worsened among those under group care and the control group

(1.5±0.5) and control patients (1.4±0.5) alike, $p<0.05$ both.

On average, group care required 34 min for preliminary checking of blood test results and case notes, 45 min for the session itself and 24 min for elective individual visits. An average of 8.4 patients attended the 12 sessions monitored, resulting in 12.4 min per patient-session or 196 min spent by INHS staff per patient over the study. Seeing 58 patients individually during five different clinics required 698 min, or 12.0 min per patient, or 150 min of INHS staff per patient over the study.

Direct costs to INHS and patients are detailed in Table 5. In total, staff and material costs were 108.87 US $ per patient on group care and 82.50 per control patient. Hypoglycaemic treatment cost US $ 488.57 per patient and 488.02 per control patient. Drug costs on group care were US $ 0.26 per patient-day at baseline and 0.36 at year 4. Those for the control patients were 0.23 and 0.44 US $, respectively. Average transportation time was 38 min per patient-visit. Since patients on group care were accompanied by others in 20.8% of cases, they and their caregivers spent 104 min per consultation or 1643 min over the study. Corresponding figures for the control patients and caregivers were 37.5%, 69 min per visit and 850 min in total. The average estimated value of personal time was US $ 0.07 per min, with a total cost of US $ 115.02 per patient on group care and US $ 60.38 per control patient. In total, each patient on group care cost US $ 756.54 and each control US $ 665.77, with a difference of US $ 90.77 per patient treatment over the observation period. Taking the differential DQOL/Mod score as a proxy outcome, each incremental improvement in QoL on group care was obtained with an expenditure of only US $ 2.12.

Discussion

Routine diabetes care is still dominated by the traditional therapeutic relationship in which doctors, nurses, dieticians and other members of the health care team interact with patients on a one-to-one basis. This

Table 5. Cost analysis

Costs and outcomes	Group care patients		Control patient		Difference group-controls
	Per session	Overall	Per session	Overall	Overall
Staff costs	6.42	101.44	6.40	80.00	21.44
Other costs	0.47	7.43	0.20	2.50	4.93
Pharmaceuticals		488.57		488.02	0.55
Total INHS direct costs		597.43		570.52	26.91
Transportation costs	2.79	44.08	2.79	34.88	9.21
Opportunity-costs	7.28	115.02	4.83	60.38	54.65
Total patients' costs	10.07	159.11	7.62	95.25	63.86
Total direct costs		756.54		665.77	90.77
Differential DQOL/Mod scores		–23.60		19.20	–42.80
Cost-effectiveness ratio					2.12

All costs in US $. Costs were originally calculated in ITL, and converted into US $ with an exchange rate of 0.46985 US $/1000 ITL (weighted average of annual official exchange rates during 1996–2000) [22]. INHS costs included clinical procedures and pharmacological treatment costs (the latter being almost the same for both test and control patients). Total patients' costs included transportation expenditures incurred by patients and their caregivers and opportunity-cost of time spent (information collected by questionnaire [21]). The difference in total direct costs (+90.77 US $ per patient on group care over control) was related to differential DQoL/Mod scores (–42.80), taken as a proxy end-point outcome, obtaining a cost-effectiveness ratio of 2.12 US $ for each incremental improvement in QoL on group care

leads to active prescription of diet, medication and advice on healthy practices but may not stimulate durable patient cooperation. We show that Type II diabetes is managed more effectively by an intervention model based on group care, which shifts the emphasis on interactive educational techniques and reserves individual medical attention for elective situations. Routine group care was more effective than the one-to-one approach in promoting appropriate health behaviours, better knowledge of diabetes and, ultimately, improving metabolic control and QoL in the medium to long-term. It also reduced progression of retinopathy and use of hypoglycaemic agents. Group care required a new programme and re-organization of current practice but additional time and resources were minimal and the procedure was feasible and cost-effective.

Group care improved metabolic control by stabilizing HbA_{1c}, lowering BMI and increasing HDL cholesterol. Stabilisation of HbA_{1c} should be underlined as a very positive outcome, compared to increasing values in the control patients (Fig. 1). Long-term follow up of patients in the United Kingdom Prospective Diabetes Study (UKPDS) [1], whether on conventional or intensified pharmacological treatment, suggested that progressive deterioration of metabolic control could be unavoidable in the natural history of Type II diabetes. The rate of worsening of HbA_{1c} in our control patients was indeed similar to that observed during years 0 to 4 of the UKPDS. Patients on group care, in contrast, maintained their initial HbA_{1c} values despite reducing hypoglycaemic medication.

The difference in HbA_{1c} between group and control patients remained significant after adjusting for BMI, suggesting that weight reduction was only part of the effect obtained by permanent group care. A recent systematic review of weight reduction programs in obese people [23] concluded that dietary therapy results in modest (2–6 kg) weight loss, which is usually not sustained longer than 2 years unless backed by long-term dietary counselling. Reiterated messages on food selection and moderate daily exercise, as delivered during the group sessions, could have contributed to our result. However, the patients of this study were only moderately overweight and it remains to be seen whether our approach would have a similar, or greater, effect in obese people.

Although known to improve clinical outcomes of Type II diabetes through lifestyle changes [2], and to reduce requirements for hypoglycaemic medication over 1 year [24, 25] structured patient education is still conceived as side-support to individual clinical care and offered, or "prescribed", as time-limited reinforcement courses. Little is known on how long its efficacy persists after such courses. Health education should not confine itself to providing information on disease and treatment options, because most notions are either not retained or easily forgotten. Socio-cultural barriers make traditional top-down academic teaching, whether in clinic or a classroom setting, particularly ineffective [4, 26]. For education to become a useful therapeutic tool, patients should be involved in hands-on activities, role-playing, problem-solving and other interactive techniques [27]. Group settings are particularly effective because they add motivation, experience and peer identification.

Improving scores of knowledge of diabetes among group patients shows that information was successfully retained over 4 years. That knowledge was effectively put to practice is suggested by the health behaviours, or conducts (Condotte di Riferimento, CdR), questionnaire and the clinical results. When planning this programme, we analysed the system of beliefs and behaviours the patients made reference to in applying their everyday health practices, whether correct or incorrect. Group care aimed at modifying the existing reference system, thus providing guidance to eating, exercise and healthy practices in general. Modifying lifestyle by inducing fully conscious conducts, rather than passive behavioural changes, was the ultimate goal of this approach. The CdR questionnaire was developed to explore the patients' ability to move within their reference system, recognize situations of potential risk for a person with diabetes and react by appropriate conducts [6, 7]. Multivariate analysis showed that improvement in the scores did not depend on age, duration of diabetes, length of attendance in the clinic or schooling. The latter was taken as an indicator of literacy and socioeconomic status, suggesting that the approach had overcome cultural and social barriers.

Improved QoL with group care had been observed at year 2 of this trial [7] but worsening at year 4 was unexpected among the control patients. QoL, assessed by other tools, was reported to correlate with metabolic control in Type II diabetes in a cross-sectional survey [28] and with onset of complications, independently of intensive pharmacological treatment, in a longitudinal study [29]. Our results suggest that it could progressively worsen in Type II diabetes, along with increasing HbA_{1c} and/or the emergence of complications. An interactive group approach can counteract this trend by promoting patients' adaptation to their chronic illness [30].

As this study was not powered to detect effects of group care on retinopathy, reduced progression and clearing of microaneurysms were unexpected. Stabilization or improvement of mild retinopathy were reported in previous intervention studies [5, 31] and, in the group patients, could have resulted from keeping HbA_{1c} around 7% [1, 5, 32] and lowering blood pressure [33]. A very long known duration of diabetes (up to 39 years), on the other hand, might have facilitated progression in some control patients. Before firm conclusions are drawn, however, this encouraging result should be confirmed in larger populations.

Relative cardiovascular risk was reduced in group and control patients alike. As the Framingham score

[12] takes into account diabetes per se but not metabolic control, the main factor counteracting ageing in our patients was lower diastolic pressure. This outcome, along with similar consumption of anti-hypertensive drugs by group and control patients confirms that due attention was paid to hypertension, whose role in the pathogenesis of diabetic complications had become increasingly evident while this trial was being carried out [33, 34, 35]. That the Framingham risk calculation decreased in all patients also suggests that: (i) control patients did receive at least as good standard clinical care as group patients, and (ii) group care has an additional advantage even over "optimised" individual care, assuming that reducing the relative cardiovascular risk over 4 years can be defined as such.

Since no study of this kind can be run as a double-blind trial, it could be argued that attention and care differed between the control and test patients. To prevent performance bias, physicians were blinded to which patients in the general diabetes clinic served as the control patients. Overall results and the improvement in cardiovascular risk among all patients suggest maintenance of satisfactory standards of care. Selection bias might have been another problem because, despite randomization, the control patients had a better education and knowledge of diabetes at baseline. Accordingly, results were adjusted for education on multivariate analysis, and knowledge of diabetes was reversed already at year 1 [6]. Attrition bias was ruled out by lack of baseline differences between drop-outs and remaining patients. Finally, all outcomes were measured blindly for the treatment group.

Reduced need for hypoglycaemic medication after patient education has been reported to lower pharmaceutical expenses [24, 25]. In this study dosages decreased among patients on group care and increased in the control subjects, with average daily costs increasing by 35.2%, among the former versus 86.9% among the latter. Group care was cost-effective, as each point gained on the QoL score required only an extra US $ 2.12.

This paper suggests that lifestyle intervention can be successfully implemented in diabetes through routine group care. Our patients spent more time than ever before with the health care team while the waiting room was virtually abolished. Health care providers found the diabetic clinic had become less repetitive and more professionally rewarding. Group sessions were like adult education classes for our patients, who enjoyed the new relationship established among themselves and with the health care team and almost unanimously declared that, given the choice, they would not go back to individual care.

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