# Group Visits Improve Metabolic Control in Type 2 Diabetes

## A 2-year follow-up

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**OBJECTIVE** — To evaluate whether group visits, delivered as routine diabetes care and structured according to a systemic education approach, are more effective than individual consultations in improving metabolic control in non–insulin-treated type 2 diabetes.

**RESEARCH DESIGN AND METHODS** — In a randomized controlled clinical trial of 112 patients, 56 patients were allocated to groups of 9 or 10 individuals who participated in group consultations, and 56 patients (considered control subjects) underwent individual visits plus support education. All visits were scheduled every 3 months.

**RESULTS** — After 2 years, $HbA_{1c}$ levels were lower in patients seen in groups than in control subjects ($P < 0.002$). Levels of HDL cholesterol had increased in patients seen in groups but had not increased in control subjects ($P = 0.045$). BMI ($P = 0.06$) and fasting triglyceride level ($P = 0.053$) were lower. Patients participating in group visits had improved knowledge of diabetes ($P < 0.001$) and quality of life ($P < 0.001$) and experienced more appropriate health behaviors ($P < 0.001$). Physicians spent less time seeing 9–10 patients as a group rather than individually, but patients had longer interaction with health care providers.

**CONCLUSIONS** — Group consultations may improve metabolic control in the medium term by inducing more appropriate health behaviors. They are feasible in everyday clinical practice without increasing working hours.

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The U.K. Prospective Diabetes Study has confirmed that maintaining good metabolic control prevents chronic complications in patients with type 2 diabetes. However, this study also suggests that a progressive increase in $HbA_{1c}$ may be inevitable in the natural history of the disease (1). Optimizing control requires multidisciplinary efforts aimed both at correcting lifestyles and addressing intercurrent medical problems (2). Most patients with non–insulin-treated type 2 diabetes receive individual consultations combined with noncontinuous educational support, if available (3,4). This helps address clinical problems but is unlikely to induce appropriate health behaviors. In particular, information and knowledge offered during these visits are believed to be in conflict with daily actions and habits and are thus easily ignored or forgotten by the patients. There is a need, therefore, for more efficient approaches to modifying lifestyle while improving metabolic control in individuals with diabetes (5,6).

We aimed to verify whether individual visits can be replaced by interactive group visits as the main form of outpatient diabetes care. Individual visits may be repetitive for health care providers and may not be sufficiently effective for patients. In addition, patient education (7) should not be limited in time or format as a mere adjunct to diabetes care. Therefore, the individual visits and patient education should be merged into a permanent clinical pedagogic process, with one-to-one visits reserved for regular screening for complications and/or emerging intercurrent problems. On the other hand, prolonging patients' contact with the diabetes care team should not increase the already heavy workloads of the health care providers. During group consultations, patients seen together over 1 h would benefit from longer exposure to interactive techniques, positive dynamics, and identification with other members. For the health care providers, group visits would take the same amount of time, or possibly less time, than seeing the same patients on an individual basis, and targeted one-to-one medical intervention would be rewarding and less repetitive. Preliminary results showed the feasibility of this approach over 1 year (8) and suggested that the clinical efficacy should be tested over a longer period of time.

## RESEARCH DESIGN AND METHODS

— A total of 112 patients with type 2 diabetes, treated either with diet alone or with diet and oral administration of hypoglycemic agents, who had attended our diabetes clinic for at least 1 year were enrolled in the study after giving informed consent. The study conformed with the principles stated in the Declaration of Helsinki (9). After randomization by random table numbers, 56 patients were assigned to six groups of 9 or 10 persons, whereas the other 56 (control subjects) continued with traditional consultations.

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**Abbreviations:** CdR, *Condotte di Riferimento*; DQOL, Diabetes Quality of Life; GISED, Education Study Group of the Italian Society for Diabetes.
A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

**Table 1—*Educational objectives of patient tutoring by group consultation, as tested by the CdR questionnaire***

- Reach desirable body weight
- Learn to shop for food (reading labels for contents, energy value, etc.)
- Choose appropriate quality and quantity of food at home or restaurant
- Increase physical activity, when feasible
- Take medication properly and regularly
- Know the meaning of the main laboratory tests of metabolic control
- Recognize early symptoms of and be able to react to hypoglycemia
- Take appropriate action in the case of intercurrent illnesses
- Care for feet and buy appropriate footwear
- Regularly attend the clinic and screening checks for complications

Two hospital physicians, a general practitioner, two postgraduate medical students, an educationist, a clinical psychologist, and a psychometrist contributed to planning activities, developing educational material, simulating patient sessions before starting the program, and evaluating outcomes. In every session, one or two physicians and the educationist (M.T.) acted as facilitators of the group activity (10).

## Group sessions

The group program was based on a systemic education approach (10,11) including observation and assessment of educational needs (educational diagnosis) (6), definition of specific goals, development of session procedure and program, evaluation of the learning process, and overall assessment of clinical outcomes and efficacy of the intervention (10).

During the observation phase, data were collected on patients' education, occupation, leisure activities, health beliefs, and eating habits. The first two items were obtained by interviews. Evidence on the other three items was collected by the educationist (M.T.), who spent 6 months before the project observing patients in the waiting room and assessing their interests, habits, and concerns using a structured checklist.

The goals to be reached by the patients were defined (Table 1), and a detailed plan was prepared to establish the messages to be delivered and the methods and setting in which to deliver them during each visit (12).

Simple support material was developed, including visual aids, food (real, models or packages, as applicable), graduated containers, and a flip chart. Care was taken to avoid delivery of contradictory information or messages (13). Medical or scientific jargon was intentionally avoided, and simplified yet correct wording was preferred. Concepts such as "glycated hemoglobin," "calories," and "sensorial nervous fiber" were described using images, metaphors (14), and examples so the patients could develop vivid mental representations.

## Procedure

In accordance with routine practice in our clinic, blood samples were collected a few days in advance and the results and case notes were checked by the physician before the group consultation. Patients in need of individual clinical attention (i.e., those who had completed the annual screening for complications and those with large variations in their usual blood and/or urine results) as well as any who requested it were seen on a one-to-one basis by the same physician at the end of the group session.

The program consisted of four sessions that focused on the undesirability of being overweight, meal planning, improving and checking metabolic control, and preventing chronic complications.

Each group session was structured into four phases: *1*) welcome and introduction to the subject to be discussed; *2*) interactive learning; *3*) discussion of some of the patients' experiences; and *4*) conclusions, with directions for follow-up "homework," information about the next appointment, and where necessary, individual visits with the physician (see above).

During phase 1, the "homework" (see below) from the previous visit was collected and checked. The patients were given sealed envelopes containing the results of their blood tests; these results were discussed collectively only if the patients so desired. During phases 2 and 3, which were not strictly separated, various hands-on activities, group work, problem-solving exercises, real-life simulations, and role playing were proposed. To induce positive group dynamics (15,16), the facilitators helped each patient identify and share his/her problems and successes with the other members. The patients were encouraged to report their personal experiences, if they so desired. If patients related examples of unintentionally incorrect behavior, this was not criticized but was used as a source of positive learning for the group. Similarly, all questions were considered relevant. The emergence of group leaders was encouraged, while maintaining the full involvement of all other members. Less extroverted patients were helped, but never forced, to participate during all phases. To reinforce cohesion and interpersonal relationships, the same patients and facilitators took part in the same groups over time. Relatives who wished to participate were welcomed. During phase 4, a diary for weekly monitoring of body weight and food intake was distributed as homework to be collected during phase 1 of the following session. Relatives were instructed in the procedure to help patients with literacy problems. The four-session cycle was repeated for a second year.

## Individual care in control subjects

Control patients continued to follow habitual consultations every 3 months in the diabetes clinic, unless they had intercurrent problems, and they were seen by the same physicians in charge of group consultations. Physicians did not know which patients in the clinic served as control subjects for this study. In keeping with routine practice, blood samples were collected a few days before each visit and patients were asked to complete the same weekly diaries of body weight and nutrition as the group patients. They received individual education sessions from the same educationist involved in the group activities, with special reference to proper eating habits, home monitoring of blood glucose levels, and prevention of complications. Their knowledge was checked annually, at the time of screening for complications, and educational reinforcement was offered accordingly.

## Evaluation of results

Body weight, fasting blood glucose level (glucose-oxidase), and $HbA_{1c}$ level (high-performance liquid chromatography) were measured during each visit. Routine screening for complications was performed annually, including blood tests for serum creatinine level, total and HDL cholesterol levels, level of triglycer-

ides, and microalbuminuria/creatininuria ratio.

At baseline and after 1- and 2-year follow-up, three questionnaires were administered to measure the following:

*1*) Quality of life: a modified version of the Diabetes Quality of Life (DQOL) questionnaire (17), which had been translated into Italian and revalidated (18), was used. The questionnaire was slightly modified from the original version: six questions were omitted (items 1–3 and 5–7 from the "Worry: Social/Vocational" section) because they pertained to young patients with type 1 diabetes. The modified version included 39 items and was called "DQOL/Mod." Patients were asked to answer the questions using a five-point Likert scale: 1 (very satisfied) to 5 (very dissatisfied).

*2*) Knowledge of diabetes: a questionnaire developed by the Education Study Group of the Italian Society for Diabetes (GISED) (19) was used. This questionnaire, which included 38 items, was also slightly modified to clarify the meaning of some terms; one point was assigned for each correct answer and no points were assigned for incorrect answers.

*3*) Health behaviors ("*Condotte di Riferimento*" [CdR]) (8): a purposely built questionnaire composed of 16 items was used. Questions posed hypothetical situations using the "What would you do if . . ." format to test whether the patients were able to identify underlying health problems and react correctly. One point was assigned for each correct answer, and no points were assigned for incorrect answers.

If the patients had problems with literacy, the questionnaires were completed with the help of a health care provider.

The three questionnaires were checked for internal consistency using Cronbach's α-coefficient (20) and for internal validity by cluster analysis (21).

### Statistical analysis

Unless otherwise specified, results are expressed as the mean ± 1 SD (if the variable is approximately normally distributed) or as mean and range (if the variable is skewed or noncontinuous). The SPSS for Windows software package (SPSS, Chicago, IL) was used for statistical calculations and for checking the validity of questionnaires. Differences between baseline and 2-year values of the outcome variables within and between group patients and control patients were tested by fitting a generalized linear model for repeated measures, which takes into consideration the independent effect of group and group × time interactions. Differences between discrete variables were checked by $\chi^2$ or Wilcoxon's rank-sum tests. Spearman's rank or Pearson's correlation coefficients were computed, as applicable.

**RESULTS** — Clinical data of the patients at baseline are shown in Table 2. Despite the initial randomization, control subjects had higher levels of education and better knowledge of diabetes (according to the GISED questionnaire). Two years later, 22 patients were no longer participating in the study. Of 13 patients who had started group visits, 3 died and 10 moved to other locations. Of the nine control subjects, one died, five moved to other locations, and three were lost to follow-up. Clinical details after 2 years are also listed in Table 2. No differences were noted between the patients who continued follow-up and those who left the study (for any reason). The patients seen in groups completed an average of 7.9 visits (range 7–8) during the 2 years; the control subjects completed 8.2 visits (range 5–11).

After 2 years, $HbA_{1c}$ levels had remained stable in the group patients but had worsened in control subjects ($P < 0.002$) (Fig. 1). In the group patients, a tendency toward lower BMI was noted ($P = 0.06$). HDL cholesterol levels were initially similar in the two cohorts, but later they were lower in group patients only ($P < 0.05$); in the group patients, a tendency toward lower triglyceride levels was also observed ($P = 0.053$). Administration of insulin, either alone or in combination with oral agents, was necessary in two of the group patients and five control subjects. Changes in drug treatment and dose of oral hypoglycemic agents did not differ between the two cohorts.

Cronbach's α-coefficient (20) for the DQOL/Mod at baseline was 0.70 for all patients (0.56 for group patients and 0.77 for control subjects) and increased to 0.90 after 2 years (0.91 for group patients and 0.88 for control subjects). The α-coefficient for the GISED questionnaire was 0.88 initially (0.71 for group patients and 0.85 for control subjects) and 0.89 after 2 years (0.88 for group patients and 0.90 for control subjects). The α-coefficient for the CdR questionnaire was 0.71 at baseline (0.61 for group patients and 0.76 for control subjects) and 0.71 at the end of the study (0.64 for group patients and 0.73 for control subjects). Cluster analysis (21) confirmed the internal validity of all three questionnaires (data not shown).

At baseline, the results of the CdR and GISED questionnaires correlated both in group patients and control subjects ($r = 0.62$, $P < 0.001$ and $r = 0.63$, $P < 0.001$, respectively). CdR scores in all patients correlated with their level of education ($r = 0.37$, $P < 0.001$), although this was verified only in the group patients ($r = 0.43$, $P < 0.001$). The GISED questionnaire correlated with the level of education in both group patients and control subjects ($r = 0.49$, $P < 0.001$ and $r = 0.42$, $P < 0.001$, respectively). The DQOL/Mod scores did not correlate with those of the other two questionnaires or with any of the other parameters listed in Table 2.

Among group patients, scores improved for the DQOL/Mod ($P < 0.001$), GISED ($P < 0.001$), and CdR questionnaires ($P < 0.001$), but no changes in score occurred among the control subjects (Table 2). The group patients had adopted more appropriate health behaviors, and their initially lower knowledge of diabetes had been reversed. Correlations between the scores of the CdR and GISED questionnaires persisted at the end of the 2 years ($r = 0.69$, $P < 0.001$ for group patients and $r = 0.75$, $P < 0.001$ for control subjects).

The GISED and CdR scores obtained by all patients at 2 years correlated negatively with the differences between the initial and final $HbA_{1c}$ values ($\Delta$-$HbA_{1c}$) ($r = -0.32$, $P < 0.005$ and $r = -0.29$, $P < 0.005$, respectively).

Each group consultation lasted ~50 min. The physicians spent ~30 min before each session to examine the case notes and the results of the patients' blood tests and another 30 min meeting individually with all patients who had specific clinical problems and/or had completed their yearly screenings for complications. Each individual control visit required 15–20 min. In total, 150–200 min were needed to see 10 patients with the traditional approach, whereas group consultations did not take longer than 120 min.

**CONCLUSIONS** — This study suggests that managing patients with non–

**Table 2—*Clinical data of patients at the beginning and end of the study***

| | Group patients | | Control subjects | | Statistical significance |
|---|---|---|---|---|---|
| | Beginning of study | End of study | Beginning of study | End of study | |
| *n* | 56 | 43 | 56 | 47 | — |
| Sex (M/F) | 27/29 | 22/21 | 34/22 | 30/17 | NS |
| Age | 62.0 (35–80) | 63.0 (37–82) | 61.0 (43–78) | 64.0 (45–80) | NS |
| Schooling* | N=15, P=31, M=5, H=3, U=0 | N=11, P=24, M=5, H=3, U=0 | N=2, P=41, M=11, H=1, U=2 | N=1, P=33, M=11, H=0, U=2 | † |
| Occupation‡ | H=14, R=24, W=4, B=7, O=7 | H=11, R=18, W=3, B=6, O=5 | H=10, R=27, W=2, B=8, O=9 | H=7, R=24, W=2, B=7, O=7 | NS |
| Known duration of diabetes (years) | 9.4 (1–23) | 11.7 (3–25) | 9.8 (1–39) | 12.3 (3–41) | NS |
| Attendance in clinic (years) | 4.8 (1–11) | 6.8 (3–13) | 4.8 (1–9) | 7.0 (3–11) | NS |
| Family history of diabetes | 37 | 30 | 31 | 25 | NS |
| Self-monitoring blood glucose | 12 | 10 | 16 | 14 | NS |
| Smoking (currently/never/stopped) | 10/32/14 | 6/25/12 | 15/27/14 | 11/20/14 | NS |
| Hypertensive | 34 | 26 | 25 | 22 | NS |
| Hypoglycemic treatment: | | | | | |
| Diet only | 6 | 2 | 10 | 5 | NS |
| Sulphonylureas | 27 | 18 | 21 | 13 | NS |
| Metformin | 5 | 3 | 6 | 6 | NS |
| Sulphonylureas + metformin | 18 | 18 | 19 | 25 | NS |
| Insulin | — | 2 | — | 5 | NS |
| Quality of life (DQOL/Mod score) | 67.6 ± 19.0 | 55.6 ± 15.9 | 66.7 ± 25.0 | 80.8 ± 31.5 | $P < 0.001$ |
| Knowledge of diabetes (GISED score) | 14.9 ± 7.9 | 24.0 ± 6.6 | 20.2 ± 7.4 | 17.4 ± 8.6 | $P < 0.001$ |
| Health conduct (CdR score) | 11.1 ± 2.7 | 15.8 ± 2.9 | 12.0 ± 4.3 | 11.3 ± 4.3 | $P < 0.001$ |
| Body weight (kg) | 77.4 ± 13.1 | 76.0 ± 13.4 | 78.2 ± 14.6 | 77.1 ± 14.7 | NS |
| BMI (kg/m$^2$) | 29.7 ± 4.5 | 29.0 ± 4.4 | 27.8 ± 4.1 | 27.6 ± 4.2 | $P = 0.06$ |
| Fasting blood glucose (mmol/l) | 9.8 ± 2.6 | 9.9 ± 2.7 | 10.0 ± 3.1 | 9.2 ± 2.9 | NS |
| $HbA_{1c}$ (percentage of total hemoglobin) | 7.4 ± 1.4 | 7.5 ± 1.4 | 7.4 ± 1.4 | 8.3 ± 1.8 | $P < 0.002$ |
| Total cholesterol (mmol/l) | 5.8 ± 1.1 | 5.7 ± 1.2 | 5.5 ± 0.9 | 5.6 ± 1.2 | NS |
| HDL cholesterol (mmol/l) | 1.2 ± 0.3 | 1.4 ± 0.4 | 1.3 ± 0.3 | 1.3 ± 0.3 | $P < 0.05$ |
| Triglyceride (mmol/l) | 2.6 (0.7–11.5) | 2.1 (0.7–6.9) | 1.7 (0.5–5.2) | 1.7 (0.6–3.9) | $P = 0.53$ |
| Creatinine, (μmol/l) | 91.6 ± 14.2 | 88.8 ± 16.5 | 90.0 ± 14.0 | 87.8 ± 17.2 | NS |
| Albuminuria (none/micro or macro) | 32/24 | 20/21 | 37/19 | 19/22 | NS |
| Diabetic retinopathy (none/mild/more severe) | 42/8/6 | 35/5/3 | 38/13/5 | 33/7/7 | NS |
| Foot ulcers (never/past/active) | 54/0/2 | 42/1/0 | 53/2/1 | 45/1/1 | NS |

Data are mean ± 1 SD, median range, or absolute numbers, as applicable. *N = No formal education, P = primary school, M = middle school, H = high school, U = university degree; †patients followed by group consultations had less education than those in one-to-one care (N versus P versus all others, $P < 0.01$; N versus all others, $P < 0.005$); ‡H = housewife, R = retired, W = white-collar worker; B = blue-collar worker, O = other.

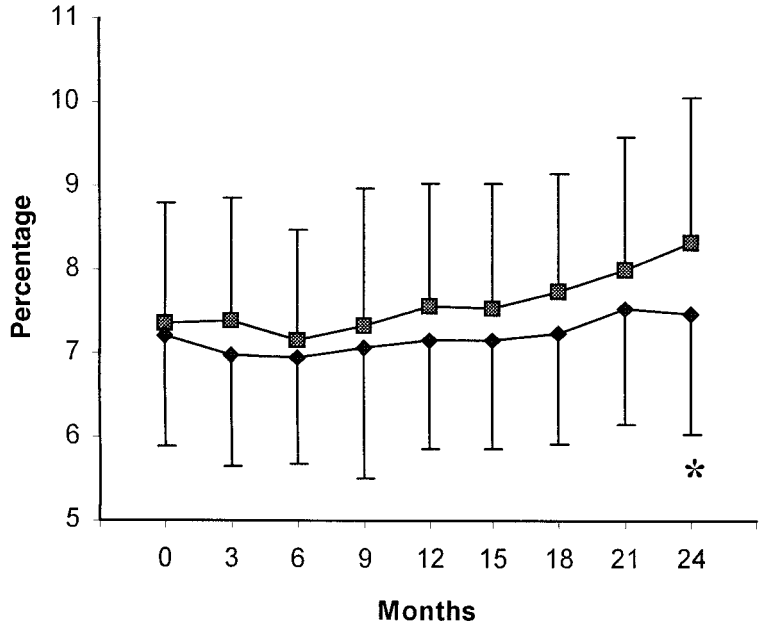


**Figure 1**—*Levels of $HbA_{1c}$ in the patients who participated in group visits (◆, case subjects) and those who received individual care and education (▨, control subjects). *P = 0.015.*

insulin-treated type 2 diabetes by group visits is feasible in busy clinics and is possibly more effective than traditional physician-patient one-to-one visits. A group of adult patients, some with low levels of education, were successfully supported in keeping their $HbA_{1c}$ levels stable and increasing the HDL cholesterol levels while reducing their BMIs and serum triglyceride levels (Table 2, Fig. 1). Quality of life, knowledge of diabetes, and health behaviors were all improved. Control patients who were followed with more traditional individual consultations and support education, although they started with higher levels of education and knowledge of diabetes, did not achieve the same results, and their $HbA_{1c}$ levels worsened, in accordance with what seems to be the natural evolution of type 2 diabetes (1). The negative correlation between $\Delta$-$HbA_{1c}$ and the 2-year scores of the CdR questionnaires, with no differences in pharmacological management between patients followed by group or individual consultations, strongly suggests that the group approach did play a role in stabilizing metabolic control by improving health behaviors.

Some potential limitations in the experimental design deserve consideration. First, a selection bias might have occurred at the time of recruitment because patients who were willing to participate in the experimental procedure might have been more receptive to the group approach. However, none of the patients who fulfilled the inclusion criteria and were randomly selected from the clinic database refused to participate. Second, health care providers may have been biased because they could not be blinded. This problem was limited, in part, by ensuring that physicians were unaware of which patients in the general diabetes clinic served as control subjects.

It is important to develop adult learning strategies that take both literacy (22) and health beliefs (13) of patients into consideration because these are often quite different from those of medical personnel. Three questionnaires, validated for consistency and homogeneity, were used to assess the efficacy of group visits. The increased number of correct answers on the GISED, assessing the level of knowledge about diabetes (19), shows that the concepts and messages covered during group sessions were indeed acquired by the patients. The CdR results correlated with those of GISED, suggesting that improved knowledge was accompanied by development of appropriate skills. In contrast, the scores of neither questionnaire changed in the control subjects. Because these patients were also offered individual care and information by the same personnel who cared for the groups, the result suggests that the group approach, with its motivation, experience, and peer identification, made an important difference on behaviors as well as quality of life. The original DQOL (17) was used in the Diabetes Control and Complications Trial (23) and was adapted for this study because it remains the most extensively used tool to assess quality of life of patients with diabetes. The values obtained for Cronbach's $\alpha$-coefficient are similar to those reported in the original publication (17), suggesting that the modifications made did not impair the validity of the questionnaire.

Criteria, methodologies, and outcomes of patient education have been assessed by Brown et al. (24), Clement (25), Funnell and Haas (26), and Albano et al. (27), among others. In general, group education was shown to be a useful adjunct to traditional diabetes consultations (28). Reductions in $HbA_{1c}$ from levels higher than those seen in our patients were reported by Mazzuca et al. (29), in a large (532 patients) randomized controlled 4-year study of group education in patients with type 1 and type 2 diabetes by Raz et al. (30) (although their patients were offered only formal teaching over 1 year), and by Sadur et al. (31), who observed improvement in patient self-care and satisfaction after a 6-month cluster-visit model run by a diabetes nurse with two diabetologists. Anderson et al. (32), similarly to our study, discarded the compliance-based approach in favor of patient empowerment. Over 6 weeks, they found improved indicators of self-care and self-efficacy as well as decreased $HbA_{1c}$ levels in the intervention group. Kronsbein et al. (33) reported decreases in body weight and nonfasting triglyceride levels but no change in $HbA_{1c}$ levels in non–insulin-treated type 2 diabetic subjects who participated in group teaching while under the care of their general practitioners. In these patients, the dose of sulfonylurea was reduced, whereas administration of insulin was necessary in some of the control subjects.

Education is generally applied for limited amounts of time, although in this study, we focused on verifying whether consultations and education could be merged into a continuing process. A study performed in Germany (34) suggests that group education may work if physicians receive financial compensation. The Italian health care system gives minimal sup-

port to education in chronic disease management, in terms of reimbursement (group education, charged partly to the patients, is reimbursed at 1/10 of individual routine visits, which are completely free to patients) and recognition of professional educationists, who have no access to hospital jobs. Consequently, because most clinics do not have educationists, this program was developed with the intention of making it applicable elsewhere by any physician, nurse, and/or dietitian after appropriate training. Group consultations, including preparation of case notes and personal attention to patients with specific needs, took less time and worked better than examining the same number of persons individually. Although additional follow-up is necessary to assess the long-term effects, these results suggest that managing patients with type 2 diabetes by group visits may be a feasible and more efficient alternative to traditional consultations in busy clinics.

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