Diabetes Interactive Diary: A New Telemedicine System Enabling Flexible Diet and Insulin Therapy While Improving Quality of Life

An open-label, international, multicenter, randomized study

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OBJECTIVE — Widespread use of carbohydrate counting is limited by its complex education. In this study we compared a Diabetes Interactive Diary (DID) with standard carbohydrate counting in terms of metabolic and weight control, time required for education, quality of life, and treatment satisfaction.

RESEARCH DESIGN AND METHODS — Adults with type 1 diabetes were randomly assigned to DID (group A, $n = 67$) or standard education (group B, $n = 63$) and followed for 6 months. A subgroup also completed the SF-36 Health Survey (SF-36) and World Health Organization-Diabetes Treatment Satisfaction Questionnaire (WHO-DTSQ) at each visit.

RESULTS — Of 130 patients (aged 35.7 ± 9.4 years; diabetes duration 16.5 ± 10.5 years), 11 dropped out. Time for education was 6 h (range 2–15 h) in group A and 12 h (2.5–25 h) in group B ($P = 0.07$). A1C reduction was similar in both groups (group A from 8.2 ± 0.8 to $7.8 \pm 0.8\%$ and group B from 8.4 ± 0.7 to $7.9 \pm 1.1\%$; $P = 0.68$). Nonsignificant differences in favor of group A were documented for fasting blood glucose and body weight. No severe hypoglycemic episode occurred. WHO-DTSQ scores increased significantly more in group A (from 26.7 ± 4.4 to 30.3 ± 4.5) than in group B (from 27.5 ± 4.8 to 28.6 ± 5.1) ($P = 0.04$). Role Physical, General Health, Vitality, and Role Emotional SF-36 scores improved significantly more in group A than in group B.

CONCLUSIONS — DID is at least as effective as traditional carbohydrate counting education, allowing dietary freedom for a larger proportion of type 1 diabetic patients. DID is safe, requires less time for education, and is associated with lower weight gain. DID significantly improved treatment satisfaction and several quality-of-life dimensions.

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There is universal consensus about the link between tight glycemic control and prevention of diabetes complications. According to American Diabetes Association recommendations (1), good metabolic control can be achieved not only by regular self-monitoring of blood glucose and A1C

measurements but also through a system by which nutritional care and the specific lifestyle recommendations are provided, involving patients in the decision-making process (medical nutrition therapy). Aims of medical nutrition therapy are to provide sufficient and appropriate energy intake, to encourage healthy lifelong eating habits, and to achieve and maintain the best possible glycemic control and ideal body weight (2). Several studies reported that medical nutrition therapy and specific diet-related behaviors result in a decrease of 0.25–1.0% in A1C in patients with diabetes (3–5).

In this context, carbohydrate counting education represents a key point (6). Carbohydrate counting consists of estimating the grams of carbohydrate in foods being eaten and relating that estimate to the insulin bolus dose. The method does not designate a specific percentage of energy as carbohydrate, but carbohydrate intake is based on individual preferences, diabetes medication, and maintenance of energy balance. The only caveat is to not exceed energy requirements to avoid undesired weight gain (6–8).

A flexible carbohydrate intake is immediately translated into a flexible insulin therapy (7), in which bolus insulin is adjusted to match the dietary carbohydrate at each meal, identifying the most appropriate dose needed by the patient. Previous studies indicated that carbohydrate counting and insulin dose adjustment at each meal promote dietary freedom, quality of life, and glycemic control, without worsening severe hypoglycemia or cardiovascular risk (9).

However, it is clear that flexible diet and insulin therapy require complex training for patients, who need to be educated in the type and amount of carbohydrate found in foods, portion estimation, glycemic index, relationships among blood glucose levels and food, diabetes medication, and physical activity,
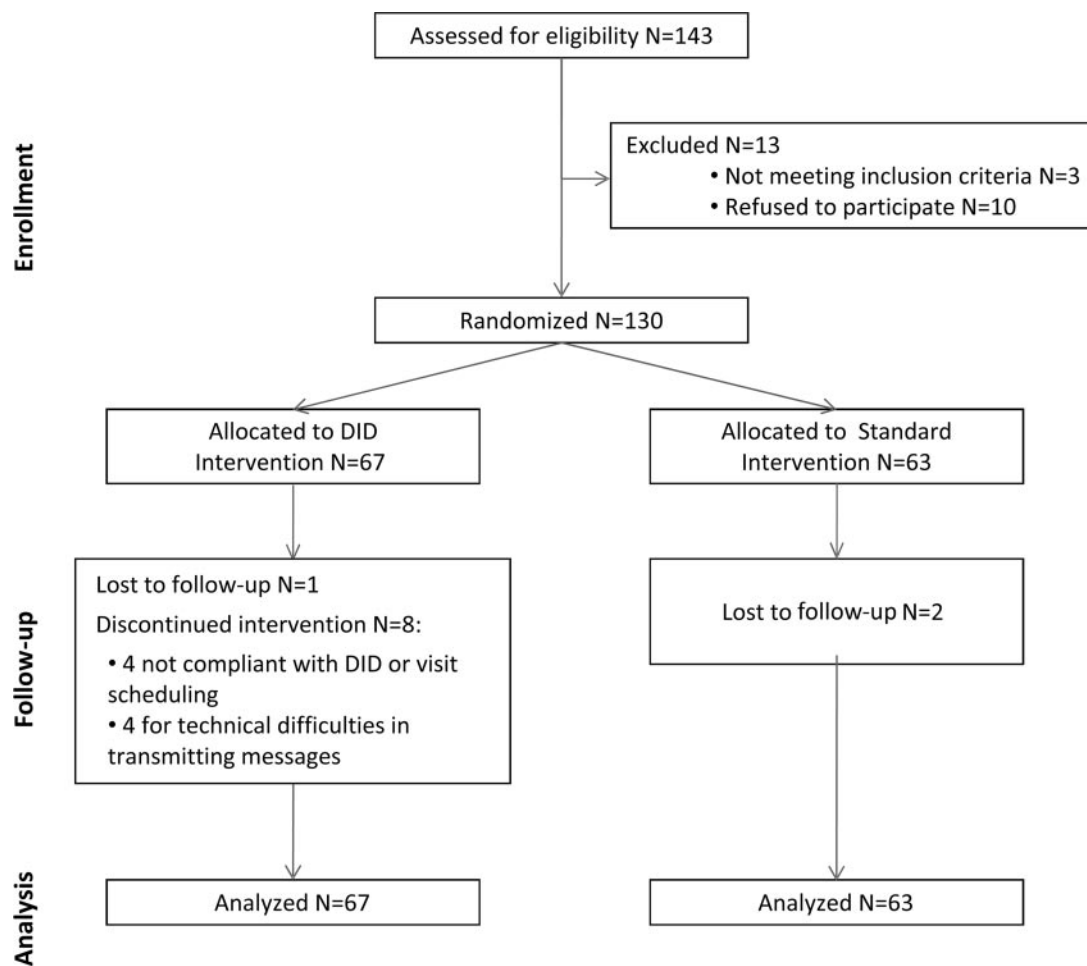
Figure 1—*Study flow chart.*

carbohydrate-to-insulin ratio, and specific algorithms to adjust insulin doses (6,7). The complexity of this educational approach limits widespread use of carbohydrate counting as an effective strategy to promote dietary freedom, quality of life, and glycemic control.

New advanced technologies represent a possible solution to overcome the complex educational requirement. Data available so far show that telemedicine solutions for diabetes care are feasible and acceptable, but their effectiveness in improving A1C, reducing costs while maintaining A1C levels, or improving other aspects of diabetes management is not fully clarified because of methodological flaws in study design (10,11).

Among the new devices, the Diabetes Interactive Diary (DID) represents an automatic carbohydrate/insulin bolus calculator to be installed in the mobile phone of the patient; it also works as a telemedicine system based on patient-physician communication via short text messages. Feasibility, acceptability, and safety of the

DID have been already documented in a phase 1 study (12). We designed a randomized trial aiming to evaluate whether DID could be effective in improving metabolic control in type 1 diabetes, while avoiding weight gain and reducing time devoted to education. In addition, in this study we investigated whether and to what extent DID could affect quality of life.

RESEARCH DESIGN AND METHODS

DID system
The DID is a new tool incorporating different functions; it is a carbohydrate/insulin bolus calculator, an information technology device, and a telemedicine system based on the communication between a health care professional (physician or dietitian) and a patient via text messages. It allows patients to manage a flexible diet and to calculate the matching insulin bolus at each meal. In addition, it includes an algorithm for the calculation

of basal insulin dose, based on the values of fasting blood glucose and the presence of hypoglycemic episodes.

DID consists of software to be installed in the patient's mobile telephone and enables the phone to be used as a small computer to record the blood glucose values and dose of insulin injections in real time; the system is also able to suggest the daily carbohydrate intake, summing the amount of carbohydrate consumed progressively (Fig. 1). Every patient can decide what to eat during the meal, choosing between all the foods listed in the software; the quantification of the total calories and carbohydrate consumed is facilitated by a list of pictures showing the specific food and the amount ingested. The carbohydrate-to-insulin ratio and the glycemic correction factor, identified and prescribed by the health care professional, together with other information already filled out in the DID (e.g., physical activity, glycemic target, insulin dose, and specific events), allow it to automatically calculate and suggest the

most appropriate insulin dose to be injected.

Besides the collection of data on blood glucose measurements, carbohydrate intake, and insulin doses, the use of DID is associated with regular feedback for the patient. In fact, data stored in the mobile phone are periodically sent as short text messages and reviewed on the personal computer of the physician. Then, any new therapeutic and behavioral prescription can be sent from the computer to the mobile phone, improving the communication between patients and physician.

Study design and outcomes
The DID study was an open-label, international, multicenter, randomized (1:1), parallel-group study, having the primary goal of evaluating whether the use of DID could improve glycemic control (A1C) in a shorter time and more easily than the carbohydrate counting standard educational approach. Secondary end points were changes in fasting blood glucose (FBG) levels, body weight, lipid profile (serum total cholesterol, HDL cholesterol, LDL cholesterol, and triglycerides), and blood pressure; furthermore, safety-related problems (frequency of hypoglycemic episodes and hospitalizations) and differences in time dedicated to educational activities were taken into consideration. Finally, quality of life and patient treatment satisfaction were investigated in the subgroup of Italian patients. Data were collected at baseline and at 3 and 6 months after the randomization. The study involved seven Diabetes Outpatient Clinics: three in Italy, two in England, and two in Spain. All of the centers habitually provided carbohydrate-counting education and used electronic databases.

Participants
Every center was asked to enroll 20 patients satisfying all of the following inclusion criteria: diagnosis of type 1 diabetes, age ≥18 years, no previous education on carbohydrate counting, and treatment with multiple daily injections of short-acting and long-acting insulin analogs or with continuous subcutaneous insulin infusion; patients practiced self-monitoring of blood glucose at least three times a day. Other important requirements in the selection of patients were adequate familiarity in the use of mobile phones, according to the physician judgment, and possession of a personal mobile phone card. All of the patients were requested to give

written informed consent to gain entrance to the study. Patients were excluded if they were being treated with NPH insulin or soluble regular insulin, had an eating disorder, were pregnant, were unable to send or receive short text messages, were unable or unwilling to give informed consent, or had any other disease or condition that may interfere with compliance with the protocol or completion of the study.

Randomization
Eligible patients were randomly assigned to start the standard carbohydrate counting educational program or the DID approach. Randomization was performed through a telephone call to the coordinating center. Random lists were stratified by center. To ensure equal allocation rates within centers, permuted block randomization was used.

Interventions
Patients randomly assigned to the experimental group attended a course on the use of DID lasting up to 2 weeks. The course was provided as an outpatient program of three encounters with the physician and/or dietitian.

Patients randomly assigned to the control group received the standard educational approach usually used in the center, lasting up to 3 months. Before the start of the study, an investigators' meeting was organized to establish some fundamental rules in the educational training and in the prescription of carbohydrate-to-insulin ratio and the correction factor.

Data collection
At study entry (visit 0), at 3 months (visit 1), and at 6 months (visit 2) clinical information was collected on case report forms. Baseline information included sociodemographic (age, sex, and highest level of school education reached) and clinical characteristics (diabetes duration, insulin therapy, presence and severity of diabetes complications, comorbidities, and concomitant treatments). Blood pressure, body weight, FBG, A1C, and lipid profile were measured at each visit. Each of the local laboratories used standard methods to measure these parameters. Additional information was collected at the end of the study, including the number of contacts between the patient and the diabetes specialist (both short text messages and office visits) and any serious hypoglycemic episode requiring medical intervention.

Changes in health-related quality of life substudy
Changes in the health-related quality of life were evaluated in the subgroup of Italian patients, using generic (SF-36 Health Survey [SF-36]) and diabetes-specific (World Health Organization-Diabetes Treatment Satisfaction Questionnaire [WHO-DTSQ]) measures:

- The SF-36 is one of the most widely used measures of health-related quality of life and consists of 36 items covering eight dimensions: physical functioning, role limitations caused by physical health problems, bodily pain, general health perception, vitality, social functioning, role limitations caused by emotional health problems, and mental health (13). These eight domains may be further aggregated into two summary measures: the physical component summary measure and the mental component summary measure (13). These aggregated scores are transformed to norm-based scores (50 ± 10 mean $\pm$ SD), with higher scores indicating more favorable physical functioning/psychological well-being. The SF-36 has been used in large population studies and in many different clinical conditions, showing excellent psychometric properties (14). It has been translated and validated in several languages, including Italian (15).
- The WHO-DTSQ has been specifically designed to measure satisfaction with diabetes treatment regimens and is appropriate for patients with type 1 and type 2 diabetes (16). The instrument was originally developed to detect changes in satisfaction related to changes in treatment modalities, but it is also appropriate for comparing levels of satisfaction in subjects using different treatment regimens. It is composed of eight items, six of which are summed in a single score ranging from 0 (very dissatisfied) to 36 (very satisfied). The remaining two items are treated individually and explore the perceived frequency of hyperglycemic and hypoglycemic episodes. The WHO-DTSQ has been validated in the Italian language among type 1 and type 2 diabetic patients, showing adequate psychometric properties (17).

Statistical analysis
Sample size was estimated by assuming a between-group mean difference of 0.5% in A1C levels after 3 months and an A1C

SD of 1.0 (as derived from the DID pilot study). Given these assumptions, 63 patients per group were needed to ensure a statistical power of 80% ($\alpha = 0.05$). Taking into account a dropout rate of ~10%, 70 patients per group had to be enrolled. Analysis was based on all the patients randomized, according to the intention-to-treat principle. For patients lost to follow-up the last information available was used, by means of the last observation carried forward approach. Comparison of A1C and other secondary end points between groups was performed after 3 and 6 months from randomization based on the Mann-Whitney U test. Within-group differences achieved after 3 and 6 months from randomization were evaluated using the Wilcoxon signed-rank test. Because it was hypothesized that the telemedicine approach could help in achieving the desired goals in a shorter period of time, between-groups mean differences at 3 and 6 months were compared separately, instead of using repeated-measures ANOVA.

RESULTS — Overall, 130 individuals were recruited (Fig. 1). Fewer patients than those scheduled (130 vs. 140) were involved, as a result of organizational problems in two centers. However, because results show a SD of A1C of 0.76% and the dropout rate was 8.5%, the a posteriori study power to detect a difference between groups of 0.5% in A1C levels was 95%. The study also had a statistical power of 80% to detect a between-groups difference in A1C levels of 0.38%.

Patients' characteristics according to the randomization arm are shown in Table 1. The two groups did not differ for any sociodemographic and clinical characteristic, with the exception of slightly higher levels of triglycerides in the DID group. Patients in the DID arm also had a higher prevalence of retinopathy and symptomatic neuropathy, although statistical significance was not reached.

Overall, 11 patients dropped out during the study, 2 in the standard group and 9 in the DID group (Fig. 1). In the control group, both patients were lost to follow-up. In the DID group, 2 patients found it difficult to use the DID system, 4 had difficulties in sending text messages because of poor mobile network coverage in their area, 2 were not compliant with visit scheduling, and 1 moved to another area. Between- and within-group changes after 3 and 6 months are shown in Table 2.

Table 1—Patients' characteristics according to the randomization arm

	DID	Standard	P*
n	67	63	
Male sex (%)	44.8	41.0	0.67
Age (years)	35.4 ± 9.5	36.1 ± 9.4	0.63
Highest level of school education completed (%)			0.23
Low level (less than college degree)	18.8	17.7	
Intermediate level (less than university degree)	68.7	58.1	
High level (university degree)	12.5	24.2	
Duration	17.1 ± 10.3	15.8 ± 10.7	0.37
Short-acting and/or long-acting analogs (%)	80.6	80.9	0.96
Continuous subcutaneous insulin infusion (%)	19.4	19.1	0.96
Self-monitoring (years)	14.7 ± 7.3	13.2 ± 8.4	0.10
No. of daily blood glucose tests	2.3 ± 1.1	2.4 ± 1.1	0.77
A1C (%)	8.2 ± 0.8	8.4 ± 0.7	0.19
Fasting glucose (mg(dl)	183 ± 86	177 ± 68	0.62
Systolic blood pressure (mmHg)	122 ± 17	120 ± 11	0.50
Diastolic blood pressure (mmHg)	74 ± 7	74 ± 8	0.72
Weight (kg)	69.9 ± 12	69.4 ± 11.9	0.98
Total cholesterol (mg/dl)	180 ± 30	184 ± 34	0.40
Triglycerides (mg/dl)	95 ± 55	80 ± 54	0.03
HDL cholesterol (mg/dl)	58 ± 15	61 ± 16	0.15
LDL cholesterol (mg/dl)	102 ± 28	106 ± 27	0.37
Retinopathy (%)	28.8	20.6	0.28
Lower-limb complications (%)	0	1.6	0.34
Nephropathy (%)	4.6	3.2	0.67
Symptomatic neuropathy (%)	9.1	3.2	0.17

Data are means ± SD or frequency. *P values refer to the χ^2 test for categorical variables or the Mann-Whitney U test for continuous variables.

A significant reduction in A1C levels of ~0.5% was documented in both groups after 3 months and maintained until the end of study. This improvement in metabolic control was obtained by devoting to carbohydrate counting education a median (range) of 6 (2–15) h in the DID group and 12 (2.5–25) h in the standard group ($P = 0.07$). Furthermore, after 6 months there was a nonsignificant decrease in FBG in the DID group (from 182.8 ± 85.6 to 162.9 ± 67.0 mg/dl) and a nonsignificant increase in the standard group (from 176.9 ± 68.4 to 186.3 ± 79.1 mg/dl) (between-groups $P = 0.13$). The increase in body weight was lower in the DID group (0.7 ± 3.6 kg) than in the standard group (1.5 ± 2.3 kg), but the difference was not statistically significant ($P = 0.22$). Furthermore, although we found no differences in mean daily doses of short-acting insulin between the two groups (DID group 20.6 ± 8.2 IU/day and standard group 20.1 ± 7.8 IU/day; $P = 0.92$), mean daily doses of long-acting insulin were lower in the DID group than in the standard group, although statistical significance was not reached (DID group 17.4 ± 7.4 IU/day and standard group 21.4 ± 10.0 IU/day; $P = 0.12$). The DID group showed a significant decrease in triglyceride levels in comparison with the standard group; no other between-groups changes were documented.

Within-group changes were also considered. The DID group generally showed a tendency toward a small, not significant improvement in all the measures considered, whereas in the standard group all parameters, except diastolic blood pressure and HDL cholesterol, tended to slightly increase at the end of the study.

No patients in either group were admitted to the hospital during the study, and none reported any severe hypoglycemic episode requiring assistance. In each group, two patients reported episodes of mild hypoglycemia ($P = 0.93$).

The median (range) number of text messages sent by each patient during the study was 52 (6–75), whereas the number of text messages sent by the physician was 39 (22–70). In other words, patients sent about 2 text messages/week to their physician, and the physician regularly re-

Table 2—Between- and within-group differences in clinical parameters and quality-of-life scores at visit 1 and visit 2 with respect to baseline values

	DID group			Standard group			P					
							Between groups*		Within DID†		Within standard†	
	Baseline	3 months	6 months	Baseline	3 months	6 months	3 months vs. 0	6 months vs. 0	3 months vs. 0	6 months vs. 0	3 months vs. 0	6 months vs. 0
n	67			63								
A1C (%)	8.2 ± 0.8	−0.5 ± 0.8	−0.4 ± 0.9	8.4 ± 0.7	−0.4 ± 0.6	−0.5 ± 1	0.95	0.68	<0.0001	<0.0001	<0.0001	0.0002
FBG (mg/dl)	182.8 ± 85.6	−1.7 ± 105	−22 ± 99.8	176.9 ± 68.4	3.8 ± 94.7	15.5 ± 90.8	0.83	0.13	0.92	0.13	0.81	0.39
Systolic blood pressure (mmHg)	121.5 ± 12.8	−1.8 ± 13.7	−0.8 ± 8.6	119.2 ± 11.5	0.4 ± 11	0.7 ± 11.5	0.19	0.71	0.63	0.60	0.70	0.51
Diastolic blood pressure (mmHg)	74.4 ± 7.5	−2.4 ± 7.9	−1.3 ± 6.5	74.1 ± 7.6	−2.3 ± 6.8	−1.1 ± 7.6	0.83	0.89	0.0004	0.16	0.01	0.27
Total cholesterol (mg/dl)	179.5 ± 29.9	−3.8 ± 29.1	−3.6 ± 32.3	184.3 ± 34	3.1 ± 26.6	2.7 ± 28.9	0.15	0.33	0.96	0.47	0.31	0.42
HDL cholesterol (mg/dl)	57.6 ± 15.3	0.9 ± 9.4	1.6 ± 8.5	61.1 ± 16.4	−1.7 ± 9.8	4.8 ± 10.3	0.49	0.14	0.57	0.11	0.15	0.0005
LDL cholesterol (mg/dl)	101.9 ± 28	−0.8 ± 26.4	−3.4 ± 29.1	105.8 ± 27.4	5.7 ± 23.3	0.3 ± 27.6	0.26	0.79	0.18	1.0	0.05	0.17
Triglycerides (mg/dl)	94.5 ± 54.9	−10.7 ± 48.8	−10.7 ± 56.1	79.9 ± 54	1.9 ± 43.7	8.2 ± 43.4	0.06	0.04	0.30	0.17	0.69	0.15
Weight (kg)	69.9 ± 11.8	−0.1 ± 3.8	0.7 ± 3.6	69.4 ± 11.9	0.7 ± 1.9	1.5 ± 2.3	0.15	0.22	0.30	0.16	0.006	<0.0001
DTSQ‡ Score	26.7 ± 4.4	1.8 ± 3.6	3.4 ± 4.2	27.5 ± 4.8	0.6 ± 3.9	1 ± 4	0.2	0.04	0.009	0.0002	0.43	0.17
Hyperglycemia	3.6 ± 1.6	−1 ± 1.4	−0.4 ± 1.7	3.1 ± 1.3	−0.3 ± 1.7	0.2 ± 1.8	0.05	0.19	0.0006	0.21	0.23	0.50
Hypoglycemia	2.3 ± 1.1	0.4 ± 1.3	0.5 ± 1.7	2.5 ± 1.5	−0.2 ± 1.6	−0.1 ± 1.7	0.08	0.16	0.19	0.12	0.51	0.76
SF-36‡												
Physical functioning	90 ± 13.3	−3.3 ± 16.8	4.3 ± 12.3	94.1 ± 8.3	−0.7 ± 11.8	0.2 ± 7.3	0.95	0.22	0.28	0.10	0.76	0.89
Role physical	72.5 ± 36.2	8.7 ± 38.0	7.1 ± 43.0	85.8 ± 27.6	−12.1 ± 38.2	0 ± 28.3	0.05	0.27	0.26	0.49	0.09	0.96
Bodily pain	78.4 ± 21.5	3.9 ± 18.3	−2.2 ± 23.9	71.2 ± 19.2	−2.5 ± 21.4	10 ± 25.5	0.35	0.09	0.29	0.51	0.67	0.04
General health	56 ± 23.3	4.8 ± 8.9	6.5 ± 16.8	61.4 ± 16.4	−2.8 ± 13.1	−4.6 ± 14.7	0.02	0.02	0.009	0.06	0.30	0.08
Vitality	57.8 ± 15.8	4.3 ± 16.0	8.2 ± 17.9	66.7 ± 15.7	−5.1 ± 13.9	0.3 ± 14.1	0.02	0.1	0.04	0.04	0.07	0.91
Social functioning	73.3 ± 17.3	0.9 ± 16.0	4.5 ± 23.1	76.3 ± 20.3	4.3 ± 19.8	3.3 ± 22.2	0.53	0.8	0.82	0.35	0.22	0.42
Role emotional	60 ± 36.5	14.9 ± 40.4	17.9 ± 52.5	83.9 ± 27.8	−4 ± 22.6	−4 ± 35.5	0.02	0.05	0.07	0.14	0.33	0.51
Mental health	68.7 ± 16.3	−0.3 ± 10.9	4 ± 19.2	70.8 ± 14.9	−1.4 ± 12.1	−0.8 ± 12.8	0.67	0.23	0.82	0.33	0.59	0.73
Physical component score	50.3 ± 8.9	1.3 ± 6.6	0.6 ± 7.3	50.6 ± 4.9	−1.7 ± 7.0	1 ± 4.9	0.09	0.77	0.39	0.72	0.27	0.27
Mental component score	43.5 ± 10.6	2.2 ± 8.1	4.2 ± 12.5	48.1 ± 8.1	−0.3 ± 6.8	−0.8 ± 10.2	0.18	0.14	0.16	0.11	0.84	0.70

Data are means ± SD. 3 months and 6 months columns show the mean variation at visit 1 and visit 2 with respect to baseline (0) values. *P values refer to the Mann-Whitney U test. †P values refer to the Wilcoxon signed-rank test. ‡Questionnaires were administered to a subgroup of 60 patients (30 in the DID group and 30 in the standard group).

plied to confirm the therapeutic scheme or to modify the parameters set in the DID (carbohydrate-to-insulin ratio, insulin sensitivity factor, and/or blood glucose target). In terms of costs for the patient, assuming a cost of 10–15 € cents per message, and considering that on average each patient sent 52 messages, the overall cost sustained did not exceed €8.

Results of quality of life evaluation performed on the subsample of 60 patients enrolled in the Italian centers are shown in Table 2. Clinical and sociodemographic characteristics at baseline did not differ between the two groups. A statistically significant difference in favor of the DID group was documented for treatment satisfaction, as expressed by the WHO-DTSQ score. Similarly, the score testing the perceived frequency of hyperglycemic episodes significantly decreased after 3 months in the DID group but not in the control group. Several SF-36 subscales (Role Physical, General Health, Vitality, and Role Emotional) also showed significantly higher improvements in the DID group than in the standard group.

In addition, pre– to post–within-group comparisons underlined the beneficial effects of DID in the experimental group in terms of WHO-DSTQ-score, perceived frequency of hyperglycemic episodes, general health perception, and vitality; on the other hand, all scores within the standard group tended to worsen at 3 months, although statistical significance was not reached.

CONCLUSIONS — The complexity of the educational approach needed to teach carbohydrate counting and consequent insulin adjustment can represent an obstacle for many patients, thus limiting the possibility of its widespread use as an effective self-management tool. The carbohydrate/insulin bolus calculator is coupled with a telemedicine system based on short text messages. At the present time, the most common way of data communication between patient and diabetologist is represented by the paper diary, which is often perceived as a boring document not adequately filled in; furthermore, even if it is sufficiently complete, it cannot facilitate a day-by-day adjustment of the insulin dose and lifestyle (18). In contrast, DID is installed on the mobile phone, which is a familiar device already used in daily life by the majority of individuals. DID facilitates not only the automatic storage of blood glucose measurements, carbohydrate intake, and

insulin doses but also the exchange of information between patient and care provider via text messages. In this respect, although previous, small studies have evaluated the efficacy of telemedicine systems based mainly on the transmission of self-monitoring of blood glucose values and feedback from the health care provider (10), this is, to our knowledge, the first study investigating a multipurpose instrument, replacing the classic approach to insulin dose modification.

Our data show that DID can represent a useful device, incorporating several features helping patients promote dietary freedom and flexible insulin bolus. The first pilot study previously showed that the system is safe, easy to use, and well accepted by the vast majority of patients. What these new results add is that the use of DID is at least as effective as the traditional educational approach to carbohydrate counting in reducing A1C levels, while producing different concomitant benefits. First, it allowed patients to avoid the complexities of carbohydrate counting and insulin dose adjustment with a halving in the time dedicated to education and thus potentially increasing the proportion of individuals with type 1 diabetes adopting this method. Of note, despite the higher rate of dropouts in the DID group, only two patients interrupted the study because of difficulties in using the telecare system, thus confirming that the device can be easily used by the majority of patients.

Second, the use of DID was associated with lower weight gain, probably because of the requirement of lower doses of long-acting insulin. It is worth mentioning that, despite the use of lower doses of long-acting insulin, patients assigned to the DID group showed a reduction in FPG levels during the study, whereas levels slightly increased in the control group. This finding is important in light of the need to adopt therapeutic strategies that achieve good metabolic control while minimizing insulin dosage.

Third, the use of DID was also associated with a significant improvement in several mental and physical components of the SF-36 Health Survey, compared with the standard group. This also translated into a marked improvement in treatment satisfaction, thus suggesting that the use of telemedicine can increase the level of acceptance of insulin treatment and help patients cope with the disease.

Some limitations of this study need to be discussed. First, we were not able to

measure the effect of DID in reducing glucose variability. In fact, by allowing greater flexibility, one can speculate that telemedicine produced positive effects on postprandial blood glucose excursions also. Second, even if specific guidelines were established in the prestudy investigators' meeting, the DID educational intervention was influenced by the individual practice of the different international participating centers, thus varying in duration. Nevertheless, the randomization was stratified by center, making the comparison between telemedicine and usual care unbiased.

In summary, DID was at least as effective as traditional carbohydrate counting education, allowing dietary freedom to a larger proportion of type 1 diabetic patients. DID required less time for education and did not increase the risk of hypoglycemic episodes. DID also significantly improved treatment satisfaction and several quality-of-life dimensions. Larger studies are needed to reach more solid conclusions regarding the effects of DID on FBG, body weight, and insulin dosage.

APPENDIX — Participating centers (in alphabetical order by town): Bournemouth Dorset, U.K.: David Kerr and Anita Bowes; Brescia, Italy: Angela Girelli, Emanuela Zarra, and Antonino Cimino; Coventry, U.K.: Antonio Ceriello, Anwar Aresh, Lynda Dobson, and Lisa Walker; Padua, Italy: Daniela Bruttomesso, Michela Dal Pos, and Silvana Costa; Ravenna, Italy: Paolo Di Bartolo, Cipriana Sardu, and Sara Brandolini; Sevilla, Spain: Angel Sendon Perez and Carmen De la Cuesta Mayor; and Valencia, Spain: Francisco Javier Ampudia and Lara Sorribes Querol. Coordinating center: Riccarda Memmo.

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