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An Interactive Diary for Diet Management (DAI): A New Telemedicine System Able to Promote Body Weight Reduction, Nutritional Education, and Consumption of Fresh Local Produce

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Abstract

Background: The aim of this multicenter, longitudinal, single-arm, pre-post comparison was to test a telemedicine system able to promote body weight reduction, nutritional education, and consumption of fresh local produce.
Methods: DAI® (MeTeDa srl, San Benedetto del Tronto, Italy) is a software for mobile phones to support patients following a specific dietetic program. It facilitates the communication between the patient and dietician via short text messages. Overall, three specialized dieticians enrolled 140 consecutive patients with body mass index (BMI) $\geq$25 kg/m^2 who voluntered to follow a specific diet program to be managed with DAI. At baseline and after 20 weeks, data on body weight, waist circumference, BMI, fasting blood glucose, lipid profile, food habits, and physical activity were collected and compared by the Wilcoxon test or the McNemar test.
Results: Overall, 115 individuals (82.1%) completed the follow-up. The mean (95% confidence interval) reduction in body weight was −2.5 (−3.2; −1.8) kg, whereas the reduction in waist circumference was −3.7 (−4.6; −2.9) cm, and that in BMI was 1.0 (−0.7; −1.2) kg/m^2. The software was useful as an educational tool: participants achieving the Mediterranean diet targets increased from 14.4% to 69.8% after 20 weeks. On average, each patient recognized and chose fresh local vegetables eight times per week during the follow-up. Participants regularly communicated with dieticians through short text messages.
Conclusions: This study allowed the documentation of the efficacy of a new telemedicine system in supporting people who need to lose body weight. The tool was also suitable for a more articulated initiative of "nutritional education" aiming to promote the healthy properties of the Mediterranean diet and the consumption of local produce.

Introduction

Obesity represents the most common metabolic disorder in industrialized countries, while excess weight is a global burden.[1] Even if the proportions of overweight and obese people are lower in Italy than in many other European and American countries, they are reaching alarming proportions. In fact, one out of three (31.3%) adults are overweight, while 9.1% is obese.[2] Translating the percentages into numbers, this implies that the Italian healthcare system has to manage 15 million overweight people and over 4 million residents needing weight loss to prevent health complications. In fact, many studies documented a strong association between obesity and risk of developing different diseases, such as hypertension, dyslipidemia, nocturnal apnea, osteoporosis, and cancer (particularly breast and colon cancer).[3–7] Nevertheless, the greatest threat in terms of public health and costs[8] regards the increased incidence of diabetes[9] and cardiovascular disease in overweight and obese people.[10–15]

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Similarly, it has been widely documented that the adherence to a Mediterranean diet is an important resource and care strategy.[16] In fact, this dietary regimen can reduce coagulative and pro-inflammatory processes[17] and mortality due to cancer and heart disease by 25%.[18] Reasons for these documented protective effects are the low content in saturated and trans lipids and the presence of omega-3 fatty acids, polyphenols (especially flavonoids), antioxidant vitamins, and fiber; these substances play a key role in the inhibition of atherogenesis and in the protection of endothelial cells of blood vessels.[19]

In this context, it is also widely recognized that the nutritional properties and beneficial effects of foods increase when seasonal fresh local products are consumed. After a long market dominance of industrial distributions, many initiatives of "short loop" distribution based on the direct contact between consumer and producer of fresh and organic products have been disseminated throughout Italy in recent years. This approach implies different advantages, e.g., lack of intermediate commercial professionals to reduce costs, improved quality of food in terms of taste and nutritional properties, knowledge of the food origin, and ecologic benefits due to reduced transportation and packaging. The short loop is estimated to be accessed by 20–40% of Italian families today, according to the different national macro-areas.

Given these premises, it would be interesting to find a system able to integrate the healthy culture of the Mediterranean diet and the "short loop" with the need to fight the epidemics of excess weight and obesity.

Correct nutritional education and reduction in calories intake represent the cornerstone of any intervention for weight loss[20]; nevertheless, a structured dietary program can be hard to follow by the vast majority of overweight and obese patients because of difficulties in getting prescribed foods, need to weigh food, progressively decreased motivation, or boring diets. The use of innovative communication and information technologies for the delivery of clinical care (telemedicine systems) can be helpful to overcome these barriers and to support people in managing a dietary intervention.

The aim of this study was to evaluate feasibility and acceptability of a new telemedicine system for store-and-forward, remote monitoring, and interactive services called DAI® and produced by MeTeDa srl, San Benedetto del Tronto, Italy. DAI is a software to be installed on a mobile phone, supporting patients undertaking a dietary program prescribed by professional dieticians. The software lists foods prescribed during the day, allowing the patient to easily estimate the portions by a food pictures atlas and to exchange prescribed foods with others that have equivalent nutritional content. Furthermore, DAI allows patients to communicate with their dieticians via Short Message Service (SMS).

This study has been specifically designed to evaluate whether and to what extent DAI could have an impact on weight loss and nutritional education, while enhancing the consumption of fresh local produce.

Research Design and Methods

Inclusion and exclusion criteria

The study involved three Italian registered dieticians operating in diabetes outpatient clinics located in the area of Ascoli Piceno (Marche Region, Italy). They were asked to enroll adults ($\geq$18 years old) with a body mass index (BMI) of $\geq 25\,kg/m^2$. Other important requirements in the selection of patients were an adequate familiarity with the use of mobile phones, according to the physician's judgment, and the possession of a personal SIM card. All the participants were requested to give written informed consent to gain entrance to the study.

Exclusion criteria were pregnancy, diabetes mellitus, eating disorders, severe concomitant diseases, and illiteracy or inability to comply with the study requirements.

Local ethics committees approved the protocol.

Recruitment

The initiative was publicized in local meetings and on billboards, to inform the general population about the chance to use the DAI system to lose weight and receive a specific training on the healthy properties of the Mediterranean diet and the advantages deriving from the consumption of fresh local produce.

Overall, three specialized dieticians enrolled 140 consecutive individuals meeting the inclusion criteria, from those voluntarily referring to the centers and accepting joining the initiative.

Study design

This is a multicenter, longitudinal, controlled before and after study designed to test feasibility, acceptability, and safety of the system on a group (single arm) of individuals who have the characteristics of the future users of the system. These preliminary results are fundamental in the identification of key information needed to plan a larger randomized trial evaluating the efficacy of the system as compared to the standard programs for weight loss.

The protocol included two face-to-face encounters between participants and dieticians during a 20-week period. At baseline (visit 0), sociodemographic and clinical data on age, gender, highest level of completed school education, physical activity, body weight, waist circumference, comorbidities, and pharmacologic therapies were collected; furthermore, diet habits were investigated (diet anamnesis), and a blood sample test was performed to determine fasting blood glucose and lipid profile (total cholesterol, triglycerides, low-density lipoprotein-cholesterol, and high-density lipoprotein-cholesterol). The DAI system was delivered to participants after an educational session provided by the dietician and lasting up to 2 h.

Participants used the system to become familiar with it for the following 2 weeks after visit 0. Therefore, they received the prescription of the customized dietary program via short text messages, without further encounters with the dietician.

After 20 weeks from visit 0, the same data collection performed at baseline was repeated to measure the variations in the clinical parameters during follow-up. In addition, a questionnaire including 13 items was administered to all participants to investigate satisfaction with the DAI system.

Experimental intervention

All enrolled patients were involved in a weight loss and nutritional education program, including the following components:

1. *Customized diet intervention*. Each patient received a personalized nutritional plan aiming to achieve a specific weight target and to increase knowledge of a correct nutritional regime. The plan was elaborated by the dieticians for each participant according to his or her individual characteristics. The dietary intervention balanced carbohydrates, proteins, and lipids and promoted the choice of fresh vegetables, previously identified and codified according to their seasonality. In addition to the prescription diet, dietitians suggested to participants strategies to increase the time devoted to physical activity following the standard approach used in their routine clinical practice.
2. *DAI system.* DAI is an information technology and a telemedicine system based on direct communication between patient and dietician via SMS. It consists of a software to be installed on the patient's mobile phone, without modifying the normal use of the SIM card. DAI allowed a continuous consultation of the diet program on the mobile phone and supported patients in the daily management of food intake. At each meal the prescribed foods were shown as pictures with the suggested portions. These pictures are contained in a very large food atlas. The software allowed storage of the amount and type of all foods eaten during the day in a memory card. Foods were automatically recorded by choosing their picture, and then the software calculated the nutritional value. When prescribed foods were displayed at each meal, patients could choose to accept or refuse them. In the case of refusal, the software suggested alternative foods (and specific portions) of equivalent nutritional value (dynamic diet). For each modification in type or portion of food eaten with respect to those prescribed, DAI automatically adjusted the subsequent food prescriptions to ensure the adherence to the established nutritional targets (calories, carbohydrates, proteins, and lipids) at the end of the day. Furthermore, DAI allowed the storage of data on the physical activity performed (type and duration) and provided feedback about the calories burned. This function could motivate people to increase the amount of exercise during their daily life. The data recorded were sent via SMS to the dietician every 1–3 weeks. Dieticians reviewed the data on their PC and replied from their PC to the patient's mobile phone via SMS, confirming or modifying the dietary program or giving useful suggestions.
3. *Proactive call center*. Participants received weekly proactive telephone calls provided by a trained operator aiming to reinforce some fundamental concepts about correct nutrition and physical activity. The operators of the proactive call centers were instructed on the use of standardized materials to explain some main concepts about the benefits of physical activity on clinical outcomes.

Data collection

Dieticians were supported in data management by an electronic clinical record system (Metadieta®, produced by MeTeDa srl) able to:

- Manage personal and clinical data of patients
- Register nutritional anamnesis
- Develop the customized dietary program to be sent via SMS to DAI
- Monitor and graphically represent the results

All patients' data were downloaded by electronic clinical records and DAI, without need for further case report forms. Each of the local laboratories used standard methods to measure fasting blood glucose and lipid profile.

End points

The primary end point was the change in body weight from baseline to end of study.

Secondary end points were the changes after 20 weeks in clinical parameters and nutritional anamnesis, in particular, the variations in BMI, waist circumference, lipid profile, and fasting blood glucose were evaluated. In addition, the change in the percentage of patients reaching the correct mean daily distribution of the main macronutrients (60% carbohydrates, 25% fats, and 15% proteins)—representing the "Mediterranean diet target"—was calculated.

Moreover, pre-post changes in the mean daily content in carbohydrates, fats, and proteins of meals and variation of the mean daily fiber intake (overall and from fresh local vegetables) were investigated.

Finally, satisfaction of participants with DAI was evaluated through a post-study questionnaire specifically developed for the purpose.

Statistical analysis

Sample size estimation. Assuming a SD of baseline body weight of 12.0 kg, it was estimated that a sample of 128 individuals would be needed to detect a change of 3.0 kg in body weight from baseline to end of study with a power of 80% ($\alpha = 0.05$). Assuming a dropout rate of about 10%, the required sample was 140 individuals.

Data analysis. Baseline clinical data were expressed as mean and SD or frequencies. Additional information on the use of the system was expressed as median and range or frequencies. Pre-post changes in the mean levels of clinical and nutritional parameters were expressed as means and 95% confidence intervals. Baseline and end-of-study levels were compared using the Wilcoxon test.

The McNemar test was used to compare variation in the categorical variables, e.g., changes in the physical activity level and change in the percentage of patients reaching the Mediterranean diet target.

Results

Overall, 140 participants were recruited, of whom 24 (17.3%) dropped out. Table 1 shows the differences in the characteristics of patients who dropped out and those who completed the study. Compared with the completers, patients who dropped out were more often female and had a significantly higher daily calorie intake compared with patients who completed the follow-up; in addition, they showed a more marked consumption of fats and proteins and a lower fiber intake.

One patient who completed the follow-up was excluded a posteriori from the analysis because he did not meet the

Table 1. Comparison Between Baseline Participants' Characteristics According to Whether They Completed the Study

Characteristic	*Completers* (n = *116*)	*Withdrawals* (n = *24*)	P*
Gender (%)			
Female	58.3	74.8	0.10
Male	41.7	25.2	
Highest level of school education completed			
Low level (less than college degree)	16.5	8.3	
Intermediate level (less than university degree)	53	62.5	0.54
High level (university degree)	30.4	29.2	
Level of physical activity (%)			
Light	90.4	95.8	
Moderate	9.6	4.2	0.39
Intense	0	0	
Age (years)	42.9 ± 12.2	45.1 ± 12.4	0.4
Body weight (kg)	83.3 ± 14.8	87.8 ± 15.6	0.22
BMI (kg/m^2)	31.1 ± 4.4	31.8 ± 5	0.5
Waist circumference (cm)	99 ± 11.8	101 ± 11	0.37
Diet anamnesis			
Calories (Kcal)	1,783 ± 480	2,049 ± 653	0.02
Total carbohydrates (g)	231 ± 78	247 ± 84	0.26
Simple carbohydrates (g)	71 ± 25	72 ± 25	0.86
Lipids (g)	68 ± 25	85 ± 36	0.004
Cholesterol (mg)	177 ± 82	233 ± 94	0.001
Proteins (g)	79 ± 58	85 ± 26	0.01
Alcohol (g)	3 ± 8	6 ± 13	0.44
Sodium (mg)	1,383 ± 692	1,497 ± 736	0.41
Total fiber (g)	24 ± 8	23 ± 8	0.91
Fiber in 1,000 calories (%)	14 ± 5	11 ± 5	0.03
Laboratory tests			
Glycemia (mg/dL)	93 ± 12	90 ± 8	0.37
Cholesterol (mg/dL)	198 ± 37	190 ± 43	0.32
Triglycerides (mg/dL)	110 ± 68	93 ± 47	0.34
HDL-cholesterol (mg/dL)	52 ± 15	49 ± 14	0.32
LDL-cholesterol (mg/dL)	126 ± 33	117 ± 33	0.32

Results are expressed as frequencies (%) or mean ± SD values. BMI, body mass index; HDL, high-density lipoprotein; LDL, low-density lipoprotein.
*χ^2 test for categorical variables and Mann-Whitney test for continuous variables.

eligibility criteria because of a baseline BMI of <25 kg/m^2. For the pre-post comparisons 115 (82.1%) patients were evaluated.

Effects of experimental intervention are summarized in Table 2. In spite of the analyzed sample being smaller than the one estimated in the protocol, it was sufficient to document a significant reduction in body weight of 2.5 kg, in waist circumference of 3.7 cm, and in BMI of 1 kg/m^2. Among the participants who reduced their body weight (68%), 24% lost 1–2 kg, 18% lost 3–4 kg, and 26% lost 5–19 kg; on the other hand, 12% of participants did not modify their body weight, whereas 14% increased in body weight by 1–2 kg and 5% by 3–5 kg.

Among the study completers, 48 (41.2%) individuals received chronic therapies at baseline, of whom 17 received antihypertensive drugs, seven thyroid hormone replacement therapy, six antidepressive agents, five statins, five antiplatelet therapy, four nonsteroidal anti-inflammatory drugs, four oral contraceptive pill/hormone replacement therapy, and two antihistamine drugs. One patient was treated with orlistat. No changes were found in the prescriptions used for chronic therapies from baseline to the end of study. Therefore, the observed results were independent of concomitant treatments. The patient receiving orlistat reduced his body weight of 2 kg, thus in line with the mean reduction of the whole sample.

The diet program promoted by DAI was effective in terms of nutritional education, as demonstrated by its impact on the diet anamnesis: total calorie intake was reduced by about 300 Kcal, with a simultaneous reduction in the daily consumption of carbohydrates, fats, and proteins and an increase in fiber intake. On average, each participant chose fresh local products as sources of fiber 137 (79; 200) times during the study, i.e., eight times per week. Goals of the Mediterranean diet were reached at the end of the study by a larger proportion of patients (from 14.4% at baseline to 69.8% at end of study). Participants not reaching the targets showed a lower daily consumption of carbohydrates, a higher consumption of fats, and a similar consumption of proteins compared with those achieving the targets. We found that the two groups did not differ in terms of reduction in daily calories intake [−289.8 (−176.6; −403) Kcal in individuals at target vs. 284.7 (−177.6; −391.8) Kcal in individuals not at target; $P = 0.73$] but only in the distribution of macronutrients.

Furthermore, the efficacy of DAI was more marked in individuals achieving the Mediterranean diet goals than in

Table 2. Comparison Between Baseline and End-of Study Participants' Characteristics ($N = 115$) and Efficacy of the Intervention

Characteristic	*Baseline*	*Changes at follow-up*	P*
Body weight (kg)	83.3 ± 14.8	−2.5 (−3.2; −1.8)	< 0.0001
BMI (kg/m^2)	31.1 ± 4.4	−1 (−1.2; −0.7)	< 0.0001
Waist circumference (cm)	99 ± 11.8	−3.7 (−4.6; −2.9)	< 0.0001
Physical activity			
Light	97.6%	70.0%	< 0.0001
Moderate/intense	2.4%	30.0%	
Diet anamnesis			
Mediterranean diet goals	14.4%	69.8%	< 0.0001
Calories (Kcal)	1,783 ± 480	−287.4 (−365.2; −209.5)	< 0.0001
Total carbohydrates (g)	231 ± 78	−37.1 (−50.8; −23.4)	< 0.0001
Simple carbohydrates (g)	71 ± 25	−3.7 (−8.4; 1.1)	0.12
Lipids (g)	68 ± 25	−14.9 (−19.2; −10.6)	< 0.0001
Cholesterol (mg)	177 ± 82	−12.7 (−28.1; 2.7)	0.02
Proteins (g)	79 ± 58	−10.5 (−21; 0)	0.02
Alcohol (g)	3 ± 8	−0.7 (−2; 0.6)	0.18
Sodium (mg)	1,383 ± 692	−195.1 (−330.2; −60)	0.003
Total fiber (g)	24 ± 8	0.4 (−0.9; 1.7)	0.49
Fiber in 1,000 calories (%)	14 ± 5	2.4 (1.5; 3.2)	< 0.0001
Laboratory tests			
Glycemia (mg/dL)	93 ± 12	−0.2 (−1.9; 1.5)	0.94
Cholesterol (mg/dL)	198 ± 37	1.3 (−3.4; 6)	0.51
Triglycerides (mg/dL)	110 ± 68	2.7 (−9.5; 14.9)	0.87
HDL-cholesterol (mg/dL)	52 ± 15	0.1 (−1.8; 1.9)	0.33
LDL-cholesterol (mg/dL)	126 ± 33	−2.3 (−6.4; 1.7)	0.53

Baseline values are expressed as frequencies (%) or mean ± SD values; increases/decreases at follow-up are expressed as frequencies or means (95% confidence interval). BMI, body mass index; HDL, high-density lipoprotein; LDL, low-density lipoprotein.
*The McNemar test for categorical variables and the Wilcoxon test for continuous variables.

those not reaching them: in fact, the reduction in body weight was −3.2 (−2.2; −4.3) kg versus −1.7 (−0.9; −2.6) kg ($P = 0.04$). The reduction in BMI was −1.2 (−0.8; −1.7) kg/m^2 versus −0.6 (−0.3; −1) kg/m^2 ($P = 0.03$). Finally, the decrease in waist circumference was −4.3 (−3; −5.5) cm versus −3.1 (−2; −4.3) cm ($P = 0.19$).

The study also showed an increase in the level of physical activity in over one out of four of the participants.

The intervention did not produce any relevant pre-post modifications in the laboratory parameters.

The median (range) number of text messages sent by each patient during the study was 35 (17; 55), i.e., one or two text messages per week. In terms of costs, assuming a cost of 15 Euro cents per message and considering that on average each participant sent 35 text messages, the overall cost sustained did not exceed 4 Euros.

On the other hand, the dieticians sent a median (range) number of six (six; eight) text messages to transmit the diet program to the DAI and 29 (19; 39) messages with suggestions, comments, and prescription modifications per patient.

The post-study questionnaires investigating the patients' satisfaction with the DAI system documented that overall DAI was judged as "excellent" or "good" by 95% of the patients, 70% of participants were "extremely" or "very satisfied" with its use, the system was defined as "extremely useful" or "very useful" in the dietary program management by 65% of enrolled subjects, and 76% were "definitely" or "probably interested" in buying it when introduced on the market. Furthermore, the set-up process was considered "very" easy or "somewhat" easy to use by 82% of the patients and "very much" effective or "much" effective in the communication between dietician and patient by 83% of the participants. Furthermore, 76% of the sample declared that DAI increased "very much" or "much" their understanding of the qualitative and quantitative content of food, 46% stated that DAI increased their knowledge of the relationship between food and territory, and 41% stated that DAI promoted the seeking and purchase of local produce. The satisfaction was particularly high in subjects who had lost 5 kg or more.

The function considered as the most useful was the "list of food exchange," followed by the "calculation of residual food prescribed," "food diary," and "counting of carbohydrates, fats, and proteins."

The most appreciated qualities of the software were the constant support, the flexibility of the diet, the chance of not using the balance, and the easy and constant communication with the dietician. Among the limitations, patients pointed out the time required to record food eaten, the lack of some food in the atlas, and the technical difficulty of deleting mistaken data.

Conclusions

The STAR study represents an initiative to promote a correct nutritional education and to recover the habit of eating genuine local produce rather than those deriving from large distribution. Patients who voluntarily referred to the centers to be included in the study largely exceeded the requested number; this wide interest underlines how excess weight and obesity are perceived by the community as real threats to health. On the other hand, data on the dropout rate and characteristics of the participants who dropped out confirm

poor compliance and difficulty in reaching beneficial and durable results, especially in patients with less motivation, higher levels of excess weight and obesity, and more severe eating disorders.

In spite of the existing discrepancy between the estimated sample size and the analyzed sample, the number of evaluated patients ($n = 115$) was sufficient to significantly document the intervention's efficacy.

Dietary prescription managed by DAI in association with educational telephone calls was surprisingly effective, especially taking into consideration the short follow-up. The use of DAI resulted in a decrease in the different obesity indexes (body weight, BMI, and waist circumference) and was effective in modifying the qualitative and quantitative content of meals by reducing total calories, by proportioning macronutrients (carbohydrates, proteins, and fats) according to the Mediterranean diet targets, and by increasing the overall fiber intake.

It is noteworthy that better results were obtained in individuals who reached Mediterranean diet goals compared with those diverging from them, while finding a similar reduction in calorie intake in the two groups.

In this context, the role of fresh local produce was important because they were recognized and chosen by participants on average at least once a day, while a large proportion declared that the system enhanced the purchase of such foods.

It is also important to underline that these outcomes were obtained without further face-to-face contacts between dietician and participant after the dietary prescription. More specifically, participants attended the diabetes center at the enrollment phase and after 20 weeks with the only specific aim being the collection of the study data. Intermediate contacts to prescribe and monitor the dietary program were exclusively managed by SMSs.

Moreover, the study was conducted from October 2008 to April 2009, thus including prevalently cold months with a limited choice of seasonal vegetables and fruits; it is intuitive that additional benefits could be obtained by extending the use of the system throughout a whole calendar year, to expand the choice of all available local products according to their season.

Results of this project are in line with other intervention studies testing different strategies or tools for weight loss.[22–27] In the different studies significant weight reductions from 0.1 to 1.0 kg were obtained in short time intervals. The next step will be to test if the benefits of DAI are maintained long-term and whether and to what extent it could impact on quality of life and satisfaction.

Finally, some limits of the study need to be discussed. First, this was a pilot study to test the feasibility and acceptability of the system. The lack of a control group did not allow the comparison of results obtained using DAI with those obtained using standard approaches or other experimental interventions. Second, the short follow-up did not allow assessment of the durability of the weight loss/nutrition education or detection of the relevant modifications in the laboratory parameters.

In addition, the effect of the dietary program on pre-post blood pressure levels was not investigated because data were collected in a non-standardized way.

In conclusion, the results of this pilot study enabled the clarification of the potential of an innovative information technology and telemedicine system to support people needing to reduce their body weight. The tool was also suitable for a more articulated initiative of "nutritional education" aiming to promote the healthy properties of the Mediterranean diet and the consumption of fresh local produce. The promising results of this pilot study will be used to design a controlled randomized trial to provide more robust evidence on the efficacy of the DAI.

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Author Disclosure Statement

G.V. is a medical consultant of MeTeDa srl. M.C.R., C.P., C.C., T.A., P.F., N.G., P.N., S.T., and D.B. declare no competing financial interests exist.

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