

PAPER

Effectiveness of home-centered care through telemedicine applications for overweight and obese patients: a randomized controlled trial

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OBJECTIVE: To determine if home-centered monitoring through telemedicine has an impact on clinical characteristics, metabolic profile and quality of life in overweight and obese patients.

DESIGN: Randomized controlled trial, 6-month duration.

SETTING: Tertiary care academic hospital.

SUBJECTS: A total of 122 patients were eligible to participate as they met the inclusion criteria of increased body mass index (BMI > 25 kg/m²), age > 18 and < 70 y and ability to operate electronic microdevices.

INTERVENTIONS: All patients in the control group ($n = 77$) received standard hospital care. Patients in the intervention group ($n = 45$), additionally, measured three times a week, for 6 months, their blood pressure and body weight and transmitted them to an automated call center. These values were not shared with the patients' physician or dietician.

MAIN OUTCOME MEASURES: Clinical (body weight, BMI, blood pressure), laboratory (fasting plasma glucose, triglycerides, HDL-cholesterol, total cholesterol) and quality of life parameters (SF-36[®], Visual Analog Scale of European Quality-5 Dimensions, Obesity Assessment Survey). Data were analyzed in an intention-to-treat-way (last observation carried forward).

RESULTS: Drop-out rate was similar in the control and intervention groups: 12 vs 11 percent, respectively, $P = NS$. There were no significant differences at baseline between intervention and control groups in all main outcome parameters. There were significant decreases for patients in the intervention group in body weight (from 101.6 ± 22.4 to 89.2 ± 14.7 kg, $P = 0.002$, $P = 0.05$ vs controls at 6 months), total cholesterol (from 247.6 ± 42.0 to 220.7 ± 42.6 mg/dl, $P = 0.002$, $P = 0.05$ vs controls at 6 months) and triglycerides (from 148.4 ± 35.0 to 122.3 ± 31.4 mg/dl, $P = 0.001$, $P = 0.01$ vs controls at 6 months). Intervention group patients made a total of 1997 phone contacts. The number of phone contacts was correlated positively with Social Functioning (SF), Vitality (VT) and Mental Health (MH) scores of SF-36[®] at baseline ($r = 0.48$, $r = 0.41$, $r = 0.41$, respectively, $P = 0.05$) but not with weight loss.

CONCLUSIONS: Home-centered, intense treatment through the use of telemedicine can be effective in improving short-term obesity outcomes.

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Introduction

Obesity is one of the most important medical and public health problems of our time, since it is associated with a

shorter expectation of life, increased morbidity and cost to the community. Using a body mass index (BMI) greater than 30 kg/m², the percentage of obese men has nearly doubled between 1991 and 1998, and the percentage of obese women increased by 50 percent.¹ The prevalence of obesity in the US increased from 17.9 percent in 1998 to 19.8 percent in 2000.² Obesity is often accompanied by elevated levels of lipids and blood pressure, giving rise to an increased risk of mortality

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from coronary heart disease, stroke, certain types of malignancy and diabetes mellitus type II.^{3,4} It is also associated with gallbladder disease, osteoarthritis, gout and impaired respiratory and hepatic function.^{5,6}

Given the magnitude of the problem and its consequences, obesity management remains an extremely challenging field. Unfortunately, pharmacotherapy does not constitute an effective and uniform way of weight loss, especially in the long term.⁷ Therefore, the cornerstone of obesity management remains behavior modification,⁸ diet⁹ and exercise.¹⁰ The role of telemedicine in the field of obesity treatment remains poorly studied. Theoretically, telemedicine applications have a series of advantages, such as better communication between physicians and patients, involvement of patients in the decision-making and follow-up procedures and change of the management pattern from hospital-centered to home-centered.^{11,12} Effective communication between physicians and patients, who have different understandings of health and illness, is required in any current healthcare environment. Balas *et al*¹³ evaluated 80 studies of telemedicine applications in clinical practice. In total, 61 of them (76 percent) analyzed provider-initiated communication with patients and 50 (63 percent) reported positive outcome, improved performance or significant benefits, including studies of computerized communication (7 of 7), telephone follow-up and counseling (20 of 37), telephone reminders (14 of 23), interactive telephone systems (5 of 6), telephone access (3 of 4) and telephone screening (1 of 3). The authors concluded that telemedicine technology enables greater continuity of care by improving access and supporting the coordination of activities by a clinician. The benefits of distance technologies in facilitating communication between clinicians and patients indicated that application of telemedicine should not be limited to physician-to-physician communication.

To the best of our knowledge, there are no randomized controlled trials that checked the efficacy of telemedicine in the field of obesity. The vast majority of studies that applied telemedicine in the field of metabolic diseases have involved patients with diabetes mellitus.^{14–20}

Mahmud and Lenz²¹ reported an inexpensive home telemedicine system, comprising a personal unit in the patient's home connected by ordinary phone lines to a central nursing station. Telecare using this system was significantly cheaper than care delivered by conventional routes, with the average charge being about \$15 for a video visit by a nurse, compared with about \$90 for a real visit. In 1998, Bellazzi *et al*²² described a telemedicine system for diabetic patients management, designed to provide decision support in a distributed environment. Edmonds *et al*,²³ using the Vista 350 telephone, developed a system that enabled patients with diabetes to record home monitoring data to a central database and receive feedback summaries. Di Biase *et al*²⁴ studied the use of telemedicine in the domain of management of the diabetic woman during pregnancy, using a completely automatic system (DIANET). Treatment with

DIANET vs conventional therapy resulted in improved metabolic control as estimated by profile of blood glucose absolute values. Finally, Piette *et al*²⁵ evaluated the impact of automated telephone disease management (ATDM) calls with telephone nurse follow-up as a strategy for improving outcomes such as mental health, self-efficacy, satisfaction with care, and health-related quality of life (HR-QoL) among low-income patients with diabetes mellitus. Compared with patients receiving usual care, intervention patients at follow-up reported fewer symptoms of depression ($P=0.02$), greater self-efficacy to conduct self-care activities ($P=0.01$) and fewer days in bed because of illness ($P=0.03$). A meta-analysis of the effect of the use of computer-based systems on the metabolic control of patients with diabetes mellitus has been published by Montani *et al*.²⁶

The aim of this randomized controlled trial was to determine if high quality, home-centered monitoring through the use of telemedicine has an impact on the clinical parameters, metabolic profile and quality of life in overweight and obese patients.

Methods

Study Characteristics

Randomized controlled trial.

Setting

The study was conducted from September 2001 through December 2002. All study subjects were recruited from the Obesity Outpatient Clinic of Department of Endocrinology, Hippocraton General Hospital, Thessaloniki, Greece. The Department has a vast experience in the management of endocrine and metabolic patients, being the largest in Northern Greece, with more than 14 000 outpatient visits annually.

Study population

Patients were eligible to participate if they had an increased BMI ($>25\text{ kg/m}^2$), age >18 and <70 y, and were able to operate regular phones and electronic microdevices. They were on no obesity pharmaceutical treatment for at least 12 months. Patients were recruited irrespective of sex, place of residence (inner city, countryside) and educational level.

Sample size

A total of 122 patients ($n=122$) were enrolled in the trial. To obtain reliable estimates with a sufficiently low margin of error, a pretrial power calculation indicated that a minimum sample size of $n=100$ was required, assuming 0.10 level of significance and 80 percent statistical power.

Random assignment

A centralized randomization process was applied to assign patients to the intervention and control groups. Patients

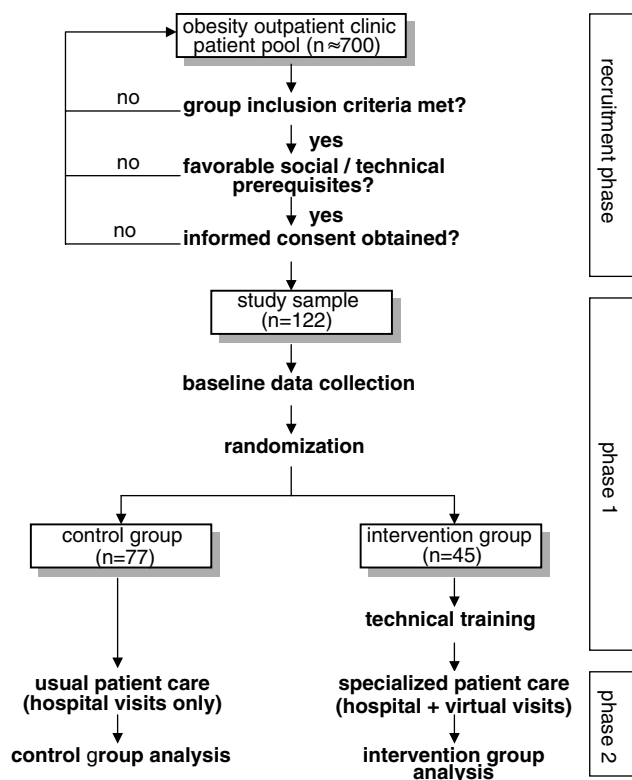


Figure 1 Study design and patient flowchart.

were randomized into intervention and control groups with a proportion of 1 : 2. Upon meeting the eligibility criteria and signing the consent form, all patients were allocated using central computerized randomization. The random numbers were generated in blocks of six. Patients who received an odd number formed the intervention group, whereas patients who received an even number served as the control group (Figure 1). Both physicians and dieticians were blinded to the treatment arm of the patient. Baseline data on the patients in the intervention and control groups were collected and tested for homogeneity.

Intervention

Study design is illustrated in Figure 1. Upon recruitment to the study, patients received an information sheet about the trial. Throughout the whole study, all participants in both intervention and control groups entered a regular, hospital-based, obesity treatment program on an outpatient basis consisted of diet and physical activity guidelines. The diet prescription was balanced in nutrients and included at least three meals a day, aiming at a caloric deficit of 500–600 kcal/day. Energy expenditure was estimated according to the revised World Health Organization equations, which take under consideration sex, age, baseline body weight and

degree of daily activity. The patients were advised to exercise for 20–30 min, at least 5 days weekly, in the forms of walking, running, swimming or structured aerobic activity. The weight reduction target for the average patient was 2–3 kg/month up to 5 percent of initial body weight.

The preintervention phase lasted for 1 month (phase 1 – Figure 1). During this phase, no other action took place than clinical and laboratory data collection and randomization. In addition, education of the intervention group subjects regarding the use of telematics systems microdevices was accomplished by means of leaflets, a demonstration of use and guided practicing.

The intervention phase lasted for 6 months (phase 2 – Figure 1). All subjects of intervention group were supplied with an electronic blood pressure monitor (Card Guard CG800BP) and an electronic weight scale (Rowenta). They were given a treatment plan, where they had to measure and transmit three times a week, for 6 months, their blood pressure and weight and answer two life style questions: ‘Did you follow your diet plan during the last 2 days?’ and ‘Did you follow your exercise plan during the last 2 days?’. The patients chose the type of data transmission they preferred among three options: Automated Call Center through a regular phone, Wireless Application Protocol (WAP) server through a cellular phone and World Wide Web (Internet) server through a personal computer. All of them chose the Automated Call Centre. One user also expressed interest in using a WAP phone and she was given one for the duration of the trial. All intervention group subjects had access to the telematics system with which they could freely interact. They were provided with a schedule in order to send their measurements (body weight and blood pressure) three times a week. The total time spent by the patient on the intervention was planned to be approximately 15 min/week. Technical details regarding the telematics intervention are given elsewhere.^{27,28}

Outpatient visits of both groups were planned at 1-month intervals. All patients were seen by both the attending physician and the dietitian. This appointment schedule was modified by the physician who could offer an earlier appointment, if the clinical situation warranted it. The patient could also ask for an earlier appointment in case of an unexpected health problem. Hospital visits included history, basic physical examination, including blood pressure and body weight recordings. An appointment with the dietician took place every month, in order to discuss compliance to diet and possibly set a new level of caloric intake. A basic laboratory set of fasting glucose, total serum cholesterol, triglycerides, HDL-cholesterol, renal profile and liver profile was performed every 3 months. Other tests were added to this basic set according to the attending physician.

The data from the telemedicine system were not reviewed by the physicians or the dieticians during the study. Therefore, they were not used in order to make clinical decisions, modify the hospital visit schedule or arrange additional contacts with the patients.

Outcome measures

The outcome measures included clinical parameters (body weight, BMI, systolic blood pressure, diastolic blood pressure), laboratory parameters (plasma glucose, serum triglycerides, serum HDL-cholesterol and total serum cholesterol), HR-QoL as measured by the SF-36[®], Visual Analog Scale (VAS) of European Quality of Life—5 Dimensions (EQ-5D) and the Obesity Assessment Survey (OAS). The SF-36[®] health survey consists of 36 questions with Likert-type multiple choice answers and yields an eight scale profile as well as two summary measures.²⁹ The SF-36[®] has already been translated in numerous languages. The translation work has been under the auspices of the International Quality of Life Project Assessment (IQOLA), housed at the Health Assessment Lab in Boston, USA. For our study, the Greek version 1.1 of the IQOLA project was used. It was sent to us by QualityMetric after formal registration. EQ-5D is also a generic measure of HR-QoL. Its VAS is a 0–100 scale where the patients mark their perceived current health status: '100' indicates excellent health and '0' corresponds to the worst imaginable situation. The Greek version of EQ-5D was used, which was sent to us by the EuroQoL Group Business Management. Unlike the SF-36[®] and the VAS, the OAS questionnaire was primarily intended for use with obese individuals, where high scores in OAS correspond to low psychological adjustment to obesity.³⁰ Patient satisfaction was measured using the Telemedicine Satisfaction Questionnaire (TSQ) in the intervention group at the conclusion of the study. TSQ consists of 20 questions and is scored at a five-point Likert scale with '1' corresponding to low and '5' corresponding to high satisfaction with use. It has been developed in the Laboratory of Medical Informatics, Aristotle University of Thessaloniki, Greece.

Data collection

Data were collected from the patients from their telephone transmissions and from audits of patient medical charts. Trial monitoring was kept separate from the administration of the intervention. Clinical, laboratory, HR-QoL and satisfaction data were stored in a Microsoft Access[®] database and Automated Call Center data were stored in an Oracle[®] database.

Ethics

The ethics committee of the Hippocraton General Hospital, Thessaloniki, Greece approved the study protocol. A signed letter of consent was obtained from all patients enrolled in the trial.

Financial support

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Statistical analysis

Data were analyzed in an intention-to-treat way using the LOFC procedure (last observation carried forward). The main effect variables were analyzed using the software SPSS version 11 (SPSS Inc., Chicago, IL, USA). Data were described as mean \pm standard deviation (s.d.). Two-tailed *t*-tests were used for continuous variables and Fisher's exact tests were used to analyze binary variables. In addition, data were analyzed using a mixed factorial analysis of variance design (ANOVA) with time as a within subjects factor (baseline, 3-month and 6-month data) and group as a between subjects factor (control and intervention data). Contrast was used as the *post hoc* test. A stepwise multiple regression analysis was performed with the weight loss as the dependent variable and sex, age, educational level, body weight at baseline, number of phone calls and HR-QoL parameters as independent variables. In all cases, a *P*-value of less than 0.05 was considered to be statistically significant.

Results

Baseline characteristics

There was no difference between the patients in the intervention and control group in the percentage of female sex (86.6 vs 89.6 percent; *P*=NS) or the age (43.6 ± 12.8 vs 45.1 ± 12.5 y, *P*=NS). In addition, there were no significant differences between the intervention and control groups at baseline in clinical, laboratory (Table 1) or HR-QoL parameters. OAS scores were marginally higher in intervention group compared to control group patients (Table 2).

Drop-out rate

The study was completed by 40 patients in the intervention and 68 patients in the control group, giving a drop-out rate of 11 and 12 percent, respectively (*P*=NS). The five intervention group patients who did not complete the study dropped out in months 1, 3, 4, 4 and 5. The nine control group patients who did not complete the study dropped out in months 1, 2, 2, 3, 4, 4, 4, 5 and 5. The main reasons for the drop-out were failure to lose weight and reach personal weight target.

Automated call center use

The 45 patients in the intervention group made a total of 1997 phone calls. The mean number of calls per patient was 44.4 ± 15.7 , representing 56.9 percent of the possible. There was no decrease in the number of phone calls over time (first trimester 22.6 ± 11.7 , second trimester 21.8 ± 14.1 , *P*=NS). The mean length of a call was 86.1 ± 40.7 s. A successful call lasted for a mean of 63 s for an experienced user (defined as

Table 1 Patient clinical and laboratory parameters at baseline and after 6-month treatment.

	Baseline			6 months			P-value ^c	P-value ^d
	Intervention group (n = 45)	Control group (n = 77)	P-value ^a	Intervention group (n = 45)	Control group (n = 77)	P-value ^b		
<i>Clinical parameters</i>								
Height (cm)	164.9 ± 6.7	164.0 ± 7.8	NS					
Weight (kg)	101.6 ± 22.4	101.6 ± 21.3	NS	89.2 ± 14.7	99.6 ± 23.8	0.05	0.05	NS
BMI (kg/m ²)	37.6 ± 8.0	37.8 ± 7.8	NS	33.7 ± 5.2	37.2 ± 8.7	0.06	0.06	NS
BP systolic (mmHg)	134.6 ± 18.2	132.1 ± 20.9	NS	123.8 ± 14.2	128.6 ± 19.4	NS	0.01	NS
BP diastolic (mmHg)	80.7 ± 11.7	79.7 ± 11.5	NS	74.6 ± 8.5	79.5 ± 14.0	NS	0.06	NS
<i>Laboratory parameters</i>								
Glucose (mg/dl)	112.6 ± 10.4	110.4 ± 29.8	NS	104.7 ± 25.0	108.3 ± 31.3	NS	NS	NS
Total cholesterol (mg/dl)	247.6 ± 42.0	244.4 ± 53.1	NS	220.7 ± 42.6	239.6 ± 41.5	0.05	0.01	NS
Triglycerides (mg/dl)	148.4 ± 35.0	144.4 ± 47.3	NS	122.3 ± 31.4	140.7 ± 37.2	0.01	0.01	NS
HDL-cholesterol (mg/dl)	44.2 ± 5.7	45.4 ± 10.6	NS	47.5 ± 12.0	45.3 ± 12.1	NS	NS	NS

Data are given as mean ± s.d. BMI, body mass index; BP, blood pressure; NS, not significant. In order to convert plasma glucose from mg/dl to mmol/l divide by 18.01. In order to convert serum cholesterol from mg/dl to mmol/l divide by 38.67. In order to convert serum triglycerides from mg/dl to mmol/l divide by 88.57.

^aP-value between intervention and control group at baseline. ^bP-value between intervention and control group at 6 months. ^cP-value within intervention group. ^dP-value within control group.

Table 2 Patient quality of life parameters at baseline and after 6-month treatment

	Baseline			6 months			P-value ^b	P-value ^c	P-value ^d
	Intervention group n = 45	Control group n = 77	P-value ^a	Intervention group n = 45	Control group n = 77				
<i>SF-36[®] parameters</i>									
Limitations in physical activities due to health problems (PF)	60.6 ± 26.3	63.4 ± 26.1	NS	51.0 ± 48.2	53.6 ± 39.1	NS	NS	NS	NS
Limitations in usual role activities due to physical problems (RP)	73.1 ± 37.4	54.2 ± 42.0	0.07	50.0 ± 71.8	43.8 ± 59.9	NS	NS	NS	NS
Bodily pain (BP)	62.3 ± 33.6	56.3 ± 33.2	NS	49.6 ± 38.1	47.5 ± 34.3	NS	NS	NS	NS
General health (GH)	60.0 ± 16.2	60.9 ± 21.1	NS	62.9 ± 20.8	56.6 ± 20.9	NS	NS	NS	NS
Vitality (VT)	57.3 ± 20.9	50.5 ± 25.4	NS	58.8 ± 17.0	53.3 ± 20.8	NS	NS	NS	NS
Limitations in social activities due to physical or emotional problems (SF)	71.6 ± 20.8	61.5 ± 27.5	NS	64.4 ± 25.4	62.2 ± 27.6	NS	NS	NS	NS
Limitations in usual role activities due to emotional problems (RE)	60.3 ± 41.2	59.3 ± 43.7	NS	39.7 ± 72.4	47.2 ± 56.6	NS	0.06	NS	NS
General mental health (MH)	63.5 ± 21.3	55.2 ± 24.9	NS	55.5 ± 23.0	58.0 ± 21.6	NS	NS	NS	NS
Physical component scale (PCS)	44.0 ± 10.2	43.0 ± 10.5	NS	40.7 ± 17.5	38.7 ± 15.2	NS	NS	NS	NS
Mental component scale (MCS)	45.9 ± 11.1	41.9 ± 13.1	NS	42.4 ± 12.4	43.3 ± 10.1	NS	NS	NS	NS
<i>Visual Analog Scale (VAS) of European Quality of Life – 5 Dimensions (EQ-5D)</i>	66.2 ± 20.4	72.7 ± 21.8	NS	70.7 ± 15.0	72.1 ± 16.3	NS	NS	NS	NS
<i>Obesity Assessment Survey (OAS)</i>	57.8 ± 14.6	51.2 ± 12.0	0.06	45.9 ± 19.6	50.8 ± 16.5	NS	0.01	NS	NS

Data are given as mean ± s.d. ^aP-value between intervention and control group at baseline. ^bP-value between intervention and control group at 6 months. ^cP-value within intervention group. ^dP-value within control group.

use of system for more than 1 month) and 141s for a user who enrolled in the trial within the last month. The patients reported their body weight, systolic blood pressure and diastolic blood pressure 73.2, 80.8 and 77.6 percent, respectively, of the total number of phone calls they have made. The patients responded in the affirmative 62.7 percent of the time that they were following their dietary plan and

34.3 percent of the time that they were following their exercise plan.

Intervention results

At the end of the 6-month treatment period, body weight was significantly lower ($P < 0.05$) among those patients in

the intervention group (who managed to lose only 2.0% of their initial body weight) compared with those patients in the control group (who managed to lose 12.2% of their initial body weight). The BMI of the patients in the intervention group was also lower than the BMI of those in the control group, but was only approaching statistical significance ($P=0.06$) (Table 1). The control group did not manage to lose statistically significant weight at the end of the 6-month treatment period. On the other hand, there was a tendency towards weight loss after a 3-month treatment period (intervention group 94.1 ± 12.7 kg vs control group 96.9 ± 24.6 kg, $P=NS$), but the greater part of it was regained at the end of the study. There were no differences observed for HR-QoL parameters (Table 2).

The mixed factorial ANOVA for body weight demonstrated a marginally nonsignificant between subjects effect (control vs intervention group, $P=0.06$) and a significant within subjects effect (baseline vs 3-month vs 6-month data, $P=0.05$, Contrast test for baseline vs 6-month data, $P<0.05$).

Patient satisfaction

The intervention group scored 3.9 ± 0.4 on the five-point Likert scale of TSQ indicating high general levels of satisfaction.

Correlation

The number of phone contacts was correlated positively with SF, VT and MH scores of SF-36[®] at baseline ($r=0.48$, $r=0.41$, $r=0.41$ respectively, with $P<0.05$). The number of phone contacts was correlated negatively with OAS score both at baseline and after completion of the trial ($r=0.47$, $r=0.50$, respectively, with $P<0.05$). The behavioral component of TSQ, showing intend to use or recommend the use of our system to other people, was correlated to age ($r=0.41$, $P<0.05$). In general, satisfaction components were mildly correlated to quality of life components, especially the physical health components of SF-36[®]. There was no correlation between number of phone contacts and weight loss or between number of phone contacts and number of hospital visits.

Prediction of weight loss

The stepwise multiple regression analysis with the weight loss as the dependent variable failed to reveal any predictive parameters, including sex, age, educational level, body weight at baseline, number of phone calls and HR-QoL parameters.

Discussion

In this randomized controlled trial, a population of obese subjects managed to decrease their body weight, total

cholesterol and triglycerides through the use of telemedicine, compared to a control group of patients with similar baseline characteristics that received standard outpatient care.

Group epidemiological characteristics (female sex 88 percent, mean age 44 y, BMI 37.7 kg/m²) are not typical of these general population. On the other hand, this profile is representative of the people approaching the outpatient obesity clinic of a tertiary hospital, as patients with lower BMI are usually confronted at an earlier level of care.³¹ Therefore, we feel that our results cannot be extrapolated to the general population, but can be applied to patients seen by obesity specialists in a hospital environment. Moreover, people seeking help in a tertiary hospital generally can be considered more motivated to lose weight by changing their life habits.

We classify our intervention mainly as a behavioral one, as the patients were on no pharmaceutical agents throughout the study and the dietary advice was uniform in all patients, irrespectively of the telemedicine intervention. In any case, compliance to diet,⁹ compliance to an exercise plan¹⁰ and regular weight measurement³² are established success factors for body weight reduction or maintenance. The patients of the intervention group referred to these success factors three times a week.

The patients of the intervention group reduced their body weight at the end of the study by 12.4 ± 3.7 kg on average, or 12.2 ± 3.4 percent of their baseline body weight. This amount of weight loss is considerable and it can easily be compared to the weight loss achieved by other interventions, for example orlistat 120 mg three times daily (9.7 percent of initial body weight in 12 months),³³ sibutramine 30 mg once daily (9.5 percent of initial body weight in 6 months),³⁴ aerobic exercise alone (3.0 kg in 30 weeks)³⁵ or exercise plus diet (11.8 kg in 6 months),³⁶ being inferior only to bariatric surgery (28 kg after procedure).⁶

The telemedicine intervention led to statistically significant reduction in fasting lipids, possibly due to weight loss. These changes were similar in their type and extend to those recorded in similar studies.^{33,37}

Despite the weight loss, there were no changes in the intervention group to any of HR-QoL parameters. This was not surprising, as it seems that more intensive intervention for a longer period of time is needed in order for such changes to be recorded. In comparison, in the Swedish Obese Subjects (SOS) study, the intervention was bariatric surgery, which led to a weight loss of 28 ± 15 kg on average and the follow-up continued for a total period of 10 years.⁶ In general, in accordance with the literature, obese subjects in our study reported lower HR-QoL scores than the general population in both the physical and mental dimensions of SF-36[®].³⁸⁻⁴⁰ There was a tight positive correlation between different tools of HR-QoL assessment. Therefore, the VAS of European Quality, being the easiest to apply, seems to constitute a practical and reliable way of quick HR-QoL assessment.

The phone call contacts were a main component of our intervention. The fact that there was no decrease in number of phone calls over time and the correlation between number of phone calls and scores of SF-36[®] reflect probably the ease of use and the overall acceptance of this approach, respectively. All intervention patients completed a minimum number of phone calls but only up to 57 percent of the scheduled. As there was no correlation between the number of phone calls and weight reduction, it seems that our approach has to be interpreted as qualitative and not quantitative.

Many aspects of the classic outpatient hospital visit were modified in the telemedicine approach. Ease of data transmission was improved as it was achieved by a means and at a time of day selected by the patient, although only one-way data transmission was established: from the patient to the physician. Frequency of communication was greatly improved from once a month to three times a week, although the majority of visits were 'virtual' through a phone line and an automated call center. Privacy was improved, as the measurements took place in the patient's home and not in the busy environment of an outpatient clinic. Nevertheless, we feel that the most important parameter of our intervention was the active patient involvement in the treatment procedure. The patients had to perform the measurements by themselves and report them in an active way, in contrast with the passive way that the same measurements take place in the outpatient clinic. The frequency of measurements, every other day, made gross weight fluctuations difficult to occur. Finally, the feeling of the patients that they were always under the surveillance of their physicians seems to have had a beneficial effect on the obesity outcomes. Another important topic was the fact that the whole intervention was introduced and delivered to the patients by their own physicians and not by an independent third party.

The drop-out rates were acceptable in both intervention and control groups and, in general, lower than the typical ones of a prospective study in the field of obesity.^{37,41} The intervention did not lead to excess drop-outs from the intervention group, suggesting that it was well tolerated by the patients. This was further conformed by the high values scored by the intervention group patients to the user satisfaction questionnaire.

Although there was correlation among system usage and HR-QoL parameters, it is very difficult to comment on which patients will accept or benefit the most from such an intervention. The stepwise multiple regression analysis performed for this purpose failed to reveal any factors that could predict a successful outcome.

From a telemedicine point of view, the results of our study seem to strengthen the role of such interventions in chronic diseases. To the best of our knowledge, there are very few studies that have investigated the role of telemedicine in the field of obesity, mainly in the form of simple interventions, such as motivation phone calls.^{42,43}

The initial concept was to equip our intervention group patients with three microdevices: weight scales, blood pressure monitors and glucometers. As 2 percent of the patients proved to be diabetic and 13 percent hypertensive, we decided to distribute only weight scales and blood pressure monitors. It is difficult to isolate the impact of weight measurements alone, an approach that would be cheaper and easier to implement. We can only hypothesize that their effect on body weight would be probably the same and that the use of blood pressure monitors and glucometers could be a valuable addition in case of hypertensive and diabetic subjects, respectively.

In conclusion, this randomized controlled trial showed that intense treatment through the use of telemedicine can be more effective in improving short-term obesity outcomes than routine intervention at a hospital outpatient basis. Of course, more work remains to be carried out in order to replicate these findings, determine the keys of success of this approach and define the type of patients that will benefit the most from such interventions. In the meantime, the main advice that can be given to the patients is that personal involvement in the treatment procedure with close monitoring of body weight can greatly contribute towards a successful outcome.

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