



Original

Artículo inglés

Mediterranean diet better adherence by digital intervention (MEDADIS study) on overweight and obese patients.

Efectos de una mejor adherencia a la dieta mediterránea por intervención digital (estudio MEDADIS) en pacientes con sobrepeso y obesidad.

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Abstract

Objective: To evaluate the impact of based behavioral interventions delivered by digital platform to increase adherence to Mediterranean diet and physical activity in overweight or obese patients detected by laboral health service.

Methods: Randomized, controlled, double-blind, parallel clinical trial comparing 2 arms, multicenter study in overweight and obese patients with a 12-month follow-up. Patients were randomized into two groups: Intervention in Primary Care Centers with a Medtep telematic platform support (G2) and a control group that was allowed to evolve under normal conditions (G1). Variables were collected: Weight, height, BMI, waist circumference, lipid parameters, blood pressure and glycemia.

Results: 120 patients were included in the study where 60 were randomized to Group 2 and 60 to Group 1. 58.6% of the study population were women and 41.4% were men. In the intervention group, the subjects reduced their weight by an average of 6.5 kg, while the control group increased slightly more than 1.5 kg.

It is observed that total cholesterol was reduced in both groups. On the other hand Triglycerides were significantly reduced more in the study group, without achieving significant differences in the control group ($p = 0.710$). HDL cholesterol was increased in both groups.

Conclusion: The group in which no intervention, weight gain normal evolution was made.

KEYWORDS

Telemedicine; Obesity; Health care

Resumen

Objetivo: Evaluar el impacto de una intervención conductual a través de una plataforma digital para aumentar la adherencia a la dieta mediterránea y la actividad física en pacientes con sobrepeso u obesidad detectados por el servicio de salud laboral.

Métodos: Ensayo clínico aleatorizado, controlado, doble ciego que comparó el estudio multicéntrico de 2 brazos en pacientes con sobrepeso y obesidad con un seguimiento de 12 meses. Los pacientes fueron asignados al azar en dos grupos: Intervención en Centros de Atención Primaria con soporte de plataforma telemática Medtep (G2) y un grupo de control que se permitió evolucionar en condiciones normales (G1). Se recogieron variables: Peso, talla, IMC, circunferencia de cintura, Parámetros, presión arterial y glucemia.

Resultados: Se incluyeron 120 pacientes en el estudio, de los cuales 60 fueron asignados al azar al Grupo 2 y 60 al Grupo 1. El 52,75% de la población estudiada eran mujeres y el 47,25% hombres. En el grupo de intervención, los sujetos redujeron su peso en un promedio de 6,5 kg, mientras que el grupo control aumentó ligeramente más de 1,5 kg.

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Se observa que el colesterol total se redujo en ambos grupos. Por otro lado, los triglicéridos se redujeron significativamente más en el grupo de estudio, sin lograr diferencias significativas en el grupo de control ($p = 0,710$). El colesterol HDL se incrementó en ambos grupos.

Conclusión: En el Grupo control que no se realizó intervención, los pacientes aumentaron de peso en evolución normal.

PALABRAS CLAVE

Telemedicina; Obesidad; Atención de Primaria de salud

Introduction

Prevalence of obesity is steadily increasing in developing countries and has become a serious public health issue. According to an estimation made by the World Health Organization (WHO), at least 500 million people worldwide were obese in 2008¹. They also predicted that by 2015, approximately 2.3 billion adults would be overweight and more than 700 million would be obese.

More than a half of Spain adults' population (60.9%) is overweight or obese² which greatly increases their risks for type 2 diabetes, hypertension, hyperlipidemia, heart disease, stroke, and some types of cancer. Even modest weight loss of 5%–10% of initial body weight can reduce the risk of these negative health consequences^{3, 4, 5}. National guidelines target the reduction of total and abdominal obesity through increased physical activity, caloric restriction and behavioral lifestyle interventions⁶. Although the primary recommendations for treatment of obese patients include calorie reductions through diet, increasing physical activity, and behavior modification^{7, 8} research has demonstrated that frequently and unfortunately, proactive discussions do not always occur between patients and health care providers^{9, 10}.

Although physicians see an estimated 25% of the US population every month¹¹ and similarly proportion happens in Spain, the adult population of middle age do not visit their family physician for laboral reasons and it has been increased after economical crisis. On the other hand this population is visited by laboral health care systems annual in our country. Frequently after that the patient shows at his doctor the results and again nothing is done. In fact, only 29% to 42% of overweight and obese patients report that they had been counseled by their physicians to lose weight^{12, 13}. Similarly, obesity-related counseling is included in approximately 20% to 36% of visits with primary care physicians^{14, 15}. Limited weight loss counseling may reflect the many barriers physicians face, including limited time, lack of reimbursement, limited training, and perceived lack of interest on the part of their patients¹⁶.

Patients who report receiving physician counseling about weight loss are up to 2 times more likely to report that they are currently trying to lose weight^{12, 17}.

For those that present overweight or obesity at report laboral health care systems, it could be a moment to deal with the overweight and obese problem. Attending that limited time, is one of barriers physicians have. Busy health professionals need effective tools and easy strategies less time consumer to facilitate healthy eating and increase physical activity in their overweight and obese patients. Communication technologies such as mobile phones offer a potentially powerful approach for addressing common barriers to health behavior change through delivering convenient, individually tailored, and contextually meaningful behavioral interventions with less effort. There is research evidence suggesting that smartphones are a useful tool for interventions seeking to improve health outcomes¹⁸⁻²⁰. Cochrane database study analyzed different studies aimed to assess the effects of interactive computer-based interventions for weight loss or weight maintenance in overweight or obese people. The study concludes by saying that, compared to in-person interventions, interactive computer-based interventions result in smaller weight losses and lower levels of weight maintenance²¹. Although more than 10.000 consumer health applications for smartphones, few applications have been subjected to clinical trials to test effectiveness in changing health behaviors.

The major goals of our pilot study were to evaluate the feasibility, acceptability, and preliminary efficacy of theoretically based behavioral interventions delivered by digital platform to increase physical activity and increased adherence to Mediterranean diet based in motivational intervention resulting in weight loss in patients remitted by their laboral health service with overweight and obesity.

The **Mediterranean diet better adherence by digital intervention study MEDADIS** randomized 120 eligible participants to receive none intervention or a Smart technological by self-monitoring intervention by digital platform multiaccesorie based on mediterranean diet and exercise for 12 months.

Methods

Study design and participants

Randomized, controlled, double-blind, parallel clinical trial with 2 arms and 12-month follow-up.

From March 2015 to June 2016, all overweight or obese men and women aged 30 to 65 years diagnosed for physician health laboral services, with no evidence of participation in diet reduction programs within the last 12 months. All of them completed a personal health and medical history questionnaire which served as a screening tool. Exclusion criteria were type 2 diabetes mellitus or impaired glucose tolerance (plasma glucose levels of 140 -200 mg/dL 7.8-11.1 mmol/L 2 hours after a 75 g oral glucose load), hypertension (blood pressure 140/90 mm Hg) or if the participant was taking antihypertensive medication, cardiovascular disease, psychiatric problems, history of alcohol abuse (intake of 500 g/wk in the last year), current smoking, active cancer, hypothyroidism. No patient was pregnant or became pregnant during the study. The study was approved by the institutional committee of ethical practice and all study participants gave written informed consent. Participants were individually assigned to either the intervention or the nihilistic control group by a

number generated informatically. Neither nurses nor physician who visited participants did not have access to the randomization list.

Interventions

Patients were randomized into two intervention groups: (G1) No intervention (G2) intervention in Primary Care with the support of a digital platform in Primary Care Centers. Medtep platform offered to participants in the intervention group (G2) access to the Mediterranean Diet Adherence Screener (MEDAS) and keep ongoing about level of adherence. Adherence to the Mediterranean diet was assessed using the validated 14-point MEDAS, adaptation of a previously validated 9-item index. The MEDAS was developed within the PREDIMED study group. The MEDAS can rapidly estimate Mediterranean diet adherence and may be useful in the clinic. The 14-item screener includes 12 questions about food consumption frequency and two questions about food intake habits characteristic of the Spanish Mediterranean diet (Table 1).

Table I. Sample groups baseline data.			
	G0 (n=60)	G2 (n=60)	P
women (n;60)	35 (53,3)	34 (52,3)	
man (n;60)	25 (46,7)	26 (47,7)	0,931
Age (years)	43,85 (7,2)	47,13 (6,4)	0,946
Baseline Weight (kg)	80,86 (11,2)	86,06 (13,17)	0,329
BMI (kg/m^2)	31,13 (3,2)	30,34 (3,26)	0,735
Waist circumference (cm)	78,31 (4,73)	84,98 (9,32)	0,202

Data are reported as mean and (standard deviation) or number y (percentage). G0: control group G2:doctor's visit + Telemedicine group;; Kg: kilograms; BMI: Body mass index; Cm: centimeters; Kg / m²: kg divided by height in meters squared; Mg / dL: milligrams per deciliter. HDL: high density lipoprotein. The comparison between means was performed with Student't test for independent groups.

Participants knew their initial level of adherence previously to intervention. After that health professional asked them to answer the test every day (self monitoring food diary) and the platform gave to the participant the level of adherence weekly. In that way this tool was useful in evaluating the compliance with Mediterranean diet allowing personalized dietary advice given automatically by platform. At the same time the platform proposed to the participant getting better results in the aspects without good compliance. To facilitate it some recipes were sent to them.

The protocol applied in G1-2 after the first visit: visits were scheduled at 15 days, one month, 3 months, 6 months and 12 months. In each of the visits anthropometric data were collected, physical activity level was reviewed, adherence to the Mediterranean diet using the data recorded by the patient in the Medtep digital platform was reviewed and the patient was encouraged to improve adherence level to the Mediterranean diet.

Variables and measurements

Weight in kilograms (kg) wearing very light clothes was measured using a digital scale (range from 0.1 to 150 kg and precision of 0.1 kg), height in meters (m) with the subject barefoot using Harpenden digital stadiometer (range from 0.7 To 2.05 m and precision of 1 mm) and BMI was calculated (kg / m²). Waist-circumference was measured in the horizontal plane midway between lowest rib and the iliac crest. 0.1 cm at the end of a normal expiration.

Assays for serum total and high-density lipoprotein cholesterol, triglyceride, and glucose levels were performed in the chemistry laboratory.

Sample size

To assess the statistical power of this study "a posteriori" it was assumed, with a confidence level of 95%, a proportion of 30% to reach the objective in the control group and 70% in the experimental group. The total number of participants was 120. The study power to detect a RR other than 1 was 99.69%.

Statistical analysis

All calculations were performed using the SPSS v19.0 statistics program. Quantitative variables are presented as mean and standard deviation (SD), qualitative ones as exact amount and percentage. The comparison of means during the follow-up has been performed by analyzing the variance of repeated measures. When the criteria of normality and specificity were not met, the non-parametric Friedman test was applied.

Results

One hundred twenty participants were randomly assigned to the intervention (n= 60) or control group (n = 60). One hundred twenty participants were randomly assigned to the intervention (n= 60) or control group (n = 60). Because

participants were screened for exclusion criteria, both groups were comparable. Table I shows this comparison, without observing significant differences between the considered variables, which supports a correct randomization. It can be seen globally and in both groups that, on average, the participants were obese and presented high values of total cholesterol (TC) and triglycerides (TG). Tables II y III shows the evolution of weight, BMI and waist circumference (WC) between these two groups. An analysis of the variance of repeated measures showed that G2 group decreased in weight throughout the study but G0 Increase in weight,

Table II. Evolution of weight during follow-up			
	Basal	12 months	p
G0 (n=60)	80,86 (11.21)	81.9 (13,3)	<0,001
G2 (n=60)	86,50 (13,2)	70,4 (16,29)	<0,001
Total (n=120)	83,45 (12.49)	80,7 (13,96)	<0,001

Data, in kilograms, are reported as mean and (standard deviation). G0: Control group; G2: Consultation + Telemedicine; The comparison between the means was performed with the Friedman test (repeated measures)

Table III. Decreased weight, body mass index and waist circumference between final and initial assessment.						
	Weight different (kg) Final-Inicial	p	BMI different (kg/m ²) Final-Inicial	p	WC different (cm) Final-Inicial	p
G0 (n=60)	+1,04 (2,2)	<0,001	+1,2 (0,9)	<0,001	-0,73(0,7)	<0,001
G2 (n=60)	-6,65 (1,9)	<0,001	-2,65 (0,6)	<0,001	-2,78 (5,4)	<0,001
Total (n=120)	-3,845 (2,9)	<0,001	-1,4 (1,0)	<0,001	-2,2(5,3)	<0,001

G0: Control group; G2: doctor's visit + Telemedicine group; kg: kilograms; BMI: Body mass index; Cm: centimeters; Kg / m²: kg divided by height in meters squared. PC: waist circumference. The comparison between the means was done with Student's t-test for paired groups.

When assessing all participants (60 in G1 and 60 in G2) in G2 the initial and final examinations, a decrease in all parameters related to body weight can be observed, While increasing in G1 , except in the Waist- circumference (WC) Which also decreases but to a lesser proportion in which no significant changes were observed (p = 0.317).

Analytical parameters:

Reduction in lipid parameters was detected (Table IV). It is observed that total cholesterol was reduced in both groups. On the other hand Triglycerides were significantly reduced more in the study group, without achieving significant differences in the control group (p = 0.710). HDL cholesterol was increased in both groups.

Table IV. Lipid parameters evolution in a global and by group, both at baseline and at the year of follow-up.									
Groups	Initial TC	Final TC	p	Initial TG	Final TG	p	Initial HDL-c	Final HDL-c	p
Global (n=120)	243,53 (32.45)	235.95 (34.5)	<0.001	161 -58,9	155.3 (53.51)	0.005	52,45 (13.7)	53,98 (12.6)	<0.001
G0 (n=61)	240.5 (35.86)	235.2 (34.6)	0.027	149.43 (51.29)	157.53 (53.3)	0.003	55,07 -12,98	56,2 (12.8)	0.017
G2 (n=60)	246.76 (28.53)	236.72 (32.8)	0.007	172.58 -62,6	153.15 -54,5	0.710	49,83 (12.5)	51,55 (12.4)	<0.001

Data are reported as mean and (standard deviation). TC: Total cholesterol; TG: Triglycerides; HDL-c: high density lipoprotein cholesterol. G1: Intervention group (consultation and use of the digital platform); G2: Control group (habitual tips for losing weight in their primary care centers). The comparison of means was done with Student's t for paired data.

Discussion:

In this study we tested the hypothesis that a technology-enhanced weight loss intervention aimed at reducing body weight by 5% or more was effective at 1 year. The physiological rationale underlying this hypothesis are that obesity is a difficult problem, such that at most, only 10% of people going on a diet manage to keep the weight off in long term

In this study, the addition of telemedicine intervention was most effective in the 12-month weight loss plan.

The results of the group without advice to lose weight show a expected evolution with weight gain. This fact seems striking because studies in our environment ²² show, as in other populations, that the tendency of the adult population is to progressively increase body weight. Investing this trend can be an instrument not sufficiently valued and that can be useful in the management of this authentic pandemic.²³⁻²⁵

While the recommendation to lose weight should be given to all overweight or obese patients ^{3, 25,26} there are many studies that have shown that this is not the case in clinical practice. In the majority of them the proportion of giving

the recommendation of weight loss, is between 20 and 36%^{14,15} although in the study of Phelan et al²⁷ a proportion of 75.5% was reached. This lack of systematic recommendation happens despite the fact that patients receiving this advice from their GPs are twice as likely to achieve weight loss as those who did not receive it^{12,17}. There is no clear consensus²⁸ on the barriers that explain this phenomenon, although perhaps the most invoked have been reasons for economic management, lack of motivation on the part of the patient and the lack of time and training of the professionals themselves²⁹.

As obese individuals experience significantly higher mortality when compared with the non-obese population^{3,4}, this phenomenon has a significant socioeconomic burden, necessitating strategies not only to manage overweight and obesity, but to prevent both of them⁵. Although numerous interventions such as lifestyle modification including exercise⁸⁻¹², caloric restriction, nutritional, coaching and behavioral lifestyle interventions have been shown effective for both the prevention and treatment of obesity, some of these methods were found to have a limitation which required substantial inputs and repeated time-consuming processes³⁰.

Recently, as new technologies is suffering and exponential increase and as the number of Smartphone users is increasing dramatically, many researchers have attempted to implement Smartphone applications, ordinarily called app, for health promotion³¹ in general and for obesity treatment in particular. Many of them have demonstrated efficacy in obtained successful weight reduction³²⁻³⁵. Although these studies are made in short time periods and in small population^{32, 36}. Systematic review and meta-analysis done by Flores et al showed a significant weight reduction by mobile phone app intervention when compared with control groups²⁰. This current meta-analysis suggested that mobile phone app interventions compared with various control interventions significantly reduced body weight by 1.04 kg, reduced BMI by 0.43 kg/m², and nonsignificantly increased physical activity by an SMD of 0.40.

On the other hand our study is similar to published by Allen et al³⁷ which with a less intensive intervention with digital platform achieved a diminishing of 1.1 Kg/m² de BMI. This study randomized 68 obese adults to receive one of four interventions for six months: (1) intensive counseling intervention, (2) intensive counseling plus smartphone intervention, (3) a less intensive counseling plus smartphone intervention, and (4) smartphone intervention only achieved statistical significance differences. Authors concluded that the results of their pilot trial of a weight loss intervention provide preliminary support for using a smartphone application for self-monitoring as an adjunct to behavioral counseling. On the other hand our results are superior to the Carter et al which group followed up by digital platform showed a weight loss at six months of -1.3 kg (95% CI -2.7 to 0.1) with a change of BMI -0.5 kg/m² (95% CI -0.9 to 0.0)³⁸.

However, we are far from achieving the recently published results of the retrospective study of the cohort of users of the Noom Coach app, in which an average weight reduction > of the 5 % was obtained in near of 50 % (46.70%) of population³⁹. In this study a total of 35.921 participants were included, data entered between October 2012 and April 2014, of whom 77.9% reported a decrease in body weight while they were using app and they achieved a weight reduction of BMI changed from 30.2±0.1 to 28.1±0.1 kg/m² for males and 28.0±0.0 to 26.5±0.0 kg/m² for females, with 22.7% of all app users experiencing >10% weight reduction compared with baseline. It should be noted that it is a population with a mean BMI of 30.2 ± 0.1 kg / m² for men (obesity grade I) and 28.0 ± 0.0 kg / m² for women (overweight). While in our study we found no differences in sex, in this cohort weight loss was higher in the male population in relation to greater use of the app. This inferiority of our results would be congruent because the adherence of the app is greater than the one of the digital platform and this to the one made with support paper.

Unlike our study where the anthropometric data are those objectified by the health professional, in this the results are those referred by the users in the app. The study included users of the app participants who had registered at least twice a month for 6 months with an average follow-up of 267 days, it means almost 9 months. Dinner input frequency was the most important factor for successful weight loss (OR = 10.69; 95% CI = 6.20–19.53; p < 0.001), and more frequent input of weight significantly decreased the possibility of experiencing the yo-yo effect (OR = 0.59, 95% CI = 0.39–0.89; p < 0.001). In that way this study demonstrated the clinical utility of an app for successful weight reduction in the majority of the app users; the effects were more significant for individuals who monitored their weight and diet more frequently.

It is important to say that study was not a randomized, controlled trial (RCT) and thus comparisons with a control group not be made as it happens in our study and as we said all date are self-referred.

Our study does not allow us to know how much weight had the control factor of weight registration by health professionals and which had the use of the digital tool. Although the analysis shows that patients starting from a level of adhesion at the beginning of 8.3, improved with their use so that at the end of the study was 9.9. Numerous studies have shown that simple weight monitoring can facilitate weight loss and / or maintenance after loss on the one hand; on the other, we know that a greater adherence to the DM is followed by an optimization of the same. In the SUN study on adherence to the Mediterranean diet and long-term weight change, it was observed that the group with greater adherence to the Mediterranean diet showed a lower risk of weight gain⁴⁰. Thus, the results of both the second and third intervention groups lead us to suggest that we use new technologies to measure DM adherence and then use them to improve adherence levels. Further research will be needed to measure different programs for this purpose, programs that include different monitoring processes, intelligent, adhere to the profile of the user and can include gamification.

With the results of our study, we can observe how with a simple follow-up of both diet and physical activity through a telemedicine portal that can be easily accessed with a Smartphone, not only is it possible to stop gaining weight (+ 1,5 kg), but reduce it (-6.6 kg), thus preventing the serious consequences of obesity in the very near future.

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