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Trabajo Original

Obesidad y síndrome metabólico

Development and validation of prognostic models to estimate body weight loss in overweight and obese people

Desarrollo y validación de modelos de pronóstico para estimar la pérdida de peso corporal en personas con sobrepeso y obesidad

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Abstract

Background: predicting weight loss outcomes from information collected from subjects before they start a weight management program is an objective strongly pursued by scientists who study energy balance.

Objective: to develop and validate two prognostic models for the estimation of final body weight after a six-month intervention period.

Material and methods: the present work was developed following the TRIPOD standard to report prognostic multivariable prediction models. A multivariable linear regression analysis was applied to 70 % of participants to identify the most relevant variables and develop the best prognostic model for body weight estimation. Then, 30 % of the remaining sample was used to validate the model. The study involved a 6-month intervention based on 25-30 % caloric restriction and exercise. A total of 239 volunteers who had participated in the PRONAF study, aged 18 to 50 years, with overweight or obesity (body mass index: 25-34.9 kg/m^2), were enrolled. Body composition was estimated by dual-energy X-ray absorptiometry (DXA) and by hand-to-foot bioelectrical impedance (BIA) analysis.

Results: prognostic models were developed and validated with a high correlation (0.954 and 0.951 for DXA and BIA, respectively), with the paired t-tests showing no significant differences between estimated and measured body weights. The mean difference, standard error, and 95 % confidence interval of the DXA model were 0.067 ± 0.547 (-1.036-1.170), and those of the BIA model were -0.105 ± 0.511 (-1.134-0.924).

Conclusions: the models developed in this work make it possible to calculate the final BW of any participant engaged in an intervention like the one employed in this study based only on baseline body composition variables.

Keywords:

Body composition.
Exercise intervention.
Dietary intervention.
BIA. DXA.

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Conflicts of interest statement: the authors declare no conflicts of interest.

Authors' contributions: all authors (Rojo-Tirado, M.A., Benito, P.J., and Calderón, F.J.) have made substantial contributions to the present study's conception and design, acquisition of data, and analysis and interpretation of data. In addition, all authors have been involved in drafting the manuscript and revising it critically for important intellectual content. Moreover, all authors have given their final approval for the version to be published, and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Resumen

Antecedentes: predecir los resultados de la pérdida de peso a partir de la información recogida de los sujetos antes de que empiecen los programas de control de peso es un objetivo a largo plazo.

Objetivo: desarrollar y validar un modelo de pronóstico para la estimación del peso corporal final después de un período de intervención de seis meses.

Material y métodos: el presente trabajo se desarrolló siguiendo el estándar TRIPOD para reportar modelos pronósticos de predicción multivariable. El análisis de regresión lineal multivariable se aplicó al 70 % de los participantes para identificar las variables más relevantes y desarrollar el mejor modelo pronóstico para la estimación del peso corporal. Luego, el 30 % restante se utilizó para validar el modelo. Se realizó una intervención de 6 meses basada en la restricción calórica y el ejercicio. Los participantes fueron 239 voluntarios que habían participado en el estudio PRONAF, de 18 a 50 años de edad y con sobrepeso u obesidad (índice de masa corporal: 25-34,9 kg/m^2). La composición corporal se evaluó mediante la absorción de rayos X de energía dual y el análisis de la impedancia bioeléctrica de mano a pie.

Resultados: los modelos desarrollados se calibraron y validaron con una alta correlación (más de 0,94), no mostrando las pruebas t emparejadas diferencias significativas entre los pesos corporales estimados y los medidos.

Conclusiones: los modelos desarrollados en este trabajo permiten calcular el peso corporal final de cualquier participante que participe en una intervención como las empleadas en este estudio, conociendo únicamente sus variables de composición corporal iniciales.

Palabras clave:

Composición corporal. Intervención de ejercicio. Intervención dietética. BIA. DXA.

INTRODUCTION

The prevalence of obesity has dramatically increased worldwide among both children and adults in recent years (1,2). Forty to sixty percent of the adult population in the western world is actively attempting to reduce their body weight (BW). Nevertheless, overweight and obesity remain highly predominant sources of health problems, which suggests that many of those attempts are unsuccessful (3). Decreased caloric intake and increased physical activity remain the first line of treatment for most weight management programs (4,5).

The usual course of weight loss therapy shows that weight is lost quickly at first, and the point of greatest loss occurs 6 months after beginning treatment; then weight is slowly regained until weight returns near the original level (6). Predicting weight loss outcomes from information collected from subjects before they start weight management programs is a long-standing goal (7). In the area of human energy metabolism and body weight regulation, several mathematical models of weight change have been proposed over the past few decades (8-11). Such models provide a theoretical prediction of how body weight will change for a given energy intake and physical activity intervention assuming perfect adherence. These models have been validated under highly controlled conditions when adherence to the intervention can be assured. However, under less controlled conditions of people following an outpatient weight loss program, the ability to estimate the loss of body mass (or weight) at the end of the intervention represents an intellectual gap for health professionals. Therefore, intervention studies are needed that demonstrate the magnitude of the error in their estimates, and suggest more accessible strategies to estimate final weight. In previous literature references it was shown that no differences exist between the types of treatment followed as long as a diet is included (12,13), as has been also demonstrated within this sample (14,15). So, for health professionals it would be interesting to predict the weight that their patients will lose just by assessing easy-to-measure simple variables such as body composition variables at the start of the intervention. Therefore, the aim of this research was to explore several body composition variables in order to develop a comprehensive prognostic model for the estimation of final body weight after a particular six-month intervention period.

METHODS

SOURCE OF DATA

The sample population used for this study was drawn from a clinical trial (ClinicalTrials.gov ID: NCT01116856) conducted from January 2010 through June 2011, and followed the ethical guidelines of the Declaration of Helsinki. The Institutional Review Board at La Paz University Hospital (PI-643) reviewed and approved the study design and research protocol. Details concerning the theoretical background, protocol, and intervention of the clinical trial are described elsewhere (16). Furthermore, the present work was developed following the TRIPOD (Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis) standard for reporting prognostic models of multivariate prediction (17).

PARTICIPANTS

The study participants were recruited through several advertisement campaigns covering a wide variety of media (television, radio, press, and the internet). A total of 2,319 potential participants, recruited from the general population, were informed about the nature of the study, and those who were 18 to 50 years old, had a BMI between 25 and 34.9 kg/m^2, were non-smokers, were sedentary (i.e., two hours or less of structured exercise per week) (18), and had glucose levels < 5.6 mmol/L (< 100 mg/dL) were invited to participate in this study. Women with any disturbances in their menstrual cycle were not eligible to participate in the study. Eligible participants who were willing to participate provided their written informed consent prior to joining the study, and then completed a baseline assessment at the involved medical center,

after which they were randomly assigned to the study groups. Randomization was computer-generated (Fig. 1).

Participants underwent a 6-month diet and exercise-based intervention, focusing on behavioral change, in two different waves: one of overweight participants (from January 2010 to June 2010) and one of obese participants (from January 2011 to June 2011). Each wave was split into four randomly assigned groups, stratified by age and sex: strength group (S), endurance group (E), combined strength and endurance group (SE), and control group, which followed the physical activity recommendations. The measurements took place within the first week (pre-intervention values) for all participants at baseline and after 22 weeks of intervention, in week 24 (post-intervention values).

Before the intervention started all participants were instructed to continue their usual daily activities as performed right before the intervention period, and their physical activity was assessed by a SenseWear Pro3 Armband™ accelerometer (Body Media, Pittsburgh, PA, USA) for a full week every month. Participants were instructed to wear the monitor continuously for 5 days, including weekend days and weekdays, following general recommendations (19). Data were recorded at 1-min intervals. Daily energy expenditure was calculated using the Body Media proprietary algorithm (Interview Research Software Version 6.0). In addition, they were required to report the kind, duration, and intensity of any physical activity undertaken, and the amount of any food ingested during the intervention period by means of a personal diary.

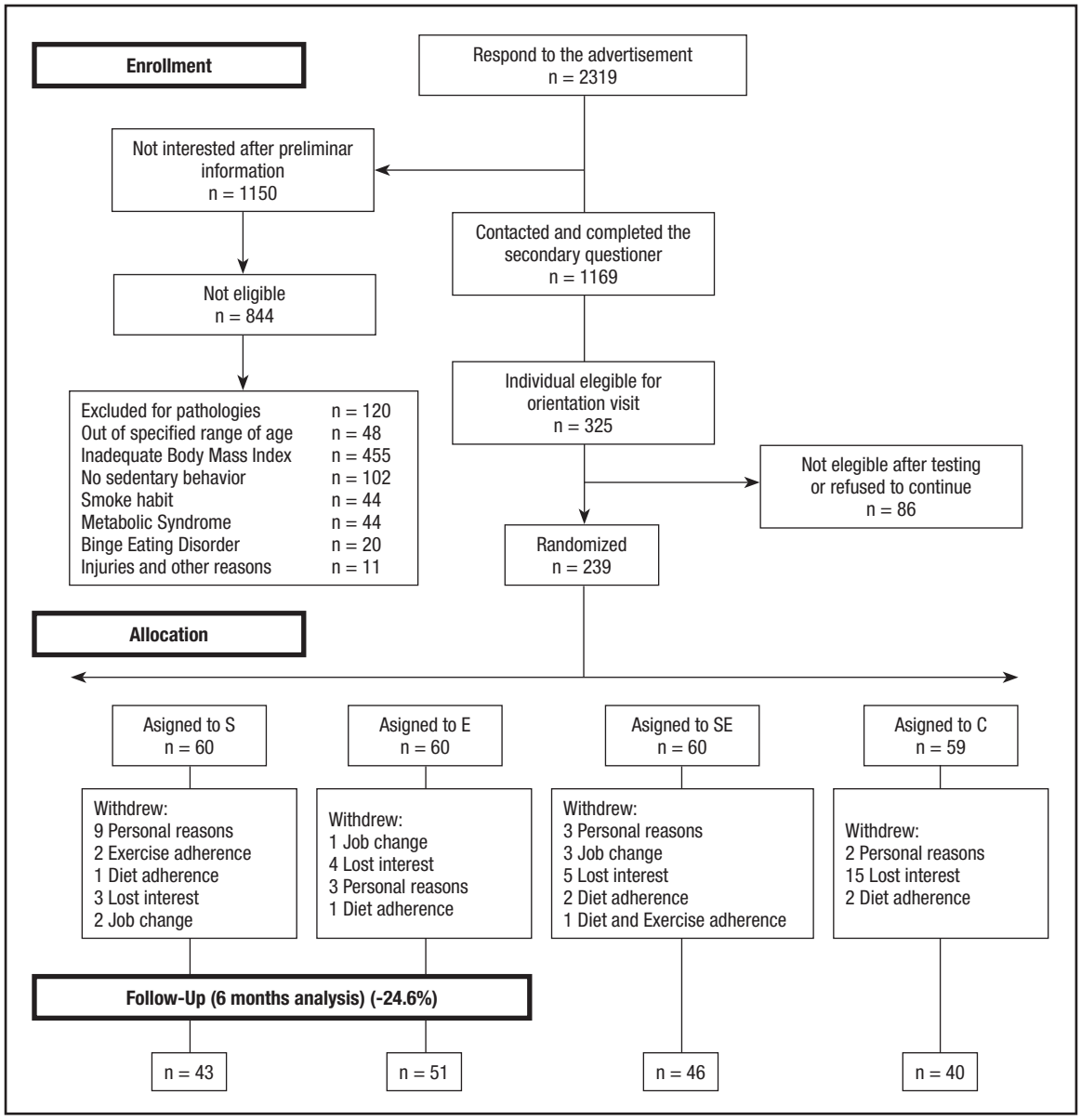

Figure 1.
Participant flow diagram.

At the beginning of the intervention the negative energy balance was calculated considering the daily energy expenditure and a 3-day food record, in order to decrease dietary energy intake by 25-30 % during the intervention. Adherence to the diet was calculated as the estimated kcal content of the diet divided by the actual kcal intake in percentage ([estimated kcal of diet / actual kcal intake] x 100), with 100 % being the highest adherence, following a methodology similar to that of other previous studies (20). Moreover, adherence to exercise was calculated by the number of sessions completed in relation to the theoretical number of sessions ([sessions performed / total sessions] x 100). Attendance of more than 90 % of training sessions, and an adherence to diet over 80 % were required.

DIET INTERVENTION

All participants followed an individualized hypocaloric diet with a 25-30 % caloric restriction (CR) from their own daily energy expenditure (21), which was measured by using the SenseWear Pro Armband™ (Body Media, Pittsburgh, PA, USA), which provides underestimates by a mean value of 8.8 % (22). Then, the macronutrient distribution was carried out according to the recommendatios issued by the *Sociedad Española de Nutrición Comunitaria* (23).

EXERCISE INTERVENTION

All exercise training groups (strength, endurance, and combined) followed an individualized training program, which consisted of exercise sessions three times a week for 22 weeks, carefully supervised by certified personal trainers. Details about the different protocols developed for these groups are described elsewhere (16).

CONTROL GROUP

Participants in the control group followed the dietary intervention and complied with the recommendations about physical activity issued by ACSM (24). Thus, control subjects were advised to undertake at least 200-300 min of moderate-intensity physical activity per week (30-60 min on most, if not all, days of the week).

OUTCOME

Body weight was measured in kilograms with a Tanita scale (TANITA BC-420MA. BioLógica Tecnología Médica SL, Spain) at baseline and just after the intervention period.

PREDICTORS

Body composition (fat mass and fat-free mass) was assessed by dual-energy X-ray absorptiometry (DXA) (GE Lunar Prodigy; GE Healthcare, Madison, WI, USA), and the scan analysis was performed using the GE Encore 2002, version 6.10.029, software to measure total fat mass in kg (FMD) and fat-free mass in kg (FFMD). Moreover, these parameters were also assessed by hand-to-foot bioelectrical impedance analysis (BIA) (OMRON BF 306W Analyzer, OMRON HEALTH-CARE Co., Ltd, Ukyo-ku, Kyoto, Japan), measuring fat mass in kg (FMB) and fat-free mass in kg (FFMB). All these predictors were measured just before and after the intervention period.

SAMPLE SIZE

The initial sample size was determined by the sample size estimation made in the clinical trial where the data for this work were obtained (25). Specifically for this study, the sample that completed the clinical trial (180 participants) was randomly divided into two subsets — with 70 % of the sample (134 participants) the prognostic model was developed, and later validated with the remaining 30 % of the sample (46 participants). In this way, the model was validated with a population that was different from the one it was developed with.

MISSING DATA

Participants who did not complete the intervention (for personal reasons, change of job, loss of interest, etc.), or whose adherence to the diet or exercise program was insufficient, had their information excluded from the analysis (Fig. 1).

STATISTICAL ANALYSIS METHODS

A one-way multivariate analysis of variance for repeated measures (MANOVA) was employed to compare the initial and final body composition variables between the development and validation subsets. Next, we applied a multivariable linear regression analysis to identify the most relevant variables associated with body weight from the development subset (70 % of the participants randomly sampled), to construct the best prognostic model for body weight estimation. These multivariable linear regression models were fitted to predict the final body weight. In each case, the dependent variable (predictor) was final body weight (in kilograms) and the independent variables were sex, initial body weight, height, type of treatment, fat mass, and fat-free mass for both the DXA and BIA models. A backward elimination approach was used to finalize the regression models. If the slope for an independent variable was not found to be significantly different than zero at $\alpha = 0.05$, that independent variable was excluded from the model. In addition, standardized coefficients of each variable and their 95 % confidence intervals were also obtained. To assess the fit of the prognostic model conventional linear regression models were used according to the coefficient of determination (R^2). After the prognostic models were fitted, they were applied to the remaining

30 % of the sample, carrying out a cross-validation and obtaining their predicted body weight measurements. Therefore, the models were validated by comparing the means from the measured and predicted body weight measurements using a paired Student's t-test. Pearson correlation coefficient (r) was used to assess the linear bivariate relationship among predicted and measured BW. In addition, mean differences, standard error of the mean (SEM), and 95 % confidence intervals were determined. Moreover, Bland-Altman plots were drawn to establish the limits of agreement for actual body weight against predicted weight, for both the DXA and BIA models. The data were statistically analyzed using the PASW Statistics software, version 18.0 for Windows (SPSS Inc., Chicago, Illinois, USA). Data was presented as mean ± standard deviation (mean ± SD). For all tests a p-value < 0.05 was considered statistically significant.

RESULTS

PARTICIPANTS

Due to the reasons shown in figure 1 the final sample consisted of 180 participants. The characteristics of the 134 participants in the development subset, and the 46 participants in the validation subset are shown in table I. After the intervention, there were there no significant differences between groups (data not shown). At baseline, both the development and validation subsets had similar characteristics for all the measured variables ($p > 0.05$). After the intervention period, both the development and validation subsets had significant and similar reductions in BW (-8.49 ± 4.40 and -8.53 ± 4.48 kg, respectively, $F_{1,175} = 0.003$; $p = 0.958$), fat mass by DXA (FMD) (-6.83 ± 3.74 and -6.69 ± 3.03 kg, respectively, $F_{1,175} = 0.048$; $p = 0.826$), fat-free mass by DXA (FFMD) (-0.36 ± 1.50 and -0.50 ± 1.18 kg, respectively, $F_{1,175} = 0.294$; $p = 0.589$), fat mass by BIA (FMB) (-7.60 ± 3.80 and -7.71 ± 3.65 kg, respectively, $F_{1,175} = 0.029$; $p = 0.865$), and fat-free mass by BIA (FFMB) (-1.03 ± 1.69 and -0.84 ± 1.85 kg, respectively, $F_{1,175} = 0.391$; $p = 0.532$) (Table I).

MODEL DEVELOPMENT AND VALIDATION

In this study two prognostic models were developed and validated: the first one employing DXA data, and the second one using BIA data. In both cases, the dependent variable was the measured final body weight (in kilograms). The multivariable linear regression analysis revealed that the independent variables for the prognostic models were initial fat mass and fat-free mass in both models (DXA and BIA), thus discarding the rest of the variables introduced (sex, initial body weight, height, and type of treatment). In addition, coefficients of determination (R^2) over 0.9 were achieved for both models. The standardized coefficients from the multiple regressions and their 95 % confidence intervals are shown in table II. In this table, it may be observed that fat-free

Table I. Participant characteristics (n = 180). Values expressed as mean ± SD

	Development subset (n = 134)						Validation subset (n = 46)					
	Initial			Final			Initial			Final		
Age (years)	38.55	±	7.78	38.55	±	7.78	37.09	±	8.51	37.09	±	8.51
Body weight (kg)	88.52	±	13.6	80.03*	±	12.80	86.75	±	12.78	78.22*	±	11.13
Height (m)	1.70	±	0.09	1.70	±	0.09	1.67	±	0.10	1.67	±	0.10
Fat mass, DXA (kg)	34.37	±	6.90	27.55*	±	7.05	34.27	±	7.25	27.57*	±	7.69
Fat-free mass, DXA (kg)	50.15	±	9.66	49.79*	±	9.67	48.42	±	9.32	47.93*	±	9.28
Fat mass, BIA (kg)	31.35	±	7.83	23.75*	±	7.19	31.03	±	7.63	23.32*	±	7.33
Fat-free mass, BIA (kg)	57.50	±	10.86	56.46*	±	10.88	55.46	±	9.76	54.62*	±	9.91

**p < 0.05: significantly different from baseline.*

Table II. Standardized coefficients from the multiple regression models

Variable	Model 1 (DXA)	p-value	Model 2 (BIA)	p-value
Sex	-0.079 (-4.700-0.693)	0.144	-0.028 (-4.456-3.035)	0.708
Initial body weight	0.092 (-0.251-0.425)	0.611	0.134 (-0.308-0.561)	0.565
Height	0.013 (-13.436-16.964)	0.819	0.057 (-7.880-23.637)	0.324
Type of treatment	-0.046 (-1.123-0.070)	0.138	0.003 (-0.620-0.692)	0.914
Fat mass	0.486 (0.793-0.986)*	< 0.001	0.532 (0.787-0.965)*	< 0.001
Fat-free mass	0.741 (0.919-1.060)*	< 0.001	0.776 (0.855-0.984)*	< 0.001

**p < 0.001: significantly included in the models.*

Table III. Mean differences and standard errors between predicted and measured body weights using the paired t-test data

	Mean differences (kg)	Standard error (kg)	95 % confidence interval	Correlation	Paired Student's t-test
Development subset (n = 134)					
Model 1 (DXA)	-0.014	0.332	-0.671 to 0.642	0.954 ($p < 0.001$)	$t_{133} = -0.043$; $p = 0.965$
Model 2 (BIA)	-0.016	0.347	-0.704 to 0.672	0.951 ($p < 0.001$)	$t_{133} = -0.046$; $p = 0.963$
Validation subset (n = 46)					
Model 1 (DXA)	0.067	0.547	-1.036 to 1.170	0.947 ($p < 0.001$)	$T_{45} = 0.122$; $p = 0.903$
Model 2 (BIA)	-0.105	0.511	-1.134 to 0.924	0.954 ($p < 0.001$)	$t_{45} = -0.206$; $p = 0.838$

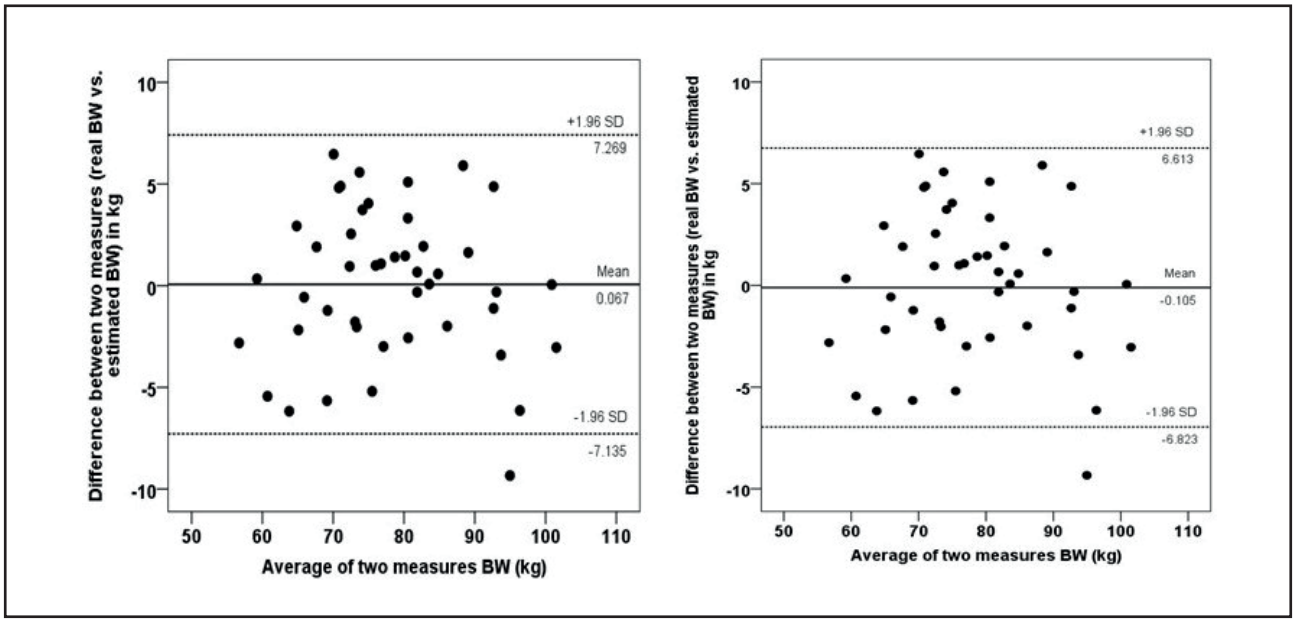

Figure 2.

Bland-Altman plot comparing the real body weight and the predicted body weight. Prognostic model with DXA data (left panel), and prognostic model with BIA data (right panel).

mass has more predictive power than fat mass in both models (0.741 vs. 0.486 for the DXA model; and 0.776 vs. 0.532 for the BIA model). Finally, the developed models were as follows:

- Model 1 (DXA, $R^2 = 0.909$; SEM = 3.87):
  Final BW (kg) = -0.379 + (0.89 x FMD) + (0.99 x FFMD)
- Model 2 (BIA, $R^2 = 0.903$; SEM = 4.01):
  Final BW (kg) = -0.344 + (0.876 x FMB) + (0.92 x FFMB)

Then, these models were validated by applying them to the remaining thirty per cent of the sample. Table III shows the mean differences between the values predicted by the models and the actual, measured weights with their standard errors and 95 % confidence intervals both in development and validation subsets. Furthermore, it may be observed that the prognostic models were developed and validated with a high correlation (over 0.95), with the paired t-tests not showing any significant differences between the predicted and measured body weights. Additionally, in the validation subset, the mean difference, standard error, and 95 % confidence interval of the DXA model were 0.067 ± 0.547 [-1.036-1.170], and those of the BIA model were -0.105 ± 0.511 [-1.134-0.924]. On the one hand, model 1 (DXA data) overestimated the change occurred in BW, which resulted in the mean predicted BW being lower than the measured one. On the other hand, model 2 (BIA) underestimated change in BW. The Bland-Altman agreement analysis for actual body weight as predicted by the two prognostic models is shown in figure 2. Finally, the standard error of the mean for the DXA model was 3.07 ± 2.21 kg, and for the BIA model was 3.19 ± 2.12 kg.

DISCUSSION

In this study we used data from a behavioral intervention program to develop prognostic models aimed at estimating final body weight after a six-month intervention, using as methodology baseline body

composition variables. Four different types of treatment were compared in this study, and this variable did not influence the analysis. Moreover, although several variables were added in the process of developing the prognostic models, only the body composition variables fat mass and fat-free mass were shown to have predictive power (Table II). The R^2 obtained in our study using the prognostic models in the validation subset were over 0.9, showing very small differences between actual and predicted BW means. The DXA model had an error of 0.82 % regarding total loss of BW, and the BIA model one of 1.29 % (Table III). These models could help health professionals estimate the loss of body mass (or weight) obtained at the end of this program, and propose more realistic strategies for their intervention, since weight loss is the primary concern of people who follow this program. With the baseline data of the participants and an intervention proposal similar to this one, similar results to those obtained in this study could be achieved, since the variables that most affect this result are the baseline body composition values and the energy balance during the intervention.

In this study we have reported values obtained using the DXA and BIA methods for assessing body composition. The most accurate method for assessing body composition is DXA (26-28). However, it is not as commonly accessible as the bioelectrical impedance method (which also has a lower cost). For this reason, both methods have been employed for the analyses. Since DXA is the most accurate method for assessing body composition, the prediction obtained based on DXA data should have been more accurate than that obtained with BIA. However, this was not the case since we could predict BW loss similarly with both methods.

We used multiple regressions to compare body composition variables in order to predict the final BW. According to the prognostic models developed, baselinel FM and FFM are the more predictive variables to estimate final BW in a weight loss program, whereas the variables sex, initial body weight, height, and type of treatment were excluded from the models (Table II). As Müller et al. reported, weight loss was associated with changes in the two major body components (FM and FFM) (5). Therefore, knowledge of the baseline FM and FFM measures would let us predict the final BW of any participant. This result was likely due to the fact that FM and FFM are the primary determinants of energy expenditure (29), and therefore the same intervention including diet and physical activity will result in a greater energy deficit in those with a higher FM and FFM, resulting in greater predicted weight loss.

In this study, it is noteworthy that final weight can be predicted based on only two variables of baseline body composition such as fat mass and fat-free mass. These models can predict final weight with a low standard error (0.55 kg), and a high correlation with actual weight (> 0.94).

The aim of weight loss is loss of FM, but inevitably a proportion of weight loss involves FFM (30,31). Loss of FFM may be undesirable if excessive, as non-adipose tissues are responsible for the majority of resting metabolic rate (RMR), regulation of core temperature, preservation of skeletal integrity, and maintenance of function and quality of life as the body ages (32,33). The fact of having a great amount of it could contribute to achieve a higher BW loss due to an increase in energy expenditure, with an increased RMR and a greater energy cost of physical activity (34-36). We suggest that any weight loss program should include exercise, especially strength training — because it maintains the FFM, contributing to the body's overall energy expenditure rate (29) —, has greater cardiometabolic health benefits (37), and prevents body weight regain (38,39). Redman showed that total daily energy expenditure was lower during weight loss with 25 % caloric restriction, and tended to be lower at weight loss maintenance (13). Brochu and Hunter showed this decreased RMR in a 6-month intervention (18,40). However, the strength trainers' group in Hunter's study did not have their RMR reduced, which led to maintenance of RMR following a return to energy balance, as this group trained at 65-80 % of the 1RM, an intensity higher than ours. This means that exercise intensity should be high in any weight loss program based on calorie restriction to maintain both the FFM and RMR.

Summarizing, the ability to estimate the loss of body weight at the end of a weight loss program represents an intellectual gap for health professionals. However, the prognostic models developed in this work make it possible to calculate the final BW of any participant engaged in an intervention using the PRONAF project methodology by only knowing their baseline body composition variables.

The use of these prognostic models could have advantages in the field of medicine and health because it would allow the prediction of the final body weight that a person could achieve at the end of his or her weight loss intervention, with non-invasive methods, in a rapid manner, and right there in the doctor's office. In addition, knowing the weight a patient could reach at the end of an intervention like that involved in the present study, a more restrictive intervention could be considered if the desired weight loss were greater. All of this could also contribute to evaluate the process at any time point throughout the intervention, allowing the health provider to redirect the intervention should body weight deviate from the established target. Further studies are needed to evaluate whether these models can be applied to other types of interventions. Moreover, it would be interesting to develop models to predict changes in the different components of body composition, beyond body weight.

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