

ORIGINAL RESEARCH

Inpatient Obesity Intervention With Postdischarge Telephone Follow-up: A Randomized Trial

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BACKGROUND: Obesity-related comorbidities frequently contribute to acute illness. Obesity interventions during hospitalization are not often utilized but may be effective.

OBJECTIVE: To examine whether inpatient weight loss intervention with postdischarge follow-up results in weight loss at 6 months when compared to control.

DESIGN: Prospective, randomized controlled trial.

SETTING: Academic medical center in Chicago, Illinois.

PATIENTS: Obese adult inpatients.

INTERVENTION: Intervention subjects viewed a weight education video, underwent personalized counseling, and set specific weight loss, dietary, and fitness goals prior to discharge. All participants were followed by phone over the subsequent 6 months. The trial was unblinded to participants, physicians, and investigators.

MEASUREMENTS: Primary outcome was weight change between groups at 6 months. Weight change from baseline and waist-to-hip ratios (WHR) were also assessed.

RESULTS: For 176 participants in the intention-to-treat analysis, mean baseline weight for the intervention group was 107.7 kg (standard deviation [SD] = 16.7) and 105.1 kg (SD = 17.4) for controls. Mean weight loss at 6 months was 1.08 kg (SD = 4.33) for intervention subjects and 1.35 kg (SD = 3.65) among controls. There was no significant difference in weight loss between groups at 6 months ($P = 0.26$). As-treated analysis yielded similar results. There were no differences in WHRs between the intervention and control at 6 months (0.04 vs 0.04, $P = 0.59$).

CONCLUSIONS: We found no difference in weight loss between the intervention and control groups at 6 months. *Journal of Hospital Medicine* 2014;9:515–520. © 2014 Society of Hospital Medicine

Obesity-related medical care remains a substantial driver in escalating healthcare costs. Not surprisingly, healthcare costs for obese patients are 40% higher annually than those for normal-weight individuals.¹ In 2002, the morbidity attributable to obesity was calculated to equal, if not exceed, that associated with smoking.² Though inpatient outcomes appear similar for obese individuals, nearly all obesity-related comorbidities can lead to hospitalization, and obesity has been linked to early mortality.^{3–5} As obesity-related costs continue to grow, so does the need to intervene in this at-risk patient population.^{3–5} Though significant efforts have focused on obesity interventions in the outpatient setting, a paucity of data exists on how best to address obesity during inpatient hospitalization.

Hospitalization itself has often been described as a “teachable moment,” a time during which a life event leads to increased receptivity to behavior change.^{6–8}

The positive effects of inpatient smoking cessation efforts are well recognized. Such initiatives typically include an inpatient counseling session, followed by supportive contact postdischarge.^{9,10} Features common to successful outpatient weight loss interventions include ongoing patient contact of variable duration, frequent self-weighing, diet modifications, and increased activity.^{11–15} To date, little is known about the effectiveness of such programs in the inpatient setting, though research has shown that obese inpatients are receptive to weight loss initiatives.¹⁶ Accomplishing even modest weight reductions in such patients has the potential to lead to significant health and cost benefits.^{1,17–19}

In this study we sought to determine whether inpatient weight loss counseling with post discharge phone follow-up would result in significant weight loss at 6 months when compared to controls. Secondary end points included weight change from baseline and changes in waist-to-hip ratios (WHRs). To our knowledge, this is the first randomized trial designed to evaluate the effect of an inpatient obesity intervention with postdischarge follow-up in a general medicine population.

METHODS

Setting/Participants

We conducted a prospective, randomized controlled trial from January 2011 to May 2012 at a single,

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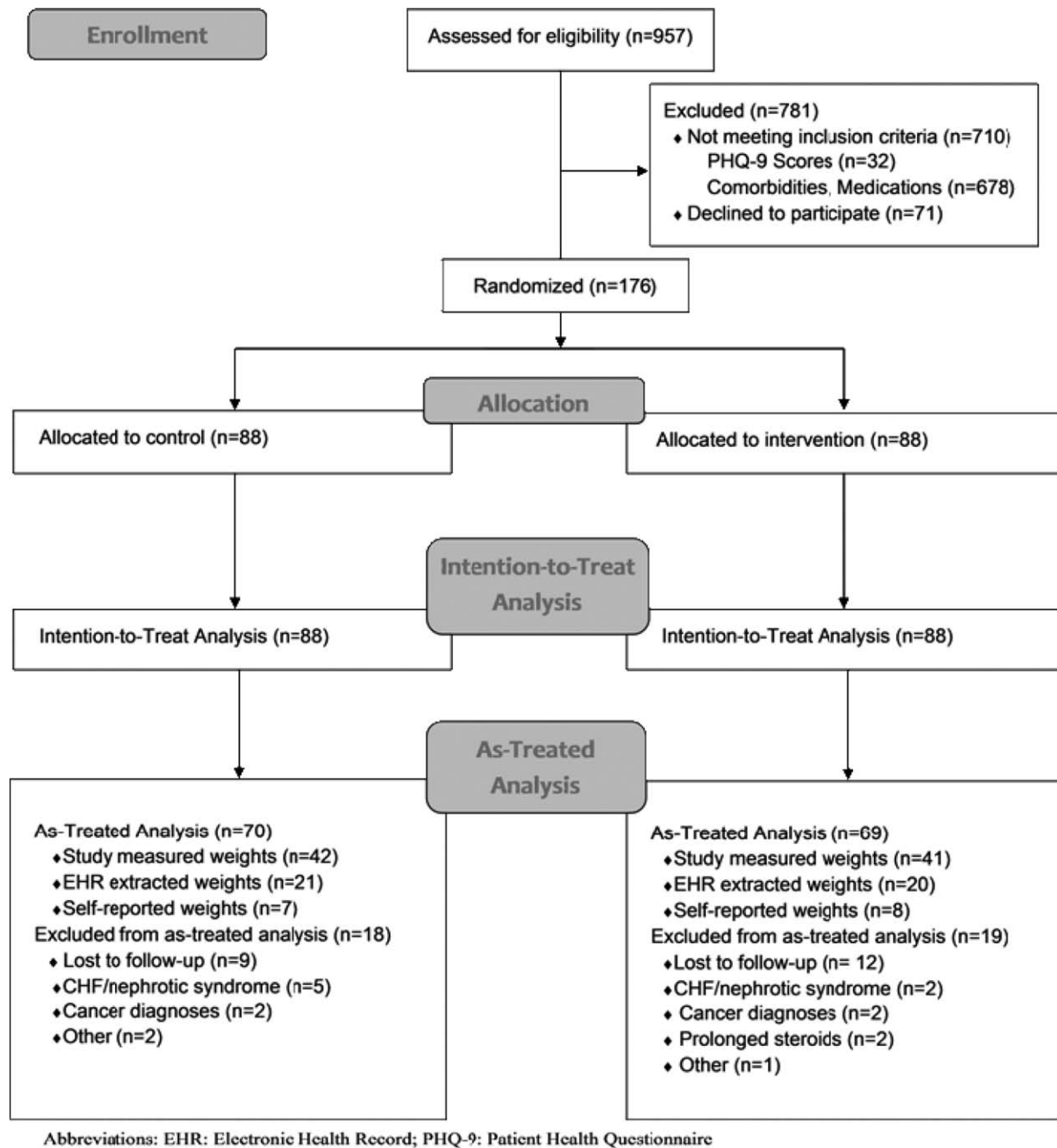


FIG. 1. Flow diagram of study participants throughout the study from enrollment to randomization to final analysis. Abbreviations: CHF, congestive heart failure.

large (854-bed), academic medical center in Chicago, Illinois. Eligible subjects were those with a body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) between 30 and 50 kg/m², ages 18 to 65 years old, admitted to an internal medicine service. Exclusion criteria included the presence of acute medical conditions known to affect weight, Charlson comorbidity index >3, moderate to severe major depression, prolonged steroid use (>2 weeks), initiation of medications known to affect weight (eg, diuretics), non-English speaking, and pre-contemplation stage of change. Upon enrollment, sub-

jects were randomly assigned to either the control or intervention group. A computer-generated block randomization scheme was used to generate group assignments. Study research assistants sequentially assigned enrolled patients according to the computer-generated randomization scheme. Group assignment was only revealed to each study participant after enrollment was complete. Figure 1 summarizes subject recruitment, randomization, and follow-up. Informed written consent was obtained from all participants. Study participants, physicians, and investigators were unblinded. Study subjects were informed that they

were participating in an obesity study as outlined on the study consent form. Study protocols and procedures were approved by the institutional review board at Northwestern University.

Interventions

After enrollment, all subjects had body weight measured on a calibrated study scale in light clothing or hospital gown without shoes. Waist circumference (narrowest circumference between the ribs and iliac crest) and hip circumference (maximum circumference of the hips) were measured to the nearest 0.1 cm. Measurements were taken in triplicate and averaged. WHR was calculated as waist circumference divided by hip circumference. All participants completed a demographic questionnaire and rated their level of agreement with 6 statements relating to weight perceptions and weight loss using a Likert scale from 1 (strongly disagree) to 10 (strongly agree).

Participants in the control group were not provided with any specific instructions regarding weight loss, diet, or exercise prior to discharge. Intervention group subjects were asked to view a 13-minute weight loss education video (addressed specific caloric intake goals for weight loss, portion sizes), undergo a 25-minute personalized counseling session with a certified health educator or study physician, and to set 3 specific lifestyle goals prior to discharge (weight loss, dietary, and fitness). A personal weight loss goal of 10% baseline body weight was set for intervention subjects based on obesity treatment guidelines suggesting subjects could safely lose 1 to 2 lb per week over the course of the study.²⁰ Clinically significant weight loss was defined as weight loss of 5% or more from baseline body weight based on literature illustrating health benefits with this amount of weight loss.¹⁷⁻¹⁹

All study subjects received a phone call schedule and weight-tracking sheet prior to discharge, with calls scheduled at weeks 1, 2, 3, 4, 8, 12, 16, 20, and 24. Phone calls for both groups were used to obtain weight and identify changes in medications or health condition and were conducted by a certified health educator or study physician. No problem solving, motivational support, or other specific instruction was provided to the control group, whereas phone calls for intervention subjects utilized motivational interviewing and problem-solving techniques.

Study subjects were asked to return for an in-person follow-up visit at 6 months. Weight was reassessed with subjects in light clothing and without shoes on the same calibrated study scale by a certified health educator. Follow-up WHRs were also collected.

Outcomes

The primary outcome of the study was the difference in mean weight change (change in kilograms from baseline) between control and intervention groups at 6 months. Secondary outcome measures included

intragroup weight change from baseline and changes in WHR.

Measured weights were obtained for subjects who returned for 6-month follow-up. For those unable or unwilling to return at 6 months, measured weights were obtained from the electronic health record (EHR) and self-reported weights requested for use in imputed weight calculations. Imputation weights for missing weight values were prioritized as follows: (1) in-person 6-month follow-up weight used if available, (2) inpatient or outpatient EHR obtained weight used if in-person weight unavailable, and (3) if neither an in-person or EHR weight was available, a self-reported weight was used.²¹ For intention-to-treat analysis, baseline weight was carried forward for subjects lacking follow-up data after enrollment, historically considered a conservative strategy in weight loss trials.^{22,23}

Statistical Analysis

Baseline patient characteristics were compared using χ^2 tests for categorical variables and 2-sample *t* tests for continuous variables. The primary study outcome of weight change over time for each group was assessed for all study participants using an intention-to-treat analysis. Separate as-treated analyses were also performed utilizing imputed weights for those who failed to follow-up at 6 months and for study completers who had a measured study weight documented at 6 months.

Three analyzable datasets were computed: intention-to-treat (using all participants randomized to the study), as-treated analysis with imputed weights, and as treated analysis with measured 6-month study weights only. Intent-to-treat analysis provides the unbiased comparisons among the treatment groups. To avoid dilution of treatment effect, as-treated analyses with imputed weights (including measured weights at 6-month follow-up obtained from other sources [eg, clinic visit]) and with measured study weights (completers only) were performed.

Weight change over time was analyzed with a longitudinal covariance pattern model, using an unstructured variance-covariance matrix. Specifically, weight was modeled at all time points (baseline and weeks 1, 2, 3, 4, 8, 12, 16, 20, and 24) using a priori contrasts and treating baseline as the reference cell to assess weight change, relative to baseline, at the 4 postbaseline time points.²⁴ Group effects on these a priori time contrasts were included to test for weight change differences between groups, and we specifically tested whether the group effect on weight change was equal or varied across the postbaseline time points.

We aimed to obtain a sample size of 176 subjects (88 in each group) in order to achieve 80% power to detect a 5-kg weight loss in the intervention group after 6 months (at most standard deviation [SD] = 15) and a 5-kg difference in weight loss between groups

TABLE 1. Baseline Characteristics of Study Participants

	Intervention, N = 88	Control, N = 88
Age, y, mean (SD)	48.9 (10.5)	48.7 (10.3)
Female, %	67.1	62.5
Race/ethnicity, %		
African American	50.0	41.4
Caucasian	36.4	46.5
Other	13.6	11.6
Education level, %		
High school	11.4	11.5
College	68.2	64.4
Graduate level	20.5	24.1
Annual income, %		
<\$50,000	43.0	45.2
\$50,000–\$100,000	45.4	33.3
>\$100,000	11.6	21.4
BMI, mean (SD), kg/m ²	38.0 (5.1)	37.5 (4.9)
BMI category, %		
30–34.9	34.1	34.1
35–39.9	28.4	37.5
≥40	37.5	28.4
Waist-hip ratio, mean (SD)*	0.95 (0.08)	0.96 (0.08)
Length of stay, d, median (interquartile range)	2.0 (1.1–3.0)	2.2 (1.3–3.3)
Diabetes, %	27.3	25.0
Admit diagnosis, %		
Cardiovascular	34.1	25.0
Gastrointestinal	15.9	18.2
Pulmonary	10.2	5.7
Infectious	11.4	13.6
Endocrine	3.4	2.3
Other	25.0	35.2

NOTE: No statistically significant differences between groups were found. Abbreviations: BMI, body mass index; SD, standard deviation.

*Waist-hip ratio was not available for 1 participant in the control group.

(SD = 10), assuming an α of 0.05 using 2-tailed testing and an attrition rate of 20%.

RESULTS

Over a period of 18 months we were able to recruit 176 subjects. We found no significant differences in baseline characteristics between groups (Table 1). Sixteen subjects developed exclusionary conditions after enrollment and were subsequently excluded from as-treated data analyses. Follow-up weight data for as-treated analysis were available for 139 study subjects through the use of in-person (n = 83), EHR (n = 41), and self-reported (n = 15) weights.

Change in Weight Loss and WHR

For the 176 participants included in the intent-to-treat analysis, mean weight loss for the intervention group and control groups was 1.08 kg (SD = 4.33) and 1.35 kg (SD = 3.64) at 6 months, respectively. We found no significant difference in weight loss between groups at 6 months ($P = 0.26$), though there was statistically significant weight loss from baseline noted in both groups ($P = 0.02$ and $P = 0.0008$, respectively) (Table 2).

Of 139 participants in the as-treated analysis utilizing imputed weights, weight loss for the intervention

TABLE 2. Mean Values for Baseline Weight, 6-Month Follow-up Weight, and Weight Change at 6 Months From Baseline

Characteristic	Intervention Group	Control Group	P Value*
Intent-to-treat analysis (all participants), kg (SD)			
No.	88	88	
Baseline	107.7 (16.7)	105.1 (17.4)	0.23
6-month follow-up	106.6 (16.1)	103.8 (17.1)	0.16
Weight change	−1.08 (4.33)	−1.35 (3.64)	0.26
As treated analysis with imputed weights, kg (SD)			
No.	69	70	
Baseline	108.9 (16.7)	104.0 (16.2)	0.08
6-month follow-up	106.1 (17.2)	102.4 (15.9)	0.18
Weight change	−2.88 (5.77)	−1.69 (5.09)	0.12
As treated analysis with measured 6-month weights (completers), kg (SD)			
No.	41	42	
Baseline	109.8 (16.2)	107.0 (18.0)	0.47
6-month follow-up	107.4 (15.0)	104.2 (17.7)	0.37
Weight change	−2.32 (6.16)	−2.83 (4.88)	0.68

NOTE: Abbreviations: SD, standard deviation.

*Compared intervention and control groups.

group and control groups was 2.88 kg (SD = 5.77) and 1.69 kg (SD = 5.09). There was statistically significant weight loss at the 6-month follow-up from baseline in both groups ($P = 0.006$, $P = 0.004$, respectively). However, there were neither statistically nor clinically significant differences between the 2 groups (1.19 kg, $P = 0.12$). Finally, for the 83 completers in the as-treated analysis with measured study weights only, weight loss for the intervention group and control group was 2.32 kg (SD = 6.16) and 2.83 kg (SD = 4.88), respectively. Though we again noted statistically significant weight loss at the 6-month follow-up from baseline in both groups ($P = 0.02$, $P = 0.0005$, respectively), we found neither statistically nor clinically significant differences in weight loss between the 2 groups (0.51 kg, $P = 0.68$). Figure 2 illustrates weight change over time for the intervention and control subjects who returned for in-person follow-up at 6 months.

For WHRs, we found no difference in WHR change between groups at 6 months (0.04 vs 0.04, $P = 0.59$). However, among those who completed the study, there was a statistically significant decrease in WHR from baseline within both groups, decreasing 0.04 ± 0.06 ($P = 0.006$) in the intervention group and 0.04 ± 0.04 ($P < 0.001$) among controls.

Weight Perceptions

Only 34% of participants accurately perceived their weight and correctly identified themselves as either obese or morbidly obese. Nearly half of the study participants (47%) classified themselves as overweight rather than obese, though all met criteria for obesity. We found weight perception was most accurate among Caucasians (48%) and least accurate among

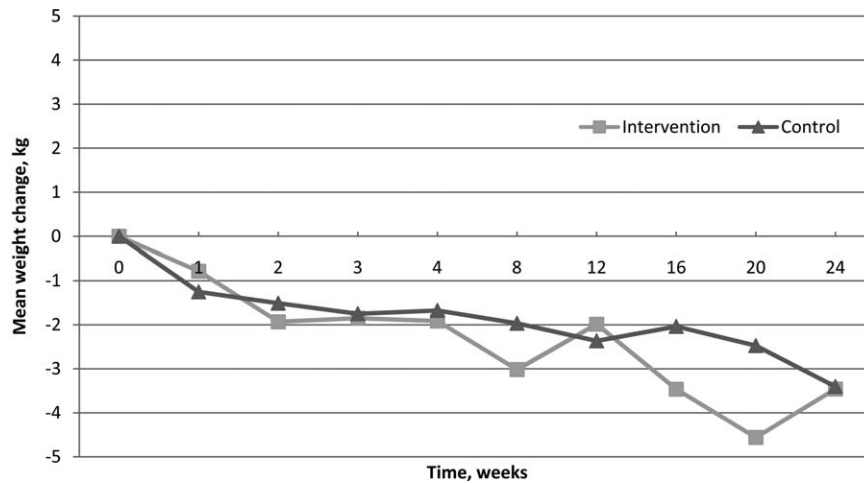


FIG. 2. Weight loss over time for intervention and control group participants with in-person follow-up weights at 6 months (ie, study completers). Participants assigned to the intervention group lost a mean of 0.83 kg more than participants in the control group at each postbaseline time point (95% confidence interval [CI]: -0.75 to 1.8 kg). In terms of the specific time points, weight loss was 1.66 kg greater for the intervention group than the control group (95% CI: 0.31 to 3.0 kg) at 16 weeks and 2.53 kg greater at 20 weeks (95% CI: 1.21 to 3.86 kg). Weight loss between the groups at other time points was not statistically significant.

African Americans (24%) and morbidly obese individuals (26%). Nearly all subjects felt weight loss was important (99%), and most assumed weight had contributed to their hospitalization (64%).

DISCUSSION

We hypothesized that intervention group subjects would lose more weight than those assigned to control given that they received weight loss interventions previously shown to be effective.^{13,25–27} However, intention-to-treat analysis showed no difference in weight loss between intervention and control subjects at 6 months. Interestingly, as-treated analyses did suggest that subjects in both study arms lost a modest amount of weight over the duration of the study. Though modest weight reductions have been shown to give rise to health benefits, neither group met our prespecified goal for clinically significant weight loss (5% of baseline body weight).^{18,19} There were also no differences in WHRs noted between the intervention and control groups. The modest reductions in WHRs from baseline in both groups are of uncertain clinical significance but of interest given the well-established graded relationship between WHR and risk of cardiovascular disease.^{28–31}

Though the control group subjects received no specific instruction regarding weight loss, we suspect that the influences of study enrollment, discussion of obesity while an inpatient, regular phone contacts, and weight tracking may have been sufficient to affect weight behaviors. Certainly, this exceeds “usual care” for hospitalized patients suffering from obesity. Though it is possible that all of obese patients lose weight over the 6-month period following hospitalization, we feel this is unlikely. The exclusion of subjects with an elevated Charlson comorbidity index lessened the likelihood of weight loss due to chronic disease, and without intervention, obese individuals tend to

gain rather than lose weight over time.³² Nonetheless, the lack of significant weight loss between groups suggests that the specific weight loss instruction provided to the intervention group did not promote more weight loss than the general education and regular phone calls provided to controls.

Our findings related to weight perception were similar to those established in prior studies. Individuals frequently misperceive their weight and weight perceptions are least accurate among severely obese individuals and nonwhites.^{16,33,34} Contrary to prior studies, we found that the majority of participants felt their weight negatively impacted their health, and most thought their hospitalization was weight-related.³⁵ Interestingly, research suggests that weight-related perception of health risk correlates with the likelihood of making a weight loss attempt, another factor that may have influenced the behavior of study participants.³⁵

This study has several limitations. It was conducted and based on practices at a single institution, thus limiting generalizability. Additionally, the percentage of subjects who returned for 6-month follow-up was lower than desired at 50%. However, high attrition rates commonly plague obesity trials, and we are unaware of any existing studies documenting expected attrition rates among obese inpatients.^{23,36–38} To help address this, we used imputed weights in our as-treated analysis to obtain follow-up weight values on 79% of subjects. Further, the intentional exclusion of subjects in the precontemplation stage of change likely resulted in selection of a more motivated patient population. However, this was done assuming that most inpatient obesity interventions would primarily target patients interested in losing weight. Finally, the lack of a “usual care” group that more accurately reflects the experience of most hospitalized obese patients—no regular postdischarge interactions—does limit

interpretation of the modest weight loss noted in both study groups.

In conclusion, an inpatient obesity intervention with post-discharge follow-up did not result in intervention subjects losing more weight than controls over a 6-month period. However, the finding of modest weight loss among both groups is of interest and may warrant further investigation. It remains unclear whether this is a naturally occurring phenomenon or whether other factors influence behavior change in this patient population. Additional studies will be needed to clarify the impact of hospitalization, obesity recognition, perception of health risk, weight tracking, and follow-up on weight behaviors. Given the proven benefits of even modest weight reductions, encouraging any amount of weight loss in these at-risk individuals would appear to be a step in the right direction. We have yet to determine whether inpatient obesity interventions represent a lost opportunity.

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