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Equivalent weight loss for weight management programs delivered by phone and clinic

Joseph E. Donnelly^{a,*}, Jeannine Goetz^b, Cheryl Gibson^c, Debra K. Sullivan^c, Robert Lee^d, Bryan K. Smith^e, Kate Lambourne^a, Matthew S. Mayo^f, Suzanne Hunt^f, Jae Hoon Lee^g, Jeffrey J. Honas^a, and Richard A. Washburn^a

^aCardiovascular Research Institute, Division of Internal Medicine, The University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS, 66160 USA

^bDepartment of Dietetics and Nutrition, The University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS, 66160 USA

^cDepartment of Internal Medicine, The University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS, 66160 USA

^dDepartment of Health Policy and Management, The University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS, 66160 USA

^eDepartment of Kinesiology and Health Education, Southern Illinois University Edwardsville, Vadalabene Center, Box 1126, Edwardsville, IL, 62026 USA

^fDepartment of Biostatistics, The University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS, 66160 USA

^gCenter for Research Methods and Data Analysis, The University of Kansas, 1425 Jayhawk Blvd., Room 470, Lawrence, KS 66045 USA

Abstract

Objective—Face-to-face weight management is costly and presents barriers for individuals seeking treatment; thus, alternate delivery systems are needed. The objective of this study was to compare weight management delivered by face-to-face (FTF) clinic or group conference calls (phone).

Design and Methods—Randomized equivalency trial in 295 overweight/obese men/women (BMI = 35.1±4.9, Age = 43.8±10.2, Minority = 39.8%). Weight loss (0–6 months) was achieved by reducing energy intake between 1,200–1,500 kcal/day and progressing physical activity to 300 minutes/week. Weight maintenance (7–18 months) provided adequate energy to maintain weight and continued 300 minutes/week of physical activity. Behavioral weight management strategies were delivered weekly for 6 months and gradually reduced during months 7–18. A cost analysis provided a comparison of expenses between groups.

*Corresponding Author: Joseph E. Donnelly, Robinson Center, Rm. 100, The University of Kansas-Lawrence, 1301 Sunnyside Avenue, Lawrence, KS 66045, Phone: 785-864-0797, Fax: 785-864-2009, (jdonnelly@ku.edu).

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Results—Weight change from baseline to 6 months was $-13.4 \pm 6.7\%$ and $-12.3 \pm 7.0\%$ for FTF clinic and phone, respectively. Weight change from 6 months to 18 months was $6.4 \pm 7.0\%$ and $6.4 \pm 5.2\%$, for FTF clinic and phone, respectively. The cost to FTF participants was \$789.58 more person.

Conclusions—Phone delivery provided equivalent weight loss and maintenance and reduced program cost. Ubiquitous access to phones provides a vast reach for this approach.

Introduction

Overweight and obesity are exhibited by approximately 68.0% of adults in the US¹. Both overweight and obesity are characterized by the accumulation of excessive levels of body fat and contribute to heart disease, hypertension, diabetes, and some cancers as well as psychosocial and economic difficulties^{2,3}. The cost of treatment for weight reduction is estimated to exceed \$148.9 billion annually⁴.

The essential characteristics of weight loss clinics include energy restriction, physical activity, and behavioral strategies to assist with weight loss and maintenance. Traditionally, the state-of-the-art clinic is delivered face-to-face (FTF) in group format^{5,6}. However, numerous barriers and burdens have been cited that diminish an individual's ability to participate and comply with traditional FTF weight management clinics. Cost of travel, lack of transportation, time, child care, and loss of anonymity are frequently cited^{7,8}. Barriers also exist for providers including the cost and availability of meeting space, utilities, inventory, and others. Reduction of barriers may increase the number of individuals who are able to participate in weight management and may likewise increase the number of providers who are able to deliver weight management programs.

To remove barriers for participation for both participant and provider, we conducted an 18-month, adequately powered, randomized, equivalency trial comparing a traditional FTF clinic to a clinic conducted using a group conference call. The primary aim was to determine if weight loss at 6 months was equivalent for participants randomized to FTF clinic or group conference calls. The secondary aim was to determine if participants randomized to FTF clinic or group conference calls had equivalent weight change during weight maintenance from 6 to 18 months. Lastly, a cost analysis of the FTF clinic and group conference calls was conducted.

Methods and Procedures

A comprehensive description of the initial participant population, rationale, design and methods has been previously published⁹. Information herein pertains to the current report.

Participants

This project was completed at The University of Kansas-Lawrence and the University of Kansas Medical Center. Three hundred ninety five individuals were randomized and initiated weight management using either traditional FTF clinics or group conference calls (phone) and were compensated \$300 for their participation in outcomes assessments.

Participants were 18–65 years of age and overweight or obese with a body mass index (BMI; kg/M²) of 25–44.9. To improve the generalizability of the results, individuals with chronic medical conditions who received clearance from their primary care physician were allowed to participate because they represent the population of individuals typically seeking weight management. For instance, individuals with hypertension or type 2 diabetes were not automatically excluded if their condition was controlled by medication. Medical conditions and medication use may be considered potential confounders; however, conditions should be similar across the 2 groups due to randomization. All participants were required to present written permission to participate in a reduced energy diet and physical activity from a physician. Participants were excluded if they were unwilling to be randomized, participated in a research project involving physical activity or weight management in the previous 6 months, reported planned exercise > 500 kcal/week, reported weight change of ± 2.27 kg for 3 months prior to intake, reported pregnancy during the previous 6 months or were lactating or planning a pregnancy during the 18 month study, reported serious medical risk (i.e., type 1 diabetes, cancer, recent cardiac event, etc.), exhibited disordered eating symptomatology determined by the Eating Attitudes Test¹⁰ or extreme weight control behaviors (i.e., binging), were taking psychotropic medications or were in active counseling, used special diets (i.e., Atkins, vegetarian, etc.), or did not have access to shopping and meal preparation (i.e., college students on meal plans, individuals in the military).

Participants were randomized to FTF clinic or phone at a 1:1 ratio by the study statistician (MSM). Participants, investigators, and health educators were not blinded to condition as this was considered impractical for a long-term investigation with an obvious intervention component (i.e., FTF clinic or phone). However, investigators did not have contact with participants and research staff who performed outcomes testing and entered data were not informed of group assignment. All participants gave written informed consent before participating in the investigation. Approval for this investigation was obtained from the Human Subjects Committee at The University of Kansas-Lawrence.

Intervention

The weight management clinics [Weight Control Research Project (WCRP)] were based on Social Cognitive Theory and have been directed by the PI (JED) of the current trial for over 25 years^{11,12}. Behavioral clinic meetings for both groups were conducted weekly during the weight loss phase (month 0 to 6), and then gradually reduced during weight maintenance (months 7–18). Meetings were held twice per month during months 7–9, monthly during months 10–12, and every other month for the remainder of the 18 months. The study was designed to provide equal attention to both FTF clinic and phone groups.

Behavioral Weight Management Clinics – Theoretical framework

WCRP utilizes strategies that are grounded in Social Cognitive Theory (SCT) to promote change in diet and physical activity. SCT is a triadic, dynamic model that indicates that an individual's behavior is uniquely determined by the reciprocal interaction of personal, behavioral, and environmental factors¹³. SCT has been used in a variety of public health interventions and many SCT constructs are applicable to weight management such as self-efficacy, self-regulation skills included planning, self-monitoring, problem-solving, relapse

prevention strategies, and adaptive self-regulation skills specific to overcoming barriers as they arise. Group discussions, in-class activities, and out-of-class assignments were used to facilitate behavior change. For example, to promote the purchase of food items appropriate for weight management, a lesson was devoted to interpretation of the information contained on food labels. Subsequently, participants performed an activity where two food labels were compared and an option was selected, followed by discussion of the appropriateness of the choice. Finally, an out-of-class grocery store activity was assigned, completed, and discussed at the next FTF clinic or phone meeting.

FTF Behavioral Clinic

Sixty minute FTF clinic behavioral meetings of 11–20 participants were conducted in the late afternoon or early evening. Participants arrived 5–10 minutes prior to the start of the meeting to allow time for individual weigh-ins. Meetings followed a standard protocol that consisted of review and discussion of self-report data including physical activity (minutes/steps via step counter) and dietary compliance (number of shakes, entrees, fruits and vegetables; 10 min); a behaviorally-based lesson on a topic related to nutrition, physical activity and lifestyle modification (30 min); and group discussion, problem solving, and assignment of activities to assist participants in developing and practicing behavioral strategies associated with successful weight management (20 min). During the weight loss phase (months 0–6), participants provided compliance records of physical activity and diet by phone, fax, or email midway between weekly meetings. Participants continued submitting weekly reports of physical activity and diet during weight maintenance (months 7–18), as the frequency of meetings was reduced.

Phone Conference Call Behavioral Clinic

The phone clinics followed a format identical to that of the FTF clinic, with slight modifications given the logistics of no FTF contact. To enter the phone conference, participants called a toll-free number approximately 5 min prior to the scheduled meeting time and dialed a unique personal identification number that allowed them to join the conference call. Participants were expected to stay on the conference call for the duration of the clinic session. In the interest of safety, participants were asked not to call in situations where attention was compromised, such as driving a motor vehicle.

Standardized Materials and Training

To assure that similar content was presented in both the FTF clinic and phone groups, all participants received identical notebooks that provided a basic outline for the intervention. The notebooks included detailed instructions for the weight loss and weight maintenance diets including recipes, instructions for physical activity, and scheduling of class meetings and mid-meeting contact. The notebooks also provided general information and guidelines for participation in the program such as confidentiality, how to be recognized without speaking over others, respect for other's opinions, etc.

Health educators held bachelors and masters degrees in nutrition, exercise physiology, behavioral counseling or psychology. All health educators had prior experience with weight management and were trained for 3–4 months in the study protocol. Health educators were

trained to lead phone groups by listening to training tapes and participating in practice sessions that simulated live phone groups. Health educators were trained to keep track of who is talking, how to best share data among the group, how to encourage group rapport through voice communication, and how to keep participants focused and motivated throughout the session. Each health educator was randomly assigned to provide instruction to 1 phone and 1 FTF clinic group to eliminate potential between-group differences due to the health educator. To monitor fidelity, each FTF clinic and phone group meeting was audio taped and initial review for fidelity was completed using a check list of topics covered in the meeting by a health educator who did not conduct the clinic. If greater than 80% of topics were not presented, follow-up with the health educator was conducted by an investigator to determine why material was not presented and if necessary, corrections and suggestions were provided by the investigator to increase presentation of each lesson as intended.

Prepackaged meal (PM) use and distribution

PMs were required during weight loss and were recommended (not required) during weight maintenance. PMs are simply liquid (shakes) or solid meals (entrees) that provide control of portion size and energy content. PMs are conveniently packaged, shelf stable, and easy to prepare. When combined with a variety of fruits, vegetables, and beverages, PMs provide a diet with all necessary nutrients specified by the Dietary Reference Intakes¹⁴. FTF clinic participants filled out order forms for the PMs they requested for the following week. FTF clinic participants picked up their PMs for the current week subsequent to the clinic meeting. If participants were absent, they communicated with the health educator to arrange an alternative time for pick-up. Phone participants ordered PMs during their mid-week check-in, the order was placed by their health educator, and the PMs arrived via ground transportation within 3–4 days.

Weight loss diet for phone and FTF clinic groups (6 months)

Energy intake was reduced to ~1200 to 1500 kcal/day using a combination of commercially available PMs (Health Management Resources, Boston, MA), fruits and vegetables, and beverages. Participants were instructed to consume a minimum daily total of 3 shakes at ~100 kcal each, 2 entrees between 140 and 270 kcal each, and 5, 1-cup servings of fruits or vegetables (no dried fruit or juices). Non-caloric beverages such as diet soda, coffee, etc. were allowed ad libitum. If participants reported hunger during the diet, they were encouraged to consume more fruits and vegetables or PMs. A 10% reduction in weight from baseline to 6 months was targeted as this conforms to the NHLBI guidelines and is known to reduce the risk of chronic diseases such as diabetes, heart disease, hypertension, and others^{15–17}. During weight loss, PMs were provided without cost to the participant; however fruits and vegetables were selected and purchased by the participant.

Weight maintenance diet for FTF clinic and phone groups (7–18 months)

All participants were instructed to consume a weight maintenance diet with an energy level designed to maintain weight loss using the equation of Mifflin et al.¹⁸. Energy levels were adjusted as needed based on an individual's subsequent weight. Participants were given a meal plan with suggested servings of grains, proteins, fruits, vegetables, dairy, and fats,

based on their energy needs and the USDA's 2005 "My Pyramid" (www.mypyramid.gov). During weight maintenance, participants were encouraged (not required) to continue consuming a minimum of 14 PM's per week and a minimum of 35 fruits and vegetables per week. All foods and beverages were purchased by the participants.

Physical activity (PA) for FTF clinic and phone groups

Three hundred minutes/week of moderately vigorous PA was targeted using a progressive protocol. PA progressed from 45 minutes/week (3 sessions, 15 minutes/session) to 300 minutes/week (5 sessions, 60 minutes/session) across the initial 3 months and remained at 300 minutes/week for the remainder of the study.

Routine FTF clinic and phone data reports from group meetings

FTF clinic and phone participants recorded daily the number of PMs, fruits and vegetables consumed, minutes of PA, and number of steps as recorded on step counters (Accusplit Eagle 120XLE) according to their meeting schedule (weekly, biweekly, monthly). Data were submitted via toll-free phone, fax, or email to the health educator twice per week during weight loss (mid-week and day of meeting) and weekly during weight maintenance. If data were not received, the health educator attempted to contact the participant for this information. The phone group provided a self-reported weight and the FTF clinic group weighed on a scale at the clinic site. These weights were used to monitor progress only and were not the weights used for outcome data. Changes in medications and adverse events were reported privately to the health educator at FTF clinic meetings. Participants in the phone group were reminded to place an email or private, toll free call to the health educator if they had changed medications or experienced an adverse event.

Assessments

The following outcome measures were obtained at baseline, 6, and 18 months by trained research assistants who were not informed of group assignment.

Body weight, height, BMI, and waist circumference—Body weight was recorded using a digital scale accurate to ± 0.1 kg (Befour Inc Model #PS6600, Saukville, WI). All participants were weighed between the hours of 6 and 10 am prior to breakfast wearing a standard hospital gown after attempting to void. Height was measured using a stadiometer (Model PE-WM-60–84, Perspective Enterprises, Portage MI) and body mass index (kg/m^2) was calculated. Waist circumference was measured using the procedures of Lohman et al.¹⁹.

Accelerometry—A sub-sample of participants was randomized to accelerometry due to availability of accelerometers. Participants wore an ActiGraph (ActiGraph GT1X, Fort Walton Beach, FL) for 7 consecutive days over the non-dominant hip on a belt provided by the investigators. Each participant received instructions and wore the ActiGraph during the baseline visit. All subsequent issue of ActiGraphs contained written instructions and photos to remind the participant of the proper procedures for wearing the ActiGraph. All issue and return of ActiGraphs subsequent to the initial issue at baseline were via a pre-addressed, padded envelope. The data collection interval was set at one minute with a minimum of 12 hours constituting a valid monitored day. The main outcome variable was the average

ActiGraph counts/minute over the 7-day periods²⁰. A custom SAS data reduction program (RW) was used to complete the analyses of accelerometry.

Diet intake—Three day diet records were obtained to assess energy and macronutrient content of the diet. Participants were instructed to record all dietary intake on 2 weekdays and 1 weekend day. Records were reviewed by a registered dietitian and the participants were contacted to clarify any items if needed. The records were entered into the Nutrient Data System for Research (NDS-R version 2007) for nutrient analysis.

Cost analysis—Resource use was measured surveying participants approximately every six months and health educators were surveyed 1 week per month. There were 741 completed surveys from 323 participants and 432 completed surveys from 15 health educators. The surveys were based on a validated process flowchart^{21,22}. We converted resource use data into costs using standard prices (e.g., the median hourly wage in the area). Complete details for the design of cost analysis have been published⁹.

Statistics and data management

Statistical power—The primary goal of this trial was to evaluate the equivalence of weight loss achieved at 6 months by a FTF behavioral clinic compared to the same clinic delivered by phone. Therefore, an equivalency analysis was conducted for this trial. Equivalence was defined as a difference in weight loss between groups of 4 kg. There are no clear guidelines for defining equivalence of weight loss. The proposed 4 kg represents a difference of approximately 1–2 BMI units for men or women of average height (men = 178cm, women = 167cm), and this difference is associated with risk of chronic disease²³. It was estimated that both the FTF clinic and phone groups would lose an average of ~11 to 13 kg over 6 months with a standard deviation of 7 kg. To be conservative, it was estimated that the FTF clinic group may lose 1.0 kg more on average than the phone group. Under these assumptions, 116 participants in each group provided in 90% power to demonstrate equivalence with an overall type I error rate of 5%.

Analysis plan- Primary outcomes—The primary analysis for equivalence of weight loss at 6 months was a two-sample t-test for equivalence and was conducted as intention-to-treat using multiple imputation to impute missing data. PROC MI in SAS was used to generate 5 imputed data sets by imputing the weight change for those subjects for whom weight change was missing. The equivalence (4 kg) of weight regain from 6 to 18 months for participants with weight data at 6 and 18 months was evaluated in a similar manner; however no imputation was utilized. The significance of within-group weight change from baseline to 18 months was evaluated using a paired t-test for each group independently, for those subjects that completed the 18 month study.

For secondary variables, change in BMI, change in % weight, and change in waist circumference, no a priori hypothesized level of equivalence was stated, therefore we compared these variables between the two groups using a two-sample t-test. We examined the distribution of weight loss based upon categories of change for 0–6 and 0–18 months between the two groups using a chi-square test of homogeneity. Diet compliance (shakes,

PMs, fruit and vegetable intake) over months 0–6 and 7–18 as well as self-reported physical activity and accelerometry data were compared between the two groups using the two sample t-test. Energy and macronutrient intake were compared between the groups at baseline, 6, and 18 months using the two-sample t-test at each time point. Complete details of power, statistics, and data management have been published⁹.

Results

Participants

Three hundred ninety-five individuals were randomized to either FTF clinic or phone groups (Figure 1). Minorities comprised 39.8% and men 33% of participants (Table 1). There were no baseline differences between participants randomized to FTF clinic or phone for age, weight, BMI, waist circumference, energy or macronutrient intake. Eighty-six percent and 84% of participants provided weights at 6 months and 74% and 72% provided weights at 18 months for FTF clinic and phone groups, respectively.

Body weight, height, BMI, and waist circumference

Analysis to determine equivalence between FTF clinic and phone groups indicated the criteria for equivalence was met the primary aim of change in weight from baseline to 6 months (Table 2). Individual tests of equivalence were conducted for all 5 imputed data sets, each individually concluded equivalence, and the summarizing of the imputed results also showed equivalence. Weight change from baseline to 6 months was $-13.4 \pm 6.7\%$ and $-12.3 \pm 7.0\%$ for FTF clinic and phone groups, respectively. Weight change from 7 months to 18 months was equivalent for FTF clinic and phone groups and was $6.4 \pm 7.0\%$ and $6.4 \pm 5.2\%$, respectively. No significant differences between phone and FTF clinic groups were observed for BMI or waist circumference at 6 or 18 months. At 6 and 18 months, participants who gained weight and those who lost 5%, 10% and >15% weight did not differ significantly between FTF clinic and phone groups (Table 3).

Fidelity, intervention compliance and dietary intake

Eighty percent of the meeting topics were presented 93.2% and 93.9% of FTF clinic and phone meetings, respectively. Participant attendance at meetings from baseline to 6 months was 70% and 73% and decreased from 6 to 18 months to 56% and 59% for FTF clinic and phone groups, respectively. Five FTF clinics were cancelled due to weather and 7 phone clinics experienced poor quality of call, although cancellation was not necessary. The number of self-reported consumption of shakes, entrees, fruits, and vegetables are depicted in Table 4. No significant differences were found between FTF clinic and phone groups. Results for diet intake are shown in Table 5. There were no statistically significant differences between FTF clinic and phone groups for total energy, percentages of fat, carbohydrate, protein, and alcohol at baseline, 6 or 18 months.

Physical activity

The average target for minutes of physical activity was 140 minutes/week from baseline to 6 months due to the ramp up of the progressive protocol to 300 minutes/week. Both groups exceeded the average target during weight loss by ~50% but did not achieve the target of

300 minutes/week during weight maintenance. The level of minutes/week of physical activity at the end of weight loss was maintained during weight maintenance and resulted in an average achievement of two thirds of the targeted 300 minutes/week. There were no significant differences between groups for self-reported steps or minutes of physical activity. Results from accelerometry for counts per day indicated no significant differences between groups at 6 and 18 months (Table 6).

Cost analysis

Participant costs per session were significantly higher in the FTF clinic group ($\$44.07 \pm 18.33$) compared to the phone group $\$22.47 \pm 13.69$ (Table 7). Using the sum of these estimates, for a participant attending all meetings (N=37) the total cost per participant would be $\$789.58$ higher in the FTF clinic group at $\$1,985.05$ compared to $\$1195.47$ for the phone group. The greatest differences were costs associated with driving and mileage costs. Health educator costs per participant per session were not significantly different for the two groups ($\$9.58 \pm 6.8$ FTF clinic versus $\$9.84 \pm 7.1$ phone, Table 8). These costs do not include the toll free line ($\$8.40/\text{month}$) and PMs ($\$4.00/\text{day}$) which were the same for both groups.

Discussion

Results from this investigation indicated that weight management clinics delivered by phone provided equivalent results compared to the traditional FTF clinics for weight loss and weight maintenance. Both FTF clinic and phone groups met NHLBI Guidelines²⁴ by reducing weight by more than 10% in 6 months. During weight maintenance, average weight increased but remained 8.5% and 7.4% below baseline weight for FTF clinic and phone groups, respectively. These results confirm the previous formative studies of Donnelly et al. and Befort et al.^{25,26} and compare favorably with the results from other investigations using technology to deliver weight management. For example, Hersey et al.²⁷ examined participants who received weight management through written materials and web access, interactive web programs, and brief telephone/mail coaching support. At 12 months participants lost between 4.0% and 5.3% weight and between 3.5% and 5.1% after 15 to 18 months. Harvey-Berino et al.²⁸ reported a 6 month intervention using InPerson, Internet, or InPerson+Internet delivery strategies. Percent weight loss was 5.8%, 8.3% and 6.4 %, respectively. Appel et al.²⁹ compared weight loss supported remotely using phone, study specific web site, and emails to in-person group and individual support, and a control condition. Weight loss at 6 months was 6.1kg and 5.8kg for remote support and in-person groups, respectively. Weight loss at 24 months was 4.6kg and 5.1kg for remote support and in-person groups, respectively.

Not all interventions that employ technology have found favorable results. A meta-analysis of randomized trials by Reed et al.³⁰ found use of computers to enhance a standard in-person intervention increased weight loss by ~1.5kg; however, interventions that delivered interventions solely through computers lost ~1.5kg less weight compared to standard in-person interventions. Van Wier et al.³¹ provided lifestyle counseling delivered by phone, email, and self-directed materials for 6 months that resulted in a modest weight loss of 2.7kg for phone and 1.8kg for email groups. In similar fashion, Sherwood et al.³² compared 6

months of phone-based weight loss programs with varying levels of treatment contact (10 vs. 20 sessions) to self-directed treatment and found 4.9kg, 3.2kg and 2.3kg weight loss, respectively, and concluded phone-based weight loss program participation was associated with modest weight loss. Modest weight loss was also reported in a study by Jeffery et al.³³ comparing mail and phone approaches to a control condition of usual care. Average weight loss was 2.4kg, 1.9kg, and 1.5kg, respectively. The authors concluded although technologies can reach a great number of people, there was a need to enhance the efficacy of these interventions.

The variation in results for studies using technology to deliver weight management is not solely dependent on the technology itself. Levels of energy restriction, type of diets, and amount of physical activity influence the magnitude of weight loss. The current investigation utilized PMs for reduction of energy, portion size, and percentage of fat and targeted 300 minutes of moderate-to-vigorous physical activity. The use of PMs has consistently been shown to provide greater levels of weight loss compared to conventional diets³⁴ and continued use likely contributes to weight maintenance³⁵. Targeting three hundred minutes of moderate to vigorous PA is congruent with the recommendations of The American College of Sports Medicine for weight loss and maintenance³⁶. Thus, the magnitude of weight loss in the current investigation may be specific to the use of this aggressive strategy and may not reflect other conventional approaches to diet and physical activity.

Attendance and self-reported consumption of PMs, fruit, and vegetables did not differ significantly between groups. Likewise, there were no differences between phone and FTF clinic groups for energy and macronutrient intake. There were no significant differences between groups for self-reported steps or minutes of PA or accelerometry counts/minute. Thus, the participants in the phone group utilized the major intervention components in similar fashion as participants in the FTF clinic group and major components of energy balance (energy intake and daily physical activity) were not significantly different between groups.

During the 6 month weight loss period there was no interruption of the delivery of food products to participants in the phone group. Although the study was designed to provide equal attention to both FTF clinic and phone groups, there were 7 incidents with interruption or poor quality of the group conference calls and 5 FTF clinics were cancelled due to weather. However, there was no evidence that these few incidents affected outcomes. As conference call technology improves, problems associated with quality or interruptions should diminish. However, inclement weather resulted in 5 cancellations of FTF clinic meetings and weather is likely to remain an issue with traditional FTF clinics. Ninety-five percent of individuals living in the US have access to a telephone³⁷ and thus the potential reach of phone-based weight management is vast. Compared to computer-based interventions, the phone is a low technology alternative without problems and cost of computer programming for the intervention, and issues of compatibility, download times, resolution, navigation, etc. The phone may represent the simplest and most cost effective alternative to the traditional FTF clinic.

Cost is frequently cited as a barrier by participants and the reduction of \$789 per participant for attending the phone meetings compared to the FTF clinic meetings represents a substantial savings. Measured costs for the health educator were similar for phone and FTF clinic groups. However, other costs such as utilities, rent, storage, etc., were not measured, and these would likely add substantially to overall costs of the health educator for program delivery using FTF clinic. A service provider using phone delivery can use an existing phone, enlist a conference call service and then deliver the program from a location of choice (i.e., home) with little or no additional costs. Moreover, the freedom to deliver the program from the site of choice may increase qualified individuals who are interested in providing weight management who would not be able to do so due to time and cost constraints of FTF clinic delivery. This may allow more service providers to engage in weight management thus providing greater opportunities for overweight individuals to seek treatment. Individuals living in remote locations (i.e., rural) and those without transportation may engage in a phone delivery of weight management and expect equivalent outcomes compared to the traditional FTF clinic.

Strengths of this study include the equivalency design and adequate power to detect the primary outcome of weight loss at 6 months and the secondary outcome of weight maintenance at 18 months. Quality assurance was conducted throughout the intervention to assure fidelity. Trained health educators provided both interventions to diminish potential differences due to the quality of program delivery. Participants were matched for attention and outcomes were obtained by research assistants who were not informed of group assignments. A cost analysis was used to determine differences in the delivery and participation in either the FTF clinic or phone groups.

Generalization of the findings of this study has limitations. Attrition averaged 27% at 18 months although this is common in longitudinal studies of weight loss maintenance and diminishes our ability to forecast longer term results^{38,39}. Although weight loss at 18 months was near the 10% recommended by NHLBI, participants showed the typical pattern of regain regardless of exposure to FTF clinics or phone interventions. The use of PMs is known to provide greater weight loss than conventional energy restricted diets and when combined with an aggressive exercise program the magnitude of weight loss and maintenance may exceed what is typically found in the literature⁴⁰.

Summary

The primary finding from this investigation was that weight management delivered using group conference calls was as effective as the traditional FTF clinic format and clinically significant weight loss was achieved by the majority of participants. Program components essential to weight management such as attendance, diet intake, and physical activity were used equally across the groups. The phone intervention was cost effective for participants compared to FTF clinic and since access to phones is ubiquitous, the reach of this intervention is potentially vast. Many barriers for participation for both provider and participant were removed by phone delivery including the necessity of proximity thereby allowing access to hard to reach populations. Future targeted studies should evaluate the phone approach in rural populations where access to health care is limited and in other hard

to reach populations such as those without transportation, those with special needs (i.e. physically disabled) single parents, etc. Additionally, examining the combination of many other features of smart phones such as text messaging, photo images, and automatic transfer of data could be combined with the delivery of the weight management clinic via phone. Regardless of delivery mode, additional work is needed to prevent the typical pattern of weight regain exhibited in this study and many others.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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References

1. Flegal KM, Carroll MD, Ogden CL, Curtin LR. Prevalence and trends in obesity among US adults, 1999–2008. *JAMA*. 2010 Jan 20; 303(3):235–241. [PubMed: 20071471]
2. Mokdad AH, Ford ES, Bowman BA, et al. Prevalence of obesity, diabetes, and obesity-related health risk factors, 2001. *JAMA*. 2003; 289:76–79. 2003. [PubMed: 12503980]
3. Kelly T, Yang W, Chen CS, Reynolds K, He J. Global burden of obesity in 2005 and projections to 2030. *Int J Obes*. 2008; 32(9):1431–1437.
4. Tsai AG, Williamson DF, Glick HA. Direct medical cost of overweight and obesity in the USA: a quantitative systematic review. *Obesity Reviews*. 2011; 12(1):50–61. [PubMed: 20059703]
5. Wing, R. Behavioral approaches to the treatment of obesity. 2nd Edition. New York: Marcel Dekker, Inc.; 2004.
6. Wadden TA, Butryn ML, Byrne KJ. Efficacy of lifestyle modification for long-term weight control. *Obes Res*. 2004 Dec; 12(Suppl):151S–162S. [PubMed: 15687411]
7. Foster GD, Wadden TA, Phelan S, Sarwer DB, Sanderson RS. Obese patients' perceptions of treatment outcomes and the factors that influence them. *Arch Intern Med*. 2001 Sep 24; 161(17): 2133–2139. 2001. [PubMed: 11570944]
8. Perri MG, Nezu PAM, McKelvey WF, Shermer RL, Renjilian DA, Viegner BJ. Relapse prevention training and problem-solving therapy in the long-term management of obesity. *J Consult Clin Psychol*. 2001 Aug; 69(4):722–726. [PubMed: 11550740]
9. Lambourne K, Washburn RA, Gibson C, et al. Weight management by phone conference call: A comparison with a traditional face-to-face clinic. Rationale and design for a randomized equivalence trial. *Contemp Clin Trials*. 2012 Sep; 33(5):1044–1055. 2012. [PubMed: 22664647]
10. Garner DM, Olmsted MP, Bohr Y, Garfinkel PE. The eating attitudes test: psychometric features and clinical correlates. *Psychol Med*. 1982; 12:871–878. 1982. [PubMed: 6961471]
11. Donnelly JE, Smith BK, Dunn L, et al. Comparison of a phone vs clinic approach to achieve 10% weight loss. *Int J Obes*. 2007 Aug; 31(8):1270–1276.
12. Fabian C, Klemp J, Kimler B, et al. Effect of successful weight loss program on biomarkers for breast cancer in postmenopausal high risk women. *J Clin Oncol*. 2010; 28(15s) Abstr 1522.
13. Bandura, A. Social Foundations of Thought and Action: A Social Cognitive Theory. Englewood Cliffs, New Jersey: Prentice-Hall; 1986.
14. Institute of Medicine. Dietary reference intake for energy, carbohydrate, fiber, fat, fatty acids, cholesterol, protein and amino acids. Vol. 3. Washington National Academic Press; 2002.
15. Stevens VJ, Obarzanek E, Cook NR, et al. Long-term weight loss and changes in blood pressure: results of the Trials of Hypertension Prevention, Phase II. *Ann Intern Med*. 2001 Jan 2; 134(1):1–11. [PubMed: 11187414]

16. Knowler WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med*. 2002 Feb 7; 346(6):393–403. [PubMed: 11832527]
17. Whelton PK, Appel LJ, Espeland MA, et al. Sodium reduction and weight loss in the treatment of hypertension in older persons: a randomized controlled trial of nonpharmacologic interventions in the elderly (tone). *JAMA*. 1998; 279:839–846. 1998. [PubMed: 9515998]
18. Mifflin MD, St Jeor ST, Hill LA, Scott BJ, Daugherty SA, Koh YO. A new predictive equation for resting energy expenditure in healthy individuals. *Am J Clin Nutr*. 1990 Feb; 51(2):241–247. [PubMed: 2305711]
19. Lohman, TG.; Roche, AF.; Martorell, R. *Anthropometric Standardization Reference Manual*. Champaign, Ill: Human Kinetics Books; 1988.
20. Matthews CE, Ainsworth BE, Thompson RW, Bassett DRJ. Sources of variance in daily physical activity levels as measured by an accelerometer. *Med Sci Sports Exerc*. 2002; 34(8):1376–1381. 2002. [PubMed: 12165695]
21. Dranove, D. *Measuring Costs*. In: Sloan, FA., editor. *Valuing Health Care: Costs, Benefits, and Effectiveness of Pharmaceuticals and Other Medical Technologies*. New York, NY: Cambridge University Press; 1996. p. 61-80.
22. Lee RH, Bott MJ, Forbes S, Redford L, Swagerty DL, Taunton RL. Process-based costing. *J Nurs Care Qual*. 2003 Oct-Dec;18(4):259–266. [PubMed: 14556582]
23. Bray GA. Overweight is risking fate. Definition, classification, prevalence, and risks. *Ann N Y Acad Sci*. 1987; 499:14–28. [PubMed: 3300479]
24. National Heart Lung and Blood Institute. [Retrieved February 2012] NHLBI Obesity Education Initiative. *The Practical Guide: Identification, Evaluation, and Treatment of Overweight and Obesity in Adults*. 2000. from http://www.nhlbi.nih.gov/guidelines/obesity/prctgd_c.pdf.
25. Donnelly JE, Stewart EE, Menke L, Smith BK. Comparison of phone vs. clinic to achieve NHLBI guidelines for weight loss. *Obes Res*. 2005; 13(Supp):A36.
26. Befort CA, Donnelly JE, Sullivan DK, Ellerbeck EF, Perri MG. Group versus individual phone-based obesity treatment for rural women. *Eating behaviors*. 2010; 11(1):11–17. [PubMed: 19962115]
27. Hersey JC, Khavjou O, Strange LB, et al. The efficacy and cost-effectiveness of a community weight management intervention: A randomized controlled trial of the health weight management demonstration. *Preventive Medicine*. 2012; 54(1):42–49. [PubMed: 22001689]
28. Harvey-Berino J, West D, Krukowski R, et al. Internet delivered behavioral obesity treatment. *Prev Med*. 2010 Aug; 51(2):123–128. [PubMed: 20478333]
29. Appel LJ, Clark JM, Yeh HC, et al. Comparative effectiveness of weight-loss interventions in clinical practice. *N Engl J Med*. 2011 Nov 24; 365(21):1959–1968. [PubMed: 22085317]
30. Reed VA, Schifferdecker KE, Rezaee ME, O'Connor S, Larson RJ. The effect of computers for weight loss: a systematic review and meta-analysis of randomized trials. *J Gen Intern Med*. 2012; 27(1):99–108. [PubMed: 21805218]
31. van Wier MF, Ariens GA, Dekkers JC, Hendriksen IJ, Smid T, van Mechelen W. Phone and e-mail counselling are effective for weight management in an overweight working population: a randomized controlled trial. *BMC Public Health*. 2009; 9:6. [PubMed: 19134171]
32. Sherwood NE. The drop it at last study: six-month results of a phone-based weight loss trial. *Am J Health Promot*. 2010; 24(6):378–383. [PubMed: 20594094]
33. Jeffery RW, Sherwood NE, Brelje K, et al. Mail and phone interventions for weight loss in a managed-care setting: Weigh-To-Be one-year outcomes. *Int J Obes Relat Metab Disord*. 2003 Dec; 27(12):1584–1592. [PubMed: 14517547]
34. Tsai AG, Wadden TA. Systematic review: an evaluation of major commercial weight loss programs in the United States. *Ann Intern Med*. 2005 Jan 4; 142(1):56–66. [PubMed: 15630109]
35. Befort CA, Stewart EE, Smith BK, Gibson CA, Sullivan DK, Donnelly JE. Weight maintenance, behaviors and barriers among previous participants of a university-based weight control program. *Int J Obes (Lond)*. 2008 Mar; 32(3):519–526. [PubMed: 18059404]
36. Donnelly JE, Blair SN, Jakicic JM, Manore MM, Rankin JW, Smith BK. American College of Sports Medicine Position Stand. Appropriate physical activity intervention strategies for weight

- loss and prevention of weight regain for adults. *Med Sci Sports Exerc.* 2009 Feb; 41(2):459–471. [PubMed: 19127177]
37. Federal, CC. Trends in Telephone Service 2005. http://www.fcc.gov/Bureaus/Common_Carrier/Reports/FCC-State_Link/IAD/trend605.pdf.
38. Wadden TA, Volger S, Sarwer DB, et al. A two-year randomized trial of obesity treatment in primary care practice. *N Engl J Med.* 2011 Nov 24; 365(21):1969–1979. [PubMed: 22082239]
39. Jakicic, JmTDFLW., et al. Effect of a stepped-care intervention approach on weight loss in adults: A randomized clinical trial. *JAMA: The Journal of the American Medical Association.* 2012; 307(24):2617–2626.
40. Heymsfield SB, van Mierlo CA, van der Knaap HC, Heo M, Frier HI. Weight management using a meal replacement strategy: Meta and pooling analysis from six studies. *Int J Obes Relat Metab Disord.* 2003 May; 27(5):537–549. [PubMed: 12704397]

What is already known about this subject?

- Alternatives to face-to-face clinic meetings are needed in weight management.
- Access to phones is ubiquitous and if weight loss and maintenance achieved using the phone is equivalent to face-to-face treatment, the reach of weight management programs would increase.

What does this study add?

- Weight management programs are as effective as face-to-face treatment when delivered over the phone using group conference calls.
- Phone-based programs cost less than face-to-face treatment.

Table 1

Participant Characteristics.

Variable	Intervention Groups	
	Phone (N=201)	FTF Clinic (N=194)
Age (yrs)	43.2 ± 10.2	44.5 ± 9.9
% Male	34	32
% Minority *	38.8	41.8
Weight (kg)	100.0 ± 17.9	101.4 ± 18.3
Body mass index (kg/M ²)	34.6 ± 4.7	34.9 ± 4.6
Waist circumference (cm)	101.9 ± 12.3	103.4 ± 13.0

Values are Means ± SD or percentages

FTF= face-to-face

* Non-Caucasian

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Table 2

Changes for Weight, BMI, and Waist Circumference.

Variable	Weight loss (0–6 months)		Maintenance (7–18 months)		Baseline to 18 months	
	Phone	FTF Clinic	Phone	FTF Clinic	Phone	FTF Clinic
Weight (kg)	-12.6 ± 8.1	-13.5 ± 7.3	5.6 ± 4.7	5.5 ± 6.3	-7.5 ± 8.1	-8.4 ± 9.1
% Weight	-12.3 ± 7.0	-13.4 ± 6.7	6.4 ± 5.2	6.4 ± 7.0	-7.4 ± 7.6	-8.5 ± 8.8
BMI (m/kg ²)	-4.3 ± 2.6	-4.7 ± 2.4	1.9 ± 1.6	1.9 ± 2.1	-1.9 ± 3.7	-2.8 ± 3.2
Waist Circumference (cm)	-9.6 ± 7.2	-11.2 ± 6.9	4.0 ± 4.5	4.1 ± 5.6	-6.7 ± 9.8	-9.3 ± 12.9

No significant differences between groups at 6 and 18 months.

Table 3

Categories of Weight Change.

Weight category	Weight loss (0–6 months)						Weight Loss + maintenance (0–18 months)					
	Phone		FTF Clinic		Phone		FTF Clinic		Phone		FTF Clinic	
	N	%	N	%	N	%	N	%	N	%	N	%
Lost 0 to 4.9%	10	6.0	17	10.3	34	26.0	36	26.5				
Lost 5 to 9.9%	34	20.4	38	23.0	32	24.4	38	27.9				
Lost 10 to 14.9%	50	29.9	50	30.3	26	20.0	19	14.0				
Lost 15% or more	68	40.7	54	32.7	20	15.3	27	19.8				
Gained	5	3.0	6	3.6	19	14.5	16	11.8				

Chi square test for significance with participants with data at 6 and 18 months. No statistically significant differences between groups for category of weight loss for either time point.

Table 4

Self-reported Weekly Diet Compliance

Variable	Weight loss (0–6 months)		Maintenance (7–18 months)	
	Phone	FTF Clinic	Phone	FTF Clinic
Shakes ^a	18.4 ± 2.4	18.0 ± 2.5	5.5 ± 4.8	5.4 ± 4.9
Entrees ^b	12.4 ± 1.4	12.3 ± 1.4	5.3 ± 3.9	5.4 ± 4.2
Fruit ^c	19.5 ± 6.4	19.8 ± 5.6	17.2 ± 7.4	17.3 ± 6.8
Vegetables ^c	20.5 ± 5.8	20.7 ± 5.1	18.8 ± 6.4	18.3 ± 5.9

Target during weight loss = ^a 21/week; ^b14/week; ^c 35/week (1-cup servings, fruit & vegetable combined).

Shakes and entrees encouraged but not mandatory during weight maintenance. No significant differences between groups at 6 and 18 months.

Table 5

Daily Energy and Macronutrient Intake

Variable	Baseline			6 months			18 months		
	Phone	FTF Clinic	Phone	FTF Clinic	Phone	FTF Clinic	Phone	FTF Clinic	
kcal/day	2219.4 ± 750.3	2322.3 ± 682.1	1406.8 ± 372.5	1472.9 ± 391.0	1619.4 ± 563.7	1718.1 ± 576.3			
carbohydrate (g)	255.2 ± 114.0	265.7 ± 87.3	220.1 ± 65.1	228.2 ± 65.3	199.9 ± 75.3	218.9 ± 85.1			
protein (g)	87.5 ± 27.1	91.9 ± 28.2	75.8 ± 17.9	78.7 ± 18.5	75.2 ± 23.5	76.6 ± 22.6			
fat (g)	93.8 ± 35.6	98.8 ± 36.6	30.0 ± 18.8	33.2 ± 20.7	58.4 ± 30.8	61.7 ± 30.6			
alcohol (g)	4.8 ± 11.3	5.1 ± 12.9	1.7 ± 5.8	0.8 ± 2.6	4.4 ± 11.3	3.1 ± 8.5			
carbohydrate (%)	46.2 ± 8.1	46.2 ± 8.1	63.0 ± 10.1	62.8 ± 8.9	50.6 ± 10.5	51.7 ± 10.6			
protein (%)	16.3 ± 3.5	16.2 ± 3.4	22.2 ± 3.9	22.1 ± 4.2	19.1 ± 4.8	18.7 ± 4.7			
fat (%)	37.6 ± 6.7	37.7 ± 6.4	18.4 ± 8.2	19.0 ± 8.1	31.2 ± 8.5	31.0 ± 8.3			
alcohol (%)	1.3 ± 2.9	1.3 ± 2.9	0.7 ± 2.2	0.3 ± 1.1	1.6 ± 4.1	1.1 ± 2.7			

No significant differences between groups at baseline, 6 and 18 months.

Table 6

Physical Activity (Self-report) and Accelerometry.

Variable	Weight loss (0–6 months)		Maintenance (7–18 months)	
	Phone	FTF Clinic	Phone	FTF Clinic
Weekly self-report data				
PA minutes	203.2 ± 92.37	207.8 ± 85.1	212.9 ± 101.8	212.7 ± 95.4
Steps	58421 ± 17726	59160 ± 118235	56060 ± 18402	60774 ± 18702
Accelerometer data *				
Counts/day	342.1 ± 189.9	339.9 ± 202.3	317.3 ± 201.5	307.3 ± 164.9
	N = 76	N = 86	N = 44	N = 50

PA=physical activity averaged across 0–6 and 7–18 months. Average target PA during weight loss 0–6 months =140 minutes/week, average target PA during weight maintenance 7–18 months = 300 minutes/week.

Accelerometry averaged for 7 day period at 6 and 18 months.

Table 7

Participant Resource Use and Cost per Participant per Session

Variable	Phone	FTF Clinic ^a	p ^b
Travel Time	1.8 ± 22.9	43.6 ± 28.0	0.00
Meeting Time	50.7 ± 13.8	59.2 ± 13.6	0.00
Mid-week Time ^c	12.3 ± 12.5	12.1 ± 12.8	0.62
Weekly Time ^d	14.7 ± 14.0	14.6 ± 16.1	0.89
Time Costs ^e	\$21.94 ± 9.53	\$35.70 ± 11.72	0.00
Mileage Costs ^f	\$0.40 ± 5.51	\$7.73 ± 7.98	0.00
Incidentals	\$0.13 ± 1.36	\$0.65 ± 3.24	0.00
Total Cost	\$22.47 ± 13.69	\$44.07 ± 18.33	0.00

^aThere were 386 respondents in the FTF Clinic and 355 in the Phone group.

^bSignificant p-value <0.05 for difference between phone and FTF clinic groups. All times are minutes.

^cMid-week Time = recording and submitting mid-week data (e.g., shakes, entrees, fruits, vegetables, physical activity, and weight).

^dWeekly Time = recording and submitting weekly data.

^eTime Costs = \$16.56/60 times the sum of Travel, Meeting, Mid-week, and Weekly Time.

^fMileage Cost = \$0.51*Mileage.

Table 8

Health Educator Resource Use and Cost per Participant per Session

Variable	Phone	FTF Clinic ^a	p ^b
Meeting Prep Time	2.34 ± 2.5	2.4 ± 2.5	0.65
Data Collection Time	2.7 ± 4.2	3.1 ± 4.0	0.25
Session Time ^c	2.9 ± 2.6	2.9 ± 2.6	0.81
Travel Time	0.3 ± 1.1	1.7 ± 2.7	0.00
Food Prep Time	0.5 ± 1.3	0.8 ± 2.4	0.11
Emails	1.5 ± 1.3	1.6 ± 1.2	0.53
Phone Calls	0.1 ± 0.1	0.1 ± 0.1	1.00
Conference Call Line Cost ^d	\$1.61 ± 1.43	0	0.00
Cost per Participant per Session ^e	\$9.84 ± 7.10	\$9.58 ± 6.80	0.65

Values are Means ± SD.

^aThere were 217 responses concerning FTF Clinic and 215 concerning Phone Groups.

^bSignificant p-value <0.05 for differences between FTF clinic and phone groups. All time in minutes.

^cData were collected on some days with no session.

^dConference Calls cost \$0.05 per person per minute with an average of 11.2 participants.

^eCost per session calculations use a wage of \$30/hour and assume each call or email took five minutes. These costs exclude toll-free call costs and prepackaged meals during weight loss.