Weight Control

Telephone-Based Diet and Exercise Coaching and a Weight-loss Supplement Result in Weight and Fat Loss in 120 Men and Women

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Abstract

Purpose. Determine the effects of telephone-based coaching and a weight-loss supplement on the weight and body fat (BF) of overweight adults.

Design. Randomized, placebo-controlled experiment with assessments at baseline, 2 months, and 4 months.

Setting. Community.

Subjects. Sixty overweight or obese men and 60 overweight or obese women, 25 to 60 years old.

Intervention. Eleven 30-minute telephone coaching sessions were spaced throughout the study; the initial conversation lasted 60 to 90 minutes. Supplement or placebo capsules were taken daily over the 17 weeks.

Measures. Weight was measured using an electronic scale, and BF was assessed using dual energy x-ray absorptiometry.

Results. Subjects taking the placebo lost 1.8 ± 3.3 kg of weight and 0.7 ± 2.2 kg of BF, whereas supplement users lost more: 3.1 ± 3.7 kg of weight (F = 4.1, P = .045) and 1.7 ± 2.6 kg of BF (F = 4.4, p = .039). Participants receiving no coaching lost 1.8 ± 3.3 kg of weight and 0.7 ± 2.2 kg of BF, whereas adults receiving coaching lost more: 3.2 ± 3.6 kg of weight (F = 4.8, p = .032) and 1.6 ± 2.5 kg of BF (F = 4.2, p = .044). Adults receiving both the supplement and coaching had the greatest losses of weight and BF, suggesting an additive effect (F = 3.2, p = .026; F = 2.9, p = .039, respectively).

Conclusions. Both treatments, coaching and the supplement, viewed separately and in combination, worked to help subjects lose weight and BF. Adults can be educated and motivated via telephone to change behaviors leading to weight loss, and a weight-loss supplement can be included to increase success. (Am J Health Promot 2008;23[2]:121-129.)

Key Words: Obesity, Weight Loss, Coaching, Education, Supplement, Overweight, Prevention Research. Manuscript format: research; Research purpose: intervention testing/program evaluation; Study design: randomized trial; Outcome measure: biometric; Setting: local community; Health focus: nutrition, weight control; Strategy: education, skill building/behavior change; Target population age: adults; Target population circumstances: geographic location

Purpose

Attaining and maintaining a healthy weight has become a significant problem for most adults. This problem is especially prevalent in the United States, where it is estimated that 66% of adults are overweight or obese. Overweight and obesity have dramatic health consequences. Adults with a body mass index (BMI) of 25 or greater are considered at risk for developing diseases and morbidities such as hypertension, dyslipidemia, type 2 diabetes, coronary heart disease, stroke, gall bladder disease, osteoarthritis, sleep apnea, and respiratory problems. There is also a higher prevalence of endometrial, breast, prostate, and colon cancers among this segment of the population. Furthermore, higher body weight is associated with increased all-cause mortality.

At the workplace, obesity results in substantially higher health care costs and absenteeism. According to Finkelstein et al., the cost of obesity (excluding overweight) in a company with 1000 workers is approximately $285,000 annually. Gorsky et al. indicate that over the next 25 years $16 billion will be spent treating health problems stemming from overweight women in the United States. Further, in a review by Schmier et al., it is pointed out that health care costs in the workplace are consistently higher among heavy employees compared with their normal weight counterparts. Further, according to Tucker and...
Although it is difficult to argue with the weight-loss success that typically accompanies significant changes in diet and exercise habits, many adults feel that they need extra help. As a consequence, many weight-loss supplements have been developed. Unfortunately, the effectiveness of weight-loss supplements is rarely evaluated using sound methods. Although prescription drugs are regulated and must be shown to be effective employing the strictest scientific investigations, supplements are not regulated and do not require scientific investigation. Hence, consumer beliefs regarding the effectiveness of most weight-loss supplements are probably based more on advertising and anecdotal tidbits than on science and research.

Logic suggests that a sound approach to promoting weight loss among adults would be to combine two weight-loss strategies that approach the challenge from different angles, one based on traditional behavior change methods (only using the telephone to educate and motivate conveniently) and the other using a weight-loss supplement to help with the process. Based on this model, the purpose of the present study was to evaluate the effectiveness of two interventions on weight and fat loss: personal weight-loss coaching via telephone and a weight-loss supplement. Specifically, the objective was to determine the extent to which personal weight-loss coaching and a weight-loss supplement, considered individually and in combination, influence changes in body weight and body fat over 2 months and 4 months, compared with placebo use and no weight-loss coaching, employing a randomized, experimental design. A secondary objective was to determine the extent to which gender played a role in the effectiveness of the telephone coaching and the supplement.

METHODS

Design
The study was a placebo-controlled, randomized experiment lasting 17 weeks. Participants were assessed at baseline, after 2 months, and after 4 months to allow the first-half and second-half effects of the treatments to be evaluated, as well as the effects over the full 17 weeks. A 2 (supplement: yes/no) X 2 (coaching: yes/no) X 2 (gender: male/female) X 3 (time: baseline/midtest/posttest) factorial design was employed. Randomization was stratified or blocked to afford equal numbers of men and women in each experimental condition. In short, the 128 participants were split into two groups based on gender, 64 men and 64 women, and then the men and women were randomly assigned separately to the two different treatments, active supplement or placebo, and coaching or no coaching, using a random numbers table. Of the 128 subjects in the investigation, 64 were assigned to the supplement group (32 men and 32 women) and 64 were assigned to the placebo group (32 men and 32 women). One-half of those in the supplement group also received personal weight-loss coaching, and one-half received no coaching. Likewise, one-half of those in the placebo group received coaching, and one-half did not. At the outset, there were 32 randomly assigned subjects (16 men and 16 women) in each of the four experimental conditions: active supplement with coaching, active supplement with no coaching, placebo with coaching, and placebo with no coaching.

Subjects were blinded to the supplement/placebo condition. For the telephone coaching condition, those who received weekly coaching obviously knew they were being coached; however, subjects not receiving coaching were not aware that a coaching condition existed. The no-coaching subjects believed that the study was only evaluating a weight-loss supplement. In this way, subjects not receiving coaching did not feel cheated or resentful because they were not receiving one-on-one help to lose weight.

Sample
Subjects were recruited using newspaper advertisements covering approximately 25 cities surrounding a university in the Mountain West. All subjects completed a questionnaire that requested information on their medical histories and lifestyle behaviors. Inclusion criteria included: age...
of 25 to 60 years, BMI between 25 and 35 kg/m², regular access to telephone, and self-reported good health other than being overweight or obese. Subjects were excluded from the study if they currently smoked or had quit smoking in the previous 6 months, if they had lost 4 or more kg of body weight in the previous 3 months, if they were pregnant or intended to become pregnant during the study, if they reported drug or alcohol abuse, or if they reported having a significant disease, such as cardiovascular, renal, hepatic, endocrine, gastrointestinal, or psychologic, including eating disorders. All subjects indicated their willingness to participate in the study by signing a consent form which had been approved by the university Institutional Review Board. Subjects were not paid to participate in the study, but they were given a certificate allowing them to participate for free for 3 months in the weight loss clinic of the university wellness program after completing the study, if they desired.

Measures

Dual energy x-ray absorptiometry (DEXA; 4500W; Hologic Inc, Bedford, MA) was used to measure the body fat of each participant in grams. The 4500W is the same DEXA model used in the ongoing government-sponsored National Health and Nutrition Examination Survey. Concurrent validity of the 4500W DEXA machine used in the present study was established by comparing the DEXA body fat results to the body fat findings produced by the Bod Pod™ employing 100 adults. The Pearson correlation between the two measures of body fat was 0.94 (p < .0001), and 0.97 (p < .0001) for the intraclass correlation. A test-retest evaluation using the same 100 adults and complete repositioning of each subject resulted in an intraclass correlation of 0.999 (p < .0001), showing excellent reliability.

Weight-loss Supplement

The supplement, used to help subjects lose weight, was formulated by TriVita, Inc (Scottsdale, AZ). The supplement and placebo were provided free to participants and were packaged in identical sealed bottles. Researchers at all levels, coaches, and participants were blinded to which bottles contained the active supplement and which contained the placebo. The codes showing which subjects received the supplement and which received the placebo were held by a third party until all data were collected. Bottles were identified with subject numbers. One-half of the subjects were given bottles containing the active supplement, and one-half received the placebo. Subjects were instructed to take four capsules daily, two in the morning and two in the evening, preferably with meals, and to record their supplement/placebo use on a printed log.

Each capsule contained 700 mg of supplement, and the four capsules together included the following: vitamin B1 (15 mg), vitamin B2 (10 mg), niacinamide (50 mg), vitamin B6 (50 mg), vitamin B12 (2 mg), vitamin C (22.5 mg), vitamin D (1000 IU), d-methylglycine (100 mg), chromium (0.05 mg), copper (0.5 mg), magnesium (200 mg), vanadyl sulphate (1 mg), manganese citrate (1 mg), zinc gluconate (10 mg), indium sulphate (25 mg), Garcinia cambogia (250 mg), Gymnema sylvestre (10:1; 100 mg), bitter melon (10:1; 70 mg), cinnamon bark (500 mg), Portia cocos (5:1; 100 mg), Rhizoma zingiberis (4:1; 50 mg), green tea (10:1; 100 mg), Korean ginseng (100 mg), L-theanine (50 mg), gamma-aminobutyric acid (50 mg), alpha lipoic acid (110 mg), Calcaria carbonica (12X; 10 mg), sodium sulphuricum (12X; 10 mg), graphites (30C; 10 mg), nux vomica (30C; 10 mg), lycopodium (30C; 10 mg), and glucomannan (700 mg). The placebo was formulated to look like the supplement but with no active ingredients. The same dosage was used for the supplement and the placebo.

Stampd, addressed envelopes were given to subjects so that they could mail in their completed logs at the end of the first and third months of the study. Subjects were instructed to bring their latest logs with them to the 2- and 4-month assessment visits. The logs were used to calculate supplement/placebo compliance. Subjects were contacted by telephone each month to remind them to mail in their logs or to come to their assessment appointments.

Subjects were given enough of the supplement or placebo to last 8 weeks (i.e., until their midtest assessments). At the conclusion of their midtest visits, subjects were given additional bottles to last them until the conclusion of the study.

Supplement Mechanisms of Action

The formulation of the supplement was designed to primarily focus on improving glycemic control, increasing metabolism, enhancing mood, and decreasing appetite, collectively leading to the goal of weight loss. The mechanism of action of each active ingredient is listed below.

Research shows that an extract of G. cambogia, hydroxycitric acid, reduces food intake and body weight regain, presumably because of its inhibiting effect on lipogenesis. Other research has found that G. cambogia inhibits cytoplasmic lipid accumulation as well as adipogenic differentiation of pre-adipocytes, and it inhibits expression of an early adipogenic transcription factor that regulates adipogenesis.

G. sylvestre extracts have antihyperglycemic properties that may help to reduce appetite. The antihyperglycemic properties of G. sylvestre are due to a combination of two mechanisms. G. sylvestre increases the activity of enzymes responsible for glucose uptake and utilization, and it inhibits peripheral utilization of glucose by somatostatin and corticotrophin.

Extracts of bitter melon have been shown to normalize blood glucose levels and reduce triglyceride levels. Research indicates that bitter melon juice leads to a reduction in visceral fat and slower weight gain in rats, partly due to enhanced sympathetic activity and lipolysis.
Using a type 2 diabetic animal model, Kim et al. found that cinnamon bark extract has a regulatory role in blood glucose and lipid levels and may also exert a blood glucose-suppressing effect by improving insulin sensitivity or slowing absorption of carbohydrates in the small intestine.

_**P. coccineus**_ is a type of mushroom. Numerous polysaccharides and polysaccharide-protein complexes have been isolated from _P. coccineus_ and used as sources of therapeutic agents. Among other therapeutic properties, polysaccharides have glucose-regulating activities, and pharmacologic research indicates that pancreatic tissues may benefit from these polysaccharides. They may also increase insulin output by beta cells, increasing the availability of insulin and facilitating the metabolism of insulin-dependent processes, which are associated with weight regulation and fat deposition.

Green tea contains both tea catechins and caffeine and acts through the inhibition of catechol-O-methyltransferase and inhibition of phosphodiesterase. Tea catechins have antiangiogenic properties that may help to prevent the development of overweight and obesity. Research has shown that green tea supplementation promotes weight loss.

Korean ginseng may be beneficial in weight management by improving blood sugar control. In a study using hyperglycemic rats, ginseng extract was found to exert its antilipolytic effects through a signaling pathway different than that of insulin.

L-theanine is a nonprotein amino acid found naturally in the green tea plant, Camellia sinensis. L-theanine crosses the blood-brain barrier and increases both serotonin and dopamine production, which tend to lower blood pressure and improve mood. Given that some adults eat to relieve feelings of stress, it is postulated that l-theanine may help with this problem.

Alpha lipoic acid enhances glucose uptake in type 2 diabetes and inhibits glycosylation. Besides blood sugar-regulating properties, alpha lipoic acid also appears to possess weight-regulating properties, exerting these effects in the hypothalamus by suppressing appetite by inhibiting AMP-activated protein kinase.

Vitamin D is both a vitamin and a hormone. It is a vitamin because the body cannot absorb calcium without it; it is a hormone because the body manufactures it in response to the skin's exposure to sunlight. Vitamin D significantly increases the absorption of calcium. Dietary calcium appears to play a role in the regulation of energy metabolism and obesity risk. One study showed that 80% of morbidly obese patients presented with vitamin D deficiencies. High calcium diets seem to attenuate body fat accumulation and weight gain during periods of overconsumption of an energy-dense diet and to increase fat breakdown and preserve metabolism during caloric restriction, thereby accelerating weight and fat loss. This effect is mediated primarily by circulating calcitriol, which regulates adipocyte intracellular calcium.

Chromium picolinate is an essential trace mineral that helps the body maintain normal blood sugar levels. Chromium has been studied extensively regarding weight and fat loss. Although findings are far from unanimous, results show that chromium supplementation tends to slow weight gain and aid in weight loss.

Glucosaminan is a water-soluble dietary fiber that is derived from the konjac root. Like other forms of dietary fiber, glucosaminan is considered a "bulk-forming laxative." Research has suggested that glucosaminan may promote weight loss. The evidence suggests that glucosaminan exerts its effects by promoting satiety and fecal energy loss, and possibly by improving glycemic status.

**Personal Weight-loss Coaching**

The weight-loss coaching intervention included talking on the telephone with a trained weight-loss coach once per week for approximately 30 minutes per session during at least 11 of the 17 weeks of the study. However, the initial telephone coaching session was scheduled to last 60 to 90 minutes for the participant and coach to get to know each other and to allow time to build a meaningful foundation from which to work.

During the initial 6 weeks of the study, subjects were encouraged to participate in weekly coaching sessions; during the final 11 weeks, subjects were asked to work with their coach every other week. If a subject requested an additional coaching session, then an extra session was added, however, subjects were not coached more than once in any week. Sessions were arranged to accommodate subjects' schedules, although most sessions were held at the same time and on the same day of the week across the study.

Subjects were encouraged to make up missed sessions as soon as possible.

The TriVita personalized health coaching service was the foundation of the coaching intervention. Three weight-loss coaches were used in the study. Subjects were counseled by the same weight-loss coach throughout the entire study. Each of the three coaches was certified through the WellCoaches program, which is endorsed by the American College of Sports Medicine.

During the telephone coaching sessions, weight-loss guidelines developed by the American College of Sports Medicine were used to assist subjects. In short, subjects were taught about the energy balance model and the importance of expending more energy than was consumed. They were educated to practice self-monitoring and were trained to become more aware of their eating habits and energy needs. Participants were encouraged to consume healthy meals; avoid extreme diets; eat smaller portions; consume more fruits, vegetables, and fiber; reduce junk food consumption; and exercise more. As subjects participated in the program, specific weight-loss problems and barriers that surfaced were discussed during coaching sessions, and possible solutions were provided. As much as possible, weight-loss strategies and diets were customized to fit the needs and interests of each participant. Moreover, each telephone coaching session served as an opportunity for participants to report back to their coaches about successes and failures and to be accountable for their behaviors.

Subjects in the weight-loss coaching group were asked to keep written logs of their coaching sessions in addition to their supplement or placebo use. The same log was used for recording both interventions, and the logs were returned via mail or in person so that compliance could be monitored.
Analyses

The PASS power analysis software (version 6.0; NCSS, Kaysville, UT) was used to calculate the sample size necessary to conclude the investigation with a minimum power of 0.80 and an effect size of 0.25. Additional subjects were included in the sample to allow for a combined attrition and noncompliance rate of 25% (actual attrition and noncompliance together was approximately 10%). Repeated-measures analysis of variance (ANOVA) was used to identify the effects of supplement use compared with placebo use, the effects of weight-loss coaching compared with no coaching, and the effects of gender on body weight and body fat across the three time periods of the 4-month study. The effect of gender was considered secondary, and because there were no gender differences and gender had no effect on any of the other relationships, the female and male data were pooled and the gender factor dropped from the analyses.

Because the investigation included a pretest, midtest, and posttest to enable evaluation of the short-term effects of the treatments, as well as the longer-term effects, the data were analyzed across the first and second halves of the study separately, as well as across the entire study. Partial correlation was employed to determine the extent to which group membership in the second treatment influenced the treatment effects. The least-squares means procedure was employed to calculate means adjusted for differences in the potential confounding variables. All analyses were performed with SAS software (version 9.1; SAS Institute Inc, Cary, NC).

An intent-to-treat strategy was also used with all subjects who began the study included in the analyses (n = 128). In short, participants who dropped out of the study and those who failed to comply with the supplement/placebo and coaching/no-coaching protocols were included.

RESULTS

Participant Characteristics

Of the 120 subjects who completed the study, 60 were men and 60 were women. Additionally, approximately 95% of the sample was white, with the remaining participants reporting Asian or Hispanic ethnicity. At baseline, the average age was 43 ± 9 years and ranged from 25 to 60 years. At baseline, the mean body weight of the sample was 91.3 ± 14.5 kg, average percent body fat was 35.8% ± 6.1%, and mean BMI was 30.6 ± 2.7 kg/m². There were no significant differences among any of the treatment groups on any of the outcome variables at baseline, indicating that random assignment of subjects to groups was successful.

Compliance

A total of 120 of the 128 (94%) original participants completed the baseline, 2-month, and 4-month assessments. Reasons for quitting the study included loss of interest (five subjects), pregnancy (one subject), divorce (one subject), and serious automobile accident (one subject). None of the dropouts reported any ailments or side effects that might have been associated with taking the supplement/placebo.

Subjects were required to record their supplement or placebo use each day on preprinted forms. The written logs were used to identify subjects who did not take their capsules on a regular basis. Subjects who reported less than 70% compliance over the 4-month study were not included in the analyses. Of the 120 subjects who completed the study, five were identified as noncompliant because of their infrequent supplement use, leaving 115 subjects (90% of the original sample) for the supplement/placebo analysis. Average supplement use compliance was 88% ± 12% with noncompliant subjects removed.

Records were also kept of each telephone coaching session. Over the 17 weeks of the study, subjects in the coaching group who did not participate in at least 11 coaching sessions were considered noncompliant and were dropped from the analyses. Of the 60 subjects in the coaching group who completed the study, seven failed to meet the 11 coaching session minimum, leaving 113 subjects (88% of the original sample) in the coaching/no-coaching comparison. Average number of coaching sessions per subject in the coaching group was 11.6 ± 0.7 over the 17 weeks among subjects who were compliant.

Effect of the Supplement

At baseline, there were no differences between the supplement and placebo groups in body weight (F = 1.3, p = .266) or body fat (F = 0.1, p = .818). However, the group by time interaction of the repeated-measures ANOVA indicated that subjects in the active supplement group lost significantly more weight (F = 4.2, p = .016) and body fat (F = 4.5, p = .013) than participants in the placebo group over the three assessment periods (Table 1). Specifically, adults who took the supplement lost 1.3 kg or 76% more body weight and 0.9 kg or 132% more body fat than their counterparts over the 4-month study duration. After controlling for membership in the coaching/no-coaching groups (i.e., the second treatment), we noted that differences in body weight (F = 4.3, p = .040) and body fat (F = 5.2, p = .025) remained unchanged and significantly different between supplement and placebo users.

Mean differences in weight (F = 6.6, p = .011) and body fat (F = 7.8, p = .006) were also significant between the supplement and placebo groups after the first 2 months of the study. During the first half of the study, supplement users lost 1.3 kg more or twice the body weight and nearly 1 kg more or 2.3 times the body fat compared with placebo users. However, differences between the supplement and placebo users in body weight (F = 0.0, p = .865) and fat (F = 0.1, p = .793) were not significant over the last 2 months of the study.

Using an intent-to-treat strategy, including all subjects who dropped out of the study and all subjects who completed the study but did not take the supplement regularly (noncompliers), weakened the treatment effect. Specifically, repeated-measures ANOVA across the baseline, midtest, and posttest were borderline significant, showing that subjects in the supplement group lost more body weight (F = 2.4, p = .091) and more body fat (F = 2.7, p = .079) than those in the placebo group. Further, with all dropouts and noncompliant subjects in-
The difference in body fat loss between weight (2.1 ± 2.8 kg) than placebo weight than uncoached participants group over the three assessment periods. There were 53 subjects in the supplement group and 62 in the placebo group (n = 113). Those who received the supplement had greater body weight and fat losses compared with each of the other groups. None of the other groups differed significantly from each other over the study.

When the analysis was limited to the first half of the study, similar findings resulted. Specifically, the active supplement + coaching group lost significantly more weight (F = 3.8, p = .017) and body fat (F = 3.6, p = .016) than each of the other groups. However, during the second half of the study, there were no significant differences in weight loss (F = 0.8, p = .485) or fat loss (F = 1.0, p = .383) among the four groups.

DISCUSSION

According to the results, both treatments helped subjects lose significant body weight and body fat, viewed separately and in combination. Specifically, regular use of the weight-loss supplement resulted in greater body weight and body fat losses compared with placebo use. Most of the benefits derived from taking the supplement surfaced within the first 2 months of the study. During the first 8 weeks, supplement users lost twice the body weight and 2.3 times more body fat compared with placebo users.

Research has indicated that early weight loss is a strong predictor of

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<tr>
<td><strong>Effect of the Supplement and Coaching Viewed Separately on Weight and Body Fat Across the Baseline, Midtest, and Posttest</strong></td>
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<tr>
<th>Treatment</th>
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<th>Posttest Body Weight (kg)</th>
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SD indicates standard deviation; and BF, body fat.

* F represents the F ratio for the group by time interaction for the two treatments viewed separately (i.e., supplement vs. placebo, coaching vs. no coaching) across the three time periods. There were 53 subjects in the supplement group and 62 in the placebo group (n = 113).
success in weight-loss programs.\textsuperscript{48,49} Early weight loss builds confidence and engenders hope concerning future weight loss. Given the rapid weight loss resulting from use of the supplement, it follows that the supplement would be valuable in jump-starting weight-loss efforts, thereby increasing success in weight-loss programs.

There were no significant differences in weight or fat loss between supplement and placebo users during the second half of the study. Apparently, the supplement promoted significant weight loss during the first 8 weeks, after which its influence diminished. Although the actual cause is unknown, it is possible that subjects adapted physiologically to the supplement, becoming less sensitive to its ingredients, making it less effective over time.

According to the findings, one-on-one coaching over the telephone also resulted in significant weight and body fat losses in men and women. However, unlike the effects of the supplement, weight loss due to coaching was less front-loaded and more balanced over the entire investigation. In short, coaching helped subjects lose weight and fat over the 4-month study, but it did not have a significant effect during the first 8 weeks like the supplement did.

Numerous investigations have shown that health coaching works.\textsuperscript{50-57} Research has indicated that the coaching strategy has helped type 2 diabetics,\textsuperscript{57} increased fitness participation,\textsuperscript{56} supported lifestyle changes,\textsuperscript{56} improved diet and food choices,\textsuperscript{54} managed stress,\textsuperscript{54} enhanced mental health,\textsuperscript{52} and lowered health care costs.\textsuperscript{51} Although rare, telephone coaching has also been used in one case to improve diabetes care.\textsuperscript{50} However, to date, few, if any, investigations have studied the extent to which coaching over the telephone is a worthwhile weight-loss strategy. Because cell phone use has become commonplace, allowing the overweight to communicate with weight-loss coaches in almost any setting, and because we live in a fast-paced society, limiting time to meet with health professionals, telephone coaching designed to help with weight loss seems to be a common-sense solution. Obese individuals who need assistance losing weight but feel too busy or too shy to meet one on one may be able to find time to work with a weight-loss coach over the telephone. Less time and less travel are required compared with attending meetings and personal visits, making telephone coaching valuable to many adults.

In the present study, the supplement and coaching were effective in producing significant weight loss in men and women. However, the two strategies worked better in combination than individually, displaying an additive effect. Specifically, adults who took the supplement and received coaching lost almost twice the weight and body fat compared with those who took the supplement but received no coaching or those who received coaching but took the placebo. In short, the two weight-loss strategies, supplement use and telephone coaching, best promote weight loss when used together.

Although there are several possibilities, the positive combined effects of the supplement and coaching may be partly a function of the time-course benefits of each treatment. The supplement had its greatest impact early in the study, likely curbing appetite while new behaviors were being adopted. Later, as the effect of the supplement diminished, behavior changes resulting from coaching continued to help with additional weight and fat losses.

Using the intent-to-treat approach for the data analyses weakened the effects of the treatments, especially for telephone coaching. Using the intent-to-treat strategy, every subject who began the study was included in the analyses, even those who dropped out and those who did not comply with the assigned protocol. Although this approach is commonly used to protect against biases that may result from dropouts and noncompliance, the intent-to-treat method may not be a good analysis strategy given the purpose of the present study. Combining subjects who should have taken the supplement but did not with those who took the supplement and combining subjects who should have received telephone coaching but did not with those who participated in the coaching intervention may introduce more bias into the study than it prevents.

In this study, the goal was to determine the direct effect of the supplement and telephone coaching on weight loss. It is doubtful that the effect of these treatments can be determined if subjects who did not receive the treatment, whether because of quitting the study or not complying, are combined with subjects who received the treatment. True, the effect of a program.
designed to use these treatments can be evaluated using the intent-to-treat approach, but it is unlikely that the direct effect of the supplement and coaching interventions can be measured using this strategy. The intent-to-treat approach was included for those who favor this method of analysis.

Strengths of the present study included a large sample size, random assignment of subjects to groups, equal number of male and female participants, low dropout rate, use of a placebo and double-blind strategy for the supplement, body fat changes measured using DEXA, and three assessment periods over the duration of the investigation. Weaknesses included little ethnic diversity and a 4-month study duration.

CONCLUSION

Approximately two in every three American adults are overweight or obese. The cost associated with overweight and obesity in the workplace is substantial. Although there are a variety of programs that can be employed to assist with weight loss, many have not been studied using sound research methodologies. The two weight-loss treatments evaluated in the present study, a weight-loss supplement and diet and exercise coaching via telephone, appear to be effective weight-loss interventions. When used separately, their benefits are significant. When used in combination, their weight-loss effects double.

Acknowledgments

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References


