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Effects of Telephone Weight Loss Coaching on Body Composition in Adults: A Randomized Controlled Study

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EFFECTS OF TELEPHONE WEIGHT LOSS COACHING ON BODY COMPOSITION IN ADULTS: A RANDOMIZED CONTROLLED STUDY

by

Amy Cook

A thesis submitted to the faculty of Brigham Young University in partial fulfillment of the requirements for the degree of Master of Science

Department of Exercise Sciences
Brigham Young University
December 2006
of a thesis submitted by

Amy Cook

This thesis has been read by each member of the following graduate committee and by majority vote has been found to be satisfactory.

Date ____________________________  Larry A. Tucker, Chair

Date ____________________________  Ronald L. Hager

Date ____________________________  James George
As chair of the candidate’s graduate committee, I have read the thesis of Amy Cook in its final form and have found that (1) its format, citations, and bibliographical style are consistent and acceptable and fulfill university and department style requirements; (2) its illustrative materials including figures, tables, and charts are in place; and (3) the final manuscript is satisfactory to the graduate committee and is ready for submission to the university library.

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Accepted for the Department

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Accepted for the College

Gordon B. Lindsay, Associate Dean
College of Health and Human Performance
ABSTRACT

EFFECTS OF TELEPHONE WEIGHT LOSS COACHING ON BODY COMPOSITION IN ADULTS: A RANDOMIZED CONTROLLED STUDY

Amy Cook
Department of Exercise Sciences
Master of Science

Objective: To determine the extent to which coaching over the telephone is an effective method in promoting the loss of body weight and body fat percentage.

Research Methods and Procedures: Over a period of four months, in a randomized, double blind, placebo-controlled study, 120 overweight and obese (BMI 25-35 kg/m²) adults either received telephone coaching or no coaching. In addition, each participant was randomly assigned to take a supplement or placebo daily. Body weight and body fat percentage were measured at baseline, two months, and four months. Body weight was measured on an electronic scale and body fat percentage was assessed using dual energy x-ray absorptiometry (DEXA). Participants in the coaching group each received a minimum of 10 coaching sessions, each at least one week apart. Age, gender, and supplement use were controlled statistically using partial correlation.
Results: When using repeated measures ANOVA, telephone coaching had a significant and favorable effect on body weight loss over the three time periods when compared to participants who received no coaching ($F = 3.9, p = 0.0216$). Also, when weight changes from baseline to four months were compared, ignoring the two-month time period, those in the coaching group lost significantly more weight than their counterparts ($F = 4.75, p = 0.0315$). When weight changes from baseline were compared to the halfway mark (two months), telephone coaching resulted in significantly greater weight loss at the trend level ($F = 3.42, p = 0.0671$). However, during the second half of the study (two months compared to four months), the effect of coaching was weaker and non-significant.

Controlling statistically for age, gender, and supplement use, individually and collectively, had no effect on the impact coaching had on body weight loss. Telephone coaching did not play a significant role in helping participants lose body fat percentage across the three time periods compared to those who received no coaching ($F = 1.28, p = 0.2797$). Similarly, baseline body fat percentage means contrasted with four-month means ($F = 1.65, p = 0.2018$) were not significant, and findings from the two halves of the study showed that telephone coaching did not have a significant effect on the loss of body fat percentage.

Discussion: Telephone coaching is an effective and inexpensive method of helping overweight and obese adults lose body weight, but not body fat percentage, over a four-month period.
ACKNOWLEDGMENTS

I would like to thank Dr. Tucker for all of the time and guidance he has provided during this entire project. I also want to express my appreciation to Neil Nokes and everyone else who assisted in making this all possible. My deepest gratitude goes to my husband, Loran and for all of the support he has given me.
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Effects of Telephone Weight Loss Coaching on Body Composition in Adults:

a Randomized Controlled Study

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Objective: To determine the extent to which coaching over the telephone is an effective method in promoting the loss of body weight and body fat percentage.

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collectively, had no effect on the impact coaching had on body weight loss. Telephone coaching did not play a significant role in helping participants lose body fat percentage across the three time periods compared to those who received no coaching ($F = 1.28, p = 0.2797$). Similarly, baseline body fat percentage means contrasted with four-month means ($F = 1.65, p = 0.2018$) were not significant, and findings from the two halves of the study showed that telephone coaching did not have a significant effect on the loss of body fat percentage.

Discussion: Telephone coaching is an effective and inexpensive method of helping overweight and obese adults lose body weight, but not body fat percentage, over a four-month period.
INTRODUCTION

According to the American College of Sports Medicine (ACSM), obesity is defined as “a surplus of adipose tissue-containing fat stored in triglyceride form, resulting from excess energy intake relative to energy expenditure” (1). Obesity is a very prevalent disease in the United States. According to the National Health and Nutrition Examination Survey (NHANES 2003-04), over 70% of the United States population aged 40 years or older is overweight (BMI 25-29.9 kg/m²) or obese (BMI ≥ 30) (2). The number of obese individuals has increased by more than 30% since 1980 (3). This percentage continues to rise every year.

Thirty-three billion dollars are spent each year by obese Americans trying to lose weight, and obese individuals cost society 56.3 billion dollars annually in health costs (3). In short, obesity is a costly problem in the United States. Moreover, a large amount of money is being spent on unsuccessful methods to lose weight. Research is needed to discover more cost effective and successful approaches to weight loss.

Numerous studies have compared different weight loss methods to determine the most effective “ingredients” of a weight loss program. However, no special formula has been found that produces long-term weight loss results.

ACSM, a reputable scientific organization, indicates that the best "intervention strategy for weight loss" consists of a combination of increased energy expenditure and decreased energy consumption. For adults who want to lose weight, ACSM recommends a deficit of 500-1000 kilocalories per day, which will result in one to two pounds (lbs) of weight loss per week. In regards to medication, their stand is, "Pharmacotherapy appears
to be most effective when used in combination with modifications of both eating and exercise behaviors" (4).

Counseling is an important tool for weight loss because most adults who need to lose weight have misconceptions about the best weight loss strategies, and many lack the support and motivation to change their lifestyles. Moreover, significant weight loss is not a simple issue. There are many factors contributing to weight gain and weight loss besides lifestyle. For example, genetics, self-image, family culture, and previous weight loss experiences are all factors that affect weight loss (1). For many, obesity is as much a result of psychological factors as physical ones. Working one-on-one with obese individuals allows problem areas to be identified and healthy solutions to be implemented.

Currently, several commercial weight loss programs that include personal counseling are available to help obese individuals lose weight. Some of the programs seem to be successful, but they tend to be very expensive.

Personal weight loss coaching over the telephone is another available option to deliver weight loss information and to motivate clients. Telephone counseling is less costly and more convenient for individuals. No travel is necessary and weight loss coaches are still able to educate and support subjects during the behavior-change process.

Because obesity is so prevalent and costly, and leads to significant health problems, research focusing on the effectiveness of various weight loss methods, specifically weight loss coaching, would be beneficial to society. Health coaching can be
an expensive process and so exploring more cost-effective methods, such as telephone counseling, would also be of great value.

The purpose of the present study was to determine the extent to which coaching over the telephone is an effective method to promote weight loss and decrease body fat percentage over a four-month period in overweight and obese (BMI 25-35 kg/m²) adults. A secondary objective was to ascertain the extent to which potential confounding factors influence the effect telephone weight loss coaching has on body weight and body fat percentage.

METHODS

Design

The proposed study was a randomized, placebo-controlled investigation. The study consisted of a pretest, midtest, and posttest. The midtest occurred two months after the pretest, and the posttest occurred four months following the pretest. Subjects were randomly assigned to a treatment group that received telephone weight loss coaching or a control group that did not receive any coaching. The dependent variable was body composition, specifically body fat percentage and body weight. The study was approved by the Institutional Review Board at Brigham Young University.

The present study was part of a larger study. The larger study consisted of four randomly assigned groups. Group 1 took a weight loss supplement and did not participate in the weight loss coaching; Group 2 took a placebo and also did not participate in the telephone coaching; Group 3 received the supplement and telephone weight loss coaching; and Group 4 received the placebo and telephone weight loss
coaching. The value of the study being placebo-controlled was that subjects in the control (placebo) group felt like they were fully involved in the study even though they did not receive telephone weight loss coaching.

**Subjects**

A total of 128 men and women between the ages of 25 and 60 years old were recruited through newspaper advertisements and phone calls. In order to qualify to be in the study, subjects had to have Body Mass Indexes (BMI) between 25 and 35 kg/m² and be in good general health aside from being overweight/obese. Potential subjects completed a medical screening questionnaire before beginning the study. If subjects met any of the criteria on the questionnaire, they were excluded from the study. Qualified subjects were randomly assigned to one of the four treatment groups. Gender was randomly and equally distributed among the groups.

Exclusion criteria included any person with a weight loss of four or more kilograms in the previous three months, a BMI of less than 25 or greater than 35, current smokers or those who had stopped smoking within the past six months, and any pregnant female, lactating mother, or female subject attempting to become pregnant. Other exclusion criteria included any person who had a significant cardiac, renal, hepatic, gastrointestinal, psychiatric, or endocrine disorder, Type 1 or Type 2 diabetes, or a history of bulimia, laxative or substance abuse, or excessive intake of alcohol (>2 oz alcohol per day). Lastly, any person who currently used medications (prescription or nonprescription) that altered appetite or weight gain/loss, or who had other significant medical or health issues was excluded from the study.
Procedure

All qualified subjects attended one of four orientation meetings. Two meetings were designated for the coaching group and two of the meetings were designated for the noncoaching (control) group. Subjects were randomly assigned to these two groups. During each orientation meeting, the study was explained, including what was required of each individual. Written instructions were provided and no dietary or exercise advice was given. All subjects signed an informed consent form. There were different forms of consent for the coaching and noncoaching groups. After the consent forms were signed, the body weight and height of each potential subject was measured and BMI was calculated from these two measurements. Individuals who had a BMI less than 25 or greater than 35 were excused from participating in the study. Moreover, individuals who did not meet the other inclusion criteria were excused from participating in the study.

A subject number representing each subject was given to the supplement company, TriVita, who randomly assigned individual numbers within the coaching and noncoaching groups to the supplement or placebo group. The researchers and subjects were blind regarding which subjects received the supplement and which received the placebo. Over the course of the study, each participant received a regular supply of supplements or placebos.

Subjects who met all of the criteria signed up for an appointment and came to Brigham Young University (BYU) where the dependent variables were measured at baseline, two months, and four months. Before each measurement session, subjects were required to change into a BYU issue swimsuit. Body weight was measured and a full
body DEXA scan was completed on each subject. Each appointment lasted approximately 20-30 minutes. After the baseline assessment, the weight loss coaching calls began. Subjects received weight loss coaching from TriVita Inc. once per week for the first six weeks. After the first six weeks, subjects received coaching every other week. The first telephone coaching session served as an orientation meeting and lasted 60-90 minutes. The remaining coaching sessions lasted approximately 20-30 minutes. All subjects returned after two months and again at four months to be measured using the same measurement methods. Subjects were reminded of their appointments by telephone calls.

All subjects received logs to record their supplement intake and exercise activities. The subjects in the coaching groups received a different log that allowed them to record the frequency of the telephone weight loss coaching calls. These logs were collected at the measurement sessions to assist in measuring the compliance of the subjects as well as experimental attrition.

All subjects were offered an incentive, specifically three months of one-on-one weight loss coaching at Y-Be-Fit, for participating in the study. The purpose of the incentive was to prevent experimental attrition.

**Instrumentation and Measurement Methods**

*Body weight and height.* Body weight was measured on a Profit electronic scale, model UC-321 (Life Source, Milpitas, CA). Body weight was measured to the nearest 0.1-lb (0.05 kg). This information was collected at the pretest, midtest, and posttest.
Test-retest reliability of all 128 initial subjects was 0.999, indicating excellent stability and repeatability over time.

*Body composition.* Body fat percentage and lean body mass were measured with a Hologic QDR 4500W (Waltham, MA) dual energy x-ray absorptiometry (DEXA) bone densitometer at baseline, two months, and four months. DEXA has been shown to be a valid and reliable instrument for measuring body fat percentage and lean body mass (5,6). Measurements were taken by licensed individuals. The DEXA equipment was calibrated each day before any scans were completed and scans were analyzed by QDR 11.2 software.

*Weight loss coaching.* Subjects in the coaching group received weight loss coaching via the telephone from TriVita. The calls were weekly for the first six weeks and then every other week for the remaining weeks of the study. Each participant had to complete at least 10 coaching sessions during the four months, and sessions were limited to one per week. The coaching was based on the Wellcoach program, a strategic alliance of the American College of Sports Medicine (7).

The Wellcoach program consists of five phases. They are assessment, establishing the coach/client relationship, the coaching “contract,” the self-change process, and measuring outcomes. The phases combine behavior change models like the Transtheoretical Model with the wellness principles of stress management, nutrition, physical activity, weight management, and health and life issues that affect wellness (8).

The Wellcoaches educated and motivated the subjects of this study to identify the factors hindering their weight management, learn how to overcome obstacles, prevent
future relapses, and set weekly goals. Goals were centered on increasing energy expenditure, eating a more healthy diet, and overcoming emotional stimuli that detrimentally affect weight management.

Data Analysis

All statistical analyses were computed using SAS software, version 9.1 (SAS Institute, Inc., Cary, North Carolina). Descriptive data (means, standard deviations, etc.) were generated for each dependent variable for each time period for each group. The extent to which subjects in different groups differed on the dependent variables across time was assessed using repeated measures ANOVA employing the SAS GLM technique (9). There was no statistical difference between the performances of the three coaches and so all of the coaching data was grouped together. The extent to which the potential confounders, age, gender, and supplement use, influenced changes in the dependent variables across time was measured using partial correlation. Alpha was set at the 0.05 level for all of the statistical analyses.

RESULTS

During the present four-month investigation, telephone weight loss coaching helped individuals lose body weight. However, telephone coaching was not successful in aiding individuals in the loss of total body fat percent (Tables 1 and 2).

Body Weight

When all three time periods (i.e., baseline, two-months, and four-months) were examined simultaneously using repeated measures ANOVA, telephone coaching had a significant and favorable effect on body weight loss when compared to the participants
who received no coaching ($F = 3.9, p = 0.0216$). Similarly, comparing weight change from baseline to the four-month assessment, ignoring the two-month testing period, revealed that telephone coaching again had a significant and positive effect on body weight loss ($F = 4.75, p = 0.0315$). More specifically, adults in the telephone coaching group lost $7.11 \pm 8.0$ lbs (3.23 kg), whereas those in the noncoaching group lost $3.99 \pm 7.23$ lbs (1.81 kg) (Tables 1 and 2). The rate of weight loss for the coaching group was 0.44 lbs (0.2 kg) per week and the rate of weight loss for the noncoaching group was 0.25 lbs (0.11 kg) per week (Figure 1). Moreover, controlling statistically for age, gender, and supplement use, individually and collectively, had no effect on the impact coaching had on body weight loss (Table 1).

As shown in Table 1, telephone coaching resulted in significant weight loss at the trend level compared to those who were not coached when changes from baseline to the two-month assessment, midway through the study, were evaluated ($F = 3.42, p = 0.0671$). After adjusting for all of the same potential confounders simultaneously, the effect of telephone coaching on body weight was favorable and borderline significant across the first half of the study ($F = 3.75, p = 0.0554$) (Table 1).

During the second half of the investigation, the effect of coaching on body weight was weaker and nonsignificant ($F = 1.94, p = 0.1665$). Adjusting for the covariates had no effect on weight loss during the second half of the study (Table 1).

In the present study, 55 subjects either received a supplement and no coaching, or the supplement and telephone coaching. Since both groups received the supplement, the effect of the supplement was cancelled in this comparison and only the effect that
coaching had on body weight was manifested. Among these participants, telephone coaching caused significant weight loss compared to no coaching over the four-month study, as depicted in Table 2 ($F = 5.59$, $p = 0.0049$).

In the present study, half of the participants either received a placebo and no coaching, or the placebo and telephone coaching. With this comparison, the effect of the placebo was cancelled and the influence that four months of telephone coaching had on body weight loss was determined to be nonsignificant ($F = 0.21$, $p = 0.8109$) (Table 2).

**Body Fat**

As shown in Table 2, telephone coaching did not play a significant role in helping participants lose body fat percentage across the three time periods of the four-month investigation ($F = 1.28$, $p = 0.2797$). Similarly, baseline body fat percentage means contrasted with the four-month means revealed that telephone coaching did not help participants lose body fat percentage compared to those who received no coaching ($F = 1.65$, $p = 0.2018$). Loss of body fat percentage did occur. Specifically, the coaching group lost an average of $0.74 \pm 2.1$ percent body fat and the noncoaching group lost $0.28 \pm 1.72$ percent (Table 1). However, these losses did not yield significant results. When age, gender, and supplement use were controlled statistically, separately and combined, impact on the effects of telephone coaching was minimal (Tables 1).

Changes in body fat percentage at two months compared to baseline between the coaching and noncoaching groups showed nonsignificant results ($F = 0.27$, $p = 0.6024$). Adjusting for the control variables had minimal effect (Table 1). Likewise, comparing changes in body fat percentage from the midtest at two-months until the conclusion of the
study at four-months, showed that telephone coaching had no significant affect on body fat percentage ($F = 1.67, p = 0.1992$) (Table 1). Adjusting for age, gender, and supplement use also did not result in significant findings.

Lastly, telephone coaching did not help subjects lose body fat percentage when those who received the supplement and telephone coaching were compared to those who received the supplement and no coaching ($F = 0.62, p = 0.5404$) (Table 2). Furthermore, telephone coaching had little effect on body fat percentage when participants who received the placebo and telephone coaching were compared to those who received the placebo and no coaching ($F = 0.90, p = 0.4107$) (Table 2).

**DISCUSSION**

During the present four-month investigation, telephone coaching helped individuals lose body weight compared to those who received no coaching. With the increasing prevalence of obesity, telephone coaching appears to be a useful tool in assisting individuals with significant weight loss.

Findings from this study agree with other studies that have investigated the effects of coaching on body weight loss (10,11). These studies showed that individual and group coaching was effective in causing weight loss in comparison to those who received no coaching.

A novel aspect of this study was that coaching was completed over the telephone. Success of the present investigation agrees with other studies that have had beneficial results using telephone coaching to help smokers quit, and to increase daily fruit and vegetable intake in adults (12,13).
Clearly both the coaching and noncoaching groups were far from reaching their ideal weights, however, telephone coaching appears effective and there are several advantages over face-to-face coaching. Talking on the telephone is convenient, especially since most adults have cell phones. This saves time and there is no obligation to be at a certain place at a certain time. In addition, talking on the telephone is less expensive for participants and the organization administering the coaching program compared to a facility-based coaching program. With rising gas prices, reducing car travel is desirable. Furthermore, telephone coaching is noninvasive and does not require face-to-face contact, which can be daunting for some people.

Although telephone coaching had a significant affect on body weight loss, coaching did not help participants lose body fat percentage, even though the general trend was toward fat reduction. One possible explanation for the findings is that measurement error is greater with body fat percentage than with body weight and as a result, there was increased within group variation reducing statistical power. As well, participants may have lost lean body mass in addition to fat weight. Lastly, the study did not control for resistance training, which can be an important factor in decreasing body fat percentage and may also increase body weight. However, random assignment of subjects to groups should have eliminated the potential affect of resistance training or any other potential confounders.

An interesting aspect of the study was that telephone coaching did not help participants who received the placebo and telephone coaching lose body weight. In short, coaching was most affective when participants received the supplement in conjunction
with the telephone coaching. However, this comparison involved only about half the sample, greatly reducing statistical power. When all subjects in the study were included, the effect of telephone coaching on body weight loss was meaningful and significant.

The most significant weight loss occurred during the first half of the four-month investigation. Benefits from the telephone coaching were less obvious in the second half of the study. Moreover, mean body weight loss between the two-month and four-month assessments was not significant when the coaching group was compared to the noncoaching group. One explanation for this trend is that participants began to lose interest and motivation during the second half of the study and their weight may have plateaued. Old habits may have crept back into lifestyles and participants may have tired from the emotional and physical effort required to lose weight.

Variables that were taken into consideration during the analyses were age, gender, and supplement use. These variables were controlled statistically, individually and collectively, and had no impact on the findings. Randomization nullified differences between these variables as well as any other unknown factors.

Since the present study was a randomized, placebo-controlled, double blind study, there were few weaknesses. One limitation of this study was that compliance was not optimal and another was that supplement use was self-reported. Statistical findings only included subjects who received a minimum of 10 coaching sessions during the four-month investigation. When noncompliers (n = 7) were included in the statistical analysis, the effect of coaching on body weight loss was not significant (p > 0.05). A program is
of no value if clients do not participate. That is why only the compliers were included in the present study.

In conclusion, telephone coaching helps overweight and obese adults lose body weight. Weight loss can be a difficult process and coaching provides emotional and psychological support as well as scientifically sound weight loss principles. Coaches share the burden of weight loss, help participants to be accountable, and are motivators. Moreover, telephone coaching is much more convenient, inexpensive, and less invasive than face-to-face visits. Although more studies need to examine the effects of telephone coaching on weight loss, this method of coaching is a promising tool in helping individuals lose weight.
REFERENCES


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**Note:** Mean (%) depicts absolute changes in body fat percentage (e.g., 37.5%-37% = -0.50%)
### TABLE 2

Differences in body fat and body weight between various treatment groups across three time periods

<table>
<thead>
<tr>
<th>Group</th>
<th>Treatment Period</th>
<th>0 months</th>
<th>2 months</th>
<th>4 months</th>
<th>F</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Body Weight (lb)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coaching (n=53)</td>
<td></td>
<td>201.99</td>
<td>31.99</td>
<td>196.76</td>
<td>32.13</td>
<td>194.88</td>
</tr>
<tr>
<td>No Coaching (n=60)</td>
<td></td>
<td>200.45</td>
<td>32.89</td>
<td>197.29</td>
<td>33.37</td>
<td>196.46</td>
</tr>
<tr>
<td><strong>Percent Body Fat (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coaching (n=53)</td>
<td></td>
<td>35.51</td>
<td>6.36</td>
<td>35.14</td>
<td>6.32</td>
<td>34.77</td>
</tr>
<tr>
<td>No Coaching (n=60)</td>
<td></td>
<td>35.89</td>
<td>6.17</td>
<td>35.65</td>
<td>6.34</td>
<td>35.61</td>
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<tr>
<td><strong>Body Weight (lb)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coaching + Supp. (n=26)</td>
<td></td>
<td>199.44</td>
<td>30.52</td>
<td>192.02</td>
<td>30.84</td>
<td>189.82</td>
</tr>
<tr>
<td>Supp. only (n=29)</td>
<td></td>
<td>198.06</td>
<td>32.73</td>
<td>194.39</td>
<td>33.26</td>
<td>193.76</td>
</tr>
<tr>
<td><strong>Percent Body Fat (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coaching + Supp. (n=26)</td>
<td></td>
<td>35.34</td>
<td>6.97</td>
<td>34.60</td>
<td>7.48</td>
<td>34.21</td>
</tr>
<tr>
<td>Supp. only (n=29)</td>
<td></td>
<td>35.70</td>
<td>6.42</td>
<td>35.29</td>
<td>6.31</td>
<td>35.06</td>
</tr>
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</table>
### TABLE 2 (continued)

**Body Weight (lb)**

<table>
<thead>
<tr>
<th></th>
<th>Coaching + Plac.</th>
<th>Placebo only (n=31)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(n=27)</td>
<td>204.45 33.73 201.33 33.25 199.75 33.10 0.21 0.8109</td>
<td>202.70 33.42 200.00 33.79 198.98 34.46</td>
</tr>
</tbody>
</table>

**Percent Body Fat (%)**

<table>
<thead>
<tr>
<th></th>
<th>Coaching + Plac.</th>
<th>Placebo only (n=31)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(n=27)</td>
<td>35.68 5.84 35.65 5.06 35.30 5.54 0.90 0.4107</td>
<td>36.06 6.03 36.00 6.45 36.12 6.04</td>
</tr>
</tbody>
</table>

Note: Coaching + Supp: refers to those who received telephone coaching and the supplement.

Supp: refers to those who received the supplement, but did not participate in coaching.

Coaching + Plac: refers to those who received telephone coaching and the placebo.

Plac: refers to those who received the placebo, but did not participate in the coaching.

SD: standard deviation
FIGURE 1

Differences in weight loss over time between the coaching and noncoaching groups
Appendix A

Prospectus
Chapter 1

Introduction

According to the American College of Sports Medicine (ACSM), obesity is defined as “a surplus of adipose tissue-containing fat stored in triglyceride form, resulting from excess energy intake relative to energy expenditure” (1). Obesity is a very prevalent disease in the United States. According to the National Health and Nutrition Examination Survey (NHANES IV), approximately 61% of the United States population between the ages of 20-and 74-years old is overweight (27.6%) (BMI 25-29.9 kg/m²) or obese (33.2%) (BMI ≥ 30) (2). The number of obese individuals has increased by 32% since 1980 (3). This percentage continues to rise every year.

Thirty-three billion dollars are spent each year by obese Americans trying to lose weight, and obese individuals cost society 56.3 billion dollars annually in health costs (3). In short, obesity is a costly problem in the United States. Moreover, a large amount of money is being spent on unsuccessful methods to lose weight. Research is needed to discover more cost effective and successful approaches to weight loss.

Numerous studies have compared different weight loss methods to determine the most effective “ingredients” of a weight loss program. However, no special formula has been found that produces long-term weight loss results.

ACSM, a reputable scientific organization, indicates that the best "intervention strategy for weight loss" consists of a combination of increased energy expenditure and decreased energy consumption. For adults who want to lose weight, ACSM recommends a deficit of 500-1000 kilocalories per day, which will result in 1 to 2 pounds of weight loss...
loss per week. In regards to medication, their stand is, "Pharmacotherapy appears to be most effective when used in combination with modifications of both eating and exercise behaviors" (4).

Counseling is an important tool for weight loss because most adults who need to lose weight have misconceptions about the best weight loss strategies, and many lack the support and motivation to change their lifestyles. Moreover, significant weight loss is not a simple issue. There are many factors contributing to weight gain and weight loss besides lifestyle. For example, genetics, self-image, family culture, and previous weight loss experiences are all factors that affect weight loss (1). For many, obesity is as much a result of psychological factors as physical ones. Working one-on-one with obese individuals allows problem areas to be identified and healthy solutions to be implemented.

Currently, several commercial weight loss programs that include personal counseling are available to help obese individuals lose weight. Some of the programs seem to be successful, but they tend to be very expensive.

Personal weight loss coaching over the telephone is another available option to deliver weight loss information and to motivate clients. Telephone counseling is less costly and more convenient for individuals. No travel is necessary and weight loss coaches are still able to educate and support subjects during the behavior-change process.

Because obesity is so prevalent and costly, and leads to significant health problems, research focusing on the effectiveness of various weight loss methods, specifically weight loss coaching, would be beneficial to society. Health coaching can be
an expensive process and so exploring more cost-effective methods, such as telephone counseling, would also be of great value.

Statement of the Problem

The purpose of this proposed study is to determine the extent to which coaching over the telephone is an effective method to promote weight loss and decrease body-fat percentage over a four-month period in overweight and obese (BMI 25-35 kg/m²) adults. A secondary objective is to ascertain the extent to which age, gender, and pretest body composition scores influence the effect personal weight loss coaching has on body composition.

Research Questions

1. To what extent does telephone weight loss coaching decrease body composition among overweight and obese adults between the ages of 25 and 60 over a four-month period compared to a control group?

2. To what extent do age, gender, and pretest body composition scores influence the effect personal weight loss coaching has on body composition?

Operational Definitions

Body Mass Index (BMI) - BMI is a weight-to-height ratio. It is an indicator of obesity and is correlated to an increased risk of cardiovascular disease. It is measured by weight in kilograms divided by height in meters squared. A body mass index (BMI) of 18.5 to 24.9 is considered a healthy weight, a BMI of 25 to 29.9 refers to overweight, and a BMI of 30 or higher is considered obese.
Dual-Energy X-ray Absorptiometry (DEXA or DXA) – An x-ray machine used for scanning with two low x-ray energies to measure bone density and body composition.

Body Composition - A construct that includes measures of body-fat percentage, fat mass, fat-free mass, and body weight.

Assumptions

1. Personal weight loss coaches will be able to successfully contact the subjects by telephone during the study.
2. The weight loss coaches will have sufficient background, knowledge, and training in weight loss.
3. Subjects will honestly report their behavior to the weight loss coaches.

Delimitations

Subjects will be 120 men and women between the ages of 25-and 60-years old. They will be overweight or obese with BMIs between 25-35 kg/m², inclusive. The sample will be predominantly white, and will be comprised of non-smokers from the Utah County area. Subjects will be volunteers responding to newspaper advertisements and phone calls. Body composition, specifically body-fat percentage, will be measured by DEXA (Hologic, Waltham, MA). Body weight will be measured by an electronic scale, model Profit/UC-321 (Life Source, Milpitas, CA). The study will last four-months and will include assessments at baseline, two months, and four months.
30

Limitations

Limitations include self-reported compliance levels, potential excessive subject attrition, and a sample comprised of volunteers.
Chapter 2

Review of Literature

Obesity is a prevalent disease and many individuals struggle with it. Hundreds of different diets, ideas, and exercises exist that are promoted as excellent methods of weight loss. Over the past twenty years, scientific research has tried to determine which methods actually provide feasible results.

Recent interventions have focused on trying to ascertain the most effective methods of delivering weight loss information to groups and individuals. Some of the different methods include worksite health promotion programs, group and individual counseling, telephone counseling, and even weight loss correspondence through the mail and the internet (5,6).

An example of using worksite health-promotion programs to foster behavioral change involved three different fire stations that were randomly assigned to one of three types of interventions to lower cholesterol. Group 1 was the control group; Group 2 received team-based curriculum; and Group 3 attended individual counseling sessions. The team-based curriculum produced an increase in coworker cohesion and healthy behaviors. The individual counseling group resulted in "significantly increased dietary self-monitoring, decreased fat intake, and reduced depressed feelings" (7). Apparently, worksites can be an effective method of delivering information, but the research may be more difficult because there are many different uncontrolled factors outside of the worksite that affect weight loss.
Another method of delivering weight loss information is through brochures. In one study, 198 subjects were randomly assigned to receive one of three different weight loss brochures. The first brochure was tailored to the individual; the second brochure was an American Heart Association (AHA) brochure; and the third brochure was an AHA brochure made to look like the tailored information. It was concluded from this study that "the tailoring of health information can significantly improve the chances the information will be thoughtfully considered and can stimulate prebehavioral changes such as self-assessment and intention" (8).

The idea of a more tailored or individualized approach has led to studies that have examined methods that require more participation from the subjects as well as more individual attention from the researcher. One such study compared group counseling to individual counseling. A total of 40 women and 20 men with mean BMIs of 43.5 kg/m² and 42.2 kg/m², respectively, were randomly assigned to one of two groups. One group received group counseling (GC) and the other group received individual counseling (IC). The GC group received weight loss assistance at a rehabilitation center for two weeks and then had 2 years of group sessions. The IC group received individual counseling and follow ups by a physician. The GC group weight loss at 3 months, and 1, 2, and 5 years was 15.6, 15.7, 5.4 and 2.1 kg among the women, and 14.9, 13.1, 1.8 and 3.0 kg among the men. In the IC group, the weight loss among the women was 8.4, 11.9, 10.4, and 3.4 kg, and 17.0, 26.2, 15.6, and 12.9 kg among the men. "Group counseling starting with an in-patient period led to rapid weight reduction, but a better and more sustained effect was achieved by individual counseling, especially in men" (9).
A more in-depth study involved 48 obese (BMI 30-44 kg/m²) female breast cancer survivors. The women were randomly assigned to one of four groups and were followed for one year. Group 1 (the control group) did not receive any specific nutrition counseling; Group 2 received free coupons from Weight Watchers to their weekly meetings; Group 3 received individual nutritional counseling from a registered dietician; and Group 4 received the one-on-one nutrition counseling as well as the free coupons to the Weight Watchers meetings. Groups 2, 3 and 4 all lost weight. Group 1 lost 1.1 ± 1.7 kg; Group 2 lost 2.7 ± 2.1 kg; Group 3 lost 8.0 ± 1.9 kg; and Group 4 lost 9.5 ± 2.7 kg. Only Groups 3 and 4 lost a significant amount of weight. Group 4, which received multiple weight loss strategies, showed the most success and was the group that attended the Weight Watchers meetings most frequently. Most of the individualized contacts were through the telephone (10, 11).

Telephone counseling is becoming a more popular method to counsel individuals. It is convenient and cost-effective with no travel necessary. The effectiveness of telephone counseling on changing behaviors has been examined in some health-related areas and there have been some successful results. However, not many telephone counseling studies have been conducted with weight loss.

Between the time period of June 2000-May 2001, the American Cancer Society (ACS) conducted a randomized trial of telephone counseling among 3,500 smokers. All of the smokers were randomly assigned to receive either self-help booklets through the mail or to receive booklets and up to 5 sessions of telephone counseling. The 3-and 6-month quit rates were significantly higher among those who received telephone
counseling than those who only received booklets. The young population (ages 18-25) had quit rates of 20% (one-on-one individual counseling) vs. 9% (self-help booklets). The older adults quit rates were 15% vs. 10%, respectively (12).

Telephone counseling has also been used in the nutrition field. The purpose of a study known as the WHEL Study (The Women's Healthy Eating and Living Study) was to teach participants through telephone counseling how to consume a high-fiber and low-fat diet, especially increasing the intake of fruits and vegetables. It was a 12-month study with 2,970 participants. Twenty-four hour food recalls were collected and plasma carotenoid concentrations were measured. The telephone counseling was effective and the intervention group's vegetable intake increased to 7.1 servings (+82%) and fruit intake increased to 3.9 servings (+18%). Fiber increased from 3.04 to 4.16 grams/(MJ·d). Energy from fat significantly decreased and many phytochemical levels increased. Those in the control group did not change their habits and had similar results as at baseline. This shows that significant results from telephone counseling are possible (13).

Another successful intervention tested 150 men and women with high cholesterol in a 7-week study to determine the effectiveness of the “usual care approach” (Group 1) vs. individual telephone counseling (Group 2) in lowering cholesterol. Group 1 received the usual care of a handout about the National Cholesterol Education Program (NCEP) Step-1 diet. Group 2 was required to consume 4 servings of high fiber foods a day and received weekly telephone counseling sessions with a personal coach who helped subjects make lifestyle changes consistent with the NCEP cholesterol-lowering guidelines. In the treatment group, total cholesterol (TC) decreased by 5.6%, LDL
decreased by 7.1%, and triglyceride (TG) levels decreased by 14.2% (P < .0167). The usual care group was as follows: TC decreased by 1.9%, LDL decreased by 1.2%, and TG decreased by 4.4%. None of the decreases in the usual care group were significant (14).

Health coaching is an effective method to change the behavior of individuals, including weight loss. Obesity is a prevalent disease in the United States and studies have shown that individualized weight loss coaching can help individuals to successfully lose weight. However, most weight loss programs are expensive. Telephone counseling can be a cost-effective substitute for these programs. Although more research needs to be conducted, studies have shown that telephone counseling can successfully change health related behaviors. A weight loss study that specifically examines the effects of telephone counseling on weight loss in overweight and obese individuals is warranted and long overdue.
Chapter 3

Methods

Design

The proposed study will be a randomized, placebo-controlled investigation. The study will consist of a pretest, midtest, and posttest. The midtest will occur two months after the pretest and the posttest will occur four months following the pretest. Subjects will be randomly assigned to a treatment group that will receive personal weight loss coaching or a control group that will not receive any coaching. The dependent variable will be body composition, specifically body fat percentage and body weight. The study will be approved by the Institutional Review Board at Brigham Young University.

Subjects

A total of 120 men and women between the ages of 25-and 60-years old will be recruited through newspaper advertisements and phone calls. In order to qualify to be in the study, subjects will have to have Body Mass Indexes (BMI) between 25 and 35 kg/m² and they must be in good general health aside from being overweight/obese. Potential subjects will complete a medical screening questionnaire before beginning the study (Appendix A-1). If subjects meet any of the criteria on the questionnaire, they will be excluded from the study (exclusion criteria listed below). Qualified subjects will be randomly assigned to either the coaching group or the noncoaching group.

Exclusion Criteria:

1. Any person with a weight loss of 4 or more kilograms in the previous 3 months.
2. Any person exhibiting a BMI of less than 25 or greater than 35.
3. Any person who currently smokes or has stopped smoking within the past 6 months.

4. Any pregnant female, lactating mother, or female subject attempting to become pregnant.

5. Any person who has a significant cardiac, renal, hepatic, gastrointestinal, psychiatric, or endocrine disorder.

6. Any person who has Type 1 diabetes mellitus (insulin-dependent diabetes mellitus).

7. Any person who has Type 2 diabetes mellitus (non-insulin dependent diabetes mellitus or NIDDM).

8. Any person who has a history of bulimia.

9. Any person who has a history of laxative abuse.

10. Any person who has a history of substance abuse.

11. Any person who has a history of excessive intake of alcohol (>2 oz alcohol per day).

12. Any person who is currently using medications (prescription or non-prescription) that alter appetite or weight gain/loss.

13. Any person who, in the opinion of the researcher, is an inappropriate subject for this study for any reason.

Disclaimer

The proposed study will be part of a larger study. The larger study will consist of four randomly assigned groups.
Group 1: R O₁ T₁ O₂ T₁ O₃
Group 2: R O₄ T₂ O₅ T₂ O₆
Group 3: R O₇ T₃ O₈ T₃ O₉
Group 4: R O₁₀ T₄ O₁₁ T₄ O₁₂

R indicates that all of the subjects will be randomly assigned to different treatment groups. O₁, O₂, O₃, etc., represents the baseline, two-month, and four-month assessment sessions. T₁, T₂, T₃, and T₄ represent the different treatment groups.

T₁ (Group 1) will take a weight loss supplement; T₂ (Group 2) will take a placebo; T₃ (Group 3) will receive the supplement and weight loss coaching; and T₄ (Group 4) will receive a placebo and weight loss coaching. The value of the study being placebo controlled is that subjects in the control (placebo) group will feel like they are fully involved in the study even though they are not receiving weight loss coaching, and this perception will likely decrease the chances of experimental mortality.

For this thesis, Group 2 will be compared to Group 4 (placebo group vs. the placebo with coaching group), and Group 1 will be compared to Group 3 (supplement group vs. the supplement with coaching group) to measure the effect that personal weight loss coaching has on body composition. If the supplement is determined to have no significant effect on body composition, then the two coaching groups (Groups 3 and 4) will be combined and considered the intervention group and the two noncoaching groups will be combined and considered the control group. Then the weight loss coaching group will be compared to the noncoaching group.
Procedure

All qualified subjects will attend one of four orientation meetings. Two meetings will be designated for the coaching group and two of the meetings will be designated for the noncoaching (control) group. Potential subjects will be randomly assigned to these two groups. During each orientation meeting, the study will be explained, including what will be required of each individual. Written instructions will be provided and no dietary or exercise advice will be given. All subjects will sign an informed consent form (Appendix A-2 and A-3). There will be different forms of consent for the coaching and noncoaching groups. After the consent forms are signed, the body weight and height of each potential subject will be measured and BMI will be calculated from these two measurements. Individuals who have BMIs of less than 25 or greater than 35 will not be allowed to participate in the study. Moreover, individuals who do not meet the other inclusion criteria will not be allowed to participate in the study.

The names and contact information of each subject will be given to a supplement company, TriVita, who will randomly assign individuals within each coaching and noncoaching group to a supplement or placebo group. TriVita will correspond directly with subjects through the mail. Over the course of the study, each participant will receive a regular supply of supplements or placebos.

Subjects who meet all of the criteria will sign up for an appointment and come to Brigham Young University (BYU) where the dependent variables will be measured at baseline, 2 months, and 4 months. Before each measurement session, subjects will be required to change into a BYU issue swimsuit. Body weight will be measured and a full
body DEXA scan will be completed on each subject. Each appointment will last about 20-30 minutes. After the baseline assessment, the weight loss coaching calls will begin. Subjects will receive weight loss coaching once per week for the first 6 weeks. After the first six weeks, subjects will receive coaching every other week. All subjects will return after two months and again at 4 months to be measured using the same measurement methods. Subjects will be reminded of their appointments by email and telephone calls.

All subjects will receive logs to record their supplement intake and exercise activities (Appendix A-4 and A-5). The subjects in the coaching groups will receive an additional log to record the frequency of the telephone weight loss coaching calls. These logs will be collected at the measurement sessions to assist in measuring the compliance of the subjects as well as experimental mortality.

All subjects will be offered an incentive, specifically three months of one-on-one weight loss coaching at Y-Be-Fit, for participating in the study. The purpose of the incentive is to prevent experimental mortality.

Instrumentation and Measurement Methods

Body Weight and Height. Body weight will be measured on an electronic scale, model Profit/UC-321 (Life Source, Milpitas, CA) after subjects have used the restroom. Body weight will be measured to the nearest 0.1 lb. This information will be collected at the pretest, midtest, and posttest. Height will be measured to the nearest 0.1 cm and will only be assessed at the orientation meeting.

Body Composition. Body fat percentage and lean body mass will be measured with a Hologic QDR 4500 W (Waltham, MA) dual energy x-ray absorptiometry (DEXA)
bone densitometer at baseline, 2 months, and 4 months. DEXA has been shown to be a valid and reliable instrument for measuring body fat percentage and lean body mass (15, 16). Measurements will be taken by licensed individuals. The DEXA equipment will be calibrated each day before any scans are completed and scans will be analyzed by QDR 11.2 software.

Weight Loss Coaching. Subjects in the coaching groups will receive weight loss coaching via the telephone from TriVita. The calls will be weekly for the first 6 weeks and then every other week for the remaining weeks of the study. The coaching will be based on the Wellcoach program, a strategic alliance of the American College of Sports Medicine that was developed in 2000 by Margaret Moore.

The Wellcoach program consists of five phases. They are assessment, establishing the coach/client relationship, the coaching “contract,” the self-change process, and measuring outcomes. The phases combine behavior change models like the Transtheoretical Model with the wellness principles of stress management, nutrition, physical activity, weight management, and health and life issues that affect wellness (17).

The Wellcoaches will educate and motivate the subjects of this study to identify the factors hindering their weight management, learn how to overcome obstacles, prevent future relapses, and set weekly goals. Goals will be centered on increasing energy expenditure, eating a more healthy diet, and overcoming emotional stimuli that detrimentally affect weight management.
Data Analysis

All statistical analyses will be computed using SAS software, version 9.1 (SAS Institute Inc., Cary, North Carolina). Descriptive data (means, standard deviations, etc.) will be generated for each dependent variable for each time period for each group. The extent to which subjects in different groups differ on the dependent variables across time will be assessed using repeated measures ANOVA employing the SAS GLM technique (18). The extent to which age, gender, and initial body composition influence changes in the dependent variables across time will be measured using partial correlation. An intend-to-treat analysis will also be used. Alpha will be set at the 0.05 level for all of the inferential statistics analyses. An intend-to-treat analysis will also be used.
References


change support service result in favorable changes in lipids and lifestyles after 7 weeks. *Journal of the American Dietetic Association* 2002; 102: 503-510.


Appendix A-1

Medical Questionnaire
**Medication Survey—Weight Loss**

In order to be considered for participation in this test, you must list any and all medications you are currently regularly taking and any medications you have taken in the last month.

<table>
<thead>
<tr>
<th>Name of Medication</th>
<th>Dosage</th>
<th>What health problem is the drug taken for?</th>
<th>How long have you been taking the drug?</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>
Medical History and Screening Questionnaire—Weight Loss

Answer all of the following questions as completely and accurately as possible by checking the appropriate box associated with each question or filling in the blank as necessary. Thank you for your cooperation in filling out this form.

1. How old are you? ______________
2. Do you consider yourself to be in good general health?
   Yes  No
   If not, what conditions or problems are keeping you from being in good general health?
3. Have you lost more than 4 kilograms (8.8 lbs) in the last 3 months?
   Yes  No
4. Do you currently smoke or have you quit smoking in the past 6 months?
   Yes  No
5. Do you have a medical history that includes any of the following (check all that apply and explain in the space provided):
   Cardiac (heart) problems
   Renal (kidney) problems
   Hepatic (liver) problems
   Gastrointestinal (stomach and digestive tract) problems
   Endocrine (thyroid or pituitary gland) problems
   Psychiatric (mental) problems
6. Have you ever been diagnosed with Type-1 (insulin-dependent) diabetes mellitus?
   Yes  No
7. Have you ever been diagnosed with Type-2 (non-insulin dependent) diabetes mellitus?
   Yes  No
8. Have you ever had or been treated for substance abuse?
   Yes  No
9. Do you consume alcoholic beverages on more than an occasional basis?
   Yes  No
   If yes, how much and how often?
10. Are you currently taking any product (prescription or non-prescription) to help you lose weight or to reduce your appetite?
    Yes  No
    If yes, what are you taking, and how much and how often are you taking the product?
11. Are you pregnant, trying to become pregnant, or a lactating mother?
    Yes  No
12. Are you currently taking any kind of hormone replacement therapy:
   Yes  No
If yes, what are you taking and how long have you been on HRT?
13. Do you have any food allergies?
   Yes  No
If yes, to what foods (whether diagnosed or not)?
14. Do you specifically have allergies to nuts, shellfish, or iodine?
   Yes  No
15. Have you ever had or suffered from an eating disorder like anorexia or bulimia?
   Yes  No
If yes, please explain.
16. Do you currently take laxatives?
   Yes  No
If yes, what kind and how much per day?
17. How many diets have you been on in the past six months?
18. How many days per week do you typically exercise? If you don’t exercise regularly, put “NONE” and proceed to the next page (skip 19-21).
19. What do you usually do for exercise?
20. When you exercise, how many minutes do you typically exercise per session?
21. If you exercise regularly, how long have you been a regular exerciser?
   months or years
Appendix A-2

Noncoaching Informed Consent
 Consent To Be a Research Subject (please read carefully)

Introduction
This study is being conducted by Larry Tucker, Ph.D., a professor at BYU. The purpose of this study is to investigate the effects of a weight loss supplement on weight loss in adults. You have been selected for participation in this study because you have indicated that you are in good general health, aside from being overweight or obese, and you do not have any known medical conditions that might interfere with the test results. Furthermore, you have indicated that you have not been diagnosed with any medical condition that might be made worse by participating in a weight loss program.

Procedures
You will be taught how to participate correctly as a subject in this study. As a subject, you will be asked to take every day a dietary supplement that has been designed to help you lose weight. In addition to taking the supplement, over the course of the study, you will be encouraged to create an energy deficit, or in other words, to burn more calories than you consume (i.e., eat less and exercise more).

This study is scheduled to last four months. Assessments of your body weight and body composition are scheduled to occur at baseline, two months, and four months. During the study, you will be asked to keep an accurate log of your dietary supplement use, and you will be required to mail the completed log to us at BYU each month. We will give you stamped, addressed envelopes so it will be easy and convenient for you to mail the logs back to us.

As a subject in this study, you will be asked to participate in an orientation meeting at BYU that will last about 60 minutes. During the orientation meeting, you will be asked to read and sign an informed consent document, complete a medical history questionnaire, and list the medications you are currently taking. Then on three different days over the next four months you will be required to come to our lab (one visit at baseline, two months, and four months), change into a BYU swimsuit, and then have your body weight and body fat measured. Photographs will be taken of you from the front and the side so that visual changes can be monitored across the study. The photographs will become the property of the study sponsor at the conclusion of the study. If you desire, you will be given the opportunity to disguise your identity before the pictures are taken.

Your body composition (body fat and lean mass) will be measured using DEXA (dual energy x-ray absorptiometry). The DEXA assessment will require you to lie on a table while a sensor above you moves back and forth scanning your body for 6 minutes. We will also measure your body weight on an electronic scale during each of your visits. In total, each of your visits to our lab will take 30-45 minutes. Parking passes will be provided so you can park near our facility.

Risks
The risks and discomforts associated with the assessments you will receive will be minimal. The DEXA assessment that will measure your body composition will expose you to a very small amount of x-ray radiation. To put the amount in perspective, every day we are exposed to radiation from the sun, TV, cell phones, etc. Your DEXA assessment will expose you to less radiation than you would get from a day snow skiing or during a round trip flight coast-to-coast in an airplane. The DEXA assessment will have an effective radiation dose that is many times less than a dental x-ray or a chest x-ray. However, if there is a chance you are pregnant, or you are hoping to become pregnant in the next six months, you should not participate in this study. There are no known risks associated with the photographs that will be taken of you, or the measurement of body weight, or the completion of the written questionnaires.

In rare cases, symptoms of intolerance or allergic reactions, such as headache, upset stomach, nausea, lower gastrointestinal distress, diarrhea, dizziness, heartburn, rash, itching, redness, and/or other reactions, could be experienced from the dietary supplements. However, such reactions are generally mild and resolve quickly. If you experience any negative reaction during the study, regardless of how minor you think it is, you should inform the Principal Investigator. The Principal Investigator will ask you a series of questions and may request an unscheduled meeting to personally evaluate your condition. If your reaction is considered serious, you may be asked to seek medical attention. Of course, the final decision to seek medical attention will be yours.

Subject's signature: ____________________________
Benefits

The main benefit that could result from participation in this study is the loss of body weight and body fat. There are many benefits associated with the loss of body weight and body fat. Furthermore, by participating in this study, you will receive a significant amount of valuable information regarding your body composition, including your body fat percentage, lean body mass, and bone density. (Bone density data will not be used as part of this study, but information about bone density will result from the DEXA scans and will be available to you after you complete the study) Having the assessments performed for free will allow you to better understand your health, encouraging you to take action to improve your health.

Also, if you serve as a subject in this research study, you will have the opportunity to participate in the BYU Y-BE-FIT weight loss program for free during the three months immediately following the conclusion of this study. However, if you drop out of the study or fail to complete any of the assignments as required, you will not receive your results, nor will you be allowed to participate in the Y-BE-FIT program for free.

Confidentiality

All data from this study will be kept strictly confidential. You agree that all data derived from this study may be used in patents, scientific presentations, and/or publications concerning the programs tested and/or the ingredients contained in the supplement you receive. When the data are stored, presented, and analyzed they will be coded by number to ensure confidentiality.

Contact Information

Programs other than this research project are available in the community that work with adults to assist with weight loss. If you have any questions regarding this research project, you may contact a member of the research team at 422-2410, or Larry Tucker, Ph.D., 237 Smith Fieldhouse, Brigham Young University at 422-4927, or at his home at 222-9517. If you have any questions regarding your rights as a participant in this study, you may contact Dr. Renea Beckstrand, IRB chair, 422 SWKT, BYU, Provo, Utah 84602; email: renea_beckstrand@byu.edu; phone: 422-3873.

Conclusion

In conclusion, you agree that you are between 25 and 60 years old. You have read, understood and received a copy of this consent form. You have had the opportunity to ask questions regarding the study and your participation as a subject, and you desire of your own free will and volition to participate in this study. You are aware that participation in this study is voluntary and that you can withdraw from the study at any time. You are also aware that if you withdraw from the study, you will not receive any of your personal results, nor will you be able to participate in the Y-BE-FIT program for free.

Subject's name (print) ______________________________________

Subject's signature: ______________________________________ Date: __________

Witness's signature: ______________________________________ Date: __________

Subject's complete mailing address:

________________________________________________________________________

________________________________________________________________________

Subject's phone # (1) __________________________

(2) __________________________

Subject's email address (please print very neatly):
Appendix A-3

Coaching Informed Consent
Consent To Be a Research Subject (please read carefully)

Introduction
This study is being conducted by Larry Tucker, Ph.D., a professor at BYU. The purpose of this study is to investigate the effects of a weight loss supplement combined with personal coaching on weight loss in adults. You have been selected for participation in this study because you have indicated that you are in good general health, aside from being overweight or obese, and you do not have any known medical condition that might interfere with the test results. Furthermore, you have indicated that you have not been diagnosed with any medical condition that might be made worse by participating in a weight loss program.

Procedures
You will be taught how to participate correctly as a subject in this study. As a subject, you will be asked to take a dietary supplement every day that has been designed to help you lose weight. Also, as a participant, you will be asked to talk with a weight loss coach over the telephone once per week for six weeks and then every other week for the remainder of the study. Each weight loss coaching session will last about 20-30 minutes. Your weight loss coach will teach you how to lose weight, including proper diet and exercise. Problems you experience as you try to lose weight and possible solutions will also be discussed. After taking the supplement and being coached for two months, you will be required to return to our lab at BYU to have your body weight and body composition measured so that changes can be monitored. After the two-month assessment, you will again be required to take the supplement every day and talk to your weight loss coach regularly until you come in for your final assessment at four months.

This study is scheduled to last four months. Assessments of your body weight and body composition are scheduled to occur at baseline, two months, and four months. During the study, you will be required to keep an accurate log of your daily supplement use, and you will be required to mail the completed log to us at BYU each month. We will give you stamped, addressed envelopes so it will be easy and convenient for you to mail the logs back to us.

As a subject in this study, you will be asked to participate in an orientation meeting at BYU that will last about 60 minutes. During the meeting, you will be asked to read and sign an informed consent document, complete a medical history questionnaire, and list the medications you are currently taking. Then on three different days over the next four months you will be required to come to our lab (one visit at baseline, two months, and four months), change into a BYU swimsuit, and then have your body weight and body fat measured. Photographs will be taken of you from the front and the side so that visual changes can be monitored across the study. The photographs will become the property of the study sponsor. If you desire, you will be given the opportunity to disguise your identity before the pictures are taken.

Your body composition (body fat and lean mass) will be measured using DEXA (dual energy x-ray absorptiometry). The DEXA assessment will require you to lie on a table while a sensor above you moves back and forth scanning your body for six minutes. We will also measure your body weight on an electronic scale during each of your visits. In total, each of your visits to our lab will take 30-45 minutes. Parking passes will be provided so you can park near our facility.

Risks
The risks and discomforts associated with the assessments you will receive will be minimal. The DEXA assessment that will measure your body composition will expose you to a very small amount of x-ray radiation. To put the amount in perspective, every day we are exposed to radiation from the sun, TV, cell phones, etc. Your DEXA assessment will expose you to less radiation than you would get from a day snow skiing or during a round trip flight coast-to-coast in an airplane. The DEXA assessment will have an effective radiation dose that is many times less than a dental x-ray or a chest x-ray. However, if there is a chance you are pregnant, or you are hoping to become pregnant in the next six months, you should not participate in this study. There are no known risks associated with the photographs that will be taken of you or the measurement of body weight or the completion of the written questionnaires.

In rare cases, symptoms of intolerance or allergic reactions, such as headache, upset stomach, nausea, lower gastrointestinal distress, diarrhea, dizziness, heartburn, rash, itching, redness, and/or other reactions, could be experienced from the dietary supplements. However, such reactions are generally mild and resolve quickly. If you experience any negative reaction during the study, regardless of how minor you think it is,

Subject's signature: ____________________________

Page 1 of 2
you should inform the Principal Investigator. He will ask you a series of questions and may request an unscheduled evaluation to personally evaluate your condition. If your reaction is considered serious, you may be asked to seek medical attention. Of course, the final decision to seek medical attention will be yours.

Benefits

The main benefits that could result from participation in this study is the loss of body weight and body fat. There are many benefits associated with the loss of body weight and body fat. Furthermore, by participating in this study, you will receive a significant amount of valuable information regarding your body composition, including your body fat percentage, lean body mass, and bone density. (Bone density data will not be used as part of this study, but information about bone density will result from the DEXA scans and will be available to you when the study is finished). Having the assessments performed for free will allow you to better understand your health, encouraging you to take action to improve your health.

Also, if you serve as a subject in this research study, you will have the opportunity to participate in the BYU Y-BE-FIT weight loss program for free during the three months immediately following the conclusion of this study. However, if you drop out of the study or fail to complete any of the assignments as required, you will not receive your results, nor will you be allowed to participate in the Y-BE-FIT program for free.

Confidentiality

All data from this study will be kept strictly confidential. You agree that all data derived from this study may be used in patents, scientific presentations, and/or publications concerning the programs tested and/or the ingredients contained in the supplement you receive. When the data are stored, presented, and analyzed they will be coded by number to ensure confidentiality.

Contact Information

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If you have questions about your rights as a subject in this study, you may contact Dr. Renea Beckstrand, IRB chair, 422 SWKT, BYU, Provo, Utah 84602; email: reneabeckstrand@byu.edu; phone: 422-3873.

Conclusion

In conclusion, you agree that you are between 25 and 60 years old. You have read, understood and received a copy of this consent form. You have had the opportunity to ask questions about the study and your participation as a subject, and you desire of your own free will and volition to participate in this study. You are aware that participation in this study is voluntary and that you can withdraw from the study at any time. You are also aware that if you withdraw from the study, you will not receive any of your personal results.

Subject's name (print) ___________________________

Subject's signature: ___________________________ Date: ____________

Witness's signature: ___________________________ Date: ____________

Subject's complete mailing address: ____________________________________________________________

__________________________________________________________________________________________

Subject's phone # (1) _____________________________

(2) ___________________________________________

Subject's email address (please print very neatly): ____________________________________________

Page 2 of 2
Appendix A-4

Noncoaching Log
Weight Loss Supplement Log

Please record your weight loss supplement use every day. Mark the number of pills you take each time you take them. You should take two pills in the morning and two in the evening. If you miss a dose, don’t leave the space blank, but put a 0 in the cell.

Remember, once you reach the end of your log, please mail it back to us in the stamped envelope. If you have lost the envelope, please mail the log to Dr. Tucker, 237 SFH, BYU, Provo, UT 84602. Also, please record the number of minutes you perform aerobic exercise each day (walk, jog, etc).

<table>
<thead>
<tr>
<th>Week</th>
<th>Day</th>
<th>Morning</th>
<th>Evening</th>
<th>Minutes of aerobic exercise performed (exercise walking, cycling, etc). If none, put 0.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>8-6, Sat.</td>
<td>2 pills</td>
<td></td>
<td>8-7, Sun. Start taking your supplement on Monday</td>
</tr>
<tr>
<td>8-8, Mon.</td>
<td></td>
<td></td>
<td></td>
<td>8-9, Tue.</td>
</tr>
<tr>
<td>8-10, Wed.</td>
<td></td>
<td></td>
<td></td>
<td>8-11, Thur.</td>
</tr>
<tr>
<td>8-12, Fri.</td>
<td></td>
<td></td>
<td></td>
<td>8-13, Sat.</td>
</tr>
<tr>
<td>2</td>
<td>8-14, Sun.</td>
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<td>8-15, Mon.</td>
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<tr>
<td>8-16, Tue.</td>
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<td>8-17, Wed.</td>
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<td>8-18, Thur.</td>
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<td>8-19, Fri.</td>
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<tr>
<td>8-20, Sat.</td>
<td></td>
<td></td>
<td></td>
<td>8-21, Sun.</td>
</tr>
<tr>
<td>3</td>
<td>8-22, Mon.</td>
<td></td>
<td></td>
<td>8-23, Tue.</td>
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<tr>
<td>8-24, Wed.</td>
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<td></td>
<td>8-25, Thur.</td>
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<tr>
<td>8-26, Fri.</td>
<td></td>
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<td></td>
<td>8-27, Sat.</td>
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<tr>
<td>4</td>
<td>8-28, Sun.</td>
<td></td>
<td></td>
<td>8-29, Mon.</td>
</tr>
<tr>
<td>8-30, Tue.</td>
<td></td>
<td></td>
<td></td>
<td>8-31, Wed.</td>
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<tr>
<td>9-1, Thur.</td>
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<td>9-3, Sat.</td>
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<td>9-4, Sun.</td>
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<td>9-9, Fri</td>
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<td>9-10, Sat.</td>
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</tbody>
</table>

Please mail your completed log to Dr. Tucker on Monday, Sept. 12th.
Appendix A-5

Coaching Log
# Weight Loss Supplement Log

Please record your weight loss supplement use every day. Mark the number of pills you take each time you take them. You should take two pills in the morning and two in the evening. If you miss a dose, don’t leave the space blank, but put a 0 in the cell. Remember, once you reach the end of your log, please mail it back to us in the stamped envelope. If you have lost the envelope, please mail the log to Dr. Tucker, 237 SFH, BYU, Provo, UT 84602. Also, please record the number of minutes you perform aerobic exercise each day (walk, jog, etc.), and the number of minutes you talk to your personal weight loss coach during each coaching call.

<table>
<thead>
<tr>
<th>Week</th>
<th>Day</th>
<th>Morning</th>
<th>Evening</th>
<th>Minutes of aerobic exercise performed (exercise walking, cycling, etc). If none, put 0.</th>
<th>Minutes of weight loss telephone coaching received</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>8-6, Sat.</td>
<td>Start taking your supplement on Monday</td>
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**Please mail your completed log to Dr. Tucker on Sep 12**