

DETAILED INTERVENTION COMPONENTS

Eligible individuals were randomized to one of three intervention groups: 1) standard behavioral weight loss program (SBWP), 2) SBWP plus intervention strategies for physical activity implemented over the initial 9 months (ADOPT), or 3) SBWP plus additional intervention strategies for physical activity implemented between months 4-18 (MAINTAIN). Treatment included both a dietary and exercise component, and the basic aspects of these components were identical for all the groups. The specifics of all aspects of the intervention are described in detail below.

Standard Intervention Schedule and Delivery of Group Intervention

All subjects, regardless of group assignment (SBWP, ADOPT, MAINTAIN), received components of a standard behavioral weight loss program. The basic behavioral program was delivered in a group format, and the standard group meeting schedule and content of the group sessions was an extension of the intervention protocol that we have successfully used in previous weight loss programs.

During the initial 24 weeks of treatment subjects were scheduled to attend weekly group sessions. Because the majority of our participants typically have family and/or work responsibilities that limit participation during the daytime hours, these groups were conducted during the evenings. The time commitment for participants for each of these group sessions was typically 30 to 60 minutes in duration. During this time, the initial 15 minutes was used to obtain a weekly weight on participants, collect weekly eating and exercise diaries, return previous eating and exercise diaries, and to distribute participant materials. The remaining 30-45 minutes was utilized to deliver the behavioral intervention. This consisted of addressing behavioral

strategies for modifying eating and exercise behaviors, and structured group interactions. The specifics of this behavioral intervention are described in greater detail below.

Following the initial 6 months of treatment, there was a reduction in the frequency of group intervention sessions. During months 7-12 participants were scheduled to attend group sessions bi-weekly (every other week), with the frequency of treatment maintained on a bi-weekly basis during months 13-18 of this trial. Participants were instructed that they should commit to attending all of the group sessions prior to enrolling in this program. However, realistically, participants may need to be out of town for business or vacations periodically during this study. Thus, a commitment to attend at least 80% of the group sessions was encouraged. Participants were also encouraged to contact the intervention team to alert them of group meetings that they may not be able to attend and to schedule an individual make-up session. Individuals who failed to contact the interventionists and failed to attend the group meeting were contacted to schedule a make-up session. In the event that a make-up session was not able to be scheduled, an attempt was made to briefly counsel the participant by telephone and the weekly intervention materials were mailed to the participant.

Theoretical Rationale and Behavioral Strategies

The major features of the behavioral modification program, *which have been used successfully by our research team in previous studies*, were based primarily on social-cognitive theory. The general components of the behavioral intervention are described below.

- **Self-monitoring**: Self-monitoring involves the systematic observation and recording of eating and exercise behaviors by the patient and is an aspect of self-control. For Months 1-6, subjects were instructed to self-monitor calorie and fat intake, and exercise participation on a

daily basis. These records were reviewed by the intervention staff at each treatment meeting. From months 7-18, subjects were instructed to continue to record their exercise participation on a daily basis, and these records were also returned to the intervention staff for review.

- Stimulus control: Stimulus control refers to a set of behavioral procedures designed to help participants change the environmental cues associated with eating behavior. Participants were instructed to reduce their cues for eating and to increase their cues for physical activity.
- Problem solving: Participants were taught to use problem solving strategies to deal with situations that pose difficulties for changing their eating and exercise behaviors. Participants were taught to define the problem, brainstorm solutions, select a solution, and evaluate the success of the solution.
- Social assertion: Being able to assert oneself in social situations is an important part of gaining control over eating and exercise behaviors. Participants were taught to behave assertively in social situations involving eating and exercise. Participants role-played the handling of difficult interpersonal situations.
- Feedback: Participants were taught to use calorie intake and exercise totals as an ongoing source of feedback on the results of efforts at behavior change. The intervention staff also monitored the progress of participants and encourage small steps toward behavior change.
- Cognitive strategies: Negative thinking (e.g. perfectionism, pessimism, self-doubt) often interferes with behavior change. Participants were helped to recognize their own negative thoughts and to counter them with thought stopping and/or positive self-statements.
- Social Support: The treatment program included training in techniques for developing and maintaining social support, and these strategies involved engaging spouses and other members of the family in weight loss and exercise efforts.

- Goal setting: Participants were taught the importance of short-term goal setting for enhancing motivation and set daily and weekly goals for calories, exercise, behavior change, and weight.

Standard Dietary Intervention

The dietary component of the proposed intervention targeted reducing both calorie and fat intake, and was based on interventions that we have successfully implemented in prior studies. Subjects were instructed to reduce calorie intake to 1200-1500 calories per day, with fat intake reduced to 20% of total caloric intake (26-33 grams per day). Subjects ≤ 200 pounds at baseline were instructed to reduce calorie intake to 1200 kcal/d, whereas those >200 pounds at baseline were instructed to reduce caloric intake to 1500 kcal/d. These intake levels theoretically should allow for a 1-2 pound weight loss per week.

The underlying philosophy of the dietary intervention was to facilitate weight loss while also assisting the individual to adopt long lasting healthful eating behaviors. To assist in this process, subjects were provided with meal plans that allow for a significant amount of choice to accommodate different food preferences. Basically, meal plans were divided into breakfast, lunch, and dinner. Subjects were provided with 3-4 complete plans for each meal from which they can choose, and within each meal there was sufficient variety, and these meals plans were developed by Registered Dietitians. Participants were encouraged to select from a limited list of choices developed by the interventionists for the initial 8-12 weeks of treatment before beginning to add additional food choices of their own to the meal plans beyond this period of time.

We were also sensitive to cultural and ethnic differences that may impact the eating behaviors of participants in our interventions. When this occurred, individuals were provided

with an additional session with the Dietitian/Nutritionist to develop a meal plan that included some of the foods that are culturally appropriate for this individual participant. In addition, issues related to meal preparation, family eating patterns, etc. may differ between individuals, and we allocate time in our group sessions, and space in our written materials, to address these issues.

Subjects were instructed to self-monitor their food intake on a daily basis. The subjects were provided a diary each week to be used for this purpose. Subjects were encouraged to weigh and measure all of their food consumption, and to use food labels and reported levels of calorie and fat. To assist with this process, subjects will be provided with a published book of the calorie and fat content of common foods. Subjects were encouraged to return the food diaries to the intervention staff on a weekly basis for review. The intervention staff provided feedback regarding food choices, meal preparation, and eating behaviors.

Common Exercise Intervention

The basic exercise intervention was similar across all treatment conditions. The goal of the exercise intervention was to progressively increase exercise participation to a minimum of 200 minutes per week. The progression of the exercise is specifically outlined in Table 1. It was recommended that subjects participate in exercise on 5 days per week, with the exercise progressing from 20 minutes per day at the onset of treatment to 40 minutes per day by the 9th week of treatment. Because dividing exercise into multiple 10 minute bouts may be beneficial for exercise adoption in this population, subjects were encouraged to use this strategy to progressively increase their exercise throughout treatment.

Table 1. Description of exercise progression which is common for all intervention groups.			
<u>Exercise Parameter</u>	<u>Time Period</u>	<u>Exercise Progression for SBWP, ADOPT, and MAINTAIN</u>	
<u>Total Minutes per Week</u>	Weeks 1-4	100	
	Weeks 5-8	150	
	Weeks 9-78	200	
<u>Days per Week</u>	Weeks 1-78	5	
<u>Minutes per Day</u>	Weeks 1-4	20	
	Weeks 5-8	30	
	Weeks 9-78	40	
<u>Exercise Intensity</u>		<u>RPE</u>	<u>%HR_{max}</u>
	Weeks 1-12	11-13	60-70%
	Weeks 13-78	11-15	60-80%

Subjects were instructed to participate in activity that was at least moderate in intensity, with intensity set at a minimum of 11-13 on the 15-point Rating of Perceived Exertion scale and/or heart rate prescribed at 60-70% of maximal heart rate. Activities that are consistent with this intensity level are activities similar to “brisk walking”.

Subjects were instructed to record their exercise in an exercise log that is part of the diary that is used for dietary intake. Similar to the dietary records, these exercise records were reviewed by the intervention staff, and written feedback will be provided to participants. This feedback included strategies for overcoming potential barriers, and feedback on the type and amount of exercise the subject was reporting. Subjects reporting exercise patterns that are greater than the recommended amount were counseled appropriately to ensure safety and minimize the risk of potential injury. Subjects were also strongly encouraged not to exceed the recommended exercise intensity.

Again, we are sensitive to cultural and ethnic differences that may impact exercise participation. Issues that we commonly need to address in our exercise programs include issues related to general hygiene and hair-care, issues related to neighborhood safety, child-care to

allow time for exercise, and acceptance from other family members. However, we are aware that these are only a few of the barriers that may be affected by cultural and ethnic factors, and others typically arise during the implementation of the intervention. We incorporated these factors in our group sessions and within our written materials that were provided to all participants.

Additional Intervention Strategies for ADOPT and MAINTAIN

The basic exercise components described above were included in all treatment groups. However, we included additional strategies into the ADOPT and MAINTAIN groups that target enhancing motivation for exercise in these interventions. The following is a summary of the components of the behavioral intervention that were added to the ADOPT and MAINTAIN interventions. The timing of implementation of these additional strategies are also illustrated in Figure 1 below.

Figure 1. Timing of delivery of the standard and enhanced-care intervention components.												
	SBWP				ADOPT				MAINTAIN			
	Weeks 1-12	Weeks 13-24	Weeks 25-52	Weeks 53-78	Weeks 1-12	Weeks 13-24	Weeks 25-52	Weeks 53-78	Weeks 1-12	Weeks 13-24	Weeks 25-52	Weeks 53-78
Weekly Intervention Sessions	✓	✓			✓	✓			✓	✓		
Bi-Weekly Intervention Sessions			✓	✓			✓	✓			✓	✓
Bi-Weekly Telephone Calls					✓					✓		
Supervised Exercise Sessions					✓	✓					✓	
Physical Activity Promotion Campaigns						✓	✓					✓

Additional Contact via the Telephone: We supplemented the group intervention sessions with individual counseling that was conducted via telephone calls. In the ADOPT group these telephone contacts occurred between Weeks 1-12, and in the MAINTAIN group occurred between weeks 13-24. For this aspect of the intervention, each participant was assigned to one of the members of the intervention team. Each telephone call was scheduled with the participant, and the call was initiated by the interventionist. The nature of this call was designed to query the participant with regard to their exercise behaviors and the barriers that may compromise their continued participation in exercise. Based on this information, the interventionist worked with the participant to problem solve and to develop strategies for addressing these potential barriers. These interactions included the following techniques: 1) providing feedback to the participant based on the achievement of exercise goals, 2) emphasizing self-responsibility to overcome the barriers and to work towards the exercise goal, 3) the therapist offering advice to the participant of potential ways to overcome the barriers, 4) the therapist working with the participant to develop a menu of options to address the barriers, 5) the therapist being empathetic to the participant with regard to the barriers that exist, and 6) focusing on improving self-efficacy related to the target behavior. Prior to the completion of the call, the participant was also reminded of the date and time of the next group meeting and the next telephone call was scheduled. The interventionist was instructed to limit the telephone call to 10-15 minutes in duration.

Opportunity for Supervised Exercise: A fitness center that was staffed by exercise staff was made available to participants in the ADOPT and MAINTAIN groups. ADOPT was given access to this facility during Weeks 1-24 (Months 1-6) and MAINTAIN was given access to this facility during Weeks 25-52 (Months 7-12). Access was only permitted on the night in

which the participant was also attending a group intervention session. These exercise session involved the use of cardiovascular exercise equipment (e.g., treadmills, elliptical trainers, recumbent cycles, adaptive motion trainers) and reflected the prescribed intensity and duration of the exercise encouraged within the intervention. A focus of these exercise sessions was to build social interactions between participants during exercise, to model appropriate exercise behaviors, and to develop self-efficacy for exercise.

Physical Activity Promotion Campaigns: We developed and implemented campaigns to encourage engagement in home-based (non-supervised) physical activity. These campaigns incorporated goal setting, self-monitoring, and reinforcement into this aspect of the intervention, and low cost pedometers were provided to participants to facilitate with this process. These campaigns were introduced during months weeks 12-36 in the ADOPT group and during Weeks 53-78 in the MAINTAIN group. The goal of the campaign was to increase the number of steps until the goal of 10,000 steps per day (50,000 total steps per week) was achieved. Participants are encouraged to work towards this goal through a combination of structured exercise (e.g., daily walking program) and other forms of physical activity in their lifestyle (e.g., taking the stairs, etc.).