

Supplementary Methods

Lifestyle Therapy Intervention

All subjects in both the AT and the LT groups completed 15 individual lifestyle modification therapy sessions during the first 12 months. This program included nutritional, physical activity, and behavioral education topics to enhance compliance with consuming a structured low-calorie diet and increasing physical activity. Dietary topics included information on energy content of foods, how to eat at restaurants and parties, holiday eating, and healthy dieting. Physical activity topics included the health benefits of physical activity and strategies for increasing daily lifestyle activity. The behavioral content emphasized strategies of self-monitoring and goal setting and included problem solving, overcoming high-risk situations for unhealthy eating, relapse prevention, and strategies for long-term weight maintenance. Subjects were provided handouts that summarized the key points of the educational content and allowed them to record their dietary intake and physical activity goals. Subjects were encouraged to keep a food record and reviewed this with the study dietitians; however, these were not formally analyzed for calorie or macronutrient content. Subjects also participated in town hall meetings every quarter with other participants in their assigned treatment group to share their experiences and review any study-related issues.

Subjects were given recommendations on energy intake based on both their starting weight and group assignment. Energy intake recommendations increased with baseline subject weight and with AT group assignment. Energy intake recommendations were 300 to 400 kcal in the AT group compared with the LT group (Supplementary Table 5). Macronutrient distribution recommendations followed the Acceptable Macronutrient Distribution Ranges for Adults.¹ Subjects in the AT group were also instructed to consume water with meals to aid with aspiration.

Follow-up Visits

Subjects in the LT group were seen at weeks 0, 2, 4, and 8 and then every 4 weeks until week 52 for a medical evaluation by the study nurse (weight, vital signs, review adverse events if any, review current medication list) and lifestyle therapy by the study dietitian. A physician evaluated subjects at baseline and weeks 24 and 52. The subjects in the AT group were seen by the study physician and study nurse 6 days after A-Tube implantation for a medical evaluation and to check for healing of the A-Tube site and at 12 days after A-Tube implantation for a medical evaluation and to place the Skin-Port, receive aspiration

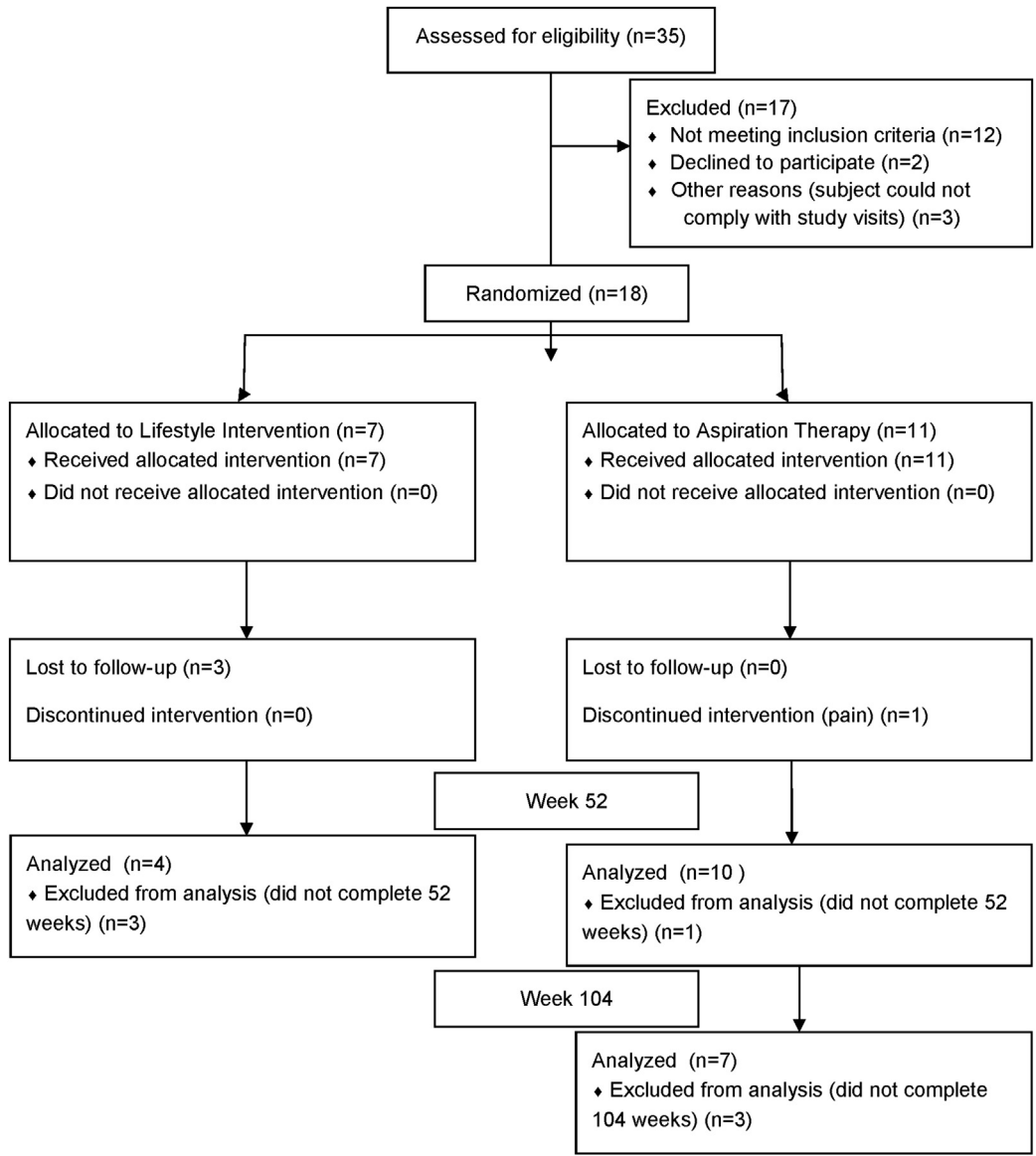
training, and participate in the first lifestyle therapy session. Subjects in the AT group were seen by the study physician again at weeks 2, 8, 24, 52, 76, and 104. They were seen by the study nurse for a medical evaluation weekly through week 4, every other week through week 24, and then every 4 weeks through week 104. The study nurse was in telephone contact with subjects in the AT group at week 5 and every other week through week 23 to review any adverse events. Lifestyle therapy was given by the study dietitian at weeks 2, 4, and 8; every 4 weeks through week 52; and every 8 weeks through week 104.

Assessment of Aspiration Efficiency

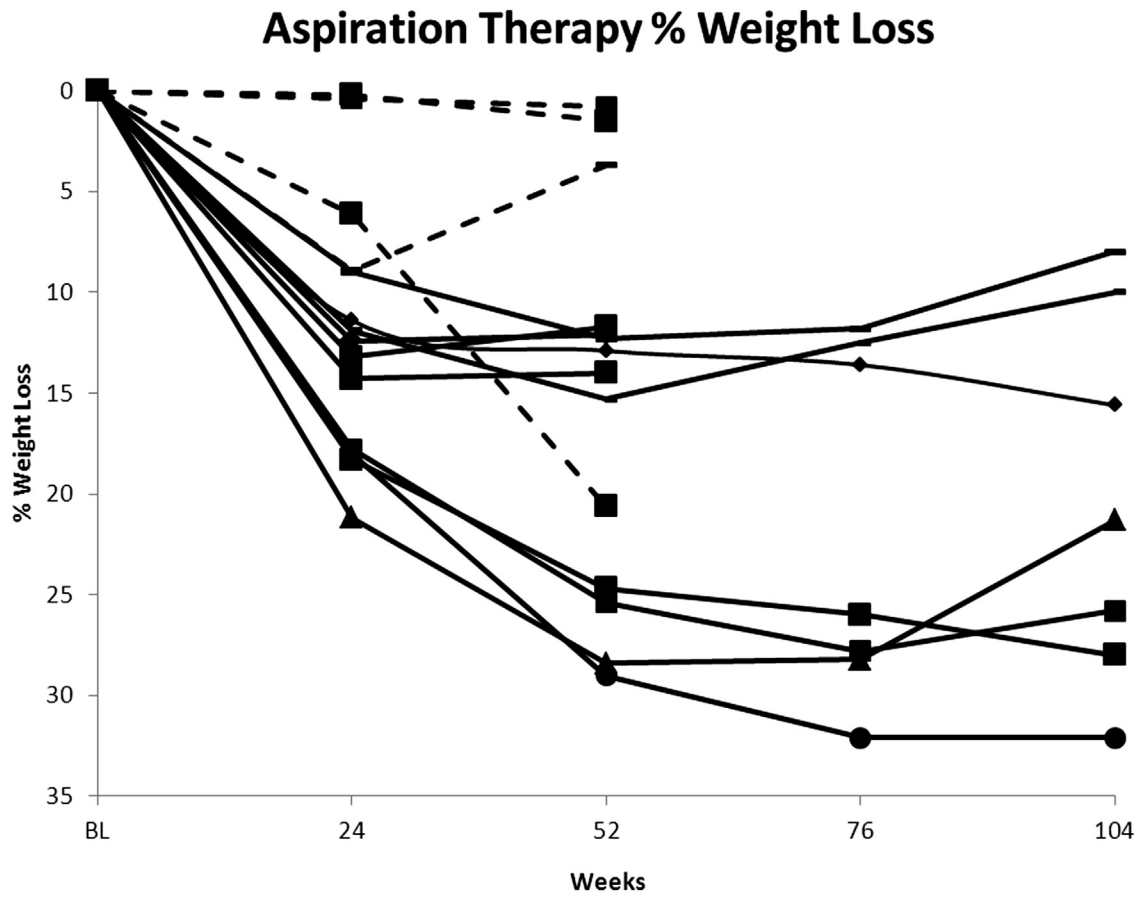
The percentage of calories ingested during a meal removed by the aspiration procedure was determined in 7 subjects. The effect of both the amount of calories consumed and the timing of aspiration after meal ingestion on aspiration efficiency was evaluated. Meals containing either 450 kcal (20% protein, 30% fat, 50% carbohydrate) or 800 kcal (also 20% protein, 30% fat, 50% carbohydrate) were prepared by the Clinical Research Unit metabolic kitchen. Subjects consumed each meal on 2 occasions 1 week apart. Two identical meals were prepared for each study; one meal was consumed by the subject in ~20 minutes, and the other was homogenized for subsequent analysis of energy content. In one study, the aspiration procedure was performed 20 minutes after the meal was consumed; in the other study, aspiration was performed 60 minutes after the meal was consumed. This time point was chosen because subjects reported frequently delaying aspiration 60 minutes or more after a meal. The gastric aspirate was collected, weighed, and homogenized (4 Liter Waring Blender; Waring Laboratory Science, Torrington, CT). The energy contents of 3 aliquots of homogenized gastric aspirate and 3 aliquots of the homogenized meal were determined using bomb calorimetry (NP Analytical Laboratory, St Louis, MO). The average value for the 3 samples was used to assess aspiration efficiency, defined as the amount of energy removed by aspiration divided by the amount of energy consumed: $(\text{Gastric Aspirate [kcal/g]} \times \text{Total Gastric Aspirate [g]}) / (\text{Total Meal [kcal/g]} \times 100)$.

Supplementary Reference

1. Institute of Medicine. National Research Council. Dietary reference intakes for energy, carbohydrate, fiber, fat, fatty acids, cholesterol, protein, and amino acids. Washington, DC: The National Academies Press, 2005.



Supplementary Figure 1. Flow of study participants.



Supplementary Figure 2. Individual percent weight loss for the LT group (*dashed lines*) and the AT group (*solid lines*).

Supplementary Table 1. EDE at Baseline and Change at Week 52

	Baseline		Change at week 52		Interaction <i>P</i> value
	LT group	AT group	LT group	AT group	
Avoidance of eating	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	NA
Avoidance of exposure	2.0 ± 0.7	2.4 ± 0.56	0.2 ± 1.1	-2.0 ± 0.54 ^a	.061
Desired weight (<i>lb</i>)	145.2 ± 3.7	156.5 ± 3.58	-2.5 ± 5.2	-4.0 ± 3.64	.825
Dietary rules	0.0 ± 0.0	0.6 ± 0.6	0.7 ± 1.5	0.6 ± 0.6	.891
Discomfort seeing body	2.75 ± 0.48	1.8 ± 0.57	-1.0 ± 1.0	-1.8 ± 0.57 ^b	.482
Eating in secret	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	NA
Desire for empty stomach	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	NA
Guilt about eating	0.75 ± 0.48	0.3 ± 0.3	-0.75 ± 0.48	-0.3 ± 0.3	.439
Importance of shape	2.5 ± 0.29	2.7 ± 0.54	-0.0 ± 1.2	-0.8 ± 0.53	.492
Importance of weight	2.25 ± 0.25	2.6 ± 0.54	0.25 ± 0.85	-0.6 ± 0.52	.404
Preoccupation with food	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	NA
Preoccupation with shape	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	NA
Reaction to prescribed weighing	0.0 ± 0.0	0.0 ± 0.0	0.75 ± 0.75	0.4 ± 0.22	.551
Social eating	0.25 ± 0.25	0.2 ± 0.13	0.0 ± 0.41	-0.2 ± 0.13	.549

NOTE. All factors but desired weight are on a 7-point scale from 0 to 7, with higher numbers indicating higher psychopathology (ie, greater frequency or severity). Data are expressed as means ± SEM. *P* value for interaction (group × time) was not computed for variables with 0.0 at both baseline and week 52.

NA, not applicable.

^aWeek 52 value different from baseline value, paired *t* test, *P* = .005.

^bWeek 52 value different from baseline value, paired *t* test, *P* = .012.

Supplementary Table 2. BDI-II at Baseline, Week 24, and Week 52

Group	Subject	Baseline	Week 24	Week 52
AT	1	4	6	5
	2	1	2	0
	3	2	5	4
	4	5	1	3
	5	2	2	0
	6	0	0	0
	7	4	4	4
	8	7	10	6
	9	1	2	1
	10	3	2	1
LT	11	0	1	0
	12	3	2	12
	13	14	28	18
	14	3	3	5

Supplementary Table 3. Stunkard Eating Inventory

Behavior trait	Baseline		Week 52		Interaction <i>P</i> value
	LT group	AT group	LT group	AT group	
Cognitive restraint	7.8 ± 1.9	8.3 ± 0.9	12.0 ± 2.2 ^a	16.1 ± 0.9 ^a	.133
Disinhibition	9.8 ± 1.3	9.2 ± 1.0	9.5 ± 1.0	4.8 ± 0.7 ^a	.026
Hunger	5.8 ± 1.1	5.8 ± 0.8	5.5 ± 2.2	2.9 ± 0.8 ^a	.168

NOTE. The 21 items for cognitive restraint, 16 items for disinhibition, and 14 items for hunger are scored from 0 to 1. A higher score indicates a higher level of cognitive restraint of eating, disinhibition of eating, or perception of hunger. All data are expressed as mean ± SEM.

^aWeek 52 value different from baseline value, paired *t* test, *P* < .05.

Supplementary Table 4. Hunger Visual Analogue Scale

Question	Baseline		Week 52		Interaction <i>P</i> value
	LT group	AT group	LT group	AT group	
How hungry did you feel over the past week?	46.8 ± 2.5	49.6 ± 3.0	56.5 ± 13.0	47.8 ± 5.7	.409
How much did you think about food over the past week?	52.8 ± 5.9	53.2 ± 4.3	48.8 ± 7.4	51.7 ± 6.4	.864
How much were you bothered or distracted by thoughts of food over the past week?	49.3 ± 11.6	26.4 ± 8.4	23.8 ± 8.3	31.2 ± 6.0	.117
How full did you feel after consuming your meals over the past week?	62.3 ± 14.2	66.5 ± 4.9	63.3 ± 14.0	67.1 ± 4.3	.970
How full did you feel in general over the past week?	57.8 ± 9.2	59.0 ± 3.7	56.3 ± 9.5	61.8 ± 4.6	.634
How often did you experience craving to eat particular types of food over the past week?	67.3 ± 13.5	55.4 ± 4.4	64.5 ± 15.3	52.1 ± 6.0	.972

NOTE. All data are expressed as mean ± SEM. All ratings are on a scale from 1 to 100, with higher numbers indicating greater degrees of the construct.

Supplementary Table 5. Recommended Energy Intake for Study Subjects Based on Initial Body Weight and Group Assignment

Body wt (<i>lb</i>)	Recommended energy intake (<i>kcal/day</i>)	
	LT group	AT group
150–199	1200	1500
200–249	1500	1800
250–299	1700	2000
300–349	2000	1350
≥350	2300	2700