

# Transtheoretical Model-Chronic Disease Care for Obesity in Primary Care: A Randomized Trial

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## Abstract

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**Objective:** To compare health benefits achieved in a transtheoretical model-chronic disease (TM-CD) minimal intervention for obesity vs. augmented usual care (AUC).

**Research Method and Procedures:** This was a 2-year, randomized clinical trial with overweight or obese men and women from 15 primary care sites. AUC ( $n = 336$ ) included dietary and exercise advice, prescriptions, and three 24-hour dietary recalls every 6 months. TM-CD care ( $n = 329$ ) included AUC elements plus “stage of change” (SOC) assessments for five target behaviors every other month, mailed SOC and target behavior–matched workbooks, and monthly telephone calls from a weight-loss advisor. Weight change was the primary outcome.

**Results:** Repeated measures models under the missing at random assumption yielded nonsignificant adjusted differences between the AUC and TM-CD groups for weight change, waist circumference, energy intake or expenditure, blood pressure, and blood lipids. The pattern of change over time suggested that TM-CD participants were trying harder

to impact target behaviors during the first 6 to 12 months of the trial but relapsed afterward. Sixty percent of trial participants maintained their baseline weights for 18 to 24 months.

**Discussion:** A combination of mailed patient materials and monthly telephone calls based on the transtheoretical model and some elements of chronic disease care is not powerful enough, relative to AUC, to alter target behaviors among overweight primary care patients in an obesogenic environment. AUC may be sufficient to maintain weights among at-risk primary care patients.

**Key words:** weight management, chronic disease, cognitive-behavioral therapy, treatment, randomized controlled trial

## Introduction

Obesity is epidemic in the general population because of a widespread polygenetic susceptibility interacting with an obesogenic environment that encourages excess energy intake and discourages energy expenditure (1–3). Thus, almost all middle-aged primary care patients, particularly among disadvantaged groups, have excess adipose tissue and have one or more obesity-related chronic diseases such as hypertension, hyperlipidemia, diabetes, osteoarthritis, asthma, lower back pain, or heart disease (4,5). Cognitive behavioral obesity interventions that are linked to primary care should reinforce public health efforts against the epidemic; however, an area of controversy is the minimum length and intensity of a primary care intervention that will maintain healthier patient behaviors in an obesogenic environment that will persist for many years (6,7). An open-ended series of weekly face-to-face contacts between a patient and a provider may be an expensive treatment modality for payers with other priorities. Thus, some research has focused on very brief physician counseling (8). Group visits, telephone calls, mail contacts, e-mail or Internet

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contacts, or referrals to the best commercial programs are feasible alternatives to multiple face-to-face visits with a clinician, but it is not clear which mix of treatment modalities is best for which patients (9).

We were interested in an intervention that would be compatible with traditional primary care practice, which is still more focused on “acute problems” than optimal chronic disease care (7). We did not want to perturb the physician, the office staff, the flow of patients (four or five per hour), or the flow of revenue, but we felt it was important to maintain some linkage between primary care and the intervention because of comorbidity issues, because primary care is where most patients enter the health system, and because of our belief that better management of obesity in primary care settings could prevent more serious sequelae and reduce aggregate health care costs (10). Because counseling resources are limited, and triage was a familiar concept, we wanted to match patients and treatments. We also wanted to be patient-centered in the sense of providing appropriate types of information and counseling to a heterogeneous population of patients with a wide distribution of “readiness” for changing key dietary and exercise behaviors. Finally, we wanted the intervention to have a strong cognitive and behavioral grounding and to be “organized and proactive,” because occasional advice to “eat less and exercise more” did not seem to be particularly effective. A primary care linked mail and telephone intervention based on the transtheoretical model (TM)<sup>1</sup> and some elements of chronic disease (CD) care seemed to meet most of our *a priori* criteria (7,11).

In this paper, we report the results from the Reasonable Eating and Activity to Change Health (REACH) trial—a randomized clinical trial of an obesity intervention derived from the TM and a chronic disease care paradigm (TM-CD) (12). The focus of the REACH trial was small changes in multiple target behaviors that should lead to small weight changes that are sustainable over time. The primary hypothesis driving the REACH trial was that, after 100 weeks of treatment, the TM-CD intervention patients would experience a greater decrease in body weight compared with augmented usual care (AUC) patients. Similar secondary hypotheses addressed changes in low-density lipoprotein (LDL)-cholesterol, energy consumption, and energy expenditure. Anxiety and depression were expected to retard stage progression, behavior change, and weight loss. A companion observational study suggested that the elapsed time in the action or maintenance stages of change is a strong predictor of weight loss in primary care patients and documented that the majority of REACH trial participants started

the trial in a preaction stage for one or more behaviors, which is a prerequisite for applying the TM (13).

## Research Methods and Procedures

### Study Design

The study was a 24-month randomized, parallel-group trial conducted at 15 primary care practices in northeastern Ohio between July 1998 and December 2002. Assessments were scheduled at 0 (baseline), 6, 12, 18, and 24 months. The initial sample size (540) was chosen to provide a power of 0.90 to detect a difference of 4.5 kg (about a 5% weight loss difference) between the TM-CD and AUC groups with a two-tailed type I error probability of 0.05 and a 20% dropout rate (14–17). The impact of alternative values for the SD and correlation of weight measurements was considered in the sample size calculations (15). The trial also had 0.90 power to detect small to moderate TM-CD vs. AUC differences in blood lipids (5%), energy intake (85 kcal/d), and energy expenditure (200 kcal/wk). The original design called for equal numbers of male and female patients and African-American patients to be in proportion to their representation in Summit County and the nation (12%). Supplemental grant funds secured in the second year of the trial allowed African-American enrollment to double (27%).

General recruitment stalled at 500 patients in the latter half of 1999 while we were waiting for the approval of additional “single project assurances” that would allow us to enroll participants at sites with larger proportions of African-American patients. After the approvals were granted, recruitment continued until the end of 2000. Recruiting eligible men and African Americans was more difficult than recruiting eligible white women. Enrollment was closed when 665 patients were enrolled.

### Study Participants

Participants were recruited when they inquired about the study after either talking to their physician or reading study brochures, posters, or letters that were mailed to potential participants identified by primary care physicians. Waiting room brochures and posters, general newspaper articles, and announcements at churches with African-American congregations were used to raise community awareness of the study. All participants were required to be patients in one of the primary care practices that were affiliated with the study. All participants provided written informed consent according to a procedure approved by three institutional review boards. Representatives of the private practices signed single project assurances. Men and women, 40 to 69 years of age, with elevated BMI ( $>27 \text{ kg/m}^2$ ) or elevated waist-to-hip ratios (WHR;  $>0.950$  for men or  $>0.800$  for women) were eligible for the study. Exclusion criteria were no access to a telephone, difficulty understanding eighth-

<sup>1</sup> Nonstandard abbreviations: TM, transtheoretical model; CD, chronic disease; REACH, Reasonable Eating and Activity to Change Health; AUC, augmented usual care; SOC, stage of change; WLA, weight loss advisor; CI, confidence interval; MAR, missing at random.

grade level spoken or written English, pregnancy, lactation, <6 months postpartum, or use of a wheel chair for mobility. Primary care physicians excluded high-risk patients with severe heart or lung disease.

### **Randomization**

After the informed consent process was completed, and baseline data were collected, participants were randomized by opening an envelope with a set of ordered tickets indicating “TM-CD” or “Traditional” care. The (NEOUCOM) Office of Biostatistics prepared the ordered randomization tickets using permuted blocks of 10. A separate randomization sequence was used for each primary care practice site. Participants and research staff at each practice were blind to the assignment of patients while obtaining baseline measures, because assignment envelopes were not opened until the end of the visit. “Stage of change” (SOC) scores and Primary Care Evaluation of Mental Disorders (PRIME-MD) scores were obtained for the intervention group after randomization (see below).

### **AUC Group**

Participants assigned to the AUC group were asked to provide anthropometric, dietary, and exercise data every 6 months, which is consistent with behavioral self-monitoring principles. After each semiannual dietary and exercise assessment, a registered dietitian also provided 10 minutes of counseling based on either the USDA Food Guide Pyramid (*Dietary Guidelines for Americans*) or a Soul Food Guide Pyramid. The dietitian prepared written dietary and exercise prescriptions based on the information from the dietary and exercise recalls. Patients were advised to discuss their lipid and blood pressure values with their primary care physician. Patients in both the AUC and TM-CD groups were paid \$25 for completing each postbaseline assessment.

### **TM-CD Group**

Participants assigned to the TM-CD group had the same basic care as the AUC group. Patients randomized to both the AUC and TM-CD groups had anthropometric, dietary, and physical activity assessments every 6 months and brief (10 minutes) advice based on general dietetic practice (*Dietary Guidelines for Americans*) and a standard prescription (reduce calories, increase fruit and vegetables, reduce fat, increase activity and exercise).

In addition, the TM-CD group was formally evaluated for anxiety, depression, and binge eating disorder every 6 months, and they completed an SOC assessment for five target behaviors every 2 months (18,19). The target behaviors were increased exercise, increased usual activity, increased dietary portion control, decreased dietary fat, and increased fruits and vegetables. Patients in an action stage at baseline were not excluded.

Mood disorder case-finding is consistent with good chronic disease care. These disorders are prevalent in primary care populations, and they can complicate the self-management of other chronic diseases such as diabetes or obesity. We selected the short PRIME-MD instrument because it facilitated valid case-finding for depression, anxiety, and (binge) eating disorder, which seem to affect a subset of patients who volunteer for weight management programs (18). We felt that it was unethical to conduct mood disorder case-finding in the AUC group without informing the primary care physicians of the results; therefore, we restricted the case-finding to the TM-CD group.

Patients were mailed stage- and behavior-matched workbooks that corresponded to their most recent SOC profile. TM-CD patients also received brief monthly telephone calls from a weight loss advisor (WLA) who was trained to apply the processes of change that corresponded to the patient’s SOC profile. The WLAs had access to a set of public domain patient handouts and other materials (menu suggestions, mall walking maps, descriptions of local walking trails) that could be mailed to TM-CD patients when they requested additional information. Primary care physicians had the option of receiving a report indicating when a TM-CD patient was “positive” for depression or anxiety.

Physicians received periodic reports summarizing TM-CD patient progress with respect to the five target behaviors. A part-time pharmaceutical representative was trained to provide academic detailing to physicians on the use of the SOC profiles, the processes of change, and how to use a small double-sided SOC flip chart when counseling patients in the examination room. We expected that primary care physicians would address obesity issues only after all “acute” concerns had been dealt with, when the patient brought up the issue, or at infrequent (one, two, or three times per year) chronic disease visits (diabetes check-up). Chart reviews at baseline and 12 and 24 months suggested a low level of physician attention to dietary, exercise, or weight issues before (15% of charts) and during (6% of charts) the trial.

Monthly WLA telephone calls averaged 15 minutes per call. TM-CD participants were taught behavioral techniques consistent with Prochaska’s description of the relationship between the “processes of change” and the “stages of change” for the target behaviors. Self-monitoring of the target behaviors was recommended for patients in action or maintenance, but self-monitoring records were not reviewed by the physician or the WLA. Daily self-weighing was not recommended because daily weight changes were expected to be small. We assumed that small daily weight changes could be either motivating or discouraging depending on expectations and the behavioral context.

Implementation of the WLA telephone protocol was monitored by the project psychologist (KS), who periodically debriefed the WLAs and advised them how to interact

with problematic patients. Patients were assigned to one of three WLAs, but personnel issues (vacation, illness, maternity leave) necessitated WLA cross-coverage for the telephone calls. However, the WLAs documented key aspects of each patient encounter in an Access database, which provided some continuity of care. The database was consulted before and during each WLA telephone call to help the WLA remember each patient's current SOC profile and other issues. Use of the WLA database to support a counseling encounter, relying on periodic proactive patient contacts, allowing the patients some latitude in selecting the target behaviors to focus on, and accommodating the entire SOC distribution are consistent with Wagner's chronic disease care model (7).

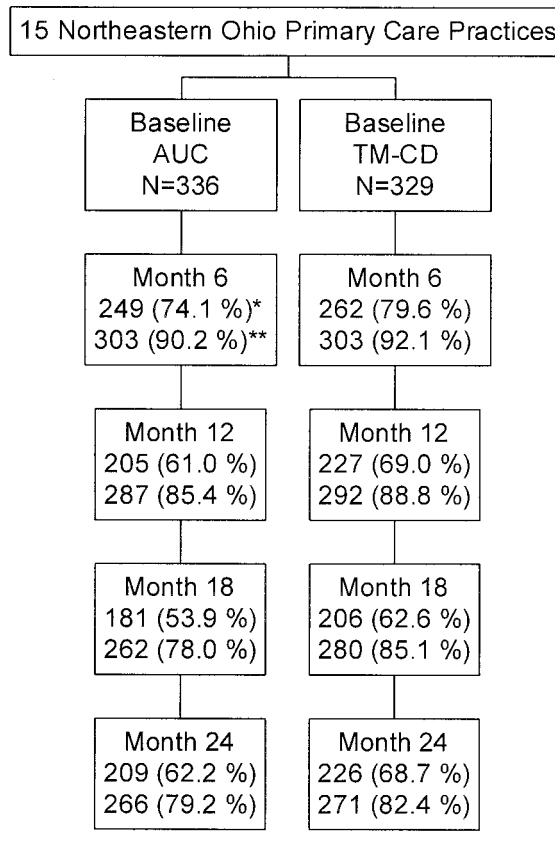
**Outcome Measures**

The main outcome measure was weight, which was measured every 6 months for 24 months at primary care physician offices using a standardized calibrated scale. Other biological risk measurements included waist girths, blood lipids (from a central laboratory), and blood pressures. Measurements with an important behavioral and cognitive component were estimates of daily energy intake from three (NDS-R) software-driven dietary recalls and total energy expenditure per kilogram per day from a metabolic equivalent-coded 7-day physical activity recall (20,21). Psychosocial measurements included scales for self-efficacy, social support, and decisional balance for healthy eating and exercise, the SF-12 subscales for general physical and mental health, and a social desirability scale (22–28). The primary outcome measure was TM-CD vs. AUC body weight change from baseline at or near the end of the 24-month follow-up.

Primary care records were abstracted once a year. Chart weights were substituted for measured weights when the latter were missing. Seventy percent of the participants had a measured weight from the 18- or 24-month follow-up visit. Eighty-eight percent of participants had either a measured or chart weight at or close to the 18- or 24-month measurement period. Pearson correlations between measured and chart weights averaged 0.99 (over repeated measures). Weight data (measured or chart) were equally available from both treatment groups at follow-up months 6, 12, and 24. At month 18, there were significantly more weight values available for the TM-CD group (85% vs. 78%;  $\chi^2 = 5.6$ ).

**Statistical Analysis**

Differences between the treatment groups at baseline were analyzed using 95% confidence intervals (CIs). The primary hypothesis test focused on the final weight change from baseline to month 24 (or month 18 if the month 24 value was missing). An intention-to-treat analysis including all randomized participants was performed using linear



\* Measured weight

\*\* Measured weight or weight abstracted from chart

Figure 1: Participant follow-up by study group.

models and linear mixed (repeated-measures) models (Proc GLM and Proc Mixed, SAS version 8.2; SAS Institute, Cary, NC) using baseline variables, unstructured covariance matrices, and a missing at random (MAR) assumption. The MAR assumption is that the dropout pattern for missing repeated measures is random conditional on all known (observed) values of the repeated measures and baseline variables (29,30). Use of the MAR assumption is more likely to yield unbiased parameter estimates than “analysis of complete data” (31). In a sensitivity analysis considering the 12% of patients with missing weights for month 18 or 24, we used baseline weight as a substitute (32). Subgroup analyses allowed for the possibility of synergistic or antagonistic effects.

**Results**

**Participant Follow-up**

Figure 1 shows the proportion of participants in each study group (AUC or TM-CD) with a measured weight (53.9% to 79.6%) and other information at the four fol-

**Table 1.** Baseline characteristics of participants by randomization group

Variables	Frequency (%)		
	AUC group (n = 336)	TM-CD group (n = 329)	95% CI on difference (AUC—TM-CD)
Age group (years)			
40 to 49	129 (38)	139 (42)	(−11, 3.6)
50 to 59	141 (42)	138 (42)	(−7.5, 7.5)
60 to 69	66 (20)	52 (16)	(−2.0, 9.6)
Men	110 (33)	97 (30)	(−3.8, 10)
African Americans	87 (27)	88 (28)	(−7.5, 5.8)
BMI group (kg/m <sup>2</sup> )			
25 to 29.9	73 (22)	59 (18)	(−2.3, 9.8)
30 to 34.5	107 (32)	119 (37)	(−12, 2.9)
35 to 39.0	82 (24)	69 (21)	(−2.9, 9.8)
40.0+	74 (22)	79 (24)	(−8.4, 4.4)
Hypertension	151 (48)	138 (44)	(−4.5, 11)
Elevated blood cholesterol	115 (38)	107 (36)	(−5.5, 8.9)
(Osteo)arthritis	103 (33)	106 (35)	(−8.6, 5.5)
Stomach problems	57 (19)	73 (25)	(−11, 0.8)
Diabetes	51 (17)	41 (14)	(−2.5, 8.0)
Prior/current psychotropic medication	79 (24)	85 (26)	(−8.9, 4.2)
Prior attempts to lose weight	303 (94)	306 (97)	(−7.0, 1.4)
Physician said to lose weight	262 (83)	246 (79)	(−3.3, 9.7)
Prior commercial program	155 (48)	147 (47)	(−6.1, 9.0)
Weight gain since 21 to 25 years of age (lb)			
10 to 49	89 (28)	87 (28)	(−6.7, 6.8)
50 to 99	158 (50)	155 (49)	(−7.7, 7.5)
100 to 149	49 (15)	47 (15)	(−5.0, 5.6)

low-up assessments. Figure 1 also shows the proportion with a measured weight or a chart weight (78.0% to 92.1%) when the latter was substituted for a missing measured weight. The majority of missing values occurred because participants declined further participation when an effort was made to schedule a follow-up appointment. Three patients died (two probable heart attacks and one automobile accident) during follow-up. After reviewing the circumstances of death, the local Institutional Review Board judged that these deaths were unrelated to trial participation.

#### *Participant Characteristics*

Characteristics of participants at baseline are shown in Table 1. All 95% CIs on differences between the AUC and TM-CD groups at baseline included zero. According to their BMIs, 20% of participants were overweight, 34% had Class I obesity, 23% had Class II obesity, and 23% had Class III

obesity. Ninety-five percent of the participants reported prior weight loss attempts, 81% reported that their physician had previously advised them to lose weight, and 47% had prior experience with a commercial weight loss program. Since their early twenties, 28% reported that they had gained an average of 36.3 lb (16.5 kg), 50% reported that they had gained an average of 71.1 lb (32.3 kg), and 15% reported that they had gained an average of 118.7 lb (54.0 kg).

#### *Final Weight Change*

The mean weight change from baseline for the TM-CD group to the end of follow-up was  $-0.39$  kg (SE = 0.38; 95% CI =  $-1.1, 0.4$ ). The mean weight change for the AUC group was  $-0.16$  kg (SE = 0.42; 95% CI =  $-1.0, 0.7$ ). The difference of 0.23 kg greater weight loss in the TM-CD group was not significant ( $p = 0.50$ ) and had a 95%

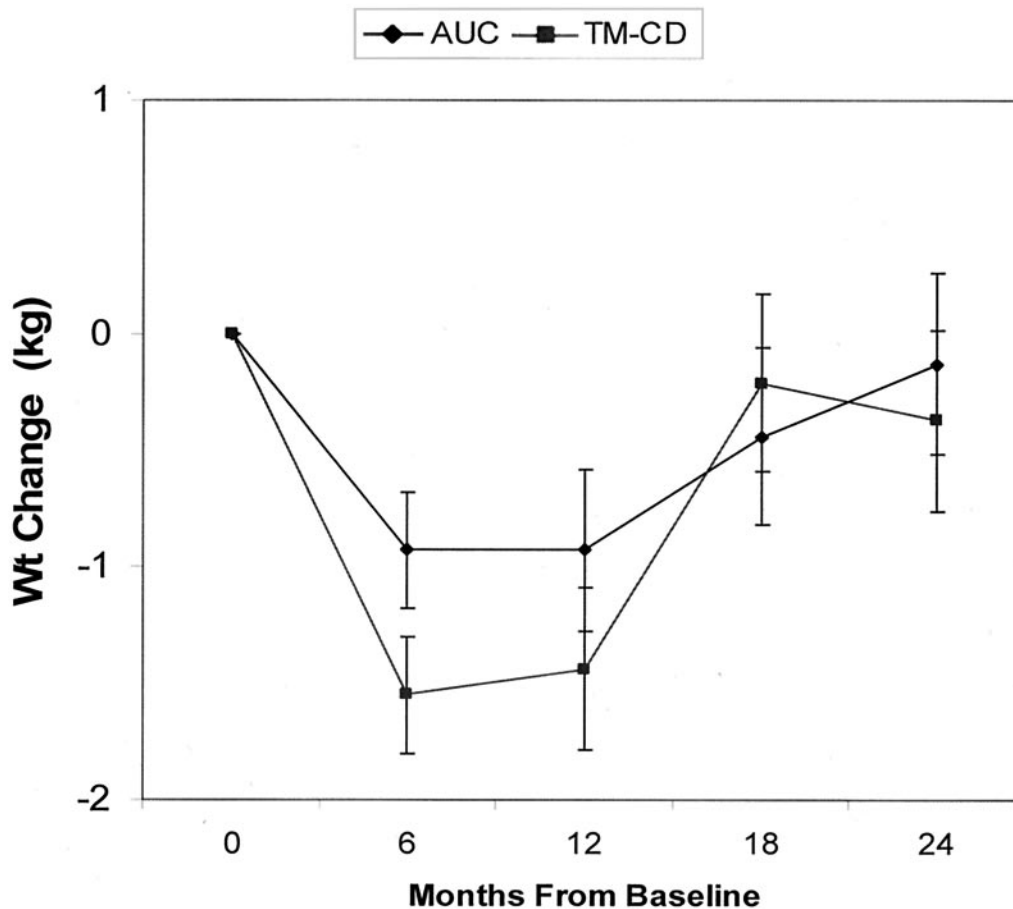


Figure 2: Mean weight change by intervention group.

CI of  $-1.4, 0.9$ . The difference after adjusting for baseline weight and other covariates was highly similar at  $0.22$  kg greater weight loss in the TM-CD group. For the final weight analysis,  $70\%$  of patients made their final visits; for another  $18\%$  of patients, medical chart weights were obtained for the same period (within 1 month of the 18- to 24-month range). The chart weights correlated  $0.99$  with measured weights when both were available. A sensitivity analysis of these results substituted baseline weights for the  $12\%$  with missing final weights data, i.e., no change was substituted for these  $12\%$ . This gave highly similar results, with a  $0.21$  kg greater weight loss in the TM-CD group. The mean change from baseline for both groups combined was  $-0.29$  kg ( $95\%$  CI =  $-0.9, 0.3$ ).

#### Repeated Measures on Weight

From Figure 2, a familiar pattern of early weight loss and regain appeared. In comparing early change (6 and 12 months) with late change (18 and 24 months) in the two groups, no significant difference was found ( $p = 0.17$ ), even though the TM-CD group appeared to lose  $0.5$  kg (SE =

$0.4$ ) more weight in the early period than the AUC group. Combining the two groups, this early loss and regain pattern (within-group change) was highly significant ( $p < 0.0001$ ). Figure 2 shows estimates of mean weight change by intervention group and data wave from the mixed repeated-measures model.

Figure 3 shows estimates of mean waist girth change by intervention group and data wave. The overall waist girth comparison of AUC and -CD groups was not significant ( $p = 0.57$ ). A significant ( $p = 0.0001$ ) decrease of  $1.7 \pm 0.4$  cm was found (for both groups combined) at 24 months.

#### Change in Energy Intake and Expenditure

An analysis of mean change in energy intake and energy expenditure by intervention group and data wave was completed. The overall AUC vs. TM-CD comparison of energy intake was not significant ( $p = 0.69$ ). As in the waist girth analysis with both groups combined, the energy intake analysis revealed a significant ( $p < 0.0001$ ) mean decrease at month 24 ( $\sim 250$  kcal/d). This decrease was consistent throughout the 6- to 24-month measurements. The overall AUC vs. TM-CD comparison of energy expenditure was not

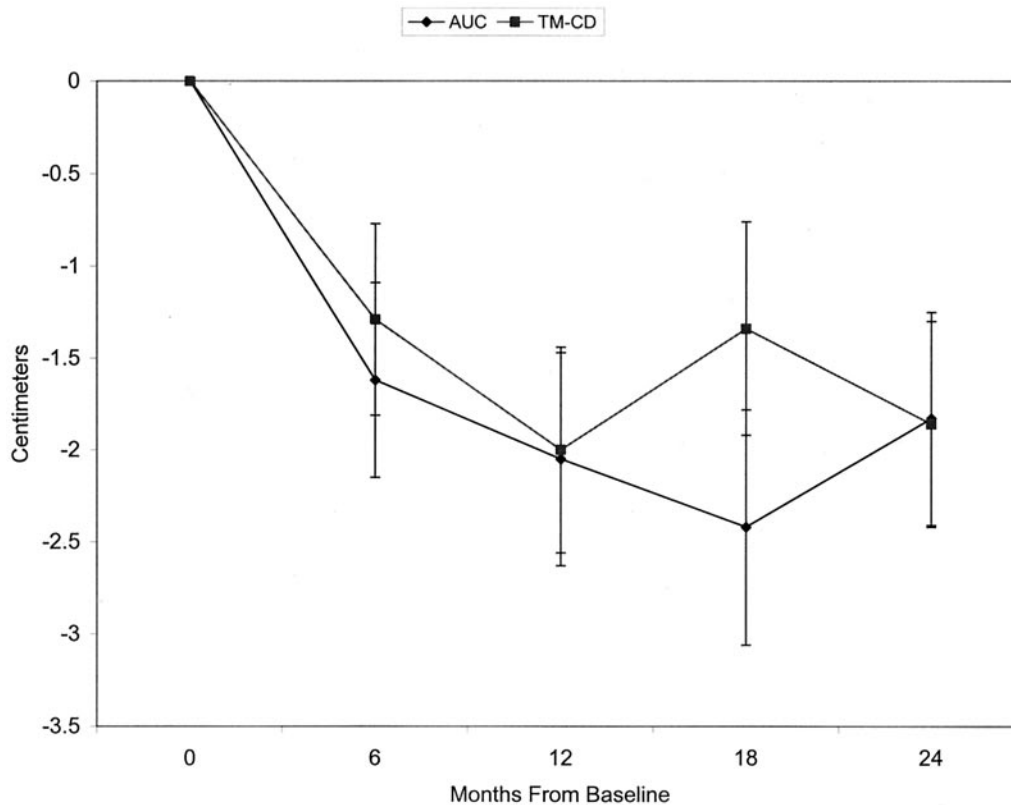


Figure 3: Mean change in waist girths by intervention group.

significant ( $p = 0.31$ ). At month 24, the increase in energy expenditure was significant ( $\sim 2$  kcal/kg per day) for both groups combined ( $p = 0.04$ ).

#### Exercise Minutes

Figure 4 shows estimates of the mean change in self-reported exercise minutes per week. The overall AUC vs. TM-CD comparison was significant ( $p = 0.008$ ). The estimate of the mean difference between the AUC and TM-CD groups was  $31.5 \pm 12$  additional minutes per week in the TM-CD group across all measurements. The difference was consistent from 6 to 24 months.

#### Lipids, Blood Pressure, and Interactions

Similar analyses of repeated blood lipid and blood pressure data yielded similar results. There were no significant lipid or blood pressure differences between the AUC and TM-CD groups during follow-up. Mixed repeated measures models of weight, waist girth, energy intake, energy expenditure, exercise minutes, lipids, or blood pressure with additional cross-product terms for intervention group  $\times$  sex, group  $\times$  BMI, group  $\times$  ethnicity, and group  $\times$  data wave provided no support for the existence of statistical interactions. Thus, it seems that our general results are not modified by the patient's sex, ethnicity, baseline BMI group, or follow-up period.

#### Discussion

The estimate of the 18- to 24-month weight change difference between the TM-CD and AUC groups was not statistically different from zero, and the 95% CI had a narrow range of 1.1 kg on either side of a 0.23 difference in favor of TM-CD. Thus, the data do not support our a priori hypothesis that overweight and obese primary care patients would lose more weight if they were exposed to the TM-CD intervention (plus AUC) vs. AUC alone. In other words, the data suggest that the combination of elements in the AUC was largely equivalent to the combination of elements of AUC plus TM-CD care. Analysis of other outcomes such as waist girth, energy intake, energy expenditure, blood lipids, and blood pressure was generally consistent with the weight change analysis. The one exception was the results for the weekly exercise minutes variable, which were more consistent with the hypothesized superiority of the TM-CD intervention. It is not clear whether misreporting biased the positive result for exercise minutes, but such an explanation suggests that we should have found similar biases for other self-reported behaviors such as energy intake. Moreover, social desirability scores were not associated with exercise minutes or other trial outcomes. WLAs were instructed to periodically bring up the subject of exercise, even when the patient did not choose to do so, because we believed that

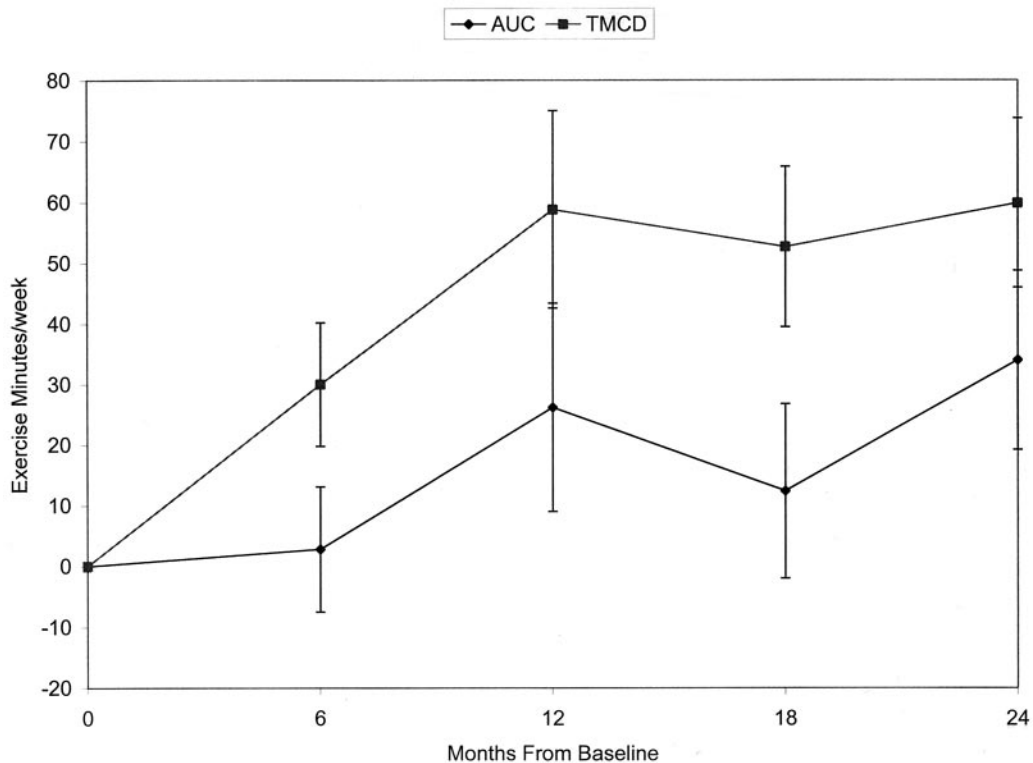


Figure 4: Mean changes in exercise minutes per week by intervention group.

many patients in our obesogenic environment focus exclusively on their diets, avoid the exercise issue, and thereby sabotage their longer-term weight loss effort.

Calibrated scales and chart weights that correlated 0.99 suggest adequate protection against measurement bias. Through random assignment, the two groups were highly similar at baseline. Relatively complete follow-up (88%) and the statistical methods used to deal with missing data suggest that biased follow-up does not explain the results. The statistical analysis also allowed for the possibility of interactions between the intervention and sex, ethnicity, and BMI group, but no evidence of these interactions was found. Finally, the sample size produced very precise estimates of effect size with narrow CIs.

One explanation of the results includes poor WLA adherence to the SOC protocol; i.e., WLA adherence to the SOC protocol remained an issue despite their extensive training through role-playing and periodic debriefings with the trial psychologist. According to the WLA database, the WLAs used stage appropriate processes of change during 47% of the telephone encounters. This reflects the fact that WLAs did not document their use of a process of change when “no barrier to change” was reported. Given that 60% of the participants had stable weights between months 6 and 24, a significant proportion of patients may have been underreporting “barriers” to additional weight loss. Thus, the WLAs had fewer opportunities than anticipated to apply

stage-appropriate processes of change, because many patients may have denied that there was an issue.

Taking the broadest view, we note that the participants in the REACH trial were at high risk for additional weight gain, yet they maintained their weight for 24 months, while significantly ( $p < 0.0001$ ) decreasing their waist girths by 2 cm and significantly decreasing ( $p < 0.0001$ ) energy intake by 250 kcal/d. Thus, weight maintenance in 60% of overweight or obese primary care patients may be accomplished by reviewing and/or renewing a standard dietary and exercise prescription that is informed by a brief anthropometric examination, sets of three dietary recalls, and a physical activity questionnaire every 6 months. The relative stability of REACH patient weights may be particularly important because weight regain, even after a major weight loss (>10% of baseline), is a recognized problem limiting the effectiveness of most behavioral interventions (33).

There have been no prior attempts to apply the TM and a CD paradigm to multiple target behaviors conducive of weight loss through periodic telephone calls from a weight loss advisor (34). Reliance on a telephone WLA is appealing because of the limited patient-clinician encounter time available in traditional acute problem-oriented primary care. Also, patients do not have to take the time to travel to the physician’s office and wait for a clinician or a group visit. However, our data suggest that once-a-month telephone weight loss advice with a strong theoretical basis may

not be effective, given the strength of the obesogenic environment. Other telephone counseling trials have had positive results, but those trials also had weekly or biweekly contact with participants (35). It is not clear that simply increasing the frequency of telephone calls is the best strategy, given the available treatment alternatives (36).

At least 18 randomized trials have reported interventions targeting one or more weight loss-related behaviors; however, the evidence supporting the value of TM theory for weight management from these trials is mixed (8,37–53). Over one-half of the trials reported no additional effect from the intervention on a least one weight-related outcome at the end of follow-up (8,37,39,41,42,44,46–48,50,53). Two trials reported nonsignificant findings for 12-month weight change (44,50).

Four recent non-TM trials suggest that modest interventions are likely to produce modest weight losses (5% to 10%) in an obesogenic environment (54–57). Womble et al. (57) compared a commercial Internet intervention to an intervention with the Lifestyle, Exercise, Attitudes, Relationships, Nutrition (LEARN) weight control manual, 11 brief blood pressure and weight assessment visits, and 4 visits with a psychologist. Jeffery et al. (55) compared a proactive 10-lesson telephone and mail-based intervention, a similar proactive mail-based intervention, and a usual managed care intervention. Ashley et al. (54) compared 26 group visits with a dietitian using the Lifestyle, Exercise, Attitudes, Relationships, Nutrition (LEARN) manual, 26 group visits with a dietitian plus meal replacement (Slimfast), and 26 visits to a primary care physician or a nurse plus meal replacement. Finally, Wadden et al. (56) compared counseling by a nutritionist or psychiatrist plus DL-fenfluramine and phentermine.

Heshka et al. (58) described their recent 24-month randomized trial comparing self-help to a commercial weight loss program. They reported small significant weight loss differences (2.9 vs. 0.2 kg) that favored the commercial program. However, an important feature of this commercial program was weekly weigh-ins, an element of care that was specifically excluded from the REACH trial protocol. The U.S. Preventive Services Task Force defines the intensity of obesity counseling in terms of the frequency of provider-patient contacts in the first 3 months of treatment (59). Monthly contact was described as “moderate” intensity, and those trials with more than monthly contact were more likely to be successful (59). Thus, given the evidence assembled by the U.S. Preventive Services Task Force since the REACH trial was designed, it now seems disingenuous to argue that minimal behavioral counseling directed at portion control (dietary energy restriction) can be an effective long-term treatment for obesity (33). The argument turns on the operational difference between intensive (once or twice a week) and minimal (once a month to once a year).

Standard behavior therapy, which is recommended by the NIH obesity treatment guidelines, involves the application of the principles of self-monitoring, contracting, modeling, reinforcement, and environmental control to weight loss-related behaviors—often in weekly meetings that continue for 6 months or longer. Weight loss in these intensive programs can approach 10% of initial body weight. However, when the meeting frequency is reduced to save costs, the lost weight tends to return. Thus, research has focused on alternatives to weekly group meetings, such as periodic telephone calls or Internet encounters. The design for the REACH trial was motivated by the apparent need for an alternative to 26 to 52 weekly group meetings in a medical specialty center setting.

Therefore, our interest was in telephone weight loss advising based on the TM and a CD paradigm. Our longitudinal data on the elapsed time in the action stages and weight loss support the concept of SOC (13). However, the comparisons of the weight change data between the AUC and TM-CD groups also suggest that some fundamental behavioral elements such as weekly telephone weigh-ins or weekly review of pedometer and portion control logs may have been missing from the TM-CD intervention (60). Finally, the link between the clinical intervention and public health programs could be strengthened. Primary care patients with different levels of obesity and clinical or social issues should be able to choose from a variety of clinical programs and formats—all of which are supported by compatible public health programs and initiatives.

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### References

1. French SA, Story M, Jeffery RW. Environmental influences on eating and physical activity. *Annu Rev Public Health*. 2001;22:309–35.
2. Blundell JE, Cooling J. Routes to obesity: phenotypes, food choices and activity. *Br J Nutr*. 2000;83(Suppl 1):S33–8.

3. **Mokdad AH, Bowman BA, Ford ES, Vinicor F, Marks JS, Koplan JP.** The continuing epidemics of obesity and diabetes in the United States. *JAMA*. 2001;286:1195–200.
4. **Noel M, Hickner J, Ettenhofer T, Gauthier B.** The high prevalence of obesity in Michigan primary care practices. An UPRNet study. Upper Peninsula Research Network. *J Fam Pract*. 1998;47:39–43.
5. **Clark JM, Brancati FL.** The challenge of obesity-related chronic diseases. *J Gen Intern Med*. 2000;15:828–9.
6. **Pignone MP, Ammerman A, Fernandez L, et al.** Counseling to promote a healthy diet in adults. A summary of the evidence for the U.S. Preventive Services Task Force. *Am J Prev Med*. 2003;24:75–92.
7. **Wagner EH, Austin BT, Von Korff M.** Organizing care for patients with chronic illness. *Milbank Q*. 1996;74:511–44.
8. **Norris SL, Grothaus LC, Buchner DM, Pratt M.** Effectiveness of physician-based assessment and counseling for exercise in a staff model HMO. *Prev Med*. 2000;30:513–23.
9. **Calfas KJ, Sallis JF, Zabinski MF, et al.** Preliminary evaluation of a multicomponent program for nutrition and physical activity change in primary care: PACE+ for adults. *Prev Med*. 2002;34:153–61.
10. **Colditz GA.** Economic costs of obesity and inactivity. *Med Sci Sports Exerc*. 1999;31(11 Suppl):S663–7.
11. **Prochaska JO, Redding CA, Evers KE.** The transtheoretical model and stage of change. In: Glanz K, Lewis FM, Rimer BK, eds. *Health Behavior and Health Education: Theory, Research, and Practice*. San Francisco, CA: Jossey-Bass; 1997:60–84.
12. **Logue E, Sutton K, Jarjoura D, Smucker W.** Obesity management in primary care: assessment of readiness to change among 284 family practice patients. *J Am Board Fam Pract*. 2000;13:164–71.
13. **Logue E, Jarjoura D, Sutton K, Smucker W, Baughman K, Capers C.** Longitudinal relationship between elapsed time in the action stages of change and weight loss. *Obes Res*. 2004;12:1499–508.
14. **Laird NM, Wang F.** Estimating rates of change in randomized clinical trials. *Control Clin Trials*. 1990;11:405–19.
15. **Rochon J.** Sample size calculations for two-group repeated measures experiments. *Biometrics*. 1991;47:1383–98.
16. **Laird N, Donnelly C, Ware J.** Longitudinal studies with continuous responses. *Stat Methods Med Res*. 1992;1:225–47.
17. **Longford N.** Random coefficient models. In: Arming G, Clogg C, Sobel M, eds. *Handbook of Statistical Modeling for the Social and Behavioral Sciences*. New York: Plenum; 1995, pp. 519–78.
18. **Spitzer RL, Kroenke K, Williams JB.** Validation and utility of a self-report version of PRIME-MD: the PHQ primary care study. Primary Care Evaluation of Mental Disorders. Patient Health Questionnaire. *JAMA*. 1999;282:1737–44.
19. **Sutton K, Logue E, Jarjoura D, Baughman K, Smucker W, Capers C.** Assessing dietary and exercise stage of change to optimize weight loss interventions. *Obes Res*. 2003;11:641–52.
20. **Buzzard IM, Faucett CL, Jeffery RW, et al.** Monitoring dietary change in a low-fat diet intervention study: advantages of using 24-hour dietary recalls vs food records. *J Am Diet Assoc*. 1996;96:574–9.
21. **Richardson MT, Ainsworth BE, Jacobs DR, Leon AS.** Validation of the Stanford 7-day recall to assess habitual physical activity. *Ann Epidemiol*. 2001;11:145–53.
22. **Baughman K, Logue E, Sutton K, Capers C, Jarjoura D, Smucker W.** Biopsychosocial characteristics of overweight and obese primary care patients: do psychosocial and behavior factors mediate sociodemographic effects? *Prev Med*. 2003; 37:129–37.
23. **Marcus BH, Selby VC, Niaura RS, Rossi JS.** Self-efficacy and the stages of exercise behavior change. *Res Q Exerc Sport*. 1992;63:60–6.
24. **Clark MM, Abrams DB, Niaura RS, et al.** Self-efficacy in weight management. *J Consult Clin Psychol*. 1991;59:739–44.
25. **Sallis JF, Grossman RM, Pinski RB, Patterson TL, Nader PR.** The development of scales to measure social support for diet and exercise behaviors. *Prev Med*. 1987;16:825–36.
26. **Marcus BH, Rakowski W, Rossi JS.** Assessing motivational readiness and decision making for exercise. *Health Psychol*. 1992;11:257–61.
27. **Ware J Jr, Kosinski M, Keller SD.** A 12-item short-form health survey: construction of scales and preliminary tests of reliability and validity. *Med Care*. 1996;34:220–33.
28. **Marlowe D, Crowne DP.** Social desirability and response to perceived situational demands. *J Consult Clin Psychol*. 1961; 25:109–15.
29. **Little RJ.** Methods for handling missing values in clinical trials. *J Rheumatol*. 1999;26:1654–6.
30. **Little RJ, Raghunathan T.** On summary measures analysis of the linear mixed effects model for repeated measures when data are not missing completely at random. *Stat Med*. 1999; 18:2465–78.
31. **Gadbury GL, Coffey CS, Allison DB.** Modern statistical methods for handling missing repeated measurements in obesity trial data: beyond LOCF. *Obes Rev*. 2003;4:175–84.
32. **Ware JH.** Interpreting incomplete data in studies of diet and weight loss. *N Engl J Med*. 2003;348:2136–7.
33. **Perri MG, Corsica JA.** Improving the maintenance of weight loss in behavioral treatment of obesity. In: Wadden TA, Stunkard AJ, eds. *Handbook of Obesity Treatment*. New York: Guilford Press; 2002:357–79.
34. **van Binsbergen JJ, Delaney BC, van Weel C.** Nutrition in primary care: scope and relevance of output from the Cochrane Collaboration. *Am J Clin Nutr* 2003;77(4 Suppl):1083S–8S.
35. **Castro CM, King AC.** Telephone-assisted counseling for physical activity. *Exerc Sport Sci Rev*. 2002;30:64–8.
36. **Pinto BM, Lynn H, Marcus BH, DePue J, Goldstein MG.** Physician-based activity counseling: intervention effects on mediators of motivational readiness for physical activity. *Ann Behav Med*. 2001;23:2–10.
37. **ACT Trial Group.** Effects of physical activity counseling in primary care: the Activity Counseling Trial: a randomized controlled trial. *JAMA* 2001;286:677–87.

38. **Bock BC, Marcus BH, Pinto BM, Forsyth LH.** Maintenance of physical activity following an individualized motivationally tailored intervention. *Ann Behav Med.* 2001;23:79–87.
39. **Bull FC, Jamrozik K, Blanksby BA.** Tailored advice on exercise—does it make a difference? *Am J Prev Med.* 1999; 16:230–9.
40. **Dallow CB, Anderson J.** Using self-efficacy and a transtheoretical model to develop a physical activity intervention for obese women. *Am J Health Promot.* 2003;17:373–81.
41. **Finckenor M, Byrd-Bredbenner C.** Nutrition intervention group program based on preaction-stage-oriented change processes of the transtheoretical model promotes long-term reduction in dietary fat intake. *J Am Diet Assoc.* 2000;100:335–42.
42. **Greene GW, Rossi SR.** Stages of change for reducing dietary fat intake over 18 months. *J Am Diet Assoc.* 1998;98:529–34.
43. **Havas S, Anliker J, Damron D, Langenberg P, Ballesteros M, Feldman R.** Final results of the Maryland WIC 5-A-Day Promotion Program. *Am J Public Health.* 1998;88:1161–7.
44. **Jones H, Edwards L, Vallis TM, et al.** Changes in diabetes self-care behaviors make a difference in glycemic control: the Diabetes Stages of Change (DiSC) study. *Diabetes Care.* 2003;26:732–7.
45. **Kirk AF, Higgins LA, Hughes AR, et al.** A randomized, controlled trial to study the effect of exercise consultation on the promotion of physical activity in people with type 2 diabetes: a pilot study. *Diabet Med.* 2001;18:877–82.
46. **Naylor PJ, Simmonds G, Riddoch C, Velleman G, Turton P.** Comparison of stage-matched and unmatched interventions to promote exercise behaviour in the primary care setting. *Health Educ Res.* 1999;14:653–66.
47. **Peterson TR, Aldana SG.** Improving exercise behavior: an application of the stages of change model in a worksite setting. *Am J Health Promot.* 1999;13:229–32.
48. **Pinto BM, Friedman R, Marcus BH, Kelley H, Tennstedt S, Gillman MW.** Effects of a computer-based, telephone-counseling system on physical activity. *Am J Prev Med.* 2002; 23:113–20.
49. **Purath J, Miller AM, McCabe G, Wilbur J.** A brief intervention to increase physical activity in sedentary working women. *Can J Nurs Res.* 2004;36:76–91.
50. **Steptoe A, Doherty S, Rink E, Kerry S, Kendrick T, Hilton S.** Behavioural counselling in general practice for the promotion of healthy behaviour among adults at increased risk of coronary heart disease: randomised trial. *BMJ.* 1999;319: 943–8.
51. **Steptoe A, Perkins-Porras L, McKay C, Rink E, Hilton S, Cappuccio FP.** Behavioural counselling to increase consumption of fruit and vegetables in low income adults: randomized trial. *BMJ.* 2003;326:855–60.
52. **Strecher V, Wang C, Derry H, Wildenhaus K, Johnson C.** Tailored interventions for multiple risk behaviors. *Health Educ Res.* 2002;17:619–26.
53. **van der Veen J, Carel Bakx C.** Stage-matched nutrition guidance for patients at elevated risk for cardiovascular disease: a randomized intervention study in family practice. *J Fam Pract.* 2002;51:751–8.
54. **Ashley JM, St Jeor ST, Schrage JP, et al.** Weight control in the physician's office. *Arch Intern Med.* 2001;161:1599–604.
55. **Jeffery RW, Sherwood NE, Brelje K, et al.** Mail and phone interventions for weight loss in a managed-care setting: Weigh-To-Be one-year outcomes. *Int J Obes Relat Metab Disord.* 2003;27:1584–92.
56. **Wadden TA, Berkowitz RI, Vogt RA, Steen SN, Stunkard AJ, Foster GD.** Lifestyle modification in the pharmacologic treatment of obesity: a pilot investigation of a potential primary care approach. *Obes Res.* 1997;5:218–26.
57. **Womble LG, Wadden TA, McGuckin BG, Sargent SL, Rothman RA, Krauthamer-Ewing ES.** A randomized controlled trial of a commercial internet weight loss program. *Obes Res.* 2004;12:1011–8.
58. **Heshka S, Anderson JW, Atkinson RL, et al.** Weight loss with self-help compared with a structured commercial program: a randomized trial. *JAMA.* 2003;289:1792–8.
59. **McTigue KM, Harris R, Hemphill B, et al.** Screening and interventions for obesity in adults: summary of the evidence for the U.S. Preventive Services Task Force. *Ann Intern Med.* 2003;139:933–49.
60. **Jeffery RW.** How can health behavior theory be made more useful for intervention research? *Int J Behav Nutr Phys Act.* 2004;1:10–4.