

**Increased Water Consumption: A Self-Regulatory Strategy for Long-Term
Weight Loss Maintenance?**

Jeremy D. Akers

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Brenda M. Davy, Chair
Kevin P. Davy
Janet W. Rankin
Richard A. Winett
Jyoti S. Savla

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ABSTRACT

One-third of the American population is obese (1), and of those successful at losing weight, most return to their baseline weight within three to five years (2). In an effort to increase the success of weight loss maintenance (WTLM), research has focused on strategies that promote self-regulation (3). Self-regulation strategies, such as daily self-monitoring of body weight (4), increased step count (5, 6), and increased fruit and vegetable intake (7) have proven to be effective in long-term WTLM interventions. To date, increased water consumption has not been researched as a WTLM strategy, yet it has been shown to decrease meal energy intake (8, 9) and increase weight loss among middle-aged and older adults (10). The purpose of our first investigation was to determine if self-monitoring of increased water consumption facilitates WTLM over 12 months among middle-aged to older adults, when combined with other self-regulation strategies. Our second investigation was a review of WTLM literature to determine the translation potential published interventions using the RE-AIM (Reach, Efficacy/effectiveness, Adoption, Implementation, Maintenance) framework (11) to provide recommendations for future research. Our first main finding was that weekly tracking of these self-regulatory behaviors (self-weighing, step counts, fruit/vegetable intake) for 12 months promotes effective long-term WTLM among middle-aged and older adults. However, daily self-monitoring of increased water consumption (48 fl oz/day) did not appear to provide an additional benefit. Secondly, we have identified significant gaps in the WTLM literature that may hinder the translatability of existing effective interventions. Specifically, current WTLM research is

limited in reporting important external validity factors (e.g. costs, adoption, participation rate). Available WTLM literature provided a more detailed overview of Reach, Efficacy, and Implementation, yet was little information on potential adoption, costs, or sustainability. Future work in this area should address these factors to increase the translation potential of WTLM interventions in clinical or community settings.

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CHAPTER 1: INTRODUCTION

Adult obesity rates have increased by almost 50% in the past 15 years (1, 2) and it is estimated that if previous trends continue, almost half the United States population will be obese by 2020 (3, 4). Obese individuals are at increased risk for cardiovascular disease, hypertension, diabetes, dyslipidemia, metabolic syndrome, gallstones, osteoarthritis, sleep apnea, and certain forms of cancer (5, 6) and obesity accounts for 5-15% of deaths each year in the United States (7, 8). Researchers have suggested that even modest weight losses at the individual level can have substantial effects on overall population health (9). However, losing weight can be a significant challenge, as is maintaining weight loss (10, 11). Following successful clinically-based weight loss programs, 30% to 35% of weight lost is regained in the first year after treatment (12) yielding only a 20% success rate for losing at least 10% of one's weight and maintaining that loss for a minimum of 1 year (13).

The increase in obesity prevalence has been seen in all regions, among all racial and ethnic groups, in both genders, among all educational levels, and among all age groups (5). Contrary to the perception that many older adults are underweight and malnourished (14), the numbers of obese older adults has noticeably increased in the past decade (15, 16). In 2005-2006, approximately 69% of adults 60 years or older were overweight or obese (16). The increasing rates of obesity and overweight in this population and the lack of age-specific health promotion have important implications for medical and social services (14, 15). Thus, older adults are a high-risk population warranting special attention.

In an effort to increase the success of weight loss maintenance (WTLM), research has focused on strategies that promote self-regulation. Maes defines self-regulation as a "systematic process of human behavior that involves setting personal goals and steering behavior toward

established goals...Overall definitions tend to embody the basic ingredients of goal setting, steering process and strategies, feedback and self-evaluation (17).” In self-regulation practices it is important to promote active rather than passive roles in individual health outcomes (18). Self-regulation strategies, such as daily self-weighing (19, 20), self-monitoring of regular physical activity (21, 22), and consuming a low energy-dense diet (e.g. low-fat, fiber-rich) (23, 24) appear to be effective WTLM interventions.

Increased water consumption has not been investigated as a WTLM self-regulation strategy. Yet, there are several reasons why increased water consumption may be an attractive dietary weight maintenance approach for middle-aged and older adults. First, water is a widely available, inexpensive dietary component that has been shown to acutely decrease energy intake and increase weight loss in this population (25-27). Second, increasing water intake has been associated with a decreased consumption of sugar sweetened beverages and self reported total daily energy intake (28). Finally, increased water consumption reduces risk of dehydration in this population with reduced thirst sensations (29-31). Given the numerous positive effects of increased water intake, primarily reduced energy intake and weight loss (26, 32), this dietary strategy should be examined as a potential self-regulation WTLM approach.

There are numerous studies examining strategies to maintain weight loss (21, 33, 34), however examining the potential of WTLM intervention dissemination is limited. Within the context of attempting to impact public health, it is critical to evaluate the extent to which WTLM intervention studies have the potential to be effective, delivered, and sustained in practice settings and “real-world” situations (35). Behavioral interventions tend to emphasize internal validity and may neglect external factors which increase the likelihood of intervention adoption and implementation (36). Reviews utilizing the RE-AIM (Reach, Efficacy/effectiveness,

Adoption, Implementation, and Maintenance) framework (37) have evaluated bodies of literature on a variety of topics and recommended strategies to increase intervention translatability (36, 38, 39). These reviews have concluded that there are deficiencies in the literature regarding important external issues (e.g. participant and setting-level representativeness, program costs, and quality of life measures).

There are two overall goals in this line of research. The first goal is to determine the effectiveness of a 12-month WTLM intervention, using self-regulatory behaviors believed to support WTLM (e.g. self monitoring of self-weighing, physical activity, fruit and vegetable consumption, and water intake). The second goal is to determine the translation potential of published WTLM intervention studies, and to provide recommendations for research based upon those findings.

Specific Aims and Hypotheses:

Aim 1: To determine if increased water intake is associated with successful long-term weight loss maintenance (WTLM) in older adults.

Hypothesis 1: Increased water consumption will result in successful long-term WTLM in older adults (i.e. less weight gain from baseline to 12 months), as compared to a WTLM intervention which does not increase water consumption.

Aim 2: To determine if daily self-monitoring of water intake, physical activity, body weight and vegetable and fruit consumption as determined by daily tracking of step counts, body weight, and vegetable and fruit servings facilitates long-term WTLM in older adults.

Hypothesis 2: Compliance with daily self-monitoring of water intake, physical activity, vegetable and fruit consumption, and body weight will be an effective self-regulation approach for long-term WTLM in older adults.

Aim 3: To review current WTLM intervention studies and determine their translation potential using the RE-AIM framework.

Hypothesis 3: WTLM literature will follow trends of other health-related intervention areas and underreport important dimensions of the RE-AIM framework (e.g. participant and setting level representativeness, quality of life, and costs) related to translational potential.

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CHAPTER 2:

Increased water consumption: a self-regulatory strategy for long-term weight loss maintenance?

ABSTRACT

Background: Previous work has shown that increasing daily water consumption is a dietary strategy which facilitates weight loss among middle-aged and older adults, yet it is not known if increased daily water consumption can improve weight loss maintenance (WTLM).

Objective: To determine if daily self-monitoring of increased daily water consumption is a dietary self-regulatory strategy that facilitates WTLM among middle-aged to older adults.

Design: Clinical intervention study of a 12-month WTLM program with and without increased daily water consumption as a self-monitoring strategy. Thirty-nine weight-reduced (mean weight lost= 6.7 ± 0.6 kg; BMI 29 ± 1 kg/m²) individuals aged 63 ± 1 yrs were enrolled in a WTLM intervention which included daily self-monitoring of body weight, physical activity (step counts), and fruit/vegetable consumption. Intervention group participants (“water group”) were instructed to consume 500 ml water before each main meal, and to record daily water intake along with these behaviors. Additional outcome measures included diet/physical activity behaviors, theoretical constructs related to health behaviors, body composition, resting blood pressure, resting metabolic rate, 24-hour urine volume, and urinary specific gravity.

Results: After 12-months, no significant group difference in weight change was detected; although both groups were successful (water: -0.98 ± 0.76 kg; non-water: -0.67 ± 1.0 kg). There were significant group differences in yearly mean step count (water: 9388 ± 72 steps/day; non-water: 7964 ± 53 steps/day) and mean fruit/ vegetable intake (water: 5.6 ± 0.0 servings/day; non-water: 5.3 ± 0.0 servings/day). Overall compliance to daily tracking was $76 \pm 5\%$, and

compliance was significantly related to successful WTLM, thus this self-monitoring approach is feasible and effective. Among water group participants, adherence to water intake goals was 66±7% (mean water daily water consumption: 50.5±0.2 ml/day). Among all participants, improvements in self-regulation strategies were noted.

Conclusion: A WTLM maintenance intervention emphasizing daily weighing, physical activity, and fruit/vegetable consumption is successful at maintaining weight loss for 12 months. Daily self-monitoring of increased water consumption does not appear to improve WTLM beyond that noted with daily self-monitoring of these strategies.

Keywords: weight loss maintenance, self-regulation, older adults, water consumption

INTRODUCTION

Weight reduction remains a challenge, and it is estimated that only one-third of individuals who lose weight are successful at maintaining that weight loss (1). Even after two years, weight regain is common; few persons recover from even minor weight gains of 1-2 kg (2) and most regain all weight lost within three years (1, 3). These poor long-term outcomes highlight the need for practical, affordable, and effective intervention strategies to maintain weight loss (4).

Self-regulatory strategies, such as daily weighing, tracking of physical activity, and increased fruit and vegetable consumption have been shown to facilitate weight loss maintenance (WTLM) (3, 5-8). Self-monitoring of body weight is associated with less weight regain, lower BMI, and healthy lifestyle behaviors such as a lower fat intake, higher levels of physical activity, and abstinence from smoking (2, 3, 5-9). The importance of daily physical activity in weight gain prevention is well known (2, 7, 10-16), and use of a pedometer with a 10,000 step per day goal is associated with increases in physical activity (2000 steps per day) and decreases in Body Mass Index (BMI) (17). With regard to dietary strategies, increasing fruit and vegetable consumption helps to maintain weight loss, in combination with other healthy lifestyle strategies (18-22).

Epidemiological investigations have indicated that water consumers ingest 194 fewer calories per day and consume more fruits, vegetables and dietary fiber than non-consumers of water, and that water consumption was inversely related to intake of sweetened beverages, added sugars, and dietary energy density (23, 24). Longitudinal studies have suggested that self-reported energy intake is lower in water drinkers compared with non-water drinkers participating in a weight loss trial; as consumption of water increased, consumption of sugar containing

beverages decreased (25). Among middle-aged and older adults, consuming 16 fl oz of water 30 minutes before an ad libitum (i.e. preload) meal significantly reduced meal energy intake compared to a no-preload water condition (26, 27). When combined with a hypocaloric diet, consuming 16 fl oz of water prior to each meal leads to approximately 2 kg greater weight loss over 12 weeks in middle-aged and older adults compared to a hypocaloric diet alone (28). However, to date no studies have examined daily self-monitoring of increased water consumption as a long-term WTLM strategy.

This intervention approach for older adults may be attractive for several reasons. First, the number of obese older adults has increased in the past decade, making this a population, one which warrants additional attention (29). In addition, the National Health and Nutrition Examination survey (NHANES) 2005-2006 reports that 24% of men and 37% of women aged 65 to 74 years old were obese (30). Second, water is a dietary component that is widely available and inexpensive, it has been shown to acutely decrease energy intake and increase weight loss in this population (26-28). In addition, increasing water consumption will reduce risk of dehydration in a population with reduced thirst sensations (31-33). Therefore, our objective was to determine if daily self-monitoring of increased water consumption is a dietary self-regulatory strategy that facilitates WTLM among older adults.

MATERIALS AND METHODS

Participants and procedures. Overweight and obese (BMI 25-40 kg/m²) men and women aged 55-75 years were recruited from the local community through newspaper advertisements to participate in a 12-week weight loss (WL) intervention (28). To be included in the 12-week WL

study, individuals were required to be weight stable ($\pm 2\text{kg}$, $> 1\text{year}$), and non-smokers.

Exclusion criteria were as follows: history of depression, eating disorders, diabetes, uncontrolled hypertension, heart, lung, kidney disease; cancer; or use of medications known to alter food intake or body weight (i.e. antidepressants, thyroid medications).

Participants in the 12-week WL intervention were assigned to one of two groups: 1) hypocaloric diet + 500ml water prior to each daily main meal (“water”) or 2) hypocaloric diet alone (“non-water”). Participants in the intervention group were provided with bottled water, and were instructed to consume one bottle prior to each main meal (3 x 500ml per day). Both groups were provided individualized instruction by a registered dietitian on a 1200-1500 kcal hypocaloric diet, and instructed to maintain their current level of physical activity throughout the 12-week intervention. Participation included laboratory-based weekly body weight assessments and dietary counseling sessions. This 12-week intervention did not include long-term WTLM, self-regulation, or self-monitoring strategies (28). Following completion of the 12-week WL intervention, participants were invited to participate in a 12-month single-blinded WTLM intervention. For the WTLM intervention, participants continued in their assigned treatment group (increased water consumption, “water”; versus no increased water consumption, “non-water”). This study protocol was approved by Institutional Review Board of Virginia Polytechnic Institute and State University. All participants provided written informed consent prior to study enrollment, although they were unaware of the exact purpose of this investigation.

12-month WTLM intervention period. An overview of the study protocol is depicted in Figure 1. After baseline testing participants received a printed program binder that included the following: an introduction to the program, detailed timeline with visit procedures, testing protocols, tracking

sheets, and a body weight tracking chart. Weekly tracking sheets included daily self-monitoring of several WTLM strategies (34, 35). For this “*WEV Changed*” program, participants were instructed to record their body weight (*W*), daily physical activity (*E*), assessed by pedometer step counts, and vegetable and fruit intake (*V*) using the tracking sheets. In addition, the “water group” was instructed to record daily water consumption. To measure body weight and step counts, participants were provided with a home-use digital scale (Tanita HD350, Tanita Inc., Arlington Heights, IL) and a pedometer (ACCUSPLIT Eagle AX120, San Jose, CA) and instructed in their use. Water group participants were provided with a 16 fl oz Nalgene water bottle, with fl oz markings and were instructed to continue to consuming water as they did in the WL phase (16 fl oz, 3 times per day, 30 minutes prior to breakfast, lunch, and dinner). All targeted health behaviors included program (i.e. external) and individual (i.e. internal) goals to motivate and guide participant’s behavior. Individual goals were determined by the participant and discussed with the study coordinator. The program goals were as follows: $\geq 10,000$ steps per day, ≥ 5 fruit and vegetable servings per day, remain at or below baseline “reduced” body weight (within 3 lbs.; 1.36kg) and consume at least 16 fl oz water three times per day (≥ 48 fl oz), prior to each main meal (water group only). Although there is no standard definition for weight loss maintenance, Stevens et al. reports that changes in daily fluid balance can yield a daily weight change of ± 3 lbs (36). Thus our criterion of successful WTLM was consistent with this level of weight stability, and that of the STOP Regain Program, where participants were in the “green zone” if they reported maintaining their weight gain of < 1.4 kg (i.e. 3 lbs) of baseline weight (3).

In addition to daily self-monitoring, participants were encouraged to develop small, attainable weekly goals. Participants were instructed to send tracking sheets to the study

coordinator each week for the duration of the 12-month study. Tracking sheets were returned by e-mail, or postal service if requested by the participant. For individuals who sent tracking sheets by postal service, pre-stamped and addressed envelopes were provided. Individualized feedback on goal achievement was provided via e-mail for ongoing and support. A feedback algorithm was utilized to standardize the e-mail feedback system. An example of a tailored weekly positive feedback for the water group would be: “Thank you for turning in your *WEV Changed* tracking sheet! Daily tracking of healthy behaviors helps to support long-term weight maintenance. You did a great job of consuming the suggested amount of daily water! Research shows that consuming water daily may help in weight management. Keep up the excellent work!”

Monthly laboratory assessments included body weight, four-day food intake records, resting blood pressure (BP), and individualized counseling. Counseling sessions were conducted by a Registered Dietitian and session topics were decided by each participant. The counseling session topics varied by participant and included but not limited to problem solving (e.g. social and holiday eating), increasing physical activity, and meal planning. Baseline assessments were repeated at six and 12 months. Following program completion, participants attended a follow-up visit to review their results, obtain certificate of WTLM success, acquire further WTLM counseling tips, and to complete an exit survey to assess knowledge of the study purpose and perceived effectiveness of the study coordinator’s counseling sessions.

Measures

Body weight and composition. Height was measured in meters without shoes using a wall mounted stadiometer, and weight was measured in kilograms without shoes wearing light street

clothes, to the nearest 0.1 kg on a digital scale (Scale-tronix 5002, White Plains, NY). BMI was calculated as weight (kg)/height (m)². Waist circumference was measured to the nearest 0.5 cm at the umbilicus, using a tape measure (Gulick, Country Technology, Gays Mill, WI).

Percentage of body fat, absolute fat mass, bone mass and fat-free mass were measured using dual-energy X-ray absorptiometry (DXA) (GE Lunar Prodigy; GE Healthcare, Madison, WI).

Clinical measures. Resting BP was measured in a seated position using an automated blood pressure monitor (Colin Pressmate, Omron Co., San Antonio, TX). After a five-minute rest, measurements were taken every three minutes until two measurements were within six mmHg for systolic and diastolic BP. The average of two measurements is reported.

To determine if there were changes in metabolic rate over the 12-month WTLM intervention (37, 38), resting metabolic rate (RMR) was measured by indirect calorimetry using a ventilated hood and a metabolic system (Parvo Medics TrueOne 2400, Sandy, UT) (39, 40). Participants were tested 30 minutes upon awakening and after a 12-hour fast. Participants were instructed to refrain from physical activity, nicotine, and caffeinated beverages the morning of the testing. After a 10-minute rest period on a hospital bed, inspired and expired gases were collected and analyzed while participants rested quietly for a 45-minute testing period. Participants collected urine for one 24-h period for assessment of total urine volume, and specific gravity was determined using a refractometer (Fisher UriSystem; Fisher Scientific, Hampton, NH).

Health Beliefs Survey. Participants completed a questionnaire to measure the Social Cognitive Theory constructs of self-efficacy, social support, outcome expectations and self-regulation for

diet and physical activity variables (41). The scales have adequate to high internal consistency (Cronbach's $\alpha = 0.68-0.90$).

Dietary intake. To assess habitual dietary intake including beverage consumption, participants were instructed in proper methods to record four-day food intake records by a Registered Dietitian. Records were kept for four consecutive days, which included three weekdays and one weekend day. Two-dimensional food diagrams were provided to assist participants in portion size determination. All food and beverage records were reviewed for accuracy and completeness and analyzed using the Nutrition Data System for Research nutrition analysis software (NDS-R 4.05, 2007, University of Minnesota, Minneapolis, MN). A second trained technician reviewed all diet analyses for data entry errors. To assess habitual beverage consumption, baseline, 6-month, and 12-month food intake records were manually reviewed to determine mean daily amounts (kcal, g) of water and other beverages consumed. Dietary energy density (kcal/g) was calculated using the baseline, 6-month, and 12-month food intake record analyses.

Statistical analyses

Independent samples *t*-tests were used to compare baseline demographic characteristics between “water” and “non-water” groups using SPSS 12.0 statistical analysis software for Windows, 2003, Chicago, IL. When group differences were present at baseline, those variables were used as covariates in subsequent analyses. A random coefficients (multi-level) model, also known as growth curve analysis, was used to determine the effects of the intervention on WTLM among the water group as compared to the non-water group over 12 months. The growth curve model was fitted using STATA 9.1 xtmixed function. Growth curve analysis, as opposed to

repeated-measures analysis of variance, is able to correct for measurement unreliability, uses all of an individual's data, and utilizes individual trajectories as opposed to each occasion's average value (42, 43). We used two levels, with the first being an estimation of the individual regression for weight change over time. The second level included the predictors of the regression parameters of individual trajectories—in this case, whether they were assigned to the water condition or the non-water condition. In this model we also wanted to determine if there was a quadratic effect of time on weight change and whether there was an interaction between treatment condition and the quadratic effect of time. Additionally, because of the small sample size, bootstrapping using 1,000 samples was used to estimate standard errors for the coefficients. Bootstrapping is the practice of estimating properties of an estimator (such as its variance) by measuring those properties when sampling from an approximating distribution (44). When data was analyzed by random coefficients model, full information maximum likelihood estimation was computed for the observed portion of each participant's data, accumulated, and then maximized to address missing data (45). Differences between groups and over time in other dependent variables were assessed using repeated measures ANOVA, when significant differences were detected, paired t-tests were used for time measures and independent samples t-tests were used between groups as post-hoc analyses.

Overall program compliance was determined by number of days tracking days completed divided by 365. Adherence to program goals (body weight, step count, water, and fruit and vegetable consumption) was determined by number of days adherent to each goal divided by the number of days recorded. Group differences in regards to the criterion for successful WTLM were assessed using a Pearson's X^2 -tests. Significance levels were set at an α level of $P < 0.05$.

RESULTS

Baseline characteristics

Forty two individuals completed the 12-week WL intervention (28) and were invited to participate in the 12 month WTLM intervention. Of these, 40 individuals enrolled and 39 completed the intervention and post-testing (Figure 1). Baseline group demographic characteristics are provided in Table 1. The sample was primarily Caucasian, and 55% female. There was a group baseline difference in previous weight loss, but no significant group differences in age, BMI, waist circumference, total body fat and fat-free mass, resting metabolic rate (RMR), urine volume, and specific gravity. Baseline percent body fat and RMR per kg fat-free mass were lower, and systolic and diastolic blood pressure were higher in the water group at baseline (Table 2). There were no baseline group differences in energy or macronutrient intake, or in weekly tracking sheet data; however, total food weight (g), total beverage (g), and water consumption (g) were higher in the water group as compared to the non-water group (Table 3).

Intervention

Both groups were successful at maintaining previous weight lost and body weight declined significantly from baseline to 6-months (Table 2). As depicted in Figure 2, there was a significant linear decline in weight ($\beta = -0.32, P < 0.01$) as well as a significant quadratic trend in weight over the 12 month study ($\beta = 0.02, P < 0.01$), suggesting that participants in both groups lost weight over time, however, weight changes leveled off in the final months of the study. No significant difference in weight change was detected between groups. ($\beta = -0.23, P = 0.10$). Using the definition of successful WTLM of three percent weight regain from baseline suggested by Stevens et al. (36), participants were categorized as successful or not successful.

There were no group differences using this criterion; as a pooled sample, 80% of the participants were categorized as successful (water: 15 participants; non-water: 16 participants). Using our more stringent criterion of ≤ 1.36 kg of weight regain from baseline, 74% of the participants were “successful” with no differences between groups.

Clinical Measures

Body composition and other clinical outcomes at baseline, 6-month, and 12-month are presented in Table 2. There was a significant difference in percent body fat at 6 months; however there were no other significant differences in body composition between groups during the 12-month intervention period. There were no group differences in body weight, BMI, and waist circumference but significant reductions over time (baseline to 6-months) in body weight, BMI, and waist circumference (all $P < 0.05$). From months six to 12, significant increases were noted in BMI and waist circumference but no group differences were observed. Twenty-four hour urine volume was significantly higher in the water group compared to the non-water group at 12 months, however no significant differences in urinary specific gravity were detected between groups or over time.

Dietary and Physical Activity Outcomes

Dietary and physical activity outcomes over the 12-month intervention are presented in Table 3. Self-reported energy intake increased over time, but no changes in macronutrient intake were detected. With respect to beverages, water intake was significantly higher among the water group participants. There were significant group differences in 12-month average mean step count (water: 9388 ± 72 steps/day; non-water: 7964 ± 53 steps/day; $P < 0.001$) and mean fruit/

vegetable intake (water: 5.6 ± 0.0 servings/day; non-water: 5.3 ± 0.0 servings/day; $P < 0.001$), although at month 12, step count was significantly higher in the water group as compared to the non-water group.

Social Cognitive Theory Determinants

Questionnaire scores for Social Cognitive Theory determinants of health behaviors are provided in Table 4; there were no significant group differences, thus data are presented for the pooled sample. Strategies to improve self-regulation (i.e. strategies to increase fruit, vegetables, and whole grains, self monitoring of physical activity, and goal setting and planning of physical activity) and increasing friend support for dietary and physical activity behaviors increased over the 12-month study period (all $P < 0.05$). Negative dietary outcome expectations declined significantly, while perceived positive benefits of physical activity increased from baseline to month 12. No changes were noted in self-efficacy for diet and physical activity behaviors.

Weekly Tracking Sheets

Compliance to the program, assessed by return rates of weekly tracking forms, and adherence to program goals ($\geq 10,000$ steps per day, ≥ 5 fruit and vegetable servings per day, remain ≤ 1.36 kg below baseline body weight, and consume at least 16 fl oz water three times per day (≥ 48 fl oz) prior to each main meal (water group only) are reported in Figure 3. Overall compliance in turning in tracking sheets was $76 \pm 5\%$ (water group, $74 \pm 7\%$; non-water group, $78 \pm 7\%$), and there was no group difference in return rate. Among water group participants, overall adherence to the daily water intake goal was $66 \pm 7\%$; water was significantly lower during months 10 through 12 compared with months two through 7 and month 9. Of the self-

monitoring behaviors, the lowest level of adherence was to the physical activity goal, and water group participants were significantly more adherent (water group, 41±7%; non-water group 25±5%; $P < 0.05$). Group differences in physical activity (step count) adherence were detected at months 4, 6, 7, and 8 (all $P < 0.05$). There were no group differences (all $P > 0.05$) in yearly mean adherence to the fruit and vegetable intake goal (water: 75±6%; non-water: 67±6%) and adherence to the daily weight goal (water: 99±1%; non-water: 96±3%).

After categorizing participants according to overall tracking sheet compliance ($\geq 85\%$ of tracking sheets turned in) vs. ($< 85\%$ of tracking sheets turned in) no significant difference in weight change was noted over the 12-month period (compliant: -1.6 ± 0.8 kg; non-compliant: 0.4 ± 1 kg; $P = 0.06$). Compliance turning in daily tracking sheets was significantly related to successful WTLM at $< 3\%$ of baseline weight regain ($X^2 = 5.516$, $P < 0.05$) and ≤ 1.36 kg weight regain ($X^2 = 3.815$, $P < 0.05$).

There were 52 tailored feedback e-mail or postal contacts and 13 monthly laboratory visit reminder e-mail or phone contacts with each participant.

Exit Survey

Of the 36 participants completing the exit survey, three (water group, $n = 2$; non-water group, $n = 1$) accurately identified the purpose of the study. There were no group differences in ratings (scale of one to five, with five being the highest rating of effectiveness) of the helpfulness of monthly counseling sessions (water group: 4.8 ± 0.2 ; non-water group: 4.7 ± 0.1 ; $P = 0.80$) and the counselor (water group: 4.9 ± 0.1 ; non-water group: 4.8 ± 0.1 ; $P = 0.84$).

DISCUSSION

To our knowledge, this is the first intervention trial investigating self-monitoring of increased water consumption as a self-regulation strategy for long-term WTLM. These findings do not indicate that daily self-monitoring of pre-meal water consumption has an additional benefit for WTLM, beyond that achieved by daily monitoring of body weight, step counts, and fruit and vegetable consumption. Previous investigations have shown that as part of a WL intervention, increasing water consumption can lead to greater weight loss (28, 46) and a reduction in meal and total daily energy intake (25-27). However, compliance to the daily water intake goal was suboptimal (i.e. 66%), thus it remains unknown if the recommended level of water consumption (≥ 48 fl oz/d) could improve WTLM outcomes.

It is important to note that for the pooled intervention groups, this simple intervention approach was efficacious at maintaining weight loss for a 12-month period. Seventy-four percent of participants were successful at meeting stringent goals of weight regain ≤ 1.36 kg of baseline weight. Overall compliance with the program was high and individuals who were more compliant and adherent to the program goals were more successful at meeting criteria. Almost sixty-six percent of the participants that were successful at keeping their weight regain ≤ 1.36 kg were compliant with the program while 70% of the unsuccessful were non-compliant. These data are consistent with other researchers that show poorer adherence to program goals result in greater weight gain over a WTLM intervention (47). Body weight declined during the first six months of the intervention, then increased linearly during the 6-month to 12-month time frame (Figure 2). These findings, as well as changes in program adherence over the 12-month study, suggest that increased intervention contact may be needed during these critical time periods of WTLM.

Numerous interventions have been evaluated to improve the success of long term WTLM. Recent WTLM research has examined internet-based and phone strategies, behavior treatments, and strict dietary interventions as potential strategies for weight maintenance. Interventions using the internet have produced mixed results. Researchers have found that internet-based weight maintenance can be successful with trained therapists-led groups (3, 48, 49) and participant-directed interactive technology (4) however, these strategies were not as effective as regular personal face-to-face contact (3, 4, 48, 49). Even given the mixed results, internet based WTLM strategies appear to have potential to become an effective weight maintenance tool (3). Phone-based WTLM consultation has shown modest improvements in WTLM outcomes when compared to no intervention contact (3, 50); however one study showed no significant differences between phone contact and no contact (51) and when compared to personal face-to-face contact or usual care groups this strategy was significantly less effective (3, 47, 50).

Behavioral change treatments have been shown to be effective in preventing weight regain (47, 52, 53). These investigations have multiple components including personal contact, social support groups, telephone and e-mail contact, increased physical activity, and problem solving therapy. Compared to control conditions behavioral programs produce significantly greater weight-losses at the end of the program. Interventions where weight regain was more likely reported were interventions including hypocaloric diets and supplements after a very low calorie diet (VLCD) weight loss trials (54-56) and strict dietary interventions (i.e. low carbohydrate diets: moderate protein) (57). In addition, the highest attrition rate (65%) was reported in a VLCD trial (54). Nevertheless, it seems the longer obese participants are in

treatment with personal contact, the longer they adhere to prescribed changes in dietary and exercise prescriptions, which leads to better outcomes (58).

The overall positive weight maintenance outcomes indicate that daily monitoring of three self-regulatory behaviors (daily weighing, fruit/vegetable consumption, step counts) is a successful WTLM strategy. This finding is consistent with others who have reported that daily weighing as an effective WTLM strategy (2, 3, 5, 6, 8), as well as the National Heart, Lung, and Blood Institute's (NHLBI) clinical obesity treatment guidelines (59). Others have demonstrated the importance of daily physical activity for WTLM, for example, Phelan et al. reported that weight-reduced individuals who experienced weight regain reported lower levels of physical activity (15), and a recent systematic review concluded that the use of pedometer and a 10,000 step per day goal is associated with decreases in BMI (17). In the present study, there was a group difference in adherence to step goals between water and non-water groups, although this did not lead to group differences in WTLM outcomes. To our knowledge, increasing daily fruit/vegetable consumption has not been investigated as a potential WTLM strategy, although consumption of foods low in energy density is an effective weight loss strategy (60). Mean daily fruit/vegetable consumption in the US is far below recommendations (i.e. 3.2 vs. five or more servings per day) with only 21 % of middle-aged to older adults consuming the recommended daily amounts (61). Our findings suggest that a WTLM approach which combines daily self-weighing, daily tracking of step counts and fruit/vegetable consumption is a simple, feasible and efficacious WTLM approach.

There are a few limitations that should be acknowledged. First, the sample size was small and included primarily Caucasian middle-aged and older adults. Although the generalizability of these data may be limited, the results of self-regulatory behaviors of this

sample are consistent with other weight loss maintenance trials. Second, no standardized laboratory test is available to objectively assess compliance with the water intake recommendation. We utilized urinary specific gravity, 24-hr urine collections, self-reported tracking sheets, and food intake records, which provided reasonable indicators of compliance when comparing the two groups over the 12-month intervention. However, self-reported compliance was less than ideal (i.e., 66%), thus it remains uncertain if the level of water consumption targeted in this investigation could produce greater WTLM outcomes. Third, we do not know the long-term effectiveness of this approach because the duration of our intervention was only 12 months. The NHBLI recommends that determining the true effect of a WTLM intervention requires an assessment of at least five years (62). Only a few trials have continued past 12 months (3, 4, 51, 63), thus longer trials are needed.

Despite these limitations, these findings are important in that feasible, effective, and sustainable WTLM interventions are clearly needed, particularly those which could potentially be translated into larger-scale settings. Such interventions must consider the limited resources often available to individuals and organizations, such as cost and time. Costs analyses of this program were not formally done but resources were minimal to the research team and participant. Considering the high cost of obesity (64), the minimal investment with the significance on WTLM in middle-aged and older adults seems worthwhile. The time commitment for this intervention was relatively low for the researcher and participants. Participants were required to have a one-on-one counseling once per month (~1 hr each) and send tracking sheets once per week. Time constraints could be further reduced if a web-based feedback system was developed and automated to provide weekly tailored feedback to participants. Future studies are needed to determine the efficacy of web-based tailored feedback

mechanisms and to determine the translatability of low-resource interventions, such as this intervention approach, into community based settings.

TABLES

Table 1 Baseline group demographic characteristics: increased daily water consumption (“water group”) and no increase in daily water consumption (“non-water group”)

	<i>Water group (n =19)</i>	<i>Non-water group (n =21)</i>
Men/women, <i>n</i>	10/9	8/13
Race, white/nonwhite, <i>n</i>	18/1	19/2
Age, years	63.7 ± 1.3	61.7 ± 1.3
Height, m	1.69 ± 0.22	1.67 ± 0.02
Body weight, kg	83.7 ± 2.7	82.7 ± 3.7
Body Mass Index, kg/m ²	29.1 ± 0.8	29.4 ± 1.3
Previous weight lost, kg ^a	-7.7 ± 1.0	-5.7 ± 0.6
Percentage of previous weight lost, %	8.2 ± 0.9	6.6 ± 0.7

Data are presented as mean ± standard error of the mean.

^aBaseline difference between groups ($P < 0.05$).

Table 2 Body composition, resting metabolic rate, and other clinical characteristics in the water and non-water groups at baseline, 6, and 12 months of the WTLM intervention*

	<i>Water group</i>			<i>Non-water group</i>		
	<i>Baseline</i>	<i>6-month</i>	<i>12-month</i> <i>(Δ Baseline to</i> <i>12-month)</i>	<i>Baseline</i>	<i>6-month</i>	<i>12-month</i> <i>(Δ Baseline to</i> <i>12-month)</i>
Body weight, kg ^a	83.7 ± 2.7	81.4 ± 2.5	81.8 ± 2.6 (-0.98 ± 0.76)	82.7 ± 3.7	81.2 ± 3.9	81.6 ± 4.3 (-0.67 ± 1.00)
Body Mass Index, kg/m ^{2a, b}	29.1 ± 0.8	27.9 ± 0.7	28.6 ± 0.7 (-0.35 ± 0.30)	29.4 ± 1.3	29.0 ± 1.3	29.6 ± 1.5 (-0.15 ± 0.33)
Waist circumference, cm ^{a, b}	99.0 ± 2.1	95.5 ± 1.7	98.4 ± 2.2 (-0.88 ± 1.20)	99.2 ± 2.8	95.4 ± 2.9	98.7 ± 3.5 (-0.98 ± 1.47)
Body fat, % ^{c, d}	36.2 ± 2.2	34.6 ± 2.0	36.0 ± 2.1 (0.29 ± 0.61)	38.5 ± 1.9	36.8 ± 2.2	38.5 ± 2.3 (0.8 ± 0.64)
Total fat mass, kg	28.2 ± 2.3	26.8 ± 1.8	28.4 ± 2.1 (-0.15 ± 0.70)	30.0 ± 2.0	29.9 ± 2.3	30.2 ± 2.5 (0.13 ± 0.73)

Total fat-free mass, kg	51.1 ± 2.3	51.2 ± 2.4	50.6 ± 2.3 (-0.39 ± 0.39)	48.1 ± 3.0	49.0 ± 3.0	48.3 ± 3.4 (0.01 ± 0.52)
Systolic BP, mmHg ^{c, d}	124 ± 2	125 ± 2	120 ± 1 (-3 ± 1)	117 ± 2	115 ± 3	118 ± 3 (1 ± 2)
Diastolic BP, mmHg ^c	72 ± 2	74 ± 2	74 ± 1 (1 ± 2)	66 ± 2	65 ± 2	65 ± 2 (0 ± 2)
RMR, kcal/day	1604 ± 50	1563 ± 58	1588 ± 49 (-2 ± 37)	1582 ± 78	1523 ± 66	1482 ± 83 (-45 ± 32)
RMR per kg FFM ^c	31.1 ± 0.7	31.2 ± 0.8	31.5 ± 0.8 (0.34 ± 0.76)	33.7 ± 0.8	32.5 ± 0.8	33.3 ± 1.2 (-0.50 ± 0.84)
Urine volume, ml ^e	2452 ± 183	2356 ± 232	2621 ± 305 (139 ± 253)	2173 ± 158	2196 ± 139	1938 ± 161 (-243 ± 174)
Specific gravity, UG	1.009 ± 0.000	1.011 ± 0.001	1.010 ± 0.001 (0.001 ± 0.001)	1.011 ± 0.001	1.030 ± 0.016	1.013 ± 0.001 (0.002 ± 0.001)

Data are presented as mean ± standard error of the mean.

^aSignificant main effect of time, baseline to 6-months ($P < 0.01$). ^bSignificant main effect of time, 6-months to 12-months ($P < 0.01$). ^cSignificant group

difference at baseline ($P<0.05$). ^dSignificant group difference at 6-months ($P<0.05$). ^eSignificant group difference at 12-months ($P<0.05$).

*Abbreviations: BP, Blood pressure; FFM, Fat free mass; RMR, Resting metabolic rate; UG, Urine Specific Gravity

Table 3 Self-reported dietary intake and physical activity in water and non-water groups at baseline, 6, and 12 months of the weight loss maintenance intervention

	<i>Water group</i>			<i>Non-water group</i>		
	<i>Baseline</i>	<i>6-month</i>	<i>12-month</i>	<i>Baseline</i>	<i>6-month</i>	<i>12-month</i>
Energy, kcal/d ^{a,b,c}	1466 ± 101	1481 ± 101	1726 ± 121	1490 ± 90	1678 ± 98	1654 ± 170
Food Weight, g/d ^{c,d,e}	3242 ± 189	3152 ± 189	3562 ± 267	2458 ± 175	2587 ± 170	2620 ± 198
Carbohydrate, % energy	50.7 ± 2.9	54.4 ± 2.3	53.4 ± 2.4	50.2 ± 2.5	53.5 ± 2.4	50.2 ± 2.1
Protein, % energy	18.2 ± 0.5	18.7 ± 1.0	18.6 ± 1.1	17.0 ± 0.6	15.6 ± 0.5	17.3 ± 1.0
Fat, % energy	31.5 ± 2.2	27.8 ± 1.9	28.8 ± 1.9	31.5 ± 1.7	31.0 ± 1.8	30.8 ± 1.8
Fiber, g/d	20.5 ± 2.0	21.6 ± 2.1	23.9 ± 1.6	20.3 ± 1.6	22.9 ± 1.7	21.8 ± 2.2
Energy density, kcal/g [*]	0.48 ± 0.04	0.49 ± 0.04	0.51 ± 0.04	0.63 ± 0.05	0.69 ± 0.06	0.68 ± 0.06
Beverages only:						
Total beverages, kcal/d	144 ± 16	174 ± 28	134 ± 17	195 ± 32	197 ± 34	211 ± 33
Total beverages, g/d ^{c,d,e}	2276 ± 166	2067 ± 204	2279 ± 206	1454 ± 138	1485 ± 170	1493 ± 213
Water, g/d ^{c,d,e}	1548 ± 295	1073 ± 147	1241 ± 144	349 ± 96	495 ± 134	451 ± 132
Non-water beverages, g/d	1078 ± 161	1042 ± 99	1014 ± 120	1103 ± 112	1292 ± 298	1041 ± 149

Weekly tracking sheet variables[†]:

Physical activity, steps/d ^e	9582 ± 605	8225 ± 752	9137 ± 762	8104 ± 735	7295 ± 729	7859 ± 711
Fruit and vegetable, servings/d	5.6 ± 0.4	5.4 ± 0.3	5.6 ± 0.3	5.6 ± 0.3	5.1 ± 0.4	5.2 ± 0.3
Water, fl oz/d	47.7 ± 4.4	49.9 ± 3.1	50.1 ± 4.3	_____	_____	_____

Data are presented as mean ± standard error of the mean.

*Calculated with all foods and beverages, including water. [†]Baseline data is the average of weeks one through four (month one), 6 month data is the average of weeks 25 through 28, and 12 month data is the average of weeks 49-52 of the weight loss maintenance intervention.

^aSignificant main effect of time, baseline to 6-months ($P < 0.05$). ^bSignificant main effect of time, baseline to 12-months ($P < 0.05$). ^cSignificant group difference at 6-months ($P < 0.05$). ^dSignificant group difference at baseline ($P < 0.01$). ^eSignificant group difference at 12-months ($P < 0.05$).

Table 4 Social Cognitive Theory determinants of diet and physical activity behaviors among middle-aged and older adults enrolled in a 12-month weight loss maintenance intervention

<i>Determinant</i>	<i>Baseline</i>	<i>6-month</i>	<i>12-month</i>	<i>Δ Baseline to 12-month</i>
Dietary Self-regulation*				
Strategies to increase fruit, vegetables, and whole grains ^{a,b}	3.9 ± 0.1	4.1 ± 0.1	4.2 ± 0.1	0.2 ± 0.1
Strategies to decrease fat and calories	4.0 ± 0.1	4.0 ± 0.1	4.0 ± 0.1	0.0 ± 0.1
Planning and tracking	3.7 ± 0.1	3.7 ± 0.1	3.7 ± 0.1	0.0 ± 0.1
Self-Efficacy**				
Reducing fat and calories	84.9 ± 1.8	84.5 ± 1.9	84.4 ± 2.1	-0.5 ± 1.3
Tracking dietary behaviors	86.2 ± 1.9	85.3 ± 2.4	86.3 ± 2.3	0.4 ± 2.0
Increasing fruit, vegetables, and whole grains	82.2 ± 2.0	81.6 ± 2.4	82.2 ± 2.0	0.4 ± 1.4
Eating healthier snacks	81.7 ± 2.4	80.1 ± 2.4	80.0 ± 2.6	-2.2 ± 1.9
Dietary outcome expectations*				
Positive expectations	4.5 ± 0.1	4.6 ± 0.1	4.5 ± 0.1	0.0 ± 0.1
Negative expectations ^{a,b}	2.5 ± 0.1	2.2 ± 0.1	2.2 ± 0.1	-0.3 ± 0.1

Dietary support*

Family support ^{b,c}	3.5 ± 0.1	3.5 ± 0.1	3.7 ± 0.1	0.2 ± 0.1
Friend support ^{a,b}	3.0 ± 0.1	3.1 ± 0.1	3.3 ± 0.2	0.3 ± 0.1

Physical activity expectations

Perceive positive benefits of physical activity ^{†b}	16.8 ± 0.8	17.2 ± 0.7	18.2 ± 0.7	1.4 ± 0.8
Perceive positive health benefits of physical activity [†]	20.8 ± 0.6	20 ± 0.8	21.5 ± 0.6	0.8 ± 0.7
Perceive negative time aspects of physical activity ^{††}	7.4 ± 0.7	7.9 ± 0.9	7.5 ± 0.8	0.4 ± 0.7

Physical activity support*

Family support	3.2 ± 0.2	3.3 ± 0.2	3.4 ± 0.2	0.2 ± 0.2
Friend support ^{a,b}	3.1 ± 0.1	3.2 ± 0.1	3.1 ± 0.1	0.4 ± 0.2

Physical activity self-efficacy and self regulation

Goal setting and planning ^{*a,b}	3.2 ± 0.2	3.7 ± 0.2	3.8 ± 0.2	0.5 ± 0.1
Self monitoring ^{*a,b}	2.8 ± 0.2	3.7 ± 0.1	3.6 ± 0.1	0.6 ± 0.2
Self efficacy ^{**}	72.0 ± 2.8	73.0 ± 3.0	72.4 ± 3.1	-0.3 ± 2.1

Data are presented as mean ± standard error of the mean.

*Scored on a scale of 1 to 5. **Scored on a scale of 0 to 100. †Scored on a scale of 1 to 25. ††Scored on a scale of 1 to 10.

^aSignificant main effect of time, baseline to 6-months ($P<0.05$). ^b Significant main effect of time, baseline to 12-months ($P<0.05$). ^c Significant main effect of time, 6-months to 12-months ($P<0.05$).

FIGURE LEGEND

Figure 1 Study Procedures: 12-month weight loss maintenance (WTLM) intervention...Page 45

Abbreviations used: DXA, dual-energy X-ray absorptiometry; BMI, body mass index; BP, blood pressure; Ht, height; WC, waist circumference; Wt, weight.

Figure 2 Body weight change among water and non-water group participants over the 12-month weight loss maintenance intervention period...Page 46

Figure 3 Monthly program compliance and self-reported goal adherence among the water group and non-water group during a 12-month weight loss maintenance intervention: (A) compliance with turning in weekly tracking sheets, (B) adherence to the weight goal, (C) adherence to the step count goal, and (D) adherence to the fruit/vegetable intake goal. ^a Significant time difference vs. month one ($P < 0.05$). *Group difference $P < 0.05$...Page 47

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Figure 1 Study Procedures: 12-month weight loss maintenance (WTLM) intervention

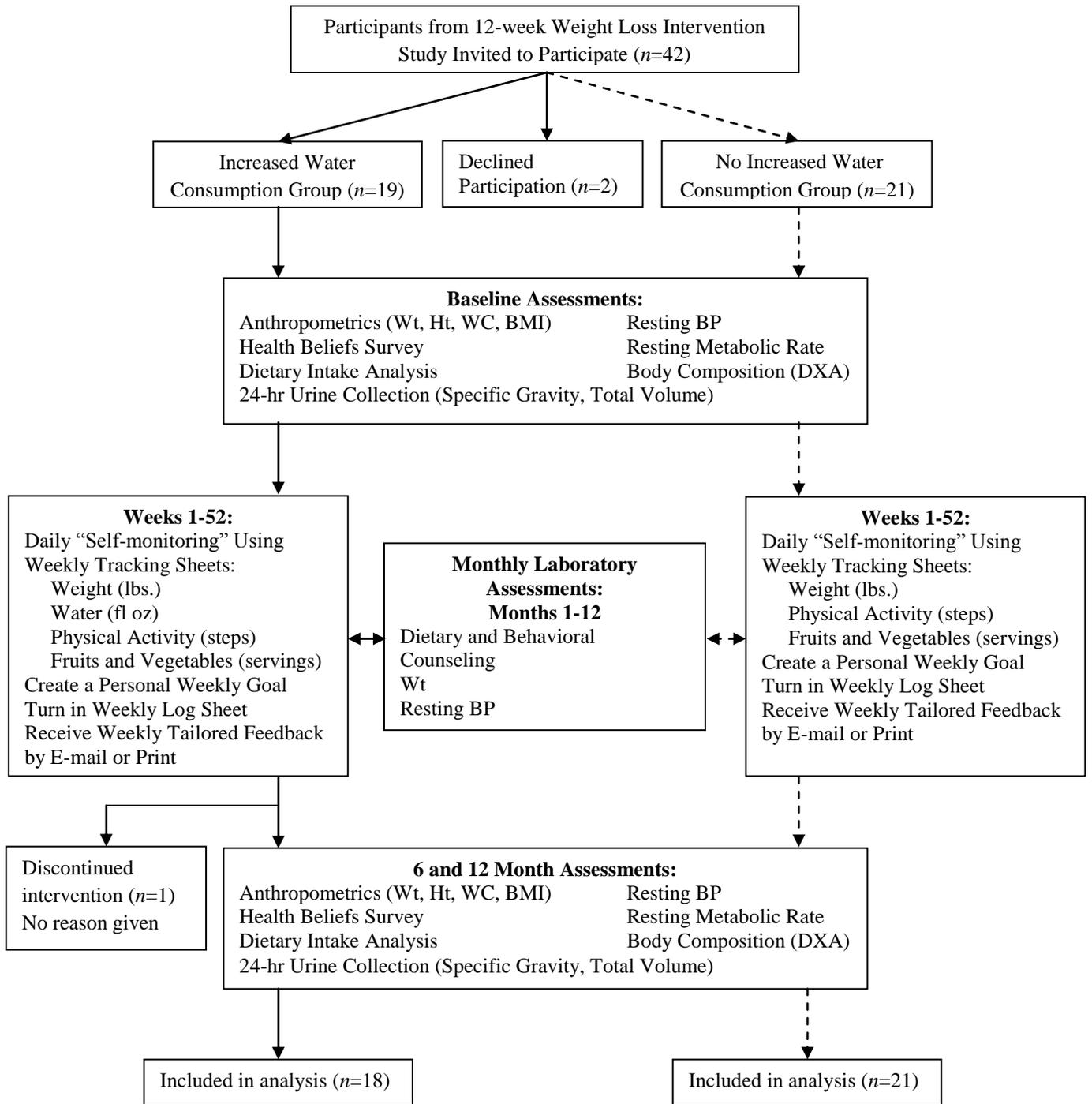


Figure 2 Body weight change among water and non-water group participants over the 12-month intervention period

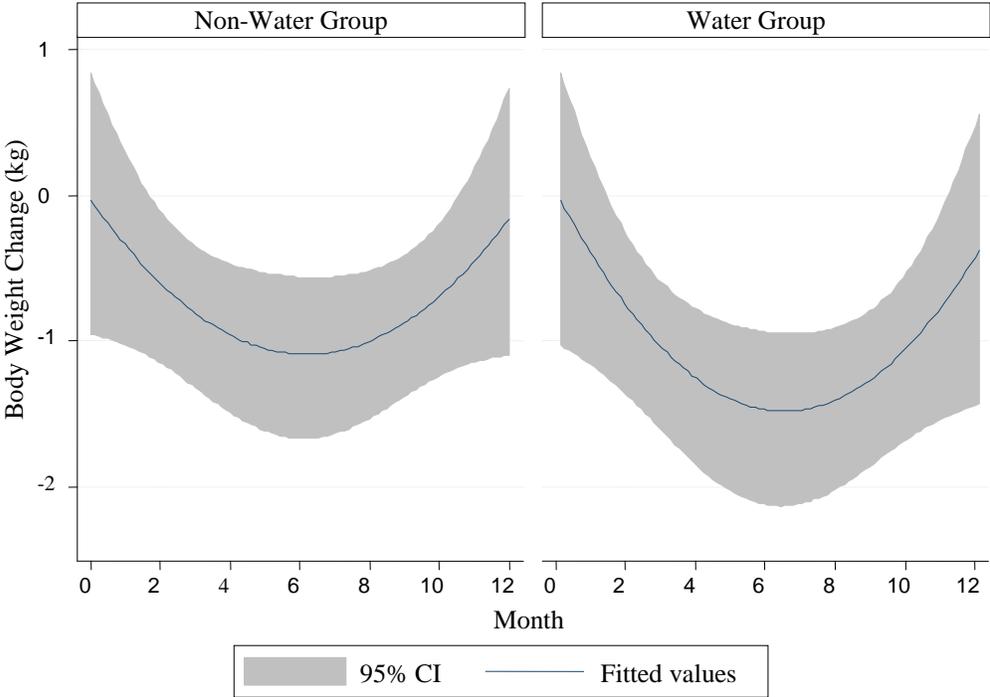
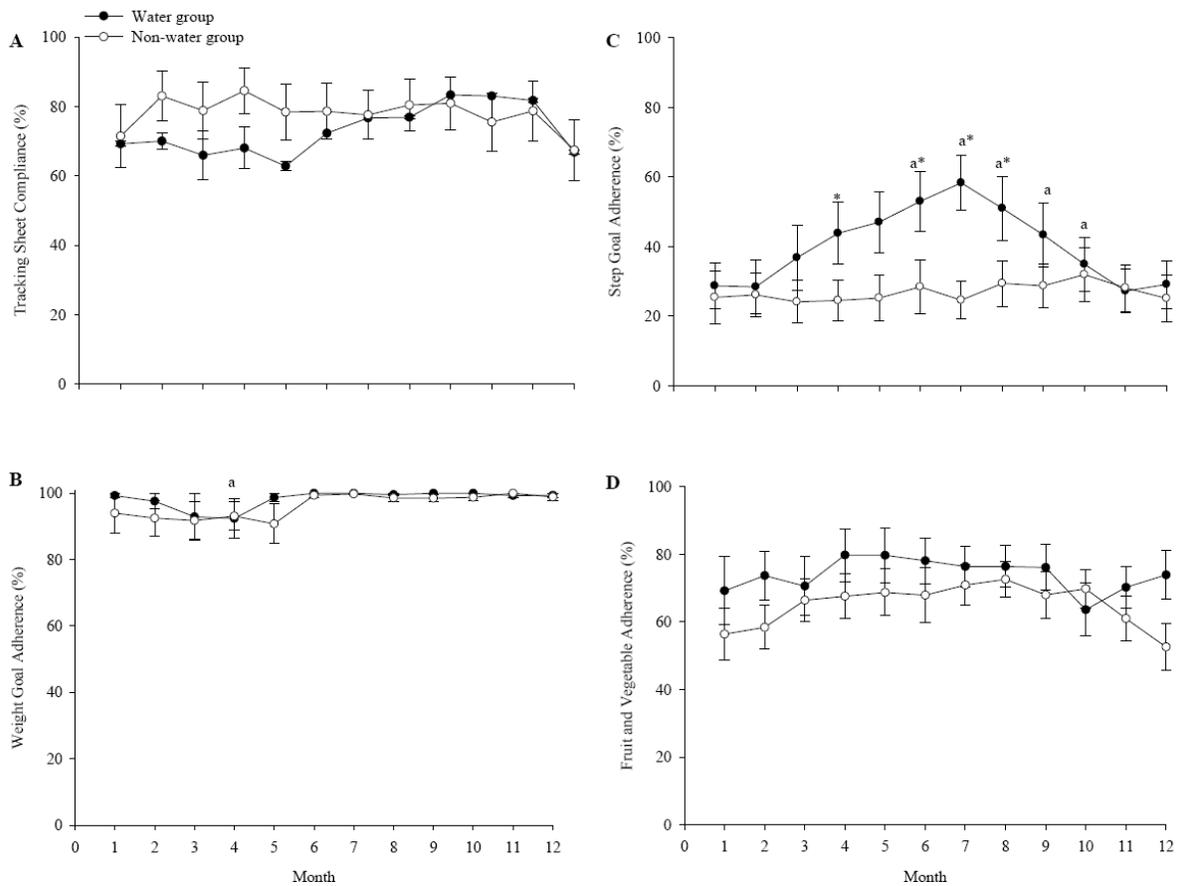


Figure 3 Monthly program compliance and self-reported goal adherence among the water group and non-water group during a 12-month weight loss maintenance intervention: (A) compliance with turning in weekly tracking sheets, (B) adherence to the weight goal, (C) adherence to the step count goal, and (D) adherence to the fruit/vegetable intake goal. ^a Significant time difference vs. month one (P<0.05). *Group difference P<0.05



CHAPTER 3:

Translational research: bridging the gap between long-term weight loss maintenance research and practice

ABSTRACT

Background: The number of U.S. adults classified as overweight or obese has dramatically increased in the past 25 years resulting in a significant body of research addressing weight loss and weight loss maintenance (WTLM). However, little is known about the potential of WTLM interventions to be translated into actual practice settings.

Objective: The purpose of this article is to determine the translation potential of published WTLM intervention studies by determining the extent to which they report information across the RE-AIM (Reach, Efficacy/effectiveness, Adoption, Implementation, and Maintenance) framework. A secondary purpose is to provide recommendations for research based upon these findings.

Design: To identify relevant research articles, a literature search was conducted using four databases; 20 WTLM intervention studies were identified for inclusion. Each article was evaluated using the RE-AIM Coding Sheet for Publications to determine the extent to which dimensions related to internal and external validity were reported.

Results: Approximately half of the articles provided information addressing three RE-AIM dimensions (Reach, Efficacy/effectiveness, and Implementation), yet only a quarter provided information addressing Adoption and Maintenance.

Conclusion: Significant gaps were identified in understanding external validity, and metrics that could facilitate the translation of these interventions from research to practice are presented. Based upon this review, it is unknown how effective WTLM interventions could be in "real-

world" situations, such as clinical or community practice settings. Future studies should be planned to address how WTLM intervention programs will be adopted and maintained, with special attention to costs for participants and for program implementation.

Key Words: Weight Loss Maintenance, Translation, RE-AIM

INTRODUCTION

The number of U.S. adults classified as overweight (BMI > 25 kg/m²) or obese (BMI > 30kg/m²) has dramatically increased in the past 25 years (1-3). Due to the adverse health outcomes associated with obesity (1, 4-6), the body of literature targeting weight loss strategies has abounded yet rates of concomitant weight regain are well documented (7-10). As a result, the need for practical, affordable, and clinically useful intervention strategies that maintain weight loss is paramount (11).

Numerous interventions have included behavioral strategies in clinical trials investigating weight loss maintenance (WTLM), described as an intervention designed to prevent weight regain following weight loss (11-31). Behavioral strategies associated with successful WTLM include high levels of physical activity (13, 16, 19, 23, 31), consuming a low-energy, low-fat diet, self-monitoring of food consumption and body weight (11, 14, 15, 32), social and interactive support (14, 15, 17, 18, 20, 24), diet interventions (21, 22, 29, 30), psychological intervention (25-28) and limiting the amount of time spent watching television (10). Interventions including weight loss medications combined with dietary modification or supplementation such as caffeine and protein, prolonged contact with study participants, problem-solving therapy, and acupuncture may also promote WTLM (33). However, the potential for these strategies to be translated into regular community or clinical environments is unknown. The following vignette is used to illustrate this point:

Paula Ellis, MS, RD, is the Director of Wellness for a large furniture manufacturer. In an effort to reduce the company's healthcare costs, she has been asked to develop a worksite weight maintenance program to follow their successful 8-week 'Biggest Loser' weight loss program. She found two recent research articles describing 12-month weight loss maintenance

interventions, and must decide which of the two approaches is best suited to implement for her company's employees. Program A was tested at a University medical clinic by graduate research assistants; it involved weekly individual behavioral health counseling sessions and weight checks. This program was effective in maintaining body weight (+/-2.3kg) in 85% of its participants, who were mostly white, college-educated women. Program B was tested in an urban YMCA by YMCA staff. The program was mostly made up of a printed program training manual and included monthly group sessions. About 40% of Program B participants maintained their weight (+/- 2.3kg), but the article said this wasn't significant. In the end Paula decided on Program B because it had a manual, appeared to be fairly successful, and seemed to be more feasible to deliver. However, she felt a bit uncertain with her decision, as Program A had a better success rate.

The purpose of this vignette is not to demonstrate that a program manual makes dissemination of a program easier nor that practitioners should choose the simpler option, even if it is less effective. The purpose is to demonstrate that examining evidence-based interventions from a practice perspective includes the consideration of many factors that are not often reported within the research context. Although there is a growing body of literature addressing methods to maintain weight loss (11, 14, 22, 25, 34, 35), there is relatively little reporting on the potential for these methods to be translated into regular practice settings. Thus, it is not surprising that within the healthcare setting, the process of translating research into evidence-based practice may take 15-20 years to occur (36, 37).

This “lag” may be attributed to a lack of reporting on factors important to the audience that would ultimately adopt and implement the intervention (38), and to the linear research production model that emphasizes internal over external validity. Specifically, Flay provides an

example of a prevalent scientific view of the translational process (39). First, an intervention must undergo an efficacy trial, defined as “tests of whether a . . . program does more good than harm when delivered under highly controlled and optimum conditions (40)”. Optimal conditions may include screening out less compliant patients (40), thus the generalizability of the interventions tested in an efficacy study is unknown. The next stage in the translation process is an effectiveness trial which “provides tests of whether a . . . program does more good than harm when delivered under real-world conditions (39).” Effectiveness trials are primarily randomized controlled trials held to the Consolidation of Standards for Reporting Trials (CONSORT) recommendations which emphasize internal validity while only providing modest descriptive recommendations for external validity factors (41). This research model has highlighted the need to focus on translational research and its clinical implications. Translational research is often defined as having two phases: 1) the translation of basic science into clinical research; and 2) how interventions are adopted, implemented, and sustained in a clinical or community setting (42).

Glasgow and colleagues (38, 43-47) have proposed a broader set of metrics and indicators that provide additional information that is needed by practitioners when considering the translation of an evidence-based intervention into routine practice. Specifically, translation of research into practice is best served when studies report more balanced information on internal and external validity. To address this need the RE-AIM (Reach, Efficacy/effectiveness, Adoption, Implementation, and Maintenance) evaluation framework was developed to provide context for practitioners to consider and compare research-based interventions (38, 43, 47). Importantly, cost is considered a key factor across the five dimensions. The five dimensions can be applied to the evaluation of health behavior interventions and estimate the potential public

health impact of interventions and information that can facilitate translation into practice. Definitions and examples reflecting each of these dimensions can be found in the Table.

The use of the RE-AIM framework may improve the reporting of factors related to external validity and more accurately inform the potential of research to be translated into practice (48). This framework can also provide meaningful information for practitioners. For example, if Paula, from our vignette knew that one of the programs (1) was delivered by someone with her level of training and expertise, (2) had demonstrated effectiveness in a setting similar to her workplace and that the effect was robust across different groups of people, and (3) attracted a large portion of an employee population to participate, cost \$3 per employee to implement, and could be sustained with minimal cost to the organization - her choice would have been more informed. Unfortunately, there is a gap in the literature related to the extent to which WTLM intervention studies report across these dimensions. Thus, the purpose of this article is to determine the translation potential of published WTLM intervention studies by determining the extent to which they report information across the RE-AIM (Reach, Efficacy/effectiveness, Adoption, Implementation, and Maintenance) framework. A secondary purpose is to provide recommendations for research based upon these findings.

MATERIALS AND METHODS

To identify research articles related to WTLM intervention for translation potential, a literature search was conducted using four databases, Medline, PubMed, PSYCinfo, and Ebscohost, using standardized search terms. Articles were limited to English language, randomized controlled trials (RCT) of a long-term weight loss maintenance intervention that included a weight loss trial and ≥ 1 year of intervention, adults (>17 years old), research

conducted after February 1988, and efficacy/effectiveness research. Articles focused on pharmaceuticals, follow-ups, surgery, and weight gain prevention were excluded. Subsequent articles reporting on the same intervention study were excluded. Search terms included weight maintenance, long-term weight loss maintenance, effectiveness weight loss maintenance, and efficacy weight loss maintenance.

Four-hundred and ninety eight relevant articles were initially identified. Most were excluded because they did not meet inclusion criteria (n=382). Others were not included due to exclusion criteria (n=95). Twenty articles met inclusion criteria, and are described in the Table. To evaluate the translation potential of WTLM studies, we utilized the RE-AIM Coding Sheet for Publications (49). The Coding Sheet includes a series of “yes” or “no” questions for indicators within each of the five RE-AIM dimensions. The Coding Sheet is provided in Figure 1, and a detailed description of the Coding Sheet is provided in the following subsection. Each study was coded by two of the three authors and results were compiled into a spreadsheet, and reported graphically in the Figure 2. A Cohen's Kappa was used as a measure of agreement between the reviewers (50). Discrepancies were discussed by all three authors and consensus was achieved across reviewed studies.

The RE-AIM Coding Sheet for Publications

The coding sheet includes six sections: article characteristics, reach, efficacy/effectiveness, adoption, implementation, and maintenance. The original coding sheet was revised for the present analysis, to include refinements of RE-AIM information (46). The Coding Sheet elements and indicators are as follows:

Article Characteristic: This section includes general study details, intervention format (e.g. group vs. individual), and general sample characteristics.

Reach: This section includes a checklist to evaluate reporting of indicators such as description and characteristics of the target population and how they were identified including denominator, participation rate, and recruitment strategies including cost, inclusion / exclusion criteria, study population demographic/behavioral characteristics, and sample size.

Efficacy/Effectiveness: This section includes general information on study design, imputation procedures if used, and analysis type (i.e. intent to treat, present at follow up). A checklist is included to evaluate if indicators such as measures, results, quality of life, unintended consequences, attrition, and cost effectiveness were presented.

Adoption: This section includes indicators such as a defined setting (description of intervention location and staff, level of expertise of staff, and how they were identified, and inclusion/exclusion criteria of setting and staff), rate of participation of staff and settings, organizational spread, characteristics of those who adopted/did not adopt, cost of adoption, and if there was evidence of dissemination beyond that expected.

Implementation: This section includes indicators such as a theoretical basis for the intervention; number, timing, and duration of participant contacts; extent of protocol delivered as intended; participant attendance and completion rates; and measures of cost.

Maintenance: This section includes indicators such as individual behavior being assessed at some duration following the completion of the study, attrition between the completion and follow up, whether the program is still in place or institutionalized, and why was it discontinued.

Specific details of the coding process are as follows. For the “demographic and behavioral information” question, “yes” was coded only if the study included gender, age, social

economic status, and race. For the question “described target population”, “yes” was coded only if the study described a specific population being targeted for intervention (e.g. intervention specifically targeted overweight or obese African American females in urban Richmond, Virginia) and not just the individuals who were enrolled (e.g., the study sample was 50% African American). For the question on reporting of the theoretical basis of the intervention, “yes” was coded only if an evidence-based theoretical model or construct was utilized (e.g. transtheoretical model, self-efficacy). For “participation rate”, two participation levels were identified (38, 51). Level 1 participation rate was calculated based on the outcome of the sample size divided by the total number of individuals projected in the target population. Level 2 participation rate was calculated based on the outcome of the sample size divided by the number of individuals who were either exposed to, or responded to, recruitment efforts. As there was little reporting of Level 1 participation rate, any study that reported Level 2 rates was coded as providing information on Reach.

Analyses

Standardized effect sizes $d=(x1-x2)/pooled\ standard\ deviation$ were calculated across studies with $x1-x2$ representing mean change in weight (kg) from baseline weight maintenance to post-intervention weight maintenance. Participation rates (when possible) were also measured. All RE-AIM coding was evaluated across raters using Cohen’s Kappa and the findings were summarized and presented in percents. Percents were computed at two levels. First, the proportion of indicators reported within each RE-AIM dimension was computed (i.e., number of indicators reported for a given dimension divided by the total number of possible indicators within in the dimension). Second, the proportion of studies that reported specific indicators

within each RE-AIM dimension was computed (i.e., number of studies that reported divided by total number of studies). These methods are similar to that recommended for analysis of the RE-AIM metrics (38, 52).

RESULTS

Scoring of the articles resulted in a substantial agreement between raters, $k=0.81$ (± 0.21), with the range -0.25 (± 0.02) to 0.89 (± 0.04) between the RE-AIM dimensions. The mean effect size of the scored articles was $d = 0.38$ (± 0.05), with effect sizes ranging from 0.00 - 1.22 . Details of the 20 studies reviewed, according to RE-AIM dimension, are presented in the Table. While half of the articles provided information addressing three RE-AIM dimensions (Reach, Efficacy/effectiveness, and Implementation), few reported information addressing Adoption and Maintenance (see Figure 2). Results across RE-AIM dimensions are summarized as follows:

Reach: Only seven (35%) articles reported more than 50% of the Reach indicators with the top two indicators reported being sample size (100%) and inclusion criteria (80%). The median number of participants was 103 and only 2 studies reported participation rates (78% & 100%). Finally, only one study reported on the representativeness of the study participants relative to the target population. No articles reported cost of recruitment or target population denominator.

Effectiveness/efficacy: Fifty percent of the Effectiveness/ efficacy indicators were reported across WTLM studies with the top three indicators being measures used (100%), results (100%), and percent attrition (90%). Median attrition rates across follow-ups were 21%. While a small proportion of the studies reported tracking unintended or negative consequences (20% reporting) and cost effectiveness (5%), no articles reported on quality of life. Of the studies reviewed, the most effective WTLM interventions were group-based behavioral treatments (relapse prevention

training and problem-solving therapy) (27) and telephone and mail personal informational contacts with individuals that had previously lost weight through an exercise-only intervention (19). The average duration of the weight maintenance intervention was 12.6 months; weight regain was more likely reported with interventions including only hypocaloric diets and supplements after a very low calorie diet (VLCD) weight loss trial (29, 30). In addition, the highest attrition rate (65%) was reported in a VLCD trial (21).

Adoption: Only about one-fourth of the Adoption indicators were reported, with most studies reporting a description of staff who delivered the intervention (90%). No articles reported methods used to identify target delivery agent, inclusion/exclusion of settings or interventionist, rate of participation, organizational spread, characteristics of adoption/non adoption, or dissemination.

Implementation: Along with Effectiveness, this RE-AIM dimension was most frequently reported across studies reviewed. More than 58% of Implementation indicators were coded with the top two indicators reported being intervention number (95%) and timing of participant contacts (95%). The least likely to be reported in this sample were measures of cost, theoretical constructs used as the basis of intervention, and extent of the protocol that was delivered as intended.

Maintenance: This RE-AIM dimension was least frequently reported throughout the sample representing 8.8% of the Maintenance indicators. Only four articles (20%) addressed any indicators in the Maintenance dimension; they were behaviors assessed after the completion of the WTLM intervention (20%) and percent attrition at that assessment (15%).

DISCUSSION

The field of inquiry within WTLM is a vibrant research area that could significantly impact population health. However, within the context of attempting to develop WTLM interventions that have the potential for translation into actual practice, it is critical to address, evaluate, and understand the extent to which interventions have the potential to reach a large proportion of the target population, be effective, align with the available delivery system resources, and be sustainable (53). This analysis, as well as others (33, 34), identified numerous effective WTLM interventions. However, in contrast to previous reviews in this area, we have identified significant gaps in reporting important factors related to external validity (e.g. costs, adoption, participation rate) and have reported on metrics that could facilitate the translation of research interventions to practice settings. To date, it remains largely unknown how effective WTLM interventions are in “real-world” situations, such as clinical or community practice settings.

Often behavioral interventions do not reach those who could benefit most, they show reduced effectiveness over time, and they do not address setting-related issues necessary to ensure institutionalization and sustainability of content delivery at the organizational level (38). It is uncertain if WTLM intervention research suffers from these same limitations, yet these findings confirm that the reporting of external validity information is greatly lacking. Of all of the studies reviewed, the one reporting the most information across RE-AIM dimensions still addressed only about half of the indicators evaluated in this review (20). While the study provided an exceptionally detailed overview of Reach, Efficacy, and Implementation, there was still little information provided on potential adoption or sustainability.

In comparison to other reviews based on the RE-AIM framework, the WTLM literature is remarkably consistent (38, 52, 54, 55, 56). Specifically, we found that only 5% of studies on WTLM reported on participant representativeness. This finding is consistent with the gap in the literature on general physical activity, nutrition and smoking cessation interventions (Glasgow et al., 2004—14% of studies reported representativeness) (38), physical activity interventions for cancer survivors (White et al., 2009—no studies reported) (52), and interventions to prevent childhood obesity (Klesges et al., 2008—10% of studies reporting) (54). It is also of note that the proportion of WTLM trials that reported on quality of life outcomes (i.e., no studies reported in our review) is similar to proportion found in a review by Glasgow and associates that reviewed 119 studies on physical activity, nutrition and smoking cessation across school, community, health care, and work site settings (7% of studies reported on quality of life) (38). In contrast, about a third of the studies examining the prevention of childhood obesity report on quality of life outcomes (54).

Also, missing across the extant literature represented across RE-AIM reviews is consistent reporting of setting level representativeness, cost, setting level maintenance, and—to a lesser extent—the reporting of the degree to which an intervention is delivered as intended. Indeed, no studies in our review and only two studies across other RE-AIM reviews (38, 54) report on setting level representativeness and potential for maintenance. Ten percent of the studies in our review reported on cost issues. This suggests that compared to other physical activity, nutrition, and smoking cessation trials that the WTLM literature has a lower attendance to cost. Glasgow and associates found about one third of the studies they reviewed includes some information on cost (38). Finally, the WTLM literature seems to be less likely to report on the degree to which an intervention is delivered as intended (i.e., about 15% of studies) when

compared to other reviews that, on average, over half of the studies reviewed contained such information (38, 52, 54, 55, 56).

Based on this evaluation and others (38, 44, 48, 57, 58), a number of recommendations may be considered for future WTLM research to better align with the RE-AIM framework:

Reach: Only the study sample size was reported with unanimous consistency across studies and reach dimensions. No study provided a denominator from which to calculate proportional reach. When participation rate was calculated it was typically done so as a proportion of people who follow-up on the advertisements, who ultimately were eligible, and enrolled in the study. When reporting on the reach of an intervention, it is recommended that authors provide a brief definition of the intended population and a proportional value that reflects the penetration of the intervention into the target population. For most efficacy trials the concern is recruiting enough participants to provide the necessary power to detect changes between groups; yet understanding the number of potential participants that were exposed to recruitment materials can provide a rough estimate of the ultimate reach the program will achieve. Collecting demographic information on both those who agree to participate and those who decline participation would provide information on subgroups within the population who may not be represented in the study sample.

Efficacy/effectiveness: While all studies reported intervention outcomes, no study examined quality of life, 40% used intent to treat analyses rather than present at follow-up. Understanding quality of life in response to WTLM interventions could provide information that can be used to enhance participant engagement, or to determine if a given intervention is successful in maintaining weight loss maintenance but also influences quality of life.

Adoption: Few *effectiveness* trials have been conducted to achieve WTLM; that is, efficacy trials are prevalent. Thus it is not surprising that adoption indicators are almost exclusively absent beyond describing where the study is taking place and the intervention staff who deliver the program. As only 25% of the adoption indicators were coded across WTLM studies, an increased focus on balanced reporting of internal vs. external validity indicators would provide meaningful information related to the applicability of a given intervention across settings and those delivering the interventions. Information on why certain delivery locations and staff were selected should also be presented.

Implementation: Intervention contact and duration was frequently reported, and ~ 75% (n=15) of studies reported participant adherence to sessions. In contrast, only 1 in 5 studies reported the underlying theoretical approach to intervention development. As theory provides an understanding of the principles by which an intervention is thought to achieve its effect (53), the specific theory or theoretical constructs used in the intervention should be reported. The extent to which the intervention was delivered as intended should also be included.

Maintenance: In spite of the research focus on weight maintenance, WTLM studies did not often report on the sustainability of effects once the intervention was complete, attrition, or potential for the programs to be sustained in regular practice. This issue would be of significant interest to practitioners. Thus, it would be beneficial for WTLM research studies to include follow-up assessments after the intervention is complete, to determine the sustainability of weight loss maintenance and other lifestyle behaviors beyond the actual intervention period.

Cost: Measures of cost of recruitment and effectiveness were absent within the reviewed literature, and <10% of the articles reviewed examined cost of implementation or adoption. We acknowledge that modeling costs across the RE-AIM dimensions is a field of scientific inquiry in

and of itself. However, it is possible for researchers to track costs and report the figures within their work (See Perri et al., 2008 for an excellent example; (25)). Understanding the cost of an intervention across these dimensions would likely also be highly valued in the practice setting. Thus, study protocols should track costs across the research process from recruitment through the implementation process, and include this data when reporting intervention effects.

For practitioners such as Paula depicted in our vignette, the internal as well as the external validity in studies should be evaluated to determine the most appropriate WTLM intervention for a particular practice setting. Examining research and selecting interventions that include a broad heterogeneous sample and defined population, consideration of program delivery personnel, costs, and a feasible intervention design will increase likelihood of success when attempting to translate programs into clinical and community settings.

The need to translate successful WTLM interventions into practice is clear. The National Institutes of Health has numerous grant opportunities for funding and planning of translational research, including research addressing WTLM. Specific to WTLM research, future projects should be planned to address how the program will be adopted and maintained with special attention to costs related to participants and program implementation, which were identified as limitations in current WTLM literature. Translational research addressing these limitations will begin to bridge the gaps between long-term WTLM research and practice.

TABLES

Table Description of RE-AIM dimensions and evaluation of dimensions within weight loss maintenance intervention trials

RE-AIM Dimension	Reach	Efficacy/Effectiveness	Adoption	Implementation	Maintenance
Definition	The proportion and representativeness of individuals willing to participate in a given intervention.	The impact of an intervention on important outcomes, including potential negative effects, quality of life, and economic outcomes.	The proportion and representativeness of locations and intervention staff willing to initiate and adopt an intervention.	How consistently various elements of an intervention are delivered as intended by different intervention staff and the time and cost of the intervention.	The extent to which participants make and maintain a behavior change and the sustainability of a program or policy in the setting in which it was intervened.
Example	Svetkey, et al. reported many Reach indicators by describing their target population and study participants. How participants were identified, and inclusion/exclusion criteria were reported (11).	Wing, et al. presented many Efficacy/Effectiveness indicators, such as a thorough explanation of the research design, measures, and results. Imputation and intent to treat procedures were identified, and unintended consequences and attrition were discussed (14).	Harvey-Berino, et al. described the setting and location of the intervention, and the expertise of the individuals delivering the intervention (18). Perri et. al. provided a detailed description of program and participant costs (25).	Wing, et al., reports Implementation indicators, including information the number of participant contacts and the timing and duration of contacts, attendance rates and the percentage of the protocol delivered as intended (15).	Leermakers, et al. provided information on Maintenance by assessing their study participants 6 months after the completion of the study. The amount of weight gain and attrition rate was reported (23).
Study	Study Design				
Fogelholm, et al. 1999 (16)	6 month RCT 3 groups: <u>Control(C)</u> : no increase in habitual walking <u>Walk 1 (W1)</u> : targeted for 1000kcal weekly expenditure <u>Walk 2 (W2)</u> : targeted for 2000kcal weekly expenditure	n= 80 29-46 years old * 80 Female* BMI 34* Inclusion*: stable weight(±3kg for at least 3 months) Exclusion*: medications other than hormonal contraceptives, physically active, pregnant or lactating, smoker, and suspected binge eater. Participation rate: 100%	(C) gained 1.7kg (W1): lost 0.7kg (W2): gained 0.2kg 6% Attrition Effect size: C-W1: 0.52 C-W2: 0.35 W1-W2: 0.19	Weekly walking sessions were supervised by an exercise instructor at a clinical institute	All groups included 6 months of weekly group meetings and the W1 and W2 groups had weekly walking sessions
					No data

Harvey-Berino, et al. 2002 (17)	12 month RCT 3 groups: <u>Internet support (IS)</u> : biweekly chat sessions and were called or e-mailed on alternate weeks <u>In-person support (F-IPS)</u> : met in-person on a biweekly basis for 52 weeks and were called or e-mailed on alternate weeks <u>Minimal in-person support (M-IPS)</u> : met in-person monthly for the first 6 mo and then no contact	n= 122* 48.4±9.6 years old* 104 Female* BMI 32.2±4.5* 120 Caucasian* 8.9% high school 27.9% some college 30.3% college degree 32.8% graduate school Inclusion* : >18 years old, BMI≥25, and a computer with specific features. Exclusion*: history of major medical or psychiatric problems, planned pregnancy, or unable to participate in an exercise program. Recruitment: newspaper advertisements*	Those in the IS gained significantly more wt than the F-IPS NS difference between groups at 2-yr More of the F-IPS and M-IPS maintained a weight loss ≥ 5% (M-IPS: 81.3%, F-IPS: 81%, IS: 44.4%) 12% Attrition Effect size: IS-MIPS: 0.62 IS-FIPS: 0.78 FIPS-MIPS: 0.00	Interventions were delivered by group therapist and peers	IS had biweekly internet sessions, F-IPS had in-person biweekly sessions, and M-IPS met monthly for 1 hour during the first 6 months Attendance to treatment sessions were 59% for F-IPS and 39% for IS Adherence to self-monitoring was 22% for F-IPS and 19% for IS	No data
Harvey-Berino, et al. 2004 (18)	12 month RCT 3 groups <u>Internet support (IS)</u> : biweekly chat sessions and were called or e-mailed on alternate weeks <u>Frequent in-person support (F-IPS)</u> : met in-person at an interactive television (ITV) studio on a biweekly basis for 52 weeks and were called or e-mailed on alternate weeks <u>Minimal in-person support (M-IPS)</u> : met in-person over ITV monthly for the first 6 mo and then no contact	n= 232 46.0±8.8 years old 194 Female BMI 29.0±4.4 232 Caucasian Education: 23 high school 61 some college 70 college degree 78 graduate school Inclusion*: >18 years old, BMI≥25, and a computer with specific features. Exclusion*: history of major medical or psychiatric problems, planned pregnancy, or unable to participate in an exercise program. Recruitment: newspaper advertisements*	No significant differences in the amount of weight loss that was maintained (8.2% IS, 5.6% F-IPS, 6.0% M-IPS) 24% Attrition Effect size**: IS-MIPS: 0.37 IS-FIPS: 0.26 FIPS-MIPS: 0.05	Interventions were delivered by master's level dietitians over ITV and assessments were given in a clinical university setting	IS had biweekly internet sessions and alternate week phone or e-mail contact, F-IPS had in-person biweekly sessions and alternate week phone or e-mail contact, and M-IPS met monthly for 1 hour during the first 6 months Participants in the F-IPS attended significantly more group meetings compared to those in the IS group (10±5.1 vs. 7.7±5.3 meetings attended) 69% of participants provided data at all assessment points	No data

	IS and F-IPS conditions also participated in a social-influence per-supported program					
King, et al. 1989 (19)	12 month RCT: 4 groups; <u>Group 1 (1A):</u> telephone and mail contact and previous wt loss through diet only <u>Group 1 (1B):</u> telephone and mail contact and previous wt loss through exercise only <u>Group 2 (2A):</u> no contact and previous wt loss through diet only <u>Group 2 (2B):</u> no contact and previous wt loss through exercise only	n= 90 44.7±7.3 years old 0 Female 94% Caucasian Mean length of education: 16.4±2.9 years Inclusion: body wt 120%-160% ideal, age 30 to 59 years old, nonsmoker, total cholesterol <8.28mmol/l, triglycerides < 5.65mmol/l, normal ECG during graded exercise test, resting blood pressure below 160/100mm/Hg, not receiving medications that may affect lipid metabolism or blood pressure, and <4 alcoholic drinks per day*.	Mean wt change for the groups: 1A: 3.2±2.9 1B: 0.8±3.1 2A: 2.6±2.8 2B:3.9±2.8 1B had a significantly greater weight maintenance compared to the 1A, 2A, and 2B. However 1A showed a more variable pattern of wt gain and weight loss during maintenance. 1B had a greater energy intake and great energy expenditure compared to 1A, 2A, and 2B. 20% Attrition Effect size: 1A-2A: 0.22 1A-1B: 0.82 1A-2B: 0.25 2A-1B: 0.62 2A-2B: 0.48 1B-2B: 1.07	No data	Group 1 received monthly mailings and phone calls lasting 5 to 10 minutes at months1, 2,3,6,9, and 12.	No data
Kumanyika, et al. 2005(20)	8-18 month RCT 3 Groups: <u>Group counseling (GC)</u> : 6-meetings biweekly then monthly <u>Staff-assisted, self-help (SH)</u> : given a self-directed resource kit, monthly calls,	n= 128 45.4±10.2 years old 116 Female BMI 37.0±5.5 128 African American Education >12 years 70.2% Inclusion*: Self-identification as African American, age 25-70 years old, BMI 30-50, and personal physician in the	Weight regain from baseline to final visit: GC: 0.02 (95% CI -1.7, 1.8) SH: 1.1 (95% CI -0.3, 2.5) C: -0.04 (95% CI -1.9,1.8) 32% Attrition	Counseling and intervention was delivered at a family practice department of an urban university health system by nutrition, exercise, or behavior change specialist, whom were 45% African American. Cost of the program	The GC groups had 6 biweekly meetings and then meet monthly until their final visit. Average group session attendance for the GC group was 40% or expected for the 6 biweekly sessions and 31% of expected for the monthly sessions.	No data

	<p>facilitator support <u>Clinic visits only (C)</u>: no intervention only semiannual FU clinic visits</p>	<p>university health system. Exclusions*: conditions or circumstances where wt reduction would be contraindicated, inappropriate, or infeasible, or that could confound interpretation of wt loss data. Recruitment*: Posters displayed in hospitals, primary care offices and examination rooms, and through presentations to physicians and staff.</p>		<p>was less than \$146 per person per year.</p>	<p>In the SH group the facilitator completed 35-55% of monthly telephone calls.</p>	
<p>Lantz, et al. 2003 (21)</p>	<p>18 month RCT 2 groups (both groups were recommended a hypocaloric diet minus 500kcal/day) <u>Intermittent (I)</u>: consume VLCD (450kcal/day) for 2 weeks every third month <u>On-demand (OD)</u>: consume VLCD when wt increases past 3kg from baseline</p>	<p>n= 334* 18-60 years old* 247 Female* BMI >30* Inclusion*: BMI>30, 18-60 years old, and referred to university hospital. Exclusion*: type I diabetes mellitus, renal or hepatic failure, unstable angina, recent myocardial infarction, chronic infections, psychotic disorders, bulimia, and previous drug abuse or obesity surgery.</p>	<p>I lost 7.0kg while OD lost 9.1kg. There were no significant differences btw groups. 65% Attrition*</p>	<p>Participants were monitored by a physician, registered dietitian, and a nurse at various time points during the study in a clinical hospital</p>	<p>Monthly meetings</p>	<p>No data</p>
<p>Layman, et al. 2009 (22)</p>	<p>8 month RCT 2 groups: <u>Low carbohydrate to protein ratio (LOW)</u>: 40% energy from carbohydrate, 30% from protein, 30% from fat <u>High carbohydrate to protein (HIGH)</u>:</p>	<p>n= 103 45.4±(SE)1.2 years old* BMI 32.6±(SE)0.8 72 Female* Exclusion: BMI<26, body weight>140kg, smoking, and any preexisting medical conditions requiring medications</p>	<p>Mean weight change(kg) from baseline: Intent to Treat: LOW: -9.3 ±(SE)1.0 HIGH: -7.4 ±(SE)0.6 Completers: LOW -10.4 ±(SE)1.2 HIGH -8.4 ±(SE)0.9 No sig. difference btw groups in mean weight</p>	<p>Group meetings were lead by a research dietitian at a weight management research facility. Any unexcused absence was followed up by a phone call</p>	<p>Both groups were required to attend a 1 hour meeting each week. The LOW group had a significantly greater number of participants (64%) complete compared to the HIGH group (45%). Compliance with group meetings was >75%.</p>	<p>No data</p>

	55% of energy from carbohydrate, 15% from protein, 30% from fat		change LOW group lost significantly more (48%) fat mass than the HIGH 31% Attrition Effect size**: LOW-HIGH: 0.31			
Leermakers, et al. 1999 (23)	6 month RCT 2 groups: <u>Exercise-focused maintenance (EFM) program</u> : designed to sustain the maintenance of physical activity <u>Wt-focused maintenance (WFM) program</u> : sessions focused on maintenance of wt loss	n= 67 50.8±11.1 years old 54 Female 63 Caucasian BMI 30.8±4.5 Recruitment: invitation	No significant differences between the 2 conditions in exercise participation and energy expenditure. 15% Attrition Effect size: EFM-WFM: 0.50	Groups were led by clinical psychology graduate students	Both groups included 6 months of biweekly group counseling sessions. Participant attendance rates were 73.1% for EFM and 70.8% for WFM	During the 18 month follow-up visit, participants in the WFM group had greater reductions in fat intake and better maintenance of wt loss. 28% Attrition Effect size 12-18 months: EFM-WFM: 0.69 Effect size 6-18 month: EFM-WFM: 0.86
Liebbrand and Fichter, 2002 (24)	18 month RCT 2 groups: <u>Maintenance (M)</u> : supportive weight maintenance program by phone consultation <u>Control (C)</u> : no support	n= 109 37.1±10.8 years old 91 Female BMI 44.8±8.7 Recruitment: referred Inclusion: BMI>30, characteristics of eating disorders or other mental disorders, and informed consent. Exclusion: Severe, wt related organic diseases, pregnant, psychotic disorders, and surgical weight reduction.	From baseline to 18months BMI increased from 42.54±6.74 to 43±7.81 in the M group and decreased from 40.62±5.67 to 40.58±6.3 in the C group 21% attrition Effect size: M-C: 0.02	Interventions were delivered by a trained psychotherapist and assessments were given in a medical clinic	M received 8 45-minute phone consultations for 9-months and 4 consultations for the last 9-months and was invited to a 2-day therapist guided booster session	No data
Pasman, et al. 1999 (13)	12 month non randomized control trial 2 groups: <u>Endurance training</u>	n= 15 37.3 ±5.2 years old 0 Female BMI 30.9±2.8 Recruitment: newspaper	The overall regain of body weight at 12 months was 65% of the whole group (52% for ET and 74% for the C)	Weekly endurance training sessions (ET) were monitored by a professional coach at a triathlon club.	ET: 3-4 weekly endurance exercise sessions for 1 hour.	No data

	<u>(ET)</u> : swim, cycle, and run 3-4 per wk <u>Control (C)</u> : not involved in a training program	advertisement	there was no significant correlation between the training hours per week and the regain of body weight at 12 months 3 participants were unwilling to continue the training program, therefore they were moved to a control.			
Perri, et al. 1988 (26)	13 month RCT: 5 groups: <u>Behavior Therapy (B)</u> : Control, received no maintenance intervention <u>Treatment contact (BC)</u> : Therapist contacts with recommended 80 minutes of exercise per week <u>BC plus social influence program (BCS)</u> : Therapist contacts plus multifaceted program of social influence strategies <u>BC plus aerobic exercise maintenance program (BCA)</u> : Therapist contacts plus aerobic exercise maintenance program <u>BC plus aerobic plus social influence (BCAS)</u> : Therapist	n= 94 22-59 years old* 97 Female* Inclusion*: 20-100% over ideal body weight, not currently involved in wt loss study, no significant health disorders, not taking medications that affect wt loss, willing to commit for 24 months, and no planned pregnancies. Recruitment*: advertisements	Weight regain over 13months for each intervention: B: 7.2kg BC: 1.76kg BCS: 2.91kg BCA: 3.91kg BCAS: 0.13kg 2% Attrition for weight maintenance and 26% Attrition	Interventions were delivered by a clinical psychologist, physician, or a nurse practitioner	BC, BCS, BCA, and BCAS received 26 biweekly therapist contacts On average participants attended 66.8% of the 26 scheduled sessions	No data

	contacts plus aerobic exercise maintenance program plus social influence					
Perri, et al. 2001 (56)	12 month RCT: 3 groups: <u>Control (BT):</u> no contact <u>Relapse Prevention therapy (RPT) (7):</u> group sessions for relapse prevention <u>Problem Solving therapy (55):</u> group sessions for problem solving	n= 80 46.6±8.9 years old* 80 Female* BMI 35.8±4.5* Education; 13.9±1.9 years Inclusion*: 21-60 years old, BMI 27-40, good health, and physician's approval. Recruitment*: newspaper advertisements	Weight regain from baseline to 12 months for each intervention: BT: +5.39 RPT: +2.56 PST: -1.51 28% Attrition Effect size 5-11 month: BT-RPT: 0.94 BT-PST: 1.22 RPT-PST: 0.29 Effect size 11-17 month: BT-RPT: 0.32 BT-PST: 0.57 RPT-PST: 1.0	No data	RPT and PST were scheduled for 6 biweekly sessions Audiotape recordings were used to examine the extent of protocol. In the RPT group 100% of relapse prevention skills were observed and 0% of problem solving skills were observed. In the PST groups 100% of the problems solving skills were observed and 33% of the relapse prevention skills were observed. Adherence to program goals decreased with each group over time and there was a significant difference in adherence between BT and PST groups.	No data
Perri, et al. 2008 (25)	12 month RCT 3 groups: <u>Group 1(A):</u> extended care which received counseling sessions over the phone <u>Group1(B):</u> extended care which received counseling sessions face to face <u>Group 2 (C):</u> education control group which	n= 234 59.4±6.1 years old BMI 36.8±4.9 234 Female 18.3% African American 2.1% Hispanic 77.3% Caucasian 2.1% Asian, Native American, or Pacific Islander Education: 37.6% ≤12 years 41% 13-15 years 21.4% ≥16 years	Groups A and B regained less wt than Group C (1.2±(SE)0.7 and 1.2±(SE)0.6 vs. 3.7±(SE)0.7), and had greater adherence to behavioral weight maintenance strategies. 6% Attrition Effect size: A-B: 0.00 A-C: 0.42 B-C: 0.43	Participant contacts were lead by Cooperative Extension Services (CES) agents with a bachelors of science or masters of science in nutrition, exercise physiology, or psychology in the rural CES offices. Costs to program (per participant): A: \$192±21 B: \$391±73	Both A and B groups received 26 biweekly counseling sessions ,Group A received 15 to 20 minute sessions and Group B received 60 minute sessions. Group C received 26 biweekly newsletters by mail. All group's education was based on Perri's 5-stage problem solving model(27). Group A and B's mean	No data

	received newsletters	<p>Annual household income: 44.4% ≤\$35,000 21.8% \$35,000-\$49,000 19.7% \$50,000-\$74,999 12.8% ≥\$75,000</p> <p>Exclusion: not history of uncontrolled diabetes mellitus and no active manifestations of cardiovascular, cerebrovascular, renal, or hepatic disease; No medications known to affect body weight; wt loss of ≥4.5kg in the preceding 6 months; No psychosocial contraindications.</p> <p>Recruitment: announcements mailed to households.</p> <p>Target population: women in rural settings</p>		<p>C: \$116±19 Costs to participant: A: \$1933±1436 B: \$2157±1449 C: \$1708±1692</p>	number of sessions attended were 13.8±8.6 and 21.1±5.7 respectively.	
Riebe, et al. 2004 (28)	<p>18 month RCT 2 Groups: <u>Extended care group (EC)</u>: received additional personalized Transtheoretical Model reports at <u>Control (C)</u>: received generic materials about diet and ex. Both groups received reports on anthropometrics, biochemical, and dietary reports</p>	<p>n= 144 50.2 ±9.2 years old BMI 32.5±3.8 Education : 1% < high school 10% high school 21% some college 28% college graduate 40% postgraduate degree Inclusion: >18 years old, BMI 27-40 Exclusion: exercise or dietary fat reduction was contraindicated, cancer or type I diabetes, symptoms of eating disorder or depression, or cardiovascular disease.*</p>	<p>Mean wt change from baseline to 24 month follow up for both groups: EC: 87.6±15.9 to 90.5±16.9 C: 84.1±14.1 to 86.9±15.4 There were no significant differences in wt change between groups.</p>	A registered dietitian reviewed food records.*	Both groups received mailed reports at 6 and 18 months but the EC group received mailed reports based on the Transtheoretical Model of Health Behavior Change at months 3 and 9 months.	Both groups were received a follow up assessment at 18 months. 32% Attrition

Ryttig, et al. 1995 (30)	12 month RCT 2 Groups: <u>Group 1 (G1):</u> balanced hypocaloric diet (1600kcal/day), of which 220kcal were provided by supplement <u>Group 2 (G2):</u> Balance hypocaloric diet (1600kcal/day) w/o supplement.	n= 52 39.1±5.5 years old* 41 Female BMI 39.1±5.5* Inclusion*: BMI ≥30, stable body weight (<3kg change within 2 months of study), and on waiting list from an obesity unit at a hospital. Exclusion*: history of renal, cardiac, cerebrovascular, gastrointestinal ulcer, or gallbladder disease, type I diabetes mellitus, gout, and porphyria, psychiatric disturbances, medications know to affect weight loss, pregnancy, lactation, vegetarian diet and/or lack of consent. Recruitment*: invitation Unintended Consequences: headache, freezing, shivering, tiredness, transient alopecia, and gall- bladder disease symptoms.	% wt gain in G1 was 9.3±9.4%: 8.0±8.2kg % wt gain in G2 was 12.3±10.0%: 12.3±(9.7kg G1 regained 39± 35.7% of weight lost during weight loss trial compared to 54±38.5% in G2 22% Attrition Effect size: G1-G2: 0.49	Interventions and assessments were delivered by a nurse with medical expertise and dietitian in a university outpatient obesity clinic	Both groups were seen for assessments every month for 7 months and then every 7 th week during the rest of the intervention.	No data
Ryttig, et al. 1997 (29)	26 month RCT 3 Groups: <u>Group 1(A):</u> Hypocaloric diet (1600 kcal) with behavior control modification <u>Group 2(B):</u> Hypocaloric diet (1600 kcal) with behavior control modification with previous wt loss program of very low	n= 77 41.6±10 years old* BMI 37.7±4.8* 44 female Inclusion*: BMI≥30, from a obesity clinic waiting list, ability to complete visual analogue scale at 3:00pm daily. Exclusion*: history of renal, cardiac, cerebrovascular, gastrointestinal ulcer, or gallbladder disease, type I diabetes mellitus, gout, and	The mean weight reduction after 26 months 7, 10, and 9.5% in groups A, B, and C respectively. Mean wt regain for the 3 groups: (A):1.7kg (B): 13.3kg (C): 13.5kg The were no significant group differences 49% Attrition	Participants were seen by a specially trained nurse with medical expertise if problems arose and eating habits and group sessions were lead by a dietitian. Assessments and groups sessions were held at an obesity unit at a hospital.	There were 4 assessment contacts for all groups at months 2, 6, 14, and 26.	No data

	calorie diet <u>Group 3(C):</u> Hypocaloric diet (1600kcal) with 239kcal of provided as 3 sachets of supplement	porphyria, psychiatric disturbances, medications know to affect weight loss, pregnancy, lactation, vegetarian diet and/or lack of consent. Unintended Consequences: headache, dizziness, fatigue, muscular weakness, gastrointestinal problems, and nausea.				
Svetkey et al. 2008 (11)	30 month RCT 3 groups: <u>Personal contact (PC):</u> participants received monthly telephone and every 4 th month face-to-face counseling <u>Interactive technology-based intervention:</u> participants were encouraged to regularly log on to an interactive Web site <u>Self-directed (control) (SD):</u> participants received minimal intervention	n= 1032 55.6±8.7 years old 654 Female 388 African American BMI 34.1±4.8 440 <\$60,000 yearly household income Education: 396 some college or less 636 college degree Inclusion*: BMI 25-45, taking medications for hypertension and/or dyslipidemia, no active cardiovascular disease, access to telephone and Internet, and be able to keep a 5 day food record. Exclusion*: medications to treat diabetes mellitus, recent cardiovascular event, medical or psychiatric conditions, wt loss >9kg in previous 3 months, recent use of wt loss medications, and/or prior wt loss surgery. Recruitment*: mass mailings of brochures, coupons, and flyers; advertisements in	PC regained 4.0kg ITI regained 5.2kg SD regained 5.5kg 71% of study participants remained below entry weight PC regained significantly less wt when compared to SD. No difference between PC and ITI 6.6% Attrition Effect size: SD-ITI: 0.05 SD-PC: 0.27 PC-ITI: 0.27	Clinical university setting	30 monthly contacts for PC group which their duration were 5-15 minutes and every 4 th month was 45 to 60 minutes.	No data

		newspaper, radio, e-mail broadcasts, screening events; physician referrals, and word of mouth. Target population: large, diverse, adult population at high risk for cardiovascular disease.				
Villanova, et al. 2006 (31)	Nonrandomized observational trial of a 6 month group fitness program (light to moderate daily physical activity)	n= 200 46±11 years old 164 Female 15% BMI 25-29.9 37% BMI 30-34.9 32% BMI 35-39.9 16% BMI ≥40 Participation rate: 78% Recruitment: invitation	Prevalence of metabolic syndrome dropped from 43.9% to 23.7% Only 1/3 of participants failed to lose ≥ 5% of body weight 84% of participants took ≥ 5000 steps/day compared to 24% at baseline 22% Attrition Effect size: 0.10	Groups were chaired by doctors, registered dietitians, and clinical psychologists in a specialist care setting	Cognitive Behavioral Therapy	During the 32 mo follow-up no significant wt regain was observed in participants (21.5%) who completed the observation period 78.5% Attrition
Wing, et al. 1996 (15)	Study 1: 12 month RCT 2 Groups: <u>Group 1 (G1):</u> telephone-assisted weight maintenance and access to a study nutritionist for further counseling <u>Group 2 (G2):</u> no-contact	n= 53 43.6±(SE)1.5 years old 53 Female BMI 32.2±(SE)0.4 Recruitment: invitation Education: 11.4% ≤high school 45.5% >high school<college degree 43.1% ≥college degree	Participants in G1 had a weight gain of 3.9±(SE)1.1kg compared to a gain of 5.6±(SE)1.0kg in G2 15% Attrition Effect size: G1-G2: 0.33	Phone calls were completed by a trainer interviewer in a university clinic	Participants were called every week for 15 minutes for the duration of the study 80% of the phone calls were completed 92% of participants were able to self report weight, 58% self reported food logs, and 62% self reported exercise logs.	No data
Wing, et al. 1996 (15)	Study 2: 12 month RCT <u>Group 1 (G1):</u> informed that they could purchase food boxes during any 4 months of the maintenance program <u>Group 2 (G12):</u> no food provisions	n= 48 40.7±(SE)1.5 years old BMI 32.4±(SE)0.4 48 Female Recruitment: invitation Education: 19.5% ≤high school 34.5% >high school<college degree 46% ≥college degree	Participants in G1 had a weight gain of 4.2±(SE)1.0kg compared to a gain of 4.3±(SE)1.1kg in G2 Only 12 participants decided to order the food provisions 0% Attrition Effect size: G1-G2: 0.02	Participants were weighed and discussed problems with a therapist.	Both groups were seen monthly for group sessions for the duration of the study.	No data

Wing, et al. 2006 (14)	18 month RCT. 3 groups: <u>Control group (C)</u> : received quarterly newsletters with no interaction with intervention staff <u>Face-to-face (FF)</u> : attended counseling session in-person and further support was given in-person <u>Internet-based (IB)</u> : attended counseling sessions via chat room and further support was given via internet	n= 314 51.3±10.1 years old BMI 28.6±4.8 255 Female Inclusion*: lost ≥10% of body weight during the prior 2 years and have someone sign a form indicating the amount and time of wt loss. Exclusion*: serious physical or psychological disorders, pregnancy, or planned move. Recruitment*: newspaper advertisements, brochures, and contacts with commercial and research wt control programs.	Mean weight gain from baseline: FF 2.5±6.7kg IB 4.7±8.6kg C 4.9±6.5kg Percentage of participants that regained ≥2.3 kg: FF 45.7% IB 54.8% C 72.4% 4.5% Attrition at 6 mo FU 7.7% Attrition at 12 mo FU 7.4% Attrition at 18 mo FU Effect size base-6 month: C-FF: 0.39 C-IB: 0.08 FF-IB: 0.29 Effect size base-12 month: C-FF: 0.29 C-IB: 0.02 FF-IB: 0.27 Effect size base-18 month: C-FF: 0.37 C-IB: 0.03 FF-IB: 0.29	Face-to-face, internet, and phone sessions focusing on self regulation were lead by nutritionists, exercise physiologists, and clinical psychologists with master's of Ph.D. degrees. The FF groups met in a hospital clinic and all groups were assed every 6 months.	FF and IB groups attended weekly meetings for the 1 st month and attended monthly meetings for the duration of the study. The percentage of sessions attended by participants: FF 78.7% (base to 6 mo) 53.5% (7 month to 12 month) 41.5% (12 month to 18 month) IB 65.7% (base to 6 month) 41.2% (7 month to 12 month) 34.2% (12 month to 18 month)	No data
<p>* Represents data from the weight loss phase. No data were provided for only the weight maintenance phase of the intervention.</p> <p>** Effect size calculated from the mean (± SD) of the change in weight (kg) from baseline of weight loss phase to post intervention of weight maintenance phase. No data was reported for weight change from baseline of weight maintenance phase to post intervention of weight maintenance phase.</p> <p>Abbreviations: BMI, Body Mass Index; RCT, Randomized Control Trial; wt, Weight.</p> <p>Data are reported as mean SD unless otherwise indicated.</p>						

FIGURE LEGEND

Figure 1 RE-AIM Coding Sheet used to evaluate weight loss maintenance intervention trials...

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Figure 2 RE-AIM dimensions and indicators within each dimension: Evaluation of published weight loss maintenance intervention trials...Page 86

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Figure 1 RE-AIM Coding Sheet used to evaluate weight loss maintenance intervention trials

Title:		Group Based	Individual	Interactive technology	Policy	Environment
(Author, Journal, Year, Page):		Comments:				
Outcome Measures: Primary Outcomes:		Behavioral		Physical activity	Diet	
REACH	Reported (Yes/No)	Data		Comments		
Described Target Population						
Demographic & behavioral information						
Method to identify target population						
Recruitment Strategies						
Inclusion criteria						
Exclusion criteria						
Target population denominator						
Sample size						
Participation rate						
Characteristics of both participation and non-participation						

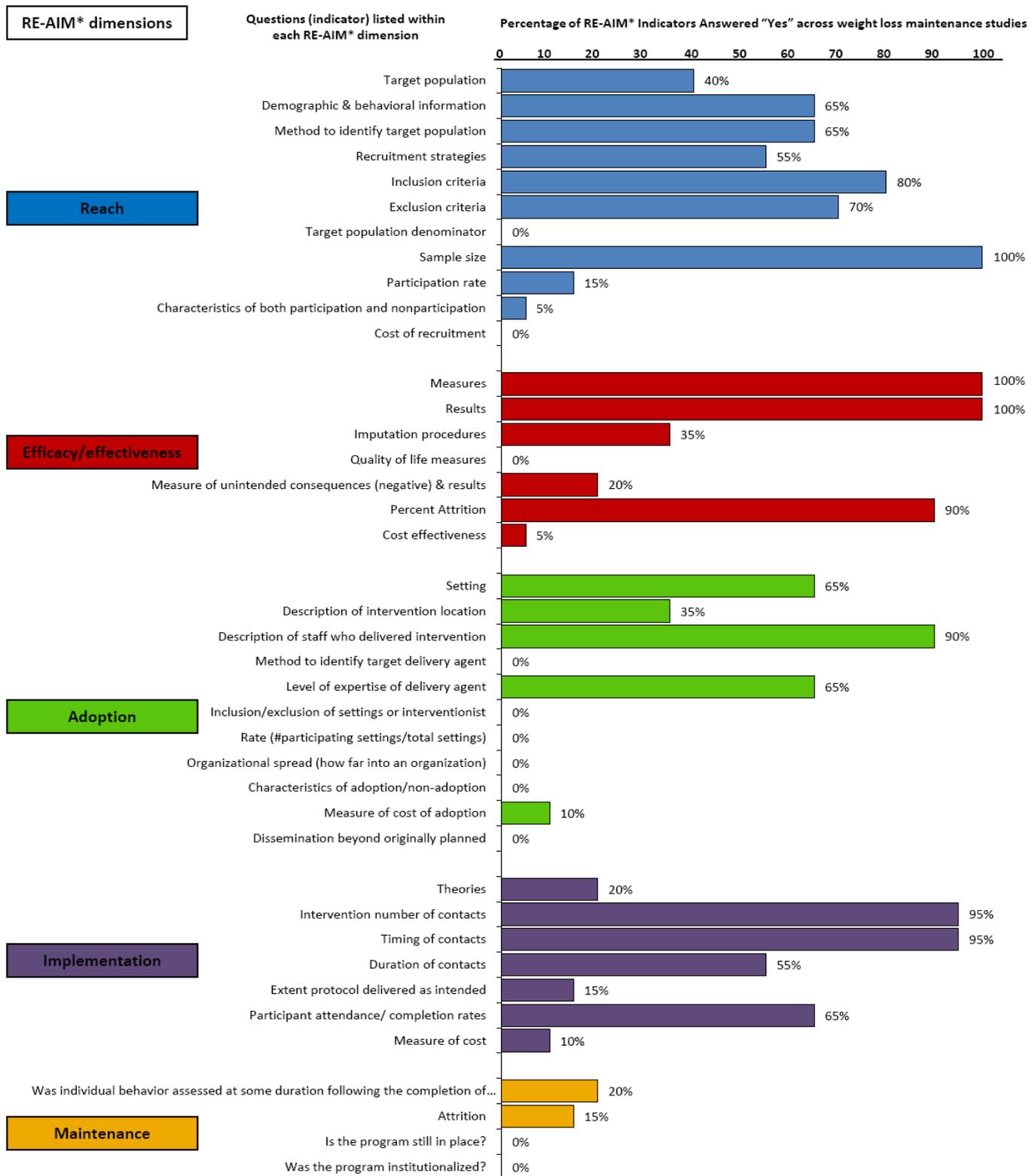
Cost of recruitment			
EFFICACY/EFFECTIVENESS	Design	Conditions	
Design/Conditions			
Efficacy, Effectiveness, Translational?			
Measures			
Results (at shortest assessment)			
<u>Intent to treat</u> or present at FU (circle one)			
Imputation procedures (specify)			
Quality of life measure			
Measure unintended consequences (negative) & Results			
Percent attrition			
Cost effectiveness			
ADOPTION - DIFFUSION - Setting Level		Reported (Yes/No)	Data
Setting			Comments
Description of intervention location			
Description of staff who delivered intervention			

Method to identify target delivery agent			
Level of expertise of delivery agent			
Inclusion/exclusion criteria of settings or interventionist			
Rate (#participating settings/total settings)			
Organizational spread (how far into an organization)			
Characteristics of adoption/non-adoption			
Measures of cost of adoption			
Dissemination beyond originally planned			
IMPLEMENTATION	Reported (Yes/No)	Data	Comments
Theories			
Intervention number of contacts			
Timing of contacts			
Duration of contacts			
Extent protocol delivered as intended (%)			
Participant attendance/completion rates			
Measures of cost			
MAINTENANCE	Reported (Yes/No)	Data	Comments
Was individual behavior assessed at some duration following the completion of the intervention?			

(give duration of follow-up)			
Attrition			
Is the program still in place?			
If no: reason for discontinuation			
If yes: was the program modified? Specify			
Was the program institutionalized?			

Note related studies (e.g., other outcomes or process)

Figure 2 RE-AIM dimensions and indicators within each dimension: Evaluation of published weight loss maintenance intervention trials



*RE-AIM (Reach, Efficacy/ effectiveness, Adoption, Implementation, Maintenance)

CHAPTER 4: CONCLUSIONS

The limited success of existing weight loss maintenance (WTLM) approaches (1, 2) suggests the need for feasible, low-resource, and effective intervention strategies. We determined that using self-regulation strategies (daily self-monitoring of weight, step counts, and fruit/vegetable intake) is effective at maintaining a previous weight loss of 7-8% of initial body weight (3) among middle-aged and older adults. In addition to maintaining body weight ≤ 1.36 kg (3 lbs.) of baseline reduced weight, participants achieved a mean daily step count of $8,597 \pm 44$ steps/day, and a fruit/vegetable intake of 5.4 ± 0.0 servings/day. Previous investigations have demonstrated that increasing water consumption is a successful weight loss strategy for this population (3), yet our investigation determined that increasing water consumption did not have any additional benefit on WTLM beyond that achieved by daily self-monitoring of the other behaviors. However, adherence to the daily water intake goal was 66%, thus future studies are needed to definitively determine if this recommended level of water intake promotes WTLM.

Compliance with turning in weekly tracking sheets ($76 \pm 5\%$) leads to more successful WTLM outcomes; this data is supported by other researchers (4). Out of the possible 14,235 days of tracking behaviors among all participants, 4,082 days were not recorded. One additional notable outcome of this investigation was the low attrition rate (3.5% attrition), which could be due to a low participant burden (e.g. time, money, resources). Participants were required to attend laboratory sessions once per month, and return weekly tracking sheets via e-mail. In addition, there was weekly e-mail contact with the study coordinator, which may have helped prevent attrition. Future studies should determine the level of coordinator contact required to produce effective outcomes, and to determine if automated weekly feedback is comparable in its

effectiveness for WTLM. Some in-person contact is likely required however, as previous work suggests this approach leads to more favorable outcomes (5-7).

There is a substantial body of efficacy literature evaluating strategies for WTLM. However, during our review of WTLM literature using the RE-AIM framework (8), we determined that there are significant gaps which should be addressed. First, researchers should provide a description of the intended population and the proportion of the population represented in the research sample. This will provide a better understanding of participants and non-participants and determine if systematic differences exist between the two groups. Without documenting the representativeness of all who were recruited, problems with selection bias cannot be determined (9). Second, quality of life indicators could reveal benefits (or unintended consequences) of an intervention, which may contribute to a behavior change (or lack thereof). Third, researchers should discuss the feasibility of the intervention across multiple settings and the background of those delivering the interventions. The translation of interventions from controlled research settings to larger and more applied venues is often hampered by problems with delivering intervention components as intended or the availability of skilled delivery staff to implement interventions. Information such as staff participation, representativeness, and costs are important for planning staff training requirements to ensure successful implementation. Fourth interventions should be theoretically-based. Theory provides an understanding of the principles by which an intervention is thought to achieve its effect (10). Finally, researchers should include assessments within an intervention that measures its sustainability. Adding follow-up investigations examining long-term behavior change, program attrition, continued weight maintenance/ weight regain, or discontinuation of programs would expand our understanding of an interventions adoption and maintenance and what occurs in “real world”

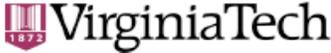
settings. Other factors like costs to the researcher and costs to the participant are important in determining if an intervention is feasible and cost effective to the clinic or community setting that is implementing the intervention, and is often a key question asked by those considering program adoption and dissemination.

We have shown that if compliant, self-monitoring of self-regulatory strategies (daily self-weighing, increased step count, and increased fruit/vegetable intake) can be an effective WTLM approach for middle-aged and older adults. However, it is still uncertain if increased water intake may have any additional benefit on WTLM. Future studies using monetary incentives or providing water to participants be an attractive option to improve water compliance issues. To determine the public health impact of this current investigation and other WTLM investigations, it is critical to detail the reach and potential for adoption of an intervention relative to the targeted population or setting (11). It is recommended that future WTLM interventions be designed to facilitate scalable and sustainable interventions for improving WTLM outcomes in this population.

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**APPENDIX A:
Institutional Review Board Approval 7/17/2006**



Office of Research Compliance
Institutional Review Board
2000 Kraft Drive, Suite 2000 (0497)
Blacksburg, Virginia 24061
540/231-4991 Fax 540/231-0959
e-mail moored@vt.edu
www.irb.vt.edu
FWA00000572 (expires 1/20/2010)
IRB # 16 IRB00000667

DATE: May 21, 2007

MEMORANDUM

TO: Brenda M. Davy
Kevin P. Davy
Janet W. Rankin

FROM: David M. Moore 

Approval date: 7/17/2006
Continuing Review Due Date: 6/25/2007
Expiration Date: 7/16/2007

SUBJECT: IRB Amendment 3 Approval: "Weight Loss In Older Adults", IRB # 06-372

This memo is regarding the above referenced protocol which was previously granted approval by the IRB on July 17, 2006. You subsequently requested permission to amend your IRB application. Since the requested amendment is nonsubstantive in nature, I, as Chair of the Virginia Tech Institutional Review Board, have granted approval for requested protocol amendment, effective as of May 21, 2007. The anniversary date will remain the same as the original approval date.

As an investigator of human subjects, your responsibilities include the following:

1. Report promptly proposed changes in previously approved human subject research activities to the IRB, including changes to your study forms, procedures and investigators, regardless of how minor. The proposed changes must not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.
2. Report promptly to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.
3. Report promptly to the IRB of the study's closing (i.e., data collecting and data analysis complete at Virginia Tech). If the study is to continue past the expiration date (listed above), investigators must submit a request for continuing review prior to the continuing review due date (listed above). It is the researcher's responsibility to obtain re-approval from the IRB before the study's expiration date.
4. If re-approval is not obtained (unless the study has been reported to the IRB as closed) prior to the expiration date, all activities involving human subjects and data analysis must cease immediately, except where necessary to eliminate apparent immediate hazards to the subjects.

cc: File

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APPENDIX B
Institutional Review Board Approval Amendment 7/17/2007



Office of Research Compliance
Institutional Review Board
2000 Kraft Drive, Suite 2000 (0497)
Blacksburg, Virginia 24061
540/231-4991 Fax 540/231-0959
e-mail moored@vt.edu
www.irb.vt.edu
FWA00000572(expires 1/20/2010)
IRB # is IRB00000667

DATE: August 21, 2007

MEMORANDUM

TO: Brenda M. Davy
Kevin P. Davy
Janet W. Rankin

FROM: David M. Moore 

Approval date: 7/17/2007
Continuing Review Due Date: 6/30/2008
Expiration Date: 7/16/2008

SUBJECT: **IRB Amendment 1 Approval:** "Weight Loss In Older Adults" , IRB # 06-372

This memo is regarding the above referenced protocol which was previously granted approval by the IRB on July 17, 2007. You subsequently requested permission to amend your IRB application. Since the requested amendment is nonsubstantive in nature, I, as Chair of the Virginia Tech Institutional Review Board, have granted approval for requested protocol amendment, effective as of August 20, 2007. The anniversary date will remain the same as the original approval date.

As an investigator of human subjects, your responsibilities include the following:

1. Report promptly proposed changes in previously approved human subject research activities to the IRB, including changes to your study forms, procedures and investigators, regardless of how minor. The proposed changes must not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.
2. Report promptly to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.
3. Report promptly to the IRB of the study's closing (i.e., data collecting and data analysis complete at Virginia Tech). If the study is to continue past the expiration date (listed above), investigators must submit a request for continuing review prior to the continuing review due date (listed above). It is the researcher's responsibility to obtain re-approval from the IRB before the study's expiration date.
4. If re-approval is not obtained (unless the study has been reported to the IRB as closed) prior to the expiration date, all activities involving human subjects and data analysis must cease immediately, except where necessary to eliminate apparent immediate hazards to the subjects.

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Appendix C
Institutional Review Board Approval Amendment 7/17/2008



Office of Research Compliance
Institutional Review Board
2000 Kraft Drive, Suite 2000 (0497)
Blacksburg, Virginia 24061
540/231-4991 Fax 540/231-0959
e-mail moored@vt.edu
www.irb.vt.edu
FWA00000572(expires 1/20/2010)
IRB # 16 IRB00000667

DATE: July 17, 2008

MEMORANDUM

TO: Brenda M. Davy
Kevin P. Davy
Janet W. Rankin

FROM: David M. Moore 

Approval date: 7/17/2008
Continuing Review Due Date: 6/29/2009
Expiration Date: 7/16/2009

SUBJECT: **IRB Full Review Continuation 2:** "Weight Loss In Older Adults", OSP #455929, 455467, IRB # 06-372

This memo is regarding the above referenced protocol which was previously granted approval by the IRB. The proposed research, having been previously approved at a convened IRB meeting, required full IRB review prior to granting an extension of approval, according to the specifications authorized by 45 CFR 46.110 and 21 CFR 56.110. The above referenced protocol was submitted for full review continuation and approval by the IRB at a recent meeting. Pursuant to your request, I, as Chair of the Virginia Tech Institutional Review Board, have, at the direction of the IRB, granted approval for this study for a period of 12 months, effective July 17, 2008.

Approval of your research by the IRB provides the appropriate review as required by federal and state laws regarding human subject research. As an investigator of human subjects, your responsibilities include the following:

1. Report promptly proposed changes in previously approved human subject research activities to the IRB, including changes to your study forms, procedures and investigators, regardless of how minor. The proposed changes must not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.
2. Report promptly to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.
3. Report promptly to the IRB of the study's closing (i.e., data collecting and data analysis complete at Virginia Tech). If the study is to continue past the expiration date (listed above), investigators must submit a request for continuing review prior to the continuing review due date (listed above). It is the researcher's responsibility to obtain re-approval from the IRB before the study's expiration date.
4. If re-approval is not obtained (unless the study has been reported to the IRB as closed) prior to the expiration date, all activities involving human subjects and data analysis must cease immediately, except where necessary to eliminate apparent immediate hazards to the subjects.

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VIRGINIA POLYTECHNIC INSTITUTE UNIVERSITY AND STATE UNIVERSITY
An equal opportunity, affirmative action institution

Appendix D
Institutional Review Board Approval Amendment 7/17/2009



Office of Research Compliance
Institutional Review Board
2000 Kraft Drive, Suite 2000 (0497)
Blacksburg, Virginia 24061
540/231-4991 Fax 540/231-0959
e-mail moored@vt.edu
www.irb.vt.edu

FWA00000572(expires 1/20/2010)
IRB # is IRB00000667

DATE: July 13, 2009

MEMORANDUM

TO: Brenda M. Davy
Kevin P. Davy
Janet W. Rankin

FROM: David M. Moore 

Approval date: 7/17/2009
Continuing Review Due Date: 6/28/2010
Expiration Date: 7/16/2010

SUBJECT: IRB Full Review Continuation 3: "Weight Loss In Older Adults", OSP #455929, 455467, IRB # 06-372

This memo is regarding the above referenced protocol which was previously granted approval by the IRB. The proposed research, having been previously approved at a convened IRB meeting, required full IRB review prior to granting an extension of approval, according to the specifications authorized by 45 CFR 46.110 and 21 CFR 56.110. The above referenced protocol was submitted for full review continuation and approval by the IRB at a recent meeting. Pursuant to your request, I, as Chair of the Virginia Tech Institutional Review Board, have, at the direction of the IRB, granted approval for this study for a period of 12 months, effective July 17, 2009.

Approval of your research by the IRB provides the appropriate review as required by federal and state laws regarding human subject research. As an investigator of human subjects, your responsibilities include the following:

1. Report promptly proposed changes in previously approved human subject research activities to the IRB, including changes to your study forms, procedures and investigators, regardless of how minor. The proposed changes must not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.
2. Report promptly to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.
3. Report promptly to the IRB of the study's closing (i.e., data collecting and data analysis complete at Virginia Tech). If the study is to continue past the expiration date (listed above), investigators must submit a request for continuing review prior to the continuing review due date (listed above). It is the researcher's responsibility to obtain re-approval from the IRB before the study's expiration date.
4. If re-approval is not obtained (unless the study has been reported to the IRB as closed) prior to the expiration date, all activities involving human subjects and data analysis must cease immediately, except where necessary to eliminate apparent immediate hazards to the subjects.

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