

## Does Step Count Feedback Enhance Counseling for Weight Loss?

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## **Does Step Count Feedback Enhance Counseling for Weight Loss?**

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### **Abstract**

**Objective:** This proposal was developed at the request of, and with input from, the Research Council of the VA's National Advisory Board for Nutrition and Food Services, in an effort to address obesity, a major health problem for VA patients. The prevalence of obesity in the United States has been increasing at an alarming rate. As a result, obesity related chronic diseases such as diabetes are also increasing in prevalence. While interventions that focus only on dietary changes can result in significant weight loss, the lost weight is often rapidly regained. Physical activity, when added to a dietary weight loss program, not only increases the initial weight loss but it also can play a critical role in preventing weight regain. The primary objective of the proposed study is to test the efficacy of and adherence to a low-cost, innovative weight loss program targeting lifestyle physical activity and diet in individuals with cardiovascular risk factors or disease.

**Study Design and Methods:** In this 3 year multi-site randomized controlled trial, we will recruit overweight and obese veterans with cardiovascular disease risk factors or known cardiovascular disease who have been referred for nutritional counseling or who have responded to advertisements for the study. Research participants will be randomized to one of three study groups: (1) nutritional counseling alone; (2) nutritional counseling with simple pedometer feedback; and (3) nutritional counseling, with both simple pedometer and enhanced pedometer (web-based) feedback. Each participant will have 5 visits with a dietitian in the course of 6 months. Participants randomized to receive pedometer feedback will review objectively monitored step-count data during their nutritional counseling sessions and will use the data to set new step-count goals. The primary outcome, weight loss, will be assessed at the sixth and final session. Adherence to the walking program will also be assessed for participants in all three arms of the study using accelerometers to objectively measure activity levels without providing feedback to the participants.

## 1. Research Objectives

### 1.a. Problem Statement:

Nearly two thirds of American adults are overweight with a body mass index of 25 or greater. Almost one third of American adults are obese with a body mass index of 30 or greater.<sup>1</sup> The prevalence of obesity in the United States has been increasing at an alarming rate.<sup>2</sup> As a result, obesity related chronic diseases such as diabetes are also increasing in prevalence. Overweight and obesity-attributable medical spending in the United States has been estimated to be as high as \$92 billion per year.<sup>3</sup> While interventions that focus only on dietary changes can result in significant weight loss, the lost weight is often rapidly regained. Physical activity, when added to a dietary weight loss program, not only increases the initial weight loss but it also can play a critical role in preventing weight regain.<sup>4-8</sup> Furthermore, physical activity has positive effects on health outcomes independent of weight loss.<sup>9</sup> The primary objective of the proposed study is to test the efficacy of a low-cost, innovative weight loss program targeting lifestyle physical activity and diet in individuals with cardiovascular risk factors or disease. Participants will be randomized to one of three study groups: (1) nutritional counseling alone; (2) nutritional counseling with simple pedometer feedback; and (3) nutritional counseling, with both simple pedometer and enhanced pedometer (web-based) feedback. This proposal was developed at the request of, and with input from, the Research Council of the VA's National Advisory Board for Nutrition and Food Services, in an effort to address obesity, a major health problem for VA patients.

### 1.b. Hypotheses:

1. The addition of a walking program incorporating objectively monitored step-count feedback to a six-month nutritional counseling weight loss intervention will **increase average weight loss** by at least 3 pounds.
2. The addition of a pedometer based walking program will **increase minutes of activity of at least moderate intensity** by at least 10 minutes over the baseline accelerometer measure of minutes of activity of at least moderate intensity.
3. The addition of the walking program will **improve health related quality of life, participant satisfaction, and attendance at nutritional counseling visits.**
4. Reviewing **computer-generated, time-stamped step-count feedback** graphs during nutritional counseling sessions will further increase weight loss and daily step-counts when added to a nutritional counseling plus walking with step-count feedback intervention.
5. **Psychological and behavioral characteristics** can be used to predict participants who are more likely to benefit from the step-count feedback interventions in terms of increased weight loss and walking adherence.

### 1.c. Specific Objectives of the Project with a Projected Timetable:

**1.c.1. Short-Term Objectives:** The **primary objective** of the proposed study includes testing the efficacy and adherence to a low-cost, innovative weight loss program targeting lifestyle, physical activity, and diet. All participants will attend a total of five one-on-one nutritional counseling sessions with registered dietitians over the course of six months. Only the physical activity component of the intervention, specifically the mode of self-monitoring of daily walking will vary across the three arms of the study. The **primary outcome testing for efficacy** will be

weight loss during the six-month intervention period. We have deliberately targeted individuals with cardiovascular disease risk factors or with known cardiovascular disease because these are the individuals most likely to benefit from physical activity.<sup>10</sup> The **primary outcome testing for adherence** is to measure the impact of objective monitoring and mode of step-count feedback on activity levels. For participants in all three arms of the study, walking adherence will be measured by calculating the increase during the six-month intervention period in activity level over seven days as objectively recorded by an Actical. Secondary objectives include increasing participant health related quality of life and participant satisfaction with nutritional counseling interventions for weight loss. If the addition of objective step-count feedback enhances satisfaction with weight loss counseling, it may also reduce dropout rates. Finally, measures of baseline psychological and behavioral characteristics will be examined to see if any particular set of participant characteristics predicts success or failure in weight loss or adherence to the walking program. This information could be used to allocate resources more efficiently if the intervention is effective for some participants but not for others.

**1.c.2. Long-Term Objectives:** The primary long-term objective of this proposal is to reduce the burden of morbidity and mortality from obesity-related chronic diseases in veterans. If this intervention successfully reduces weight and increases physical activity, it could be implemented in VA Medical Centers across the country. The intervention described in this proposal will end after six months. However, if it is effective, it may be considered as a chronic management strategy instead of a one-time intervention for obese individuals. The Diabetes Prevention Program (DPP), an intensive diet and physical activity program targeting high-risk patients, resulted in a 58% reduction in the incidence of diabetes over three years.<sup>11</sup> This substantial reduction in risk and morbidity could have a profound impact on the health of veterans across the country. Results would also be relevant to non-veteran Americans with cardiovascular disease risk factors.

**1.c.3. Timetable:** The timetable for the study is provided in Appendix A (**updated 2/15/05**). It is expected that the short-term objectives will be achieved at the end of the three-year project. The results of this project will provide a rich source of information from which to design cost-effective weight loss interventions that can be implemented on a wide scale. Because our intervention integrates well with existing nutritional counseling infrastructure, the rate of dissemination would primarily be a function of funding for the program. Results such as reduced morbidity from diabetes could be expected within three years of program implementation.

#### **1.d. Current Status:**

**1.d.1. The prevalence of obesity among Americans between the ages of 20 and 74 is high and is increasing rapidly.** The rate of obesity, defined as a Body Mass Index (BMI) of greater than or equal to 30, increased from 23% in 1990 to 30% in 2000.<sup>1,2</sup> Because obesity is a major risk factor for many chronic diseases including diabetes<sup>12, 13</sup>, cardiovascular disease<sup>14</sup>, and arthritis<sup>15</sup>, a 7% increase in the prevalence of obesity in just one decade has enormous public health implications. Current estimates suggest that in the United States approximately 300,000 deaths can be attributed to obesity each year.<sup>16</sup>

**1.d.2. Intensive lifestyle modification interventions that focus on diet, physical activity and weight loss yield substantial health benefits.** The most convincing literature focuses on the effect of lifestyle modification on the risk of developing diabetes. The Diabetes Prevention

Program (DPP) was a large multi-center randomized controlled trial that enrolled over 3,000 individuals at high risk for developing diabetes. Participants were randomized to one of three arms: usual care, metformin, or an intensive diet and physical activity lifestyle change intervention for an average of three years. Among DPP participants who were randomized to an intensive diet and exercise intervention, there were only 4.8 new cases of diabetes per 100 person-years of follow-up compared to 11.1 cases per 100 person-years in the placebo arm, a 58% reduction in risk. The average weight loss among those randomized to the lifestyle intervention arm of the DPP was a modest 5.6 kg over three years.<sup>11</sup> Two other large randomized controlled trials have replicated these findings.<sup>17, 18</sup> While the evidence for improved health outcomes is less convincing for lifestyle interventions and cardiovascular disease, there is a consistent correlation in observational studies between diet, physical activity, obesity and adverse cardiovascular events. Even low intensity activity such as walking appears to confer substantial cardiovascular health benefits.<sup>9, 19-24</sup> Lifestyle change has been shown to modify a number of important coronary heart disease risk factors. In particular, lifestyle modification has a significant impact on hypertension.<sup>25, 26</sup>

**1.d.3. Physical activity, independent of weight loss or dietary change, has a protective effect against cardiovascular disease and can improve cardiovascular disease risk factors.<sup>9</sup>**

A small randomized controlled trial of a physical activity intervention showed impressive reductions in morbidity and mortality for people with congestive heart failure.<sup>27</sup> Several larger studies to confirm this finding are ongoing. Physical activity reduces the risk of developing hypertension<sup>28-30</sup> and reduces peak blood pressure and medication doses in patients with hypertension.<sup>31, 32</sup> Physical activity also increases HDL cholesterol.<sup>33</sup> Starting a regular physical activity program has even been shown to improve smoking cessation rates, at least in women.<sup>34</sup>

**1.d.4. Adding physical activity to a nutritional weight loss counseling program can improve outcomes.** There is some debate in the obesity literature about the impact of physical activity on weight loss. In most diet and exercise interventions that have been studied, the negative energy balance induced by the dietary intervention is many times greater than the negative energy balance induced by the physical activity component of the intervention.<sup>7</sup> Thus, adding physical activity to a dietary intervention for weight loss results in a relatively small average marginal weight reduction. In one review of 11 studies comparing diet alone to diet plus physical activity, the estimated weight reduction induced by adding a physical activity component to a dietary weight loss intervention was only about 2 kg.<sup>8</sup> Increasing the dose of physical activity by increasing the intensity, frequency or duration of exercise bouts would probably improve weight loss.<sup>35</sup> However, adherence to such a program would be even worse than the already low adherence rates for more moderate interventions.<sup>36</sup> While the exact role of physical activity in initial weight loss is still being debated, there is a consensus that physical activity is critical for long-term weight control and for maintenance of weight loss obtained by dietary interventions.<sup>4-6</sup> The small but significant marginal weight reduction, the prevention of weight regain and the health benefits of physical activity that are independent of weight loss provide strong support for adding a physical activity component to nutritional counseling programs focusing on weight loss.

**1.d.5. Unfortunately, interventions to promote physical activity in a clinical setting have been generally ineffective.** While there is little doubt that intensive lifestyle change results in significant health benefits, effective interventions that promote a healthy diet, increased physical activity and weight loss, are generally expensive and have a low adherence rate. In 2002, the

U.S. Preventive Services Task Force (USPSTF) found insufficient evidence to determine whether counseling patients in primary care settings to promote physical activity leads to sustained increases in physical activity. We do know that intensive and expensive interventions can increase physical activity in high-risk patients from diverse backgrounds. Proof of this assertion can be found in the results of the Diabetes Prevention Program (DPP), a randomized controlled trial examining the impact of intensive lifestyle interventions on the incidence of diabetes in people with glucose intolerance.<sup>37</sup> The intervention used in the DPP included a 24-week intensive phase and a 2.5 year maintenance phase and included a minimum of 31 face-to-face sessions with each participant as well as telephone and mailed components, group exercise sessions and classes in lifestyle change. The intervention is meticulously described in manuals available on the Internet.<sup>38</sup> Over 3,000 individuals were enrolled in the DPP and those who were randomized to the intensive lifestyle arm significantly increased their physical activity levels, decreased their weight and also dramatically reduced their risk of developing diabetes. The cost of highly trained staff time required for the extraordinary quantity of face-to-face contact in this intervention makes it infeasible outside of the research setting.

**1.d.6. In contrast to the discouraging results of primary care intervention trials to promote physical activity in healthy people, results from several recent studies in the cardiac rehabilitation literature have been more encouraging.** Two recent randomized controlled trials have demonstrated that helping cardiac patients learn self-regulation skills for home-based exercise can be as effective as or more effective than traditional facility-based cardiac rehabilitation programs. In a study of 222 post coronary artery bypass graft surgery patients, Arthur et al compared traditional facility-based cardiac rehabilitation to a home-based activity program with telephone support and educational meetings. Their results showed similar increases in fitness and physical activity in the two groups but better health-related quality of life for the home-based group.<sup>39</sup> In another randomized controlled trial, Carlson et al compared traditional facility-based cardiac rehabilitation to a program that started out facility-based but gradually transitioned to a home-based program over the course of six months with educational support meetings and telephone follow-up. In their study of patients referred to cardiac rehabilitation (n=80), they found a 23% increase in total physical activity among those randomized to the home-based program as compared to the traditional facility-based program during the final three months of the six-month intervention.<sup>40</sup>

**1.d.7. Recent research examining characteristics of effective physical activity interventions suggest several critical aspects of intervention design.** In a quantitative meta-analysis of 127 clinical trials evaluating interventions to increase physical activity, Dishman et al found that several characteristics of interventions seemed to predict larger effect sizes.<sup>36</sup> Those interventions that were most effective tended to employ principles of behavior modification, deliver motivational messaging provided by mail, telephone or the Internet, promote low to moderate intensity activity and promote unsupervised or home-based activity. Our proposed intervention addresses all of these characteristics in that we employ behavior modification strategies including goal setting and self-monitoring. In one of the intervention arms we are using mediated delivery of step-count feedback, and we are promoting walking, a moderate intensity home-based activity.

**1.d.8. Self-regulation theory suggests that an important reason motivated individuals fail to adopt healthy behaviors is a failure to accurately self-monitor their behavior.**<sup>41, 42</sup> Applied to the problem of adopting a physical activity program, this means that individuals who

cannot accurately assess how much exercise they have done will have difficulty increasing their total amount of exercise. This failure to accurately self-monitor is particularly problematic for people who are trying to integrate physical activity into their daily routine. Individuals are not able to accurately recall how much walking they have done throughout a given day.<sup>43</sup> Step-count feedback from a pedometer can help individuals more accurately self-monitor their walking behavior and can facilitate goal setting, rewards and competition. Thus, by providing participants with pedometers to allow them to accurately self-monitor daily step-counts, we should be able to enhance adherence to the walking program. Despite widespread use of pedometers in physical activity interventions in the community, research demonstrating the effectiveness of pedometers in physical activity interventions is virtually non-existent.

**1.d.9. Another intervention characteristic that has been shown to improve adherence is individualized tailoring.** Individualized tailoring of intervention material involves changing the content of motivational messages to specifically address characteristics of the recipient. For example, a newsletter designed to increase physical activity might contain pictures of exercisers who appear to be similar in age, race and gender to the intended recipient. Tailoring is a concept that has been used extensively and successfully in smoking cessation interventions.<sup>44, 45</sup> Marcus et al extended these findings to the physical activity promotion in a randomized controlled trial comparing an individually tailored, motivationally matched intervention to a standard self-help intervention to promote physical activity in 194 sedentary adults. They found that the individually tailored group reported 151 minutes per week of physical activity compared to the standard therapy group that reported 96 minutes of physical activity per week at the six-month evaluation ( $p < 0.01$ ).<sup>46, 47</sup> The computer generated step-count graphs reviewed by participants in the enhanced pedometer arm of our study will be tailored with detailed time-stamped step-count charts illustrating each individual's walking patterns.

#### **1.e. Significance of Research:**

As we have documented in Sections 1.d above, lifestyle factors including high-calorie diets, sedentary lifestyles, and obesity contribute enormously to the burden of chronic disease in the United States. It has been definitively demonstrated in multiple randomized controlled clinical trials that lifestyle intervention can reduce the risk of developing diabetes by more than 50% in high-risk patients. Benefits with respect to cardiovascular disease risk, arthritis and other chronic conditions are also substantial. Despite the clear evidence for the health benefits of lifestyle interventions, we have been unable to translate this knowledge into feasible and effective clinical interventions. Problems with adherence, motivation and limited resources have been the major roadblocks to implementation. Capitalizing on recent research on adherence and motivation and on existing information technology, we have developed a relatively low cost but intensive lifestyle intervention built on the nutritional counseling infrastructure that already exists in the VA health system. We are targeting individuals who already have diagnoses that put them at high risk for adverse health outcomes. Thus they are more likely to be sedentary, obese and to have poor dietary habits, and they are also more likely to benefit from lifestyle change. If the intervention is effective, there should be no significant barriers to implementation throughout the VA health system. While we are only testing the intervention for six months, it is likely that in order to achieve long-term maintenance of lifestyle change and weight loss, the intervention would need to be implemented as a chronic management strategy continued indefinitely. Extrapolating the results of the Diabetes Prevention Program (DPP) we could anticipate significant benefits including a greater than 50% reduction in diabetes incidence among participants within three years of implementation.

### **1.f. Relevance of the proposed work to the VA Patient Care Mission:**

The burden of obesity-related chronic illness is high in the veteran population. In the Veterans Health Administration (VHA) in fiscal year 1997, there were a total of 150,357 hospital admissions for ischemic heart disease, including 15,182 hospital admissions for acute myocardial infarction (AMI) and 23,033 hospitalizations for unstable angina.<sup>48</sup> Diabetes is also prevalent with 12% of veterans getting diabetes-related medication or glucose monitoring equipment from the VA pharmacy, accounting for 24% of all outpatient pharmacy costs.<sup>49</sup> Access to formal cardiovascular rehabilitation is limited for many veterans because of the distance they must travel to reach a VA Medical Center. Our intervention promotes lifestyle physical activity that can be done at home but we employ objective monitoring devices to intensively monitor physical activity to enhance motivation and adherence. If we are successful at developing an effective and feasible intervention to promote weight loss and physical activity in veterans with cardiac risk factors and cardiovascular disease, veterans will move much closer to being able to benefit from the substantial decreases in morbidity and mortality that diet and physical activity lifestyle intervention studies have demonstrated.

## **2. Background and Work Accomplished**

### **2.a. Feasibility of a step-count feedback and weight loss counseling intervention:**

We are currently in the recruitment and data collection phase of a pilot study testing the feasibility of an intervention that incorporates web-based step-count feedback into a four-session nutritional counseling program for weight loss. We are recruiting at two different VA Medical Centers and are awaiting final IRB approval at a third site. We have six participants enrolled in the pilot study so far, and one participant has completed the program. Participants wear the enhanced pedometer (the same device we propose to use for this grant) every day for four weeks and return weekly for nutritional counseling and web-based step-count feedback sessions with a dietitian. During the course of the pilot study, we have successfully addressed issues of human subjects' protection and have also addressed recruitment issues by modifying our enrollment criteria and developing a more aggressive publicity and incentive program. Though we are in the early stages of data collection, participants express high satisfaction with the web-based step-count feedback intervention, and there have been no reported problems with wearing the enhanced pedometer or uploading step-count data.

**2.b. Step-count feedback in patients with co-existing diabetes and depression (Feasibility Study):** In a pilot study designed and conducted with Dr. John Piette at the Ann Arbor VA HSR&D, we obtained data from five individuals with diabetes and co-morbid depression who completed a 12-week telephone mediated cognitive behavioral therapy (CBT) intervention called Positive Steps. Simple pedometers were used to provide step-count feedback between the 6<sup>th</sup> and the 12<sup>th</sup> week of the intervention. As part of a weekly telephone call with a CBT provider, the participants were encouraged to gradually increase their step-counts and to track their physical activity levels throughout the last half of the intervention period. When the pedometers were first introduced, participants walked an average of 6,562 steps per day. Six weeks later, the average step-count was 8,829 steps per day. This average difference of 2,266 steps per day represents an approximate increase of 20 minutes of walking each day at three miles/hour ( $p=0.039$ , paired t-test). A proposal for a larger intervention trial of the Positive Steps intervention was reviewed by NIDDK recently and received positive reviews.

**2.c. Increasing Lifestyle Physical Activity in a Patient Population with Depression and Serious Mental Illness:** Dr. Richardson also examined the effect of a lifestyle diet and physical

activity intervention on participants with serious mental illness including schizophrenia, major depression and manic depression. The intervention for this study was a six-week intensive group-based education and motivation program with three months of post intervention follow-up. While there was no significant difference between the mean step-counts for the first, fifth, and fifteenth week, there was an average 5.3 lb. ( $p=0.045$ ,  $n=10$ ) weight loss between the baseline and the three-month follow up.

#### **2.d. The Benefits of Increasing Physical Activity Across Income and Cardiovascular Disease Risk Groups:**

Dr. Richardson has completed a study examining the effects of cardiovascular disease risk on the relationship between physical activity level and mortality in a nationally representative cohort of approximately 10,000 Americans who were between the ages of 51 and 61 in 1992. While other studies have shown that higher levels of physical activity are correlated with improved health outcomes including decreased mortality, this is the first nationally representative study showing that the relative benefits are similar for participants across socioeconomic and cardiovascular disease risk groups. By taking into consideration absolute death rates, rates of sedentary behavior as well as burden of cardiovascular disease in different socioeconomic status groups, we were able to show that targeting low income individuals with cardiovascular disease risk factors would maximize the potential public health impact of physical activity interventions.<sup>10</sup>

**2.e. Home-Based Exercise and Nutrition Program for Pain Control in Overweight Elderly Osteoarthritis:** (E2-2362RA, PI Budiman-Mak) In the development of this protocol, we have benefited from having a co-investigator, Sharon Foley, who is also currently a co-investigator on another VA Rehabilitation R&D funded project to promote weight loss and lifestyle physical activity in patients with knee osteoarthritis. Approximately 36 subjects have been recruited to date for this study and many of the recruitment and measurement issues are similar to those in our current proposal.

### **3. Work Proposed**

#### **3.a. Methodology:**

**3.a.1. Experimental Design and Timetable:** We propose a multi-site randomized controlled trial with three nested arms. Patients referred for outpatient nutritional counseling and patients who respond to advertisements for the study who meet eligibility criteria and give their written informed consent will complete baseline testing and will then be randomized to one of the following three groups:

- (1) 5-session nutritional counseling program (**control**);
- (2) 5-session nutritional counseling program + **simple pedometer** feedback; and
- (3) 5-session nutritional counseling program + simple pedometer feedback + **enhanced pedometer** web-based feedback.

Weight will be measured at every visit. Physical activity levels (as measured by the Actical) will be measured at baseline, at three months, and again at six months. Health related quality of life and self efficacy for physical activity will be measured at baseline and six months. Dietary stages of change will be measured at each of the six study visits and participant satisfaction will be measured at visits 5 and 6. A modified version of the Charlson Comorbidity Index will be completed by the participants as a part of the questionnaire at visit 6. Scheduling of the first through fourth nutritional counseling sessions will be flexible, allowing the program to be more easily tailored to individual participants needs.

**Measurement of weight**

Subjects will be weighed on an upright balance beam scale or a digital scale. Each study participant will be weighed on the same scale at each study visit. If the scale is moveable, it will be re-calibrated after each move. If a balance beam scale is used the main and fractional sliding weights will be placed at their respective zero positions and the zeroing weight should then be moved until the beam balances at zero. Subjects will be weighed with minimal clothing on and shoes removed. Jackets, heavy sweaters, and large belts will be removed prior to weighing along with removal of heavy items in pockets such as keys and/or wallets. The subject will stand with feet placed over the center of the platform and weight evenly distributed between both feet. Weight will be adjusted and recorded standing behind the beam to avoid reaching around the subject. Weight will be recorded to the nearest  $\frac{1}{4}$  lb. Subjects who weigh greater than 350 lbs. present a problem as that is the limit for some scales. Weights for these participants can be recorded on an alternate scale, even possibly one at a different site, as long as the above procedure is followed and the measurement takes place within 24 hours before or after the nutritional counseling session.

**Measurement of height**

The subject should stand erect with back to the vertical backboard of a stadiometer with weight equally distributed between both feet and heels together. The head, shoulder blades, buttocks and heels should touch the vertical backboard whenever possible. Arms should hang loose at sides with palms facing thighs. The subject should be instructed to look straight ahead with line of vision perpendicular to the body. The subject should be informed to take a deep breath holding that position while the horizontal headboard or lever is brought down firmly on top of the head. Stature should be measured at maximum inspiration. The measurer's eyes should be level with the headboard to avoid parallax. The measurer may need to stand on a stool if necessary. Measurements should be recorded to the nearest 0.1 cm. The presence of spinal curvature should be noted.

The estimated duration of the project is three years. A depiction of the project timeline is included as Appendix A. The process of obtaining human studies approval at the participating sites will start prior to the initiation of the study, and continue through the first three months. Refinement of data collection and patient recruitment protocols, site coordinator hiring, development of the coordinator and dietitian training program, and implementation of the training program (one-day workshop in Ann Arbor for one dietitian from each participating site) will be conducted during the first three months of the study. During this time the PI will visit each of the sites to meet with primary care providers to introduce the study and encourage referral of patients. Patient recruitment and enrollment will begin in month 4 and continue for 18 months through month 21. Six-month follow-up visits will begin in month 10 and continue through month 27. Weekly conference calls will be held between the investigators, project manager, site coordinators, and dietitians during the first few months of enrollment, and will decrease in frequency as questions/problems decrease. The PI, co-PI, or project manager will visit all of the sites in year 2 to ensure compliance with the protocol and human studies requirements. Data analyses and report/manuscript preparation will take place during the last nine months of the study.

**3.a.2. Patient Population:** Participants will be recruited over 1.5 years from 6 different VA Medical Centers (see section 3c and letters of support for details). Participants will be drawn from the pool of patients who are referred to the outpatient nutritional counseling clinic at each of the six participating VA health system clinical sites by a VA physician, and patients who respond to advertisements for the study. Please note that patients who self refer to the study cannot be randomized until medical clearance is received from a local VA care provider. The site coordinator will be responsible for obtaining medical clearance for each participant before they can be randomized. We have elected to exclude women from this trial for the following reasons: 1) There are known gender differences in responses to motivational messages related to physical activity.<sup>50-57</sup> 2) There are very few women in the VA system, thus it would be difficult to recruit enough women to do meaningful sub-sample analysis. 3) Tailoring our intervention by gender may increase its effectiveness.<sup>58</sup>

**Identifying Potential Participants:** In order to increase the pool of potentially eligible patients who are referred to and show up for an initial nutritional counseling visit, we will conduct an aggressive publicity and incentive program at each of the six participating sites. The principal investigator will meet with VA physicians and nursing staff at each of the participating sites to explain the study goals, eligibility criteria and procedures. All clinicians will receive an incentive to encourage them to identify and refer potential study participants for nutritional counseling. The incentive will be a study water bottle with the study name, logo and local coordinator contact information printed on the side of the bottle. Along with the water bottle, clinicians will receive a flyer that briefly describes study goals and eligibility criteria. We will provide clinicians with a supply of water bottles to give to potential participants at the time they are referred for nutritional counseling. This incentive is intended to encourage participants to show up for their initial nutritional counseling visit. We considered offering the incentive only to those who actually attended the first nutritional counseling session; however, according to the principle of reciprocity described by Cialdini, giving the incentive prior to the visit is theoretically more effective.<sup>59</sup> We will also advertise the study directly to VA patients by posting flyers in the participating hospitals, advertising in newsletters, posting to websites, and handing out tri-fold brochures, setting out table tents, and advertising on rolling marquis as approved by the IRBs at each site. Finally, participants who do enroll in the study will be given a \$10.00 phone card or \$10 gas card for every visit attended and they will be given a T-shirt specially designed for this study valued at approximately \$8.00 if they attend the final 6-month follow-up session and return their pedometers (see Appendix B for graphic on t-shirt).

Patients who are referred to the study or respond to an advertisement for the study will have a visit scheduled with a study coordinator to discuss eligibility and enrollment. These newly referred patients will be offered the opportunity to participate in the study if they meet the following inclusion criteria:

- a) The patient has at least one of the following diagnoses:  
diabetes, coronary artery disease, hypercholesterolemia, hypertension, obesity.
- b) They are ambulatory and able to comfortably walk at least one block.
- c) The patient has a BMI of 28 or greater.

Those who are eligible according to this brief eligibility screen will be given a study recruitment flyer and they will also have the study briefly explained. The recruitment flyers for the patients and referring clinicians are included in Appendix C. The enrollment script is included in Appendix D. A more detailed eligibility screening will be conducted by the site coordinators

with patients interested in participating in the study. These additional inclusion criteria are as follows:

- d) Able to give informed consent.
- e) Can identify a VA physician who is following them at the clinical site.
- f) Are not already regularly active (30 minutes a day, 5 days a week of moderate intensity physical activity).
- g) Must be in the contemplation or preparation stage of readiness to become more physically active.
- h) Must be willing to try a walking program.
- i) Can communicate comfortably in English.
- j) Male and at least 18 years old.

Patients will not be eligible to participate in the study if:

- a. They have used a pedometer in the past 28 days.
- b. They do not receive medical clearance from a VA physician who is following them at the study site.

A detailed eligibility form can be found in Appendix E. The medical clearance forms can be found in Appendix F.

**3.a.3. Step-count Devices:** The Actical accelerometer will be used to measure activity level at baseline, 3 months, and 6 months. The Actical is currently the gold standard for activity monitoring. The Actical accelerometer measures activity in units called activity counts. These activity counts are correlated with energy expenditure.

The Actical accelerometer is a relatively small activity monitor that can be worn on the hip, wrist or ankle. Similar to other accelerometers, it is an electronic sensor that measures both the quantity and intensity of movement, resulting in the collection and storage of daily patterns of physical activity. The Actical is an omnidirectional accelerometer. It is a much more precise and accurate instrument compared to the pedometer and has often been used to validate the pedometer (Bassett, 1996). These monitors have been validated in a variety of laboratory and field settings. In adults, the Actical has been shown to be related to metabolic measures with the correlation coefficients ranging from  $r = 0.66$  to  $r = 0.89$  (Melanson, 1995). Comparisons with oxygen consumption during treadmill exercise and self-selected speed on a track found that the Actical was highly related to both and was highly sensitive to change in speed but not changes in grade (Nichols, 2000). The Actical has been found to successfully detect bouts of moderate-intensity physical activity such as brisk walking (Masse, 1999). The Actical monitor can continuously store data for up to six weeks. Not only can it determine the time the physical activity occurred but it has the capability to break down each bout of activity, minute by minute. Data from the Actical monitor are downloaded to a computer so the potential for recording errors in the data are minimized. The accelerometer is one of the current “gold standards” in assessing physical activity levels and is often used to validate the much simpler, less expensive pedometer.

We will employ two different pedometer devices in this study, a simple pedometer and an enhanced pedometer. Pedometers are small devices worn on the hip or back that count the number of steps taken by the user. Unlike a questionnaire, the pedometer does not rely on participant recall, therefore reducing the possibility of recall bias.<sup>60</sup> In addition, pedometers can

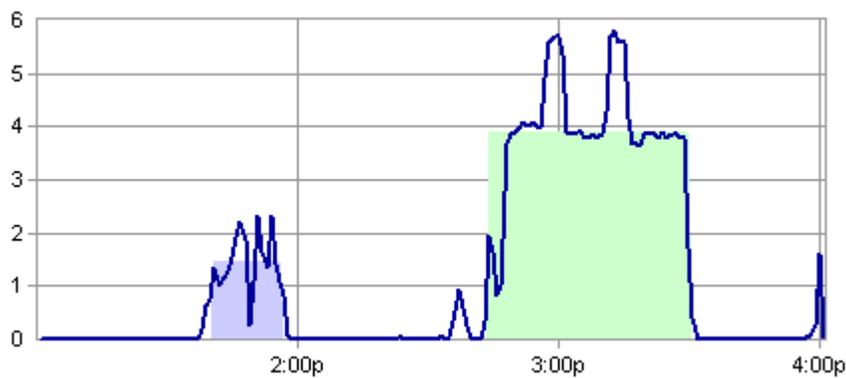
capture intermittent or continuous activity throughout the assessment period. A simple pedometer counts steps and reports the accumulated step-count on a built in display. An enhanced pedometer counts steps and stores the time-stamped, step-count data. The total accumulated step-count is not available on a local display. In order to get step-count feedback the user must upload the data to a computer. Step-count feedback from an enhanced pedometer is not as immediate as step-count feedback from a simple pedometer, but the feedback can provide much greater detail about walking patterns.

The Digiwalker SW 200 simple pedometer is a relatively low cost and remarkably accurate device that has been used extensively in lifestyle physical activity research both as a method of measuring adherence and as a motivational tool in physical activity interventions. Digiwalker pedometers have been shown to be a valid and reliable assessment tool in a variety of laboratory and field settings<sup>61, 62</sup>, and it has been validated for estimating net energy cost of walking.<sup>63</sup> The concurrent validity of the pedometer in assessing physical activity in free-living individuals provided significant correlations between the steps/day and the activity counts from the Tritrac and CSA accelerometers,  $r=0.84$  to  $r=0.93$ .<sup>61, 64</sup>

The Sportbrain enhanced pedometer is currently the least expensive, most widely used and most readily available enhanced pedometer on the market and will allow study participants to use the Sportbrain web-based feedback at home. We will require that they have access to the Internet at least once a week to review their step-count data. They can use their own home computer, or a computer at work, at a friend's house, or at a local library or community technology center. Study coordinators at each site will be able to assist participants in finding Internet access. In a small accuracy study conducted by students at the University of Michigan School of Information, accuracy when compared to the gold standard of a Digiwalker SW 200 for a person walking on a treadmill at 3 miles per hour was within three% on all trials.<sup>65</sup> Because the device is designed to be marketed to the general public, it is remarkably user friendly and simple to use. The web-based interface has a number of features that make it useful for behavior modification, including tailored motivational messages, a wide selection of graphical displays of progress and a goal setting feature. A sample of the output on the web site is shown below. Additional information on the Sportbrain can be found at [www.sportbrain.com](http://www.sportbrain.com).

### Sample Graph and Table from the Sportbrain.com web site

#### Sportivity Speed Zoom (mph) ([view the whole day](#))



Notes	Distance	Running	Steps	Duration	Speed	Running Pace	Calories
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	(Miles)	Distance		(Minutes)	(Mph)	(min/mile)	
1:39 pm 1:54 pm	0.4	0	1107	16	1.5	-	34
2:42 pm 3:28 pm	3.1	0.9	6063	47	3.9	11:07	289
All Additional Activity	.6	0	1577	-	-	-	47
<b>TOTALS</b>	4.0	.9	8747	-	-	-	370

**3.a.4. Interventions: The Control Arm – Nutritional Counseling without step-count feedback.** The nutritional counseling component of the intervention will be similar across all three arms of the trial and is based on the six-session Medical Nutrition Therapy Protocol for Weight Management (MNT protocol) published by the American Dietetics Association<sup>66</sup> (see Appendix G). This protocol utilizes a behavioral approach in which dietitians will provide basic behavior and diet guidelines and tips to encourage changes that the person can make using a gradual, practical approach, rather than trying to follow a specific calculated diet. The protocol for this study is intended to encourage the combination of calorie reduction and exercise for weight loss. This protocol was chosen by the Research Council of the VA's National Advisory Board for Nutrition and Food Services, because it most closely represents the current standard of care for nutritional weight loss counseling in VA medical centers. We have modified the protocol to simplify and standardize the intervention while still leaving study dietitians considerable leeway to tailor nutritional counseling to the needs of the participant. Basic categories of behavioral/cognitive outcomes developed by the American Dietetic Association and Morrison Health Care, Inc. in 1997<sup>66</sup> were adapted for use in this study. The categories include the following: a) Meal planning (food, hydration, fiber, alcohol), b) Food label reading, c) Recipe modification, d) Food preparation, e) Dining out and f) Physical activity. A set of recommended nutrition education materials to cover each of the categories listed above was compiled from sources frequently used by VA dietitians. Dietitians participating in the study will select the most appropriate handouts to educate each patient during individual appointments. All categories will be covered with each patient at some time during the nutrition sessions, with varying degrees of emphasis, depending on the patient's previous knowledge and interest. If the patient requests a more specific diet plan, the dietitian may add other nutrition education materials or topics as appropriate to encourage the patient to make positive diet changes in addition to the exercise intervention. The full text of the handouts can be found in Appendix H. As part of the discussion of physical activity, participants in the control group will be encouraged to walk and dietitians will discuss goal setting using timed walks instead of total daily step-counts at each of the control group sessions. As a general guideline, participants will be encouraged to increase their daily walking target by 5-10 minutes (control group with time goals) or to increase their average daily step counts by 10-25% (pedometer group with step count goals) following each of the nutritional counseling sessions.

To help ensure (and verify) consistency in the format and content of the visits across study groups and across sites, a Visit Documentation Form (Appendix I) will be completed by the dietitian at each visit. In the analysis we will use this data to look for particular styles or

techniques that enhance effectiveness of the intervention. Also, each dietitian will record a visit 2 and either a visit 3, 4, or 5 to ensure participants in one arm of the study are not receiving more enthusiastic counseling than another. These recorded sessions will provide a richer source of data on the content of the counseling sessions, and will be used to verify the Visit Documentation Form data.

Participants in the control group will not get any step-count feedback, but will be asked to keep track of their walking time on a calendar. However, they will wear an Actical accelerometer for one week at baseline, at three months, and again six months later to facilitate outcome measurement. Data from the Actical are not visible to the participants.

**The simple pedometer feedback arm: Nutritional counseling with simple pedometer feedback.**

Individuals in the simple pedometer arm of the trial will get all of the components of the nutritional counseling intervention described above. In addition, at the second study visit they will be given a simple pedometer to wear every day, all day throughout the six-month intervention period. They will be taught how to log total daily step-counts at the end of each day on a paper log sheet and they will be taught to do a “20 step test” each morning after putting the pedometer on to make sure it is positioned in such a way that it will accurately record step-counts. At follow-up nutritional counseling sessions, participants will review their step-count logs with the dietitians and the step-count data will be used to set new short- and long-term goals. As a general guideline, participants will be encouraged to increase their daily walking target by 10 to 25% following each of the nutritional counseling sessions. However, step-count goals will be negotiated with the participant. Participants who are having trouble meeting their current step-count target or participants who express discouragement might actually decrease their step-count goals to increase the chances of success and to build self-efficacy.

**The enhanced pedometer feedback arm: Nutritional counseling with simple pedometer feedback and web-based enhanced pedometer feedback.** Participants randomized to the enhanced pedometer arm of the study will get the nutritional counseling and simple pedometer feedback described above. At the second study visit, patients will be shown how to wear the Sportbrain and will go on a test walk with the dietitian, who will then upload the data from the walk, sign on to the web site, and show the patient how the data are displayed. Because the Sportbrain memory can only record data for a limited amount of time, participants in this group must have access to a computer on a weekly basis. The study coordinator will work with each participant randomized to this arm to make sure that arrangements have been made for appropriate computer access. At each follow-up visit, the dietitian will upload the Sportbrain data recorded during the week prior to each session and then review and discuss the enhanced pedometer feedback as displayed on the Sportbrain.com web site. This feedback will be used to set new walking goals. As a general guideline, participants will be encouraged to increase their daily walking target by 10 to 25% following each of the nutritional counseling sessions. Note that this arm is labeled the enhanced feedback group; only this group will be given access to the step-count data on the Sportbrain.com web site.

**Telephone contact reminders**

We will have the study coordinators at each site call the participants the day after the Actical is sent to make sure they have received it and know when to start wearing it for both the three-month activity measure and for the six-month activity measure. In addition, the study coordinator will make reminder calls to participants before every study visit.

**3.a.5. Study Assessments:** The primary study assessments will take place at the initial enrollment visit and at the final six-month follow-up.

**3.a.5.1. Outcome Measures:**

For both outcomes of weight and walking, between group outcome comparisons will be done using change scores. Specifically, outcomes will be calculated as *weight loss* (change in weight calculated as baseline weight minus six-month weight) and as the *activity level gain* (change in average daily activity level calculated as six-month minus baseline). Secondary outcomes will be calculated as *weight loss* (change in weight calculated as baseline weight minus three-month weight) and as the *activity level gain* (change in average daily activity level calculated as three-month minus baseline).

**Weight:** Weight will be measured using the balance beam or digital scale routinely used for nutritional counseling patients. If there are two such scales available, the participating dietitians will select a single scale to use for all participants throughout the trial.

**Activity Levels:** Activity levels will be measured by the Actical. Data will be collected for seven days at baseline, at three months and again at six months. The average number of minutes per day of physical activity of at least moderate intensity averaged over seven days will be the primary measure of this outcome used for analysis. Occasionally, participants may fail to record activity levels during the recording period. This is usually because they forget to put the Actical on in the morning but may also be because the device was not positioned correctly. For participants who miss more than two days during the seven-day recording period, their average daily step-count will be treated as missing. If they miss one or two days during the recording period, the average will be calculated for the days that they do activity levels. In order to minimize missing data and dropouts, participants with missing data at baseline will be given the opportunity to record for the next seven days. Similarly, participants with missing activity level data at the study follow-up will be given the opportunity to record for the next seven days. Even participants who do not attend the nutritional counseling sessions will be encouraged to complete the seven-day baseline and follow-up Actical assessments. Studies of day-to-day variation in physical activity behavior suggest that five to six days of Actical measurement should reliably capture walking behavior with an estimated correlation coefficient of 0.82. This data was collected in relatively active young men, and we anticipate that there is actually less day-to-day variation for older, sicker individuals. Because we are allowing one or two days of missed recordings, we will instruct the participants to wear the Actical for seven days. This also insures that we will get equal coverage of weekday and weekend measurement. Seasonal variation may be more of a problem with weekend measurement than with weekday measurement. Given that our participants will be followed for six months, adjustment for seasonal variation will be a critical component of our analysis (see Section 3.a.7).<sup>67, 68</sup>

**Participant Satisfaction:** This will be defined as the scores on the relevant domains of VA's Survey of Healthcare Experiences of Patients, Ambulatory Care ([http://vaww.oqp.med.va.gov/oqp\\_services/veterans\\_satisfaction/vss.asp](http://vaww.oqp.med.va.gov/oqp_services/veterans_satisfaction/vss.asp)): access, continuity,

courtesy, patient education, emotional support, preferences, and overall quality. Use of the survey will allow us to compare responses of the study patients not only to each other, but to those of other patients at the same facilities or nation-wide. The questionnaire will be revised slightly to refer specifically to the patients' visits for nutrition counseling.

***Health Related Quality of Life:*** General HRQL will be measured using the SF-12, a validated brief version of the SF-36.<sup>69</sup>

***Attendance at Nutritional Counseling Visits:*** Dietitians will report the dates of all study-related nutritional counseling sessions for each of the study participants. Patients are often late for visits. To insure consistency, if the participant shows up for any part of the scheduled visit, he will get credit for attendance.

### **3.a.5.2. Behavioral Measures for predicting outcomes:**

***Self Efficacy for Physical Activity:*** The following behavioral measures will be used in the analysis related to hypothesis #5. Self-efficacy for physical activity will be measured using a five-item instrument, which represents areas of negative affect, resisting relapse, and making time for physical activity. Prior studies have shown an alpha coefficient of this scale is 0.82, and scores have been shown to significantly differentiate subjects at most stages of motivational readiness for physical activity adoption.<sup>46, 70, 71</sup>

***Physical Activity Stage of Change:*** Motivational readiness for physical activity adoption will be assessed using the modified five-item motivational stage measure for moderate physical activity used by Marcus et al in two previous studies<sup>46, 72</sup>. The standard instrument has adequate test-retest reliability (Kappa index = 0.78) and concurrent validity with the Seven Day Physical Activity Recall Questionnaire.<sup>71</sup>

***Dietary Stage of Change:*** This questionnaire is designed to measure stage of change with respect to weight control. The questionnaire is unique from other instruments in that it uses specific dietary behaviors that influence weight loss and measures the individual's readiness to make individual dietary behavioral changes. Data obtained from using this questionnaire may help predict or explain reasons why individuals did or did not make dietary changes, which potentially could impact their ability to lose weight. A validity analysis conducted by Sharon Foley, a co-investigator on this proposal, demonstrated the reliability and validity of this instrument. For the validity study, the 42 item questionnaire was administered to a group of 100 subjects, mean age of 63 yrs  $\pm$  13.4 with a mean BMI of 30.7  $\pm$  6.0. Results showed there was a unidimensional construct with ordered response categories. Item separation index was 3.71, which translates to a reliability of .93 (unpublished data).

### **3.a.5.3. Intervening/mediating Variables**

***Single Item Global Health Assessment:*** A single survey item asking each respondent to describe his or her general health status as poor, fair, good, very good, or excellent. This variable is a strong predictor for mortality as has been documented in previous studies using this measure.<sup>73</sup>

***Cardiovascular History and Risk Factors and Current Medications:*** Participants will be asked a series of five brief questions about their cardiovascular disease history and their current medications.

*Comorbidities:* Participants will be asked a series of 18 questions modified from the Charlson Comorbidity Index.

*Age:* Calculated from date of birth.

*Body Mass Index(BMI):* BMI will be calculated from measured weight and height.

*Current Level of Physical Activity:* The Physical Activity Scale for the Elderly (PASE) is a proprietary scale developed by the New England Research Institutes, Inc. The scale was designed to measure the level of physical activity in individuals age 65 and older. We have chosen to use the PASE because it provides an excellent balance between low respondent burden and high validity, covering all occupational, household and leisure activities and it specifically assesses walking. Brief but carefully selected examples of types of physical activity are included with most of the items clarifying issues of activity intensity, and these examples are designed to be relevant to older adults from a wide range of socioeconomic groups. The PASE has been extensively validated against other self-report physical activity measures and against objective physical activity and fitness measures in older patients.<sup>74-78</sup> This self-report measure is included to further characterize baseline level of physical activity and to collect information about non-walking forms of physical activity.

**3.a.6. Data Management and Data Collection:** Self-administered questionnaires will be used for collecting data on: quality of life (SF-12); satisfaction (VA's national Survey of Healthcare Experiences of Patients); self-reported exercise; motivational, psychological and social measures for predicting behavior change; and demographics. A copy of each of the patient surveys are presented in Appendix J. Questionnaire data (identified by study identification number only) will be coded in numeric form and double entered into a web-based Survey Monkey database. More information on Survey Monkey can be found at <http://www.surveymonkey.com/home.asp?Rnd=0.5511286>. The dataset will be checked for appropriate variable ranges and for logical consistency between values. Physiologic measures including height and weight will be recorded by the dietitian and entered into an Access Database located on a secure server at the Ann Arbor HSR&D. The Sportbrain.com web site allows exporting of daily step-count totals. For each week that a participant wears the Sportbrain, we will download the data from the Sportbrain.com web site directly into the Access database to eliminate the possibility of manual data entry error. Step-count data from simple pedometers will also be recorded on a paper log by participants randomized to the simple pedometer arm of the study. This data will be manually double entered.

**Confidentiality:** Study data will not include participants' names. Only study identification numbers will be used in these files. Paper copies of study questionnaires will be stored in a locked file cabinet when not being used by authorized members of the research team. Each of the six participating sites will have a study coordinator to track study participants. The study coordinator will keep a written log linking patient names with identification numbers for that one site. This log will also be used to track participation in the five nutritional counseling sessions and in the follow-up session. Names of participants will not be transmitted to the central study coordinating team based in Ann Arbor, and names will not be entered into a computerized database. Only study identification number and VA Medical Center site will be used to identify participants in study databases.

Site coordinators will enter recruitment data and survey data into an internet based databases through the Survey Monkey website. The data entered into these databases are identified only by study identification number and VA Medical Center site.

Step-Count data from the enhanced pedometer will be uploaded by the participants in the SportBrain arm to the SportBrain website. All of these SportBrain pedometers have been registered to the Ann Arbor project manager and therefore do not contain identifying information for the study participants other than weight, height, and study site. A log is maintained at the study site and faxed regularly to Ann Arbor that links the serial number of the devices dispensed with the study identification numbers of the subjects so that the step count data can be downloaded from the SportBrain website and linked to a subject identification number.

Actual accelerometer data is uploaded by the site coordinators and sent by email to the project manager in Ann Arbor. These accelerometer files are identified only by study identification numbers.

**3.a.7. Data Analysis:** This section is organized by hypothesis. Each hypothesis is restated prior to the data analysis description.

**1. The addition of a walking program incorporating objectively monitored step-count feedback to a six-month nutritional counseling weight loss intervention will increase average weight loss by at least three pounds.**

We will compare weight loss in the control group to weight loss in the simple pedometer group using a t-test with unequal variance. We will also use a multivariable regression model with weight loss as the dependent variable in order to obtain estimates of effect size after adjusting for potential confounders. A categorical variable representing the intervention arm to which the participant was randomized (intention-to-treat) will be the primary predictor recoded into two dummy variables. The simple pedometer condition will be used as the reference category, so that tests of these dummy variables will be tests of a) the effect of adding simple pedometer feedback to nutrition counseling and b) the effect of adding enhanced pedometer feedback to the treatment including nutrition counseling and simple pedometer feedback. Body mass index, baseline health status, and age will be included in the model as potential confounders. Preliminary analyses will assess the assumptions of multivariable linear regression and remedial measures will be taken as appropriate. We will look for evidence of moderating effects of BMI and health status on the effect of the intervention using both algebraic and stratified techniques though our sample size will only be sufficient to detect large moderating effects. We will also test for influential outliers. All analyses will consider clustering by recruitment site.

**2. The addition of a walking program incorporating objectively monitored step-count feedback to a six-month nutritional counseling weight loss intervention will increase minutes of activity of at least moderate intensity by at least 10 minutes over the baseline accelerometer measure of minutes of activity of at least moderate intensity.**

Again we will use t-tests as well as a multivariable linear regression model, this time with increase in average daily activity level as the dependent variable. Intervention arm will be the primary predictor and potential confounders in the model will include body mass index, baseline health status, and age. A fourth covariate will be included representing the season of the six-month activity level measurement to control for seasonal variation in walking behavior.

**3. The addition of a walking program incorporating objectively monitored step-count feedback to a six-month nutritional counseling weight loss intervention will improve health related quality of life, participant satisfaction, and attendance at nutritional counseling visits.** Analyses similar to the above will be used to evaluate the effect of the step-count feedback interventions on these secondary outcomes.

**4. Reviewing computer-generated, time-stamped step-count feedback graphs during nutritional counseling sessions will further increase weight loss and daily activity levels when added to a nutritional counseling plus walking with step-count feedback intervention.** T-tests with unequal variance will be used for bivariate comparisons between the enhanced step-count feedback group and the simple step-count feedback group. The multivariable tests contrasting these conditions while controlling other variables will come out of the analyses used to test hypotheses 1 and 2. To test hypothesis 4, we simply attend to contrast b mentioned in analysis for hypothesis 1.

**5. Psychological and behavioral characteristics can be used to predict participants who are more likely to benefit from the step-count feedback interventions in terms of increased weight loss and walking adherence.** Looking only at those individuals randomized to one of the two step count feedback arms, we will test for participant characteristics that predict successful weight loss or increased walking adherence. Again multivariable linear regression techniques will be used and predictors added to the model will include baseline measures of readiness to change diet and exercise behavior, self-efficacy for physical activity, and health-related quality-of-life.

We will collect data on the following patient characteristics: number of comorbidities, income, education, work disability, age, smoking, social support, stress/ depression and experience using computers. These nine baseline characteristics will be examined to see if any subgroups are more or less likely to respond to the different types of interventions either with increased walking or successful weight loss.

Additionally, baseline self-efficacy and stage of change for both diet and physical activity will be examined as potential predictors of success. Self-efficacy and stage-of-change are also a potential mediating construct and will be measured at visits 1 and 6 to see if self-efficacy mediates the effect of the interventions on weight loss and walking.

### **3.a.8. Sample Size Calculations:**

The sample size was selected to provide 80% power to detect a three pound difference in weight loss between pairs of conditions (e.g., control vs. simple pedometer) in the planned comparisons with alpha of .05, two-tailed. Three pounds was judged to be a clinically significant difference by the investigator. Also, note that three pounds represents the *difference* in weight gain between the groups—not the absolute weight gain. Based on prior observations, the standard deviation of weight change over a 6-month period was estimated as 6.8 pounds. Power analysis used the methods of Cohen<sup>79</sup> as implemented in PASS2000 software<sup>80</sup> and indicated a need for 82 subjects per group after all attrition. In order to be prepared for up to 20% attrition, 103 patients will be recruited per group (103 x .8 is just over 82), for a total of 309 patients. Weight is the main outcome measure and usually one of the hardest ones to change, so power analysis

and sample size were based on it. With a sample large enough to provide 80% power to detect differences in weight loss, power to detect differences in other outcomes (e.g., SF-12 scores and activity levels) will also be ample.

### **Revised Sample Size Calculations:**

The *sample size* of 103 patients per group was selected to provide 80% power to detect a three-pound difference in weight loss between pairs of conditions (e.g., control vs. simple pedometer) in the planned comparisons with alpha of 0.05, two-tailed. The sample size calculation assumed the standard deviation (SD) of weight change over a six-month period of 6.8 pounds and 20% attrition. With the same proposed sample size, but with the potential within site clustering, the power will be smaller to detect the same effect size. The inclusion of the baseline values of the outcome variables (baseline weight) in the model, however, will likely reduce the standard errors and thus will increase the power. Hence, the statistical power of the study will remain approximately unchanged. Specific illustration is as follows: Since the assumed SD of 6.8 pounds was from pilot data of single site, the SD was essentially an estimate of within site SD. Thus, assuming the within-site SD in weight loss of 6.8, but with the assumed correlation of 0.7 between baseline weight and weight loss, the within-site SD is reduced to about 5.3. And with approximately 13 patients per site (= 82/6; complete data available from 82 patients per group) for each group and an assumed intra-cluster correlation coefficient (ICC) of 0.02, the cluster SD is expected to be 1.651. With these assumptions and six sites, the study will maintain 80% power to detect a between group difference in means of three pounds in weight loss with a two-sided 0.05 test. (Donner, 1987) Note that with a smaller ICC, the power will increase, but with a larger ICC, the power will decrease. No specific estimate of ICC for weight loss as the outcome is known, but most health study literatures including substance abuse and utilization have reported the ICC between 0.005 to 0.05, and thus the assumed ICC of 0.02 seems appropriate.

#### **3.a.8.1. Missing Data:**

All efforts will be made to minimize missing data as described in Section 3.a.5.1. Sample size calculation was also done with 20% attrition in mind, which is a conservative estimate given all our efforts to reduce missing data. The Actical data for activity level gain will be collected at three time points. Participants who do not have baseline data will not be randomized. In terms of analysis, those who are missing three-month and/or final measures will not be included in their respective analyses. However, to assess whether any baseline differences exist between patients who are missing versus patients who are not missing three-month and/or six-month outcome measures, their baseline values (such as baseline weight) will be compared using a two sample t-test. In case any statistical or clinical difference is found between these groups, such as those missing final weight being heavier at baseline compared with those not missing final outcome, the final conclusion from the comparisons will be made carefully in light of this finding. Similar comparisons will be made with other baseline potential confounding variables as well, and those variables found to be associated with missing data will be included in the final model.

#### **3.a.8.2: Clustering by site**

In order to make between group comparisons while adjusting for potential within site clustering as well as for potential confounders, we will use a *linear mixed-effect model* with the change

score (weight loss or activity level gain) as the dependent variable (Laird, 1982). In addition to the two primary predictors of dummy variables representing the intervention arms and other potential confounders described in the original proposal, the linear mixed-effect model will include site as random intercept (to account for potential clustering within site) and baseline weight as independent variable (to further adjust for baseline differences). Including site as a random-effect rather than fixed-effect has an advantage of allowing for broader inferences from this study about other sites.

### **3.a.8.3: Seasonal variation**

With the follow-up of six months seasonal variation may result in potential bias in our assessment. Two things will be done to address this: (1) randomization will be done in blocks, and (2) the above described model will also utilize an indicator variable for warmer climate (Miami, Tucson, San Diego) and categorical dummy variables for season at baseline as independent variables. The inclusion of baseline season variables will be modified after further exploratory graphical analysis to see if differential seasonal pattern exists where, for instance, seasonal effect may be more or only prominent in sites from colder climates. The project statistician will be responsible for the randomization process, which will be done within each of the 6 sites and prepared ahead in sequenced and sealed envelopes for each consecutive participant. To further enhance the balance between the number of people in the three groups during the recruitment period and thus over the various seasons, blocked randomization will be done. To prevent potential bias from the study coordinator being aware of the group assignment toward the end of each block, block sizes will also vary randomly among three, six, and nine where the order in which the group assignments are made in each block will be randomized.

### **3.a.9. Patient Safety Issues**

**Patient Safety Issues related to the nutritional counseling sessions.** These participants have been referred for nutritional counseling by their physician or dietitian, and by requiring each study participant to have their physician sign a Medical Clearance Form their physician has already determined that the benefits of nutritional counseling outweigh the potential adverse effects. We are using a conventional weight loss counseling protocol and this should not increase the risk to the patient over and above the risks commonly associated with nutritional counseling.

**Patient Safety Issues related to musculoskeletal injury.** Walking programs are much less likely than more vigorous exercise programs to result in minor musculoskeletal injury. However, musculoskeletal injury can occur even in walking programs. By gradually increasing the duration and walking speed over the course of six months, musculoskeletal injury will be reduced to the minimum possible level. Dietitians will also review the walking program handout which gives instructions on warming up and stretching and on slowly increasing the amount of walking. Patients with diabetes will be given a handout (Appendix K) to teach them about exercising safely with diabetes.

**Patient Safety Issues related to cardiovascular disease risk.** All of the participants in this study have at least one cardiovascular disease risk factor, and thus they are at increased risk of experiencing an adverse cardiovascular event during the six months of the intervention. These are the patients who are often excluded from studies of lifestyle physical activity interventions such as the one we propose here. However, because of their high baseline risk, they are also the

patients most likely to benefit from lifestyle interventions.<sup>10</sup> All study participants must have a Medical Clearance Form signed by their physician in order for them to participate in the study. Extensive testing and/or cardiology evaluation will not be required for the majority of the participants. At each visit, the dietitian will ask the participant about cardiac symptoms during walking and if any symptoms are reported, the participant will be referred to his or her physician for further evaluation. Patients with high blood pressure, as measured at the beginning of each study visit, will be temporarily suspended from the study and must have permission from their physician to return to the walking program.

Instructions to the site coordinators and site principal investigators regarding patient safety and risks are included in Appendix L, "Participant Safety."

### **Rules for suspension of participation**

As a rule, any concerns by the dietitian should result in suspension from the study until a physician treating the participant gives written medical clearance.

Criteria for temporary suspension from the study are as follows:

- Hospitalization or evaluation in the Emergency Room for any reason other than for a minor laceration or for a viral infection that has resolved, including but not limited to
  - i. cardiac evaluation for symptoms,
  - ii. syncope or TIA symptoms,
  - iii. adverse reaction to medications,
  - iv. bacterial infection on antibiotics,
  - v. Motor Vehicle Accident,
  - vi. problems with glucose control for patients with diabetes, or
  - vii. dehydration.
- outpatient cardiac evaluation for symptoms (i.e., chest pain or shortness of breath)
- any report of chest pain, shortness of breath or light-headedness when walking
- any injury or impairment that significantly limits ability to walk or increases risk for further injury while walking

At the beginning of each nutritional counseling session, dietitians will ask the participant about any of the above events. For any participant who has experienced one of the above events, the counseling session will be terminated and the participant will be informed that they have been suspended from the study. In order to be reinstated in the study, the participant will need to get written, signed medical clearance from their primary care physician or from a specialist evaluating the problem. The study coordinator at the participant's site will assist the participant in getting the written medical clearance.

If at any time the dietitian is concerned about the safety of a participant, he or she can contact the study principal investigator for guidance.

Scheduled routine cardiac testing (such as an annual stress-test) for these high risk patients will not constitute grounds for study suspension in the absence of symptoms.

### 3.b. Resources:

**Facilities:** The Ann Arbor VA HSR&D Center of Excellence is home to a large network of researchers with extensive experience conducting clinical and health services research. Dr. Lowery is Associate Director of the Center, which has approximately 80 staff, most of whom are located in contiguous space to facilitate interaction, collaboration, and consultation. Many of the studies conducted by Center staff are multi-site, employing both primary and secondary data collection efforts. Thus, there are extensive resources—both physical and personal—available for conducting the proposed study. The collaborating facilities (see below) have sufficient staff and space for conducting the proposed study, and letters of support are appended to the proposal.

**Personnel:** Please see the Budget Justification (forms 10-1313-3 and 4, included as Appendix M) for details regarding the responsibilities of the investigative team. A summary of the qualifications of the team follows:

**Caroline R. Richardson, MD** (Principal Investigator, 25%) is a Family Physician at the University of Michigan Health System and a research scientist at the Ann Arbor VA Health Services Research and Development Center for Practice Management and Outcomes Research. She is a junior investigator studying physical activity measurement and promotion for people living with chronic diseases including diabetes, cardiovascular disease, and serious mental illness. Dr. Richardson has a BS in Mathematics from MIT and a MD from Harvard Medical School. She recently completed a Robert Wood Johnson Clinical Scholars Fellowship during which she studied the association between physical activity and health outcomes. Dr. Richardson has a particular interest in innovative uses of information systems to promote physical activity.

**Julie Lowery, PhD** (Co-Principal Investigator, 10%) has served as Associate Director of the Ann Arbor HSR&D Center since 1996. She has also served as the principal investigator for a number of VA multi-site, prospective studies. Her currently funded VA studies include a 6-site evaluation of a nurse practitioner model for chronic heart failure, and a 43-site study of factors affecting implementation of diabetes hypertension guidelines. She has worked previously with a national committee of VA dietitians to validate VA's nutrition status classification scheme and to develop a clinical nutrition staffing model (HSR&D SDR #91-017, "Design and Validation of VA Clinical Dietetic Staffing Model"), which involved the participation of clinical dietitians from 27 VA medical centers. Dr. Lowery will use her extensive experience in conducting multi-site research within VHA to assist Dr. Richardson with the overall design and conduct of the proposed study. As a senior researcher with experience in mentoring junior investigators, Dr. Lowery will serve as both collaborator and mentor to Dr. Richardson during the course of the study.

**David Ronis, PhD** (Statistical Consultant, 5% year 1, 10% year 3) is a Research Health Science Specialist at the Ann Arbor VA and Director of the Statistical Consulting Team at the University of Michigan School of Nursing. He has completed postdoctoral training in mathematical psychology and behavioral statistics at the University of Michigan.

**Wendy Peebles, MSW** (Project Manager, 100%) has a Master's Degree in Social Work from the University of Michigan. She has worked for HSR&D for three years as a project manager for another multi-site study focusing on patient centered care.

**Angela Larkin, AALAT** (Project Manager, 80%) Is a program analyst at the VA HSR&D. She has twelve years of experience as a research coordinator of multi-site industry sponsored studies, multi-site NIH sponsored grants, and investigator initiated studies. This includes three years of experience as the team leader of a congestive heart failure research group at the University of Michigan Medical Center. In addition she has three years of experience as a project manager for another multi-site study at HSR&D.

**Sharon Foley, MS, RD, LD** (co-investigator 10%, contributed) will contribute expertise in the area of nutritional counseling. She is an experienced investigator and is currently a co-investigator on another obesity-related lifestyle intervention trial funded by VA Rehabilitation R&D. She has five years experience as a nutrition specialist, 15 years experience as a nutrition educator, and nine years experience supervising nutrition-related research.

### 3.c. Collaboration

**Research Sites:** The PI and Co-PI are both based in Ann Arbor, Michigan at the VAAAHCS HSR&D Center of Excellence. Participants will be recruited from six participating sites. When the study was initially proposed, we had a great deal of interest from dietitians across the country and 38 sites responded to our initial call for collaborators. To select the final list of participating sites, the following characteristics were given priority: sites that recruited patients for the pilot (Miami, Hines, Tucson), sites with established IRB mechanism, and sites with more dietitians who would be available and willing to participate. Letters of support from the following six sites have been included in this proposal. The participating sites were asked to provide estimates of the number of referrals their outpatient dietitians receive per year for weight loss. These estimates are conservative. The numbers indicate that recruitment rates of 10 to 20% should enable us to achieve our desired sample size.

(as of

November  
2003)

Site	State	No. of Dietitians	Recruitment Capacity/Year
Miami	FL	2	250
Tucson	AZ	4	600
Memphis	TN	3	300
Oklahoma City	OK	3	1000
Topeka	KS	3	540
San Diego	CA	4	150

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**Appendix A.**  
**Study Timeline**



## **Appendix B.**

### **T-shirt Graphics**



**VETERANS**

**WALK**

**FOR**

**HEALTH**

## **Appendix C.**

### **Enrollment Flyers: Patients and Primary Care Providers**

# **Does Step Count Feedback Enhance Counseling for Weight Loss?**

**Co-P.I.: Caroline Richardson, MD & Julie C. Lowery, Ph.D.**

**Site P.I.: \_\_\_\_\_**

## **Key Study Components:**

- Recruitment goal: 300 patients from 6 VAMC's**
- Participants will record step counts by wearing pedometers or record minutes walking for over approximately 6 months**
- Registered Dieticians will incorporate physical activity counseling (with or without pedometer use) and nutritional counseling to encourage gradual activity increases and weight loss among eligible patients**

## **Brief Initial Eligibility Criteria:**

- 1. Patient is newly referred from a VA physician for one of the following diagnoses:**
  - (1) Diabetes**
  - (2) Coronary artery disease**
  - (3) Hypercholesterolemia**
  - (4) Hypertension**
  - (5) Obesity**
- 2. Patient is ambulatory and able to comfortably walk at least one block**
- 3. The patient has a BMI of 28 or greater**

**A more comprehensive eligibility screening will be conducted with each potential subject by the Site Coordinator prior to enrollment into the study.**

# VETERANS WALK FOR HEALTH



## SEEKING PATIENTS FOR A RESEARCH STUDY

### Do you want help starting a walking program?

Participants will:

- Attend six study visits
- The last of the six sessions will be six months after enrollment
- Be randomly assigned to one of three treatment programs:
  - 1) Five nutritional counseling sessions
  - 2) Five nutritional counseling sessions + step counter #1
  - 3) Five nutritional counseling sessions + step counter #2

Participants will be compensated for participation including:

- A \$10.00 phone card for each of the 6 visits attended
- A “Veterans Walk” T-shirt for attending the final follow-up session

Inclusion Criteria:

- Male and 18 years or older
- Provider referral for nutritional counseling for:
  - Diabetes, Coronary Artery Disease, Hypertension, Hypercholesterolemia or Obesity
- Able to walk one block comfortably
- Sedentary but interested in starting a walking program
- Overweight

Recruitment Period: 07/2005 to 07/2007

Contact the research team

P.I.: CAROLINE RICHARDSON, [caroli@umich.edu](mailto:caroli@umich.edu)

Co P.I.: JULIE LOWERY, [julie.lowery@med.va.gov](mailto:julie.lowery@med.va.gov)

Project Manager: ANGELA LARKIN, (734) 769-7100X 6214, [angela.larkin@med.va.gov](mailto:angela.larkin@med.va.gov)

Site P.I.: \_\_\_\_\_

Site Coordinator: \_\_\_\_\_

**Appendix D.**  
**Enrollment Script**



## Veterans Walk for Health Study

### **Suggested Enrollment Script:**

If you are interested, you might be eligible for a special study we are doing on a new weight loss program.

The program would involve a total of five more visits in the next six months. These five visits will include nutritional counseling sessions focusing on weight loss. The final session will also include a follow-up session to see how well the program worked and it will be scheduled six months after enrollment. We will ask you to complete a survey at the beginning, middle, and end of the study. The survey takes approximately 20-30 minutes to complete each time.

Everyone in the study will get intensive and individualized nutritional counseling. Additionally, you will be asked to wear a device to record your activity level. If you are randomized to group one you will be asked to wear this device every day, all day for one week before some of your visits. In addition, if you are randomized to group two or three you will be asked to wear an additional similar device all day every day for the duration of the study. We will be comparing three different methods setting walking goals:

- 1) using time spent walking
- 2) using step-counts on a traditional pedometer
- 3) using step-counts and web-based feedback from a pedometer

For your time and willingness to help us evaluate this program, you will be given a phone card worth \$10.00 for each of the visits that you attend.

If you complete the program and return the step-counter device, you will also receive a t-shirt after the study is over.

**Appendix E.**  
**Eligibility Form**



## Veterans Walk for Health Study Screening for Eligibility Worksheet

LINE NUMBER (from Crosswalk Forms 1 and 2) \_\_\_\_\_

DATE: \_\_\_\_/\_\_\_\_/\_\_\_\_

SITE: (circle one) Memphis Miami Oklahoma City San Diego Topeka Tucson

HOW WAS THIS PATIENT IDENTIFIED? (circle one)

Self-referred Referred by MD Referred by Dietitian Other: \_\_\_\_\_

This form serves to determine if a patient is eligible for this study. Do not include patient identifying data on this form.

	Criteria	Eligible	Not Eligible
1	Male and at least 18 years old? Date of Birth ____/____/____ (MM/DD/YYYY)	Yes	No
2	Patient was referred by a local VA physician <small>(If not referred by a physician patient may be enrolled - once medical clearance is received from a local VA physician this box can be answered "yes" and the participant may be randomized. If medical clearance is not received this box should be answered "no" and the patient cannot be randomized.)</small> Name of MD _____	Yes	No
3	Patient referred for (circle one or more) a) Diabetes                                      b) Hypertension c) Hypercholesterolemia                      d) Obesity e) Coronary Artery Disease	Yes	No
4	Patient reports that he can comfortably walk 1 block.	Yes	No
5	Height _____ in / cm      Weight _____ lb / kg  BMI = ( $\frac{\text{Weight in Pounds}}{(\text{Height in inches}) \times (\text{Height in inches})}$ ) x 703 BMI _____ Is BMI equal to or greater than 28?	Yes	No
6	Competency: Patient appears to understand questions and answer them appropriately. There is no indication in the medical record that the participant has a serious mental illness or cognitive deficit that might impair his or her ability to consent to a research study?	Yes	No
7	Has patient worn a pedometer within the last 28 days?	No	Yes

	Criteria	Eligible	Not Eligible
8	<p>Physical Activity Level - Briefly ask the patient about his exercise and physical activity. Suggested Questions:</p> <ul style="list-style-type: none"> <li>• What kinds of exercise or physical activity do you do? How often? For how long each session? _____</li> <li>• In the past week, how many days have you been active or exercised for at least 30 minutes? _____</li> <li>• Was last week typical for you or are you usually more or less active? _____</li> </ul> <p>From this brief discussion, would you say that the patient is relatively sedentary in that he is not physically active for at least 30 minutes at least 5 days a week at a moderate intensity (such as a brisk walk)?</p>	Sedentary	Active
9	<p>Stage of Change for Physical Activity  “Are you interested in being more physically active or getting more exercise?”</p>	Yes	No
10	<p>“A great way to start being more active is to start a walking program. Would you be interested in some help with starting a walking program?”</p>	Yes	No
11	<p>Can the patient communicate comfortably in English?</p>	Yes	No

**Patient must be eligible for all of the criteria in order to be randomized into the study.**

Eligible? YES: obtain informed consent

(or)

NO: date of scheduled nutritional counseling visit \_\_\_\_/\_\_\_\_/\_\_\_\_. Enter data into Survey Monkey

Consent Signed? YES: assign enrollment ID on Crosswalk 1, participant to complete Baseline Survey

(or)

NO: date of scheduled nutritional counseling visit \_\_\_\_/\_\_\_\_/\_\_\_\_. Enter data into Survey Monkey

Randomized? YES: assign enrollment ID on Crosswalk 1. Enter data into Survey Monkey.

(or)

NO: date of scheduled nutritional counseling visit \_\_\_\_/\_\_\_\_/\_\_\_\_. Enter data into Survey Monkey

Please maintain a copy of each Screening for Eligibility Worksheet. If the participant is not eligible for enrollment or does not give informed consent keep this worksheet in a file labeled “Patients Screened but not Eligible”. If the participant is enrolled keep this worksheet in the participants study file. If you have any questions please call Angela Larkin at (734)769-7100 x6214.

**Appendix F.**

**Medical Clearance Form**

VETERANS WALK FOR HEALTH STUDY  
MEDICAL CLEARANCE FORM

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I give the research staff from the Veterans Walk for Health Study permission to contact my doctor, Dr. \_\_\_\_\_ to obtain medical clearance for me to participate in the Veterans Walk for Health Study.

Participant's Signature \_\_\_\_\_ Date: \_\_\_\_\_

---

Date: \_\_\_\_\_

To: Dr. \_\_\_\_\_

We are requesting medical clearance for your patient \_\_\_\_\_ to participate in the Veterans Walk for Health study, a randomized controlled trial of a walking intervention for people with cardiovascular disease risk factors.

For most individuals with cardiovascular disease risk factors, starting a walking program significantly decreases the risk of premature death and adverse cardiac events. However, for some individuals, the risks associated with starting a walking program may outweigh the benefits. Examples of such very high risk patients include a patient with unstable angina who is currently undergoing an evaluation for possible revascularization or a patient with decompensated congestive heart failure.

For the above named patient, please check the appropriate line below and sign. Your patient will not be able to start the walking program until this form is completed.

\_\_\_\_ This patient is an appropriate candidate to start a walking program

\_\_\_\_ This patient is currently at too high risk to start a walking program  
Details \_\_\_\_\_

\_\_\_\_ I need to schedule an appointment or conduct further evaluation before giving medical clearance for this patient to start a walking program.

\_\_\_\_ I do not know this patient and cannot evaluate.

Physician Signature \_\_\_\_\_ Date \_\_\_\_\_

Name: \_\_\_\_\_

SSN: \_\_\_\_\_

VETERANS WALK FOR HEALTH STUDY  
MEDICAL CLEARANCE FORM  
FOR RESUMING A WALKING PROGRAM

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I give the research staff from the Veterans Walk for Health Study permission to contact my doctor, Dr. \_\_\_\_\_, to obtain medical clearance for me to resume a walking program as part of the Veterans Walk for Health Study.

Participant's Signature \_\_\_\_\_ Date: \_\_\_\_\_

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Date: \_\_\_\_\_

To: Dr. \_\_\_\_\_

We are requesting medical clearance for your patient \_\_\_\_\_ to resume a walking program as part of the Veterans Walk for Health Study.

His walking program has been discontinued because of the following adverse event:

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For the above named patient, please check the appropriate line below and sign. Your patient will not be able to resume the walking program until this form is completed.

\_\_\_\_ This patient is an appropriate candidate resume the walking program.

\_\_\_\_ This patient is currently at too high risk to resume the walking program.  
Details \_\_\_\_\_

\_\_\_\_ I need to schedule an appointment or conduct further evaluation before giving medical clearance for this patient to resume the walking program.

Physician Signature \_\_\_\_\_ Date \_\_\_\_\_

## **Appendix G.**

### **ADA Medical Nutrition Therapy Protocol for Weight Management**

## WEIGHT MANAGEMENT Medical Nutrition Therapy Protocol

**Setting: Ambulatory Care (Adult 18+ years)**

**Number of sessions: 6**

No. of interventions	Length of contact	Time between interventions	Cost/charge
1	60 minutes	2 weeks	
2	30-45 minutes	2 weeks	
3 and 4	30-45 minutes	4 weeks	
5 and 6	15-30 minutes	6 weeks	

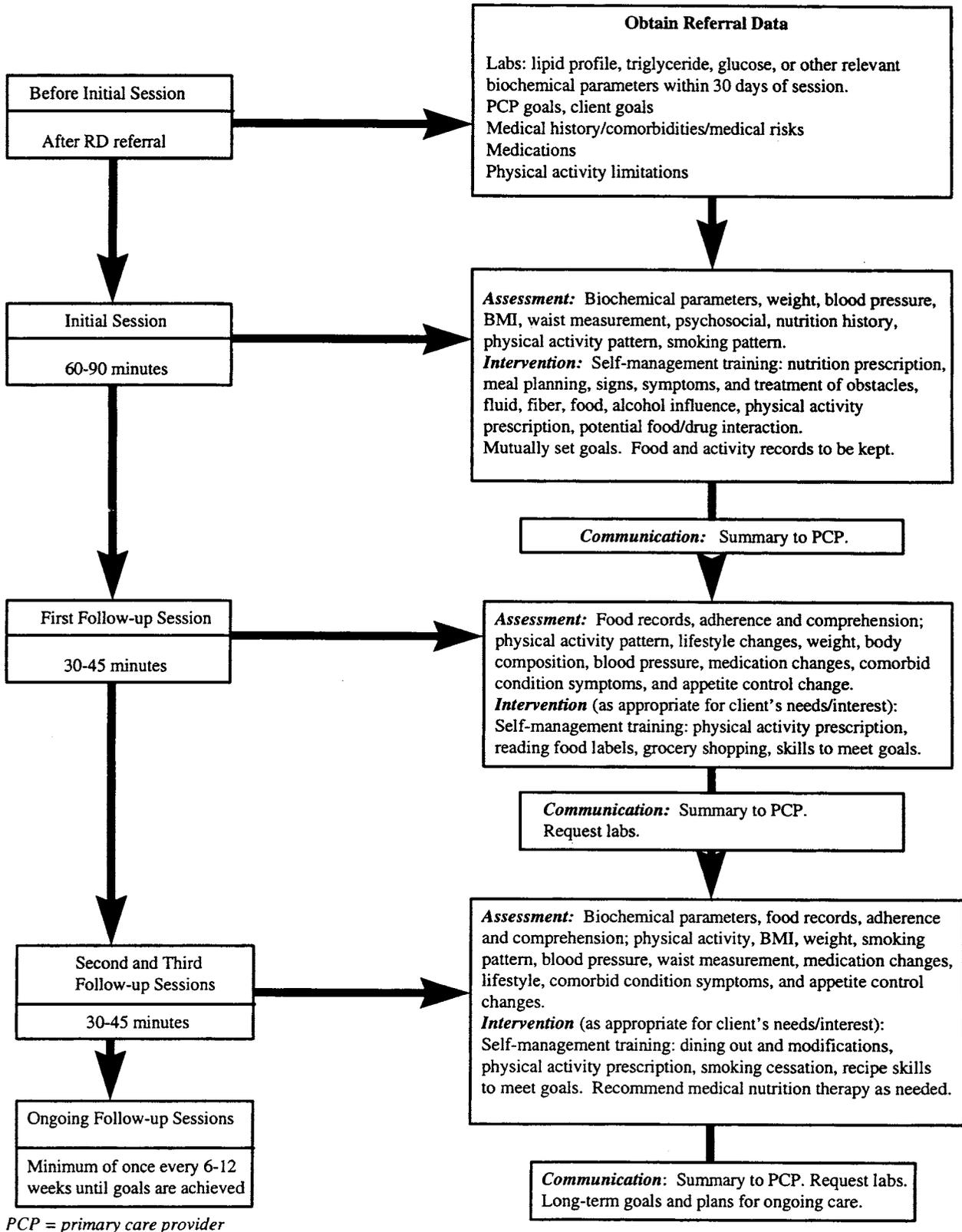
\*Quarterly follow-up one-on-one or group classes or (support group) continue for a minimum of 1 year or as needed to increase compliance.

### Expected Outcomes of Medical Nutrition Therapy

Outcome assessment factors	Base-line	Evaluation of Intervention				Expected outcome	Ideal/goal value
	Interventions						
	1	2	3-4	5-6			
<b>Clinical Outcomes</b> <ul style="list-style-type: none"> <li>Biochemical parameters (&lt; 30 days prior to nutrition session)                             <ul style="list-style-type: none"> <li>Serum glucose</li> <li>Lipid profile, triglyceride</li> </ul> </li> <li>Blood pressure (day of visit)</li> <li>Anthropometrics                             <ul style="list-style-type: none"> <li>Weight and height</li> <li>Body mass index (BMI)</li> </ul> </li> <li>Waist-to-hip ratio (WHR)</li> <li>Waist circumference</li> <li>% body fat (% BF) (optional)</li> <li>Clinical signs and symptoms</li> <li>Assess comorbid conditions</li> <li>Medications</li> </ul>	✓	✓	✓	✓	<ul style="list-style-type: none"> <li>Glucose 5-10%, Chol ↓ 2-5%;</li> <li>Trig to normal (if elevated)</li> <li>LDL-C, ↑ HDL-C or no change</li> <li>BP (if elevated)</li> <li>weight as prescribed for health benefit</li> <li>WHR, waist circumference</li> <li>&lt;40" (102 cm) males</li> <li>&lt;35" (88 cm) females</li> <li>1-2% body fat per month (&gt;4% total BF for males; &gt;14% for females)</li> <li>symptoms of concomitant problems</li> </ul>	Labs within normal range  BP < 140/90 mm Hg  Stabilize/maintain weight 6-12 months 0.5-1.5 lb/week weight loss, or 2 BMI units below BMI if initial BMI > 30 BMI range 20-27  ↓BF for males 10-25% ↓BF for females 18-32%  Decrease need for medications	
<b>Behavioral /Cognitive Outcomes*</b> <ul style="list-style-type: none"> <li>Assess readiness for weight loss</li> <li>Addresses psychological obstacles</li> <li>Meal planning (food, hydration, fiber, alcohol)</li> <li>Food label reading</li> <li>Recipe modification</li> <li>Food preparation</li> <li>Dining out</li> <li>Potential food/drug interaction</li> <li>Physical activity</li> <li>Smoking</li> <li>Lapse/relapse</li> </ul>	✓	✓	✓	✓	<ul style="list-style-type: none"> <li>Lifestyle Questionnaire or other tool evaluates readiness for weight loss and evaluates potential obstacles</li> <li>Keeps accurate food/activity records</li> <li>Chooses food and amounts according to meal plan</li> <li>Accurately reads food labels</li> <li>Modifies recipes to ↓ total saturated fat and sugar</li> <li>Uses healthy cooking techniques</li> <li>Selects appropriately from menu</li> <li>Verbalizes food/drug interaction</li> <li>Participates in physical activity</li> <li>Verbalizes importance of smoking cessation</li> <li>Demonstrates overcoming obstacles</li> </ul>	<b>MNT Goals</b> <ul style="list-style-type: none"> <li>Adhere to appropriate meal plan and self-management training program, increase or maintain adequate hydration, and adhere to physical activity to maintain or decrease weight, body fat, and risk factors</li> <li>Appropriate referral to psychosocial, exercise professional</li> </ul>	

\* Session in which behavioral topics are covered may vary according to client's readiness, skills, resources, and need for lifestyle changes.

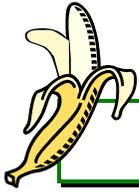
## WEIGHT MANAGEMENT Medical Nutrition Therapy Protocol



PCP = primary care provider

## **Appendix H.**

### **Nutrition Counseling Handouts**



# Nutritional Counseling Handbook



## Table of Contents

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## SUGGESTED BEHAVIOR CHANGES FOR WEIGHT REDUCTION

### Grocery Shopping

- ❖ Plan out your meals for the week and make your grocery list to match.
- ❖ Shop from a list and stick to that list. Take only enough money to pay for the food on your list.
- ❖ Don't shop when hungry.
- ❖ Do not buy high calorie desserts or snacks.



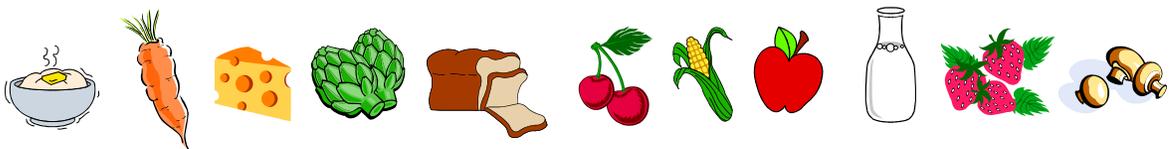
### Meal Times

- ❖ Eat in one room of the house and in one place in that room only.
- ❖ Don't watch TV, read, or do anything else while eating.
- ❖ Serve food on small plates.
- ❖ After serving yourself, put the remaining food into storage containers and directly into the fridge. ~**OR**~ Fix just enough food for one meal. Avoid nibbling on leftovers!
- ❖ Use your left hand to eat if you are right handed, and use your right hand to eat if you are left handed.
- ❖ Leave the table soon after eating.
- ❖ Eat on a regular schedule. Don't skip meals.
- ❖ Eat a variety of foods so you won't feel deprived.



## Avoid Overeating

- ❖ Stop eating half way through your meal, wait two minutes, and begin eating again if you are still hungry.
- ❖ Chew slowly. Put your fork or food down between bites. Swallow food completely before taking the next bite.
- ❖ Brush your teeth immediately after eating. You won't be as tempted to snack.
- ❖ If you know you might be in a situation where you will overeat, write down why you DO want to lose weight. This may help prevent overeating.



- ❖ Weigh yourself once a week.
- ❖ Have a family member or friend help watch your eating habits.
- ❖ Arrange for family or friends to give you a non-food reward for following your diet like clothes, workout outfit, or a hair cut.
- ❖ Do not start a long-term weight control program shortly before a holiday.
- ❖ Use measuring cups and spoons and a scale until you KNOW how much food you are getting; then weigh and measure one meal per week, just to make sure your eye hasn't "grown".



❖ Find outside interests that don't involve food. Find activities you enjoy which burn calories such as riding a stationary bike while watching TV.

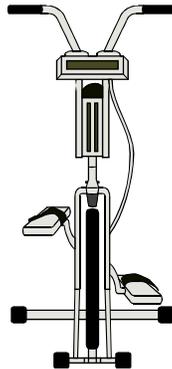
❖ No single food is fattening, nor will any food "burn fat."



❖ There is NEVER a time when calories do not count.

❖ If you eat more than 3500 calories a week than you burn through exercise, you'll gain a pound of body weight. Every little bit counts...just one extra slice of plain bread per day for five years will cause a weight gain of over 35 pounds!!

❖ Every little bit of activity will also count. Take the stairs instead of the elevator, park far away from the door to the store, etc.



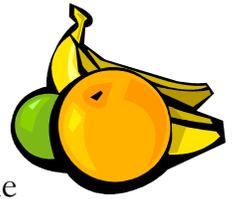
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Nutrition & Food Services (revised  
8/04)



## 20 WAYS TO THINK THIN



1. Make a list of the reasons why you want to lose weight before you begin your new eating habits. While you are changing your habits, read your reasons to help keep your willpower and focus.
2. Keep a food diary to be aware of why you overeat. Record food quantity, type, calories (if known), time of meal, and how you feel during the meal. List the reason you are eating such as hunger, mealtime, social event, etc. Read over your diary to see if there is a pattern to your overeating. Use this tool to plan meals and to stop snacking.
3. Weigh yourself 1 or 2 times each week. Weighing too often can be discouraging if you don't see results on the scale everyday. Likewise, weighing too infrequently lead to unknown weight gain. Weigh yourself periodically to maintain weight once you have reached your desired weight.
4. Take a "before" picture. You will be able to see the difference that weight loss makes when you achieve your weight goal.
5. Set reasonable goals. Weight reduction of 1/2 to 1 pound per week is good. You didn't gain weight overnight, so be realistic with the time needed to lose that unwanted fat. Focus on having small weight loss goals of 5 to 10 pounds. Once you achieve a goal, reward yourself and continue on. Keep your focus.
6. Make a shopping list before going to the grocery store. Stick to the list to avoid buying foods you don't need such as cookies and chips. Be sure to add in plenty of fresh fruits and vegetables, for both meals and snacks.
7. Never grocery shop when hungry. Food you don't need will have extra appeal when you are hungry. Resist the impulse to buy high- fat and high- sugar snack foods.
8. Be realistic about your food choices. Many foods can fit into a diet. Be aware of portion size and how often you eat certain foods. Don't make food more tempting by eliminating it from your diet.

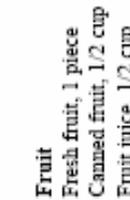


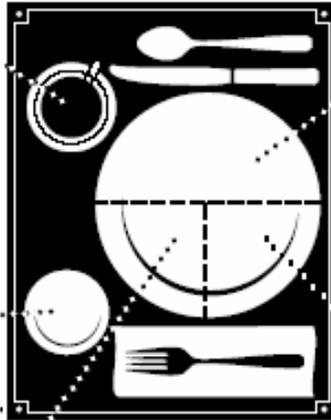
9. Turn off the television when eating. Enjoy your mealtime without the distraction of television. You may find that snacking during television viewing is a habit, not hunger.
10. Chew your food well. Take small bites that cover only  $\frac{1}{3}$  to  $\frac{1}{2}$  of your fork or spoon. Rest your utensils on your plate between mouthfuls to slow down the rate of eating. This will give your body time to recognize satiety or a full belly.
11. Brush your teeth right after meals. The mint flavor in the toothpaste will help to get rid of the taste of food so you won't think about eating as much.
12. Watch people eating when at a restaurant. Do many people have their face close to the plate, eat too fast, and barely chew their food? How does this look to you? Think of how pleasant it is to watch someone who eats slowly, takes small bites, and sits upright to dine.
13. Restrict the number of places you eat. Don't take food to the bedroom or study. This will reduce the number of places you associate with food and eating.
14. Avoid skipping meals. Missing meals leads to overeating at the next meal. Your body will think you are starving if you only eat 1 or 2 times a day. Have multiple small meals and snacks throughout the day. Just limit portions and calories each time.
15. Eat before social functions with food. You won't be tempted to overeat high-fat, high-sugar foods served at many social events. Use a small plate and take very small portions, to taste. Try to take one or two bits of buffet items just to sample them.
16. Get involved in family projects and community activities. Watch less television. Many people eat out of boredom. Find a new hobby during sitting time at home instead of snacking. Keeping your hands and mind occupied is a great distraction to thinking about food.



17. Don't attach your weight to a specific date or event. Your goal should be long-term weight reduction and control. Losing 10 pounds for an event or to fit into an outfit is the wrong approach. Lose the weight to feel better and improve health. Work on changing unhealthy eating habits and food selections.
18. Remake recipes. Get the unnecessary fat out of your favorite recipes. Don't add that extra butter for seasoning. Substitute low-fat dairy items for regular, but high-fat, whole milk, cream, and butter.
19. Serve food from the kitchen onto your plate. Try to use less "family style" dining to help with portion control. This will also eliminate the urge to take second servings of food.
20. Take a walk or do some kind of exercise instead of eating. Contrary to popular belief, exercise doesn't make you hungrier. It makes you feel better, feel good about yourself, and sleep better – all things that overeating never does.

## How Much Should I Eat?

-  **Fruit**  
Fresh fruit, 1 piece  
Canned fruit, 1/2 cup  
Fruit juice, 1/2 cup
-  **Milk or Yogurt**  
Skim or 1% milk, 1 cup  
Plain or light yogurt, 1 cup
-  **Starchy Foods (lunch and dinner)**  
1/4 plate (1 serving) of  
Noodles or pasta, 1/2 cup  
Bread, 1 slice  
Bun, 1/2  
Rice, 1/2 cup  
Corn, 1/2 cup  
Potatoes, 1/2 cup  
Tortillas, 1 small



-  **1/4 plate or less of Meat or other Protein (lunch and dinner) optional for breakfast**  
Chicken  
Fish  
Lean beef  
Lean pork  
Egg  
Tofu  
Cottage cheese  
Low-fat cheese
-  **At least 1/2 plate of Non-starchy Vegetables**  
Broccoli  
Carrots  
Green Beans  
Greens  
Leafy Vegetables  
Spinach  
Tomatoes

## What's On Your Plate?

Food choices and portions can make a big difference in your success with weight reduction. Your meal plan can also help you control your blood sugar, if you have diabetes.



- ✓ Eat \_\_\_ meals and \_\_\_ snacks at about the same time every day.
- ✓ Do not skip meals or recommended snacks.
- ✓ Get regular activity.
- ✓ Lose excess weight.
- ✓ Avoid alcohol.
- ✓ Limit foods that have a lot of sugar such as:
  - Sugar
  - Pastries
  - Cakes
  - Gum
  - Pies
  - Gelatin/Pudding
  - Ice Cream
  - Gatorade
  - Cookies
  - Honey
  - Candy
  - Molasses
  - Jelly and Jam
  - Koolaid
  - Snapple
  - Pre-sweetened Tea
  - Soda
- ✓ Limit foods with a lot of fat like fried foods or fast foods
- ✓ Avoid high fat meats like:
  - Bacon
  - Salt pork
  - Regular lunch meats
  - Sausage
  - Hot dogs
- ✓ Too many or too few servings of starches, fruits and milk can affect your blood sugar, if you have diabetes.

This guide can help you plan your meals. Dividing your plate into sections can help you eat the right amount of carbohydrates, protein and fat.





### Fruits

- Fresh or frozen
- Canned in water or juice
- Unsweetened juice with meals (limit juice to 1/2 cup)

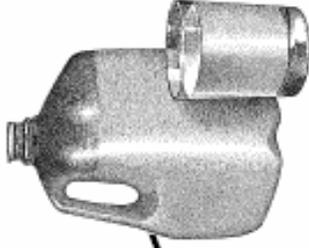


### Vegetables

- Fresh or frozen
- Low-salt canned
- Limit added sauces or fats (potatoes, corn, peas, and beans are in the starch group)

### Fats and Oils

- Soft tub margarine; or liquid oil (canola or olive oil)
- Avoid shortening, butter and/or lard



### Milk

- Low fat, reduced fat or fat-free
- Buttermilk (low fat)
- "No sugar added" non-fat yogurt or plain non-fat yogurt



### Starches

- Unsweetened cereals
- Whole grain breads
- Limit pastries
- Watch portion sizes
- Includes starchy vegetables such as corn, peas, beans, and starches such as pasta, rice and noodles.



### Meat/Proteins

- Trim fat from meats
- Remove skin from chicken or turkey
- Bake, broil, grill or boil
- Limit egg yolks to 2-4 per week
- Limit organ meats
- Use low-fat cheeses and lunch meats



If you have questions about your diet,

call \_\_\_\_\_, R.D.

## HOW TO AVOID PORTION DISTORTION



A **thumb- tip** equals a teaspoon, the amount of butter or margarine you should use. Three thumb tips is a tablespoon, about the amount of milk or creamer you would put in your coffee.



A **thumb** equals 1 oz, or approximately 25 grams, of most cheeses. So 2 thumbs would equal a serving.



A **fist** equals a cup. A fist would be equal to 1 serving of yogurt, cereal, or pasta. A fist size of raw, leafy vegetables would be a serving of vegetables.

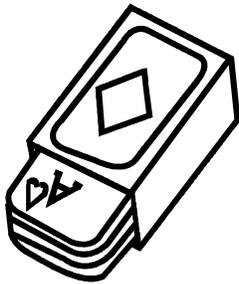


A **palm** equals a serving size of meat, fish, or poultry. That's without the fingers and thumb!

## Other HANDY TIPS for Picturing what Servings Look Like



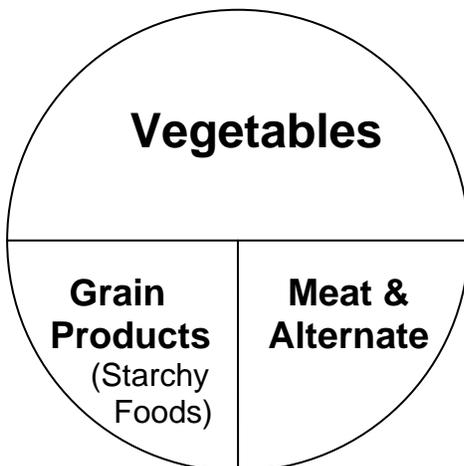
One medium size fruit = Size of a tennis ball



One serving of meat or poultry = Size of a deck of cards



1/2 cup vegetables, rice, or pasta = Size of a lightbulb



Or, keep things really simple and just make your plate look like this- and don't forget your milk and fruit.

# LIQUID CALORIES

Calories from **BEVERAGES**

can add **HUNDREDS** of extra sugar or alcohol calories to your diet.

Eating food is more satisfying than drinking your calories!

Remember that:

Soda



Sweet tea



Alcoholic beverages



Coffee with sugar and creamers



**ADD** extra calories to your day.

They lack the essential nutrients found in low fat milk products and fruit juices.

Try choosing these beverages instead:

**Unsweetened tea**, add sugar substitute if desired

**Calorie savings = 150 calories / glass**

**Sugar free soda**

**Calorie savings = 140 – 180 calories / can**

**Water** - add a squeeze of fresh lime or lemon juice

**Fat free or 1% milk** – instead of 2% or whole milk

**100% Juice**, 4 – 6 ounce servings, 1 –2 times / day

**Coffee & Hot Tea**, use sugar substitute & fat free creamer

**Limit or avoid alcohol:**

Can of beer = 150 calories

Glass of wine = 75 calories

Shot of liquor = 100 calories



## EATING AT HOME

Never eat out of boxes, cartons, or bags!!!

If one cookie is eaten out of the package, more will follow until too many are eaten at a single sitting.

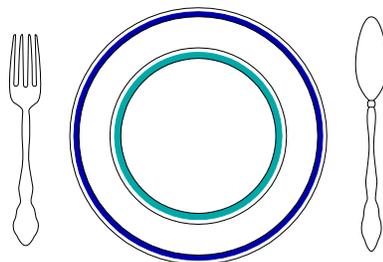
Put food on a plate or in a bowl. You can usually see how much you are eating.

Eat on smaller plates at dinnertime. The plate will look full with less food.

When eating at home, do not watch television or talk on the phone. This is a routine that can add extra calories to your meal plan. Often this is only a *habit* rather than actual hunger.

Always sit at the table to eat. Don't eat on the run; take time to enjoy the meal!

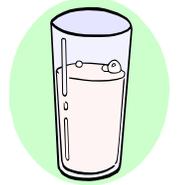
Add a salad before the main course and use a low-fat or fat-free dressing. You can also use balsamic vinegar mixed with herbs for a tasty dressing.



To add volume to your meal, without adding lots of extra calories, add several vegetables without fattening sauces. Use herbs to season and have several portions of vegetables like broccoli, carrots, cauliflower, or green beans.



If you feel hungry when eating less food, try drinking a large glass of water before the meal, and continue to drink water during the meal. This will help fill your stomach and make you feel full and satisfied.

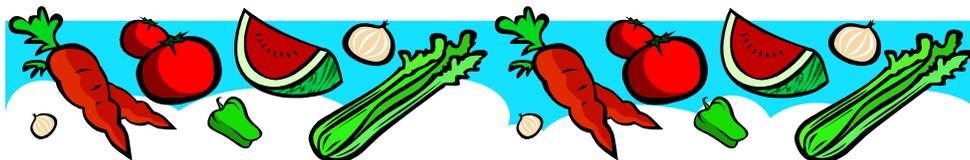


When craving foods at odd times, try to wait 15 minutes before snacking or take a short walk or work on a craft/project requiring both hands.

Hot soups made from low fat broths or vegetables such as tomato can make you feel full and eat less food at mealtime. Avoid cream soups and those with fats such as cheese.



**Eat several meals a day!**  
**Do not starve all day!**  
**Do not overeat at night or when alone!**



Endorsed by: VA National Center for Health Promotion & Disease Prevention

# The Basics of Weight Loss When You're Ready

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**When you are ready to lose weight, here's how to get started:**

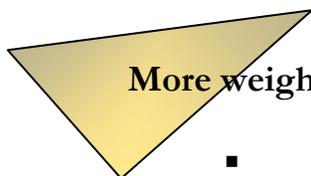
**Keep track of your journey.** Weigh yourself once each week and write it down. Keep track of everything you eat and drink for week. What about your feelings? Write those down too!



**Set realistic and specific goals.** ½ to 2 pounds each week of weight loss is reasonable- slower is fine too. Remind yourself daily of why you want to lose weight. Reward yourself when you reach short- term goals. Write down the specific changes you are making. For example: “I will eat ice cream once a week instead of everyday.”

**Decrease the calories you eat.** Find the extra calories in your diet and cut back on them. Skip high calorie snacks like chips, cheese, and cookies. Snack on vegetables instead. Skip soda or juice drinks and drink water instead. Cut back on high calorie foods at meals such as meat or cheesy casseroles- add more vegetables. Go easy on fast foods- eat food from home. Be consistent and you'll see results.

**Increase the calories you use.** Add extra activity to your day, most days of the week. Check with your provider about starting an exercise program. Keep track of your activity each day- write it down!



## More weight loss tips:

- Eat regularly – don't skip meals.
- Drink 6-8 cups of water each day.
- Increase activity a bit each day.
- Get support from family and friends.
- If you splurge don't give up.
- If you need help, ask your dietician.



# RECIPE MODIFICATION TIPS

**Try these tips when you prepare your favorite recipes. By using the suggested substitutes, you will reduce fat, cholesterol, sugar, and calories in all your recipes!**

1. Choose lean cuts of meat and trim off all visible fat. Remove skin from poultry.
2. Bake, broil, boil, grill, roast, or stir-fry meats. When pan-frying, use a non-stick pan or non-stick spray. For added moistness, use water or low salt broth.
3. Cook vegetables in a small amount of seasoned water or low salt broth.
4. For soups, stews, sauces and broth: Refrigerate and skim fat from top.
5. Whenever possible, choose low fat or nonfat versions of your favorite dressings, cheeses, dips, and sauces.
6. When buttering breads, muffins, and vegetables, dip a pastry brush in oil or melted margarine and lightly coat food so you will use less.

## FOR:

## SUBSTITUTE:

1 Egg

1/4 cup Egg Substitute or 2 Egg Whites

Heavy Cream

Evaporated Skim or Low Fat Milk

Whipped Cream

Low calorie Whipped Topping

Whole Milk

Skim or 1% Milk

Cream Cheese

Neufchatel (or "Lite") Cream Cheese,  
Fat Free Cream Cheese

FOR:

SUBSTITUTE:

Creamed Cottage Cheese (4% Fat)	Low Fat or Nonfat Cottage Cheese
Cheese	Low Fat, Fat Free, or Skim Milk Cheese
Sour Cream	Low Fat Yogurt, Lite or Fat Free Sour Cream
Nondairy Creamer	Skim Milk Powder
Butter	Margarine made with liquid Vegetable Oil, Diet Margarine
Salad Dressing	Lite or Fat Free Dressing, Yogurt mixed with Mustard, Lemon, Herbs, and Spices
Mayonnaise	Fat Free or Lite Mayonnaise, Nonfat Yogurt
1 cup Shortening	2/3 cup Vegetable Oil
1 cup Oil	1 cup Applesauce (good in baked products)
1oz Unsweetened Baking Chocolate	3 tbsp cocoa powder
Sugar	Reduce amount of sugar in a recipe by 1/4 or 1/2 or use a sugar substitute (follow package directions)
Jello	Unflavored Gelatin, sugar-free Jello

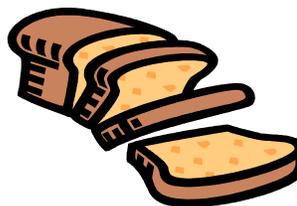
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**Nutrition and Food Service**  
**02/03**



## TIPS ON REDUCING CALORIES WHEN EATING OUT

Eating out can be easy, even while you're trying to lose weight. It can still be delicious and satisfying if you keep a few things in mind to avoid **EXCESS** fat and calories.

- ❖ Eat meals slowly. Savor what you are eating.
- ❖ Avoid extra gravies, sauces, and sugar. All of these will add extra calories.
- ❖ Ask for salad dressing to be placed “on the side.” Dip your fork in the dressing, then take a bit of salad. You’ll have dressing with every bit **AND** you will use  $\frac{1}{4}$  to  $\frac{1}{3}$  less dressing!
- ❖ Choose water, club soda, iced tea, coffee (without sugar), or diet soda instead of regular sodas or alcoholic beverages.
- ❖ Skip appetizers and hors d’oeuvres.
- ❖ Choose raw vegetables, fruit salads, or tossed salads with diet dressing as the first course.
- ❖ For entrées, choose lean meats such as broiled or grilled fish or poultry. Trim any visible fat or skin.



- ❖ If rolls or bread sticks or bread are served, pass them by if you want to have rice or potatoes with your entrée.

~ OR ~

- ❖ Ask for a second vegetable instead of the rice or potato so you can eat the rolls, bread sticks, or bread.
- ❖ Eat reasonable portions. Ask for a “doggie bag” when you order, so you can take away excess portions right away; then enjoy the normal portions you’ve created and take the “doggie bag” home for another meal.
- ❖ Avoid desserts or choose fresh fruit, sorbet, or sherbet instead.
- ❖ Be realistic – use a trade- off system. If you have to, have a drink but skip dessert.
- ❖ If you do overindulge, forget the guilt. Don’t go off the diet just because of one meal. Lighten up the next day and stay with it! The choice for good health is up to you.



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## RESTAURANT TIPS



Eat slowly and drink plenty of water with your meal. Take plenty of time to savor the food's flavor. Enjoy yourself!

Ask if meats can be “broiled dry,” without the added butter, oil, and other sauces.

Try to avoid fried selections; if you really want fried foods, remove the batter coating.

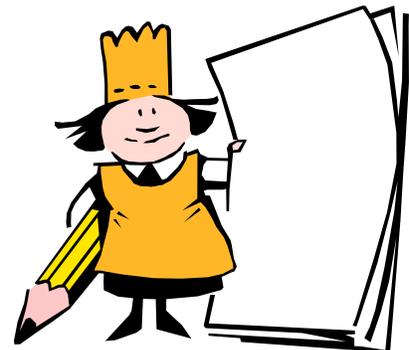
Look for choices that are roasted, poached, steamed, baked, and grilled rather than sautéed, deep- fried, or pan- fried.

For sautéed foods, choose spices, wine, and lemon juice rather than oil or butter.

Ask for salad dressing on the side with your salad order. Pick a tossed or garden salad rather than a creamy coleslaw or marinated vegetables in oil or butter.

Limit bread to 1-2 slices and try to avoid adding butter or margarine. Choose baked bread, rolls, and saltine crackers instead of croissants, biscuits, and cornbread.

Order rice or a baked potato with toppings on the side rather than French fries, stuffed potatoes, or hush puppies.



Order clear broth soups such as bouillon, vegetable, or wonton soups. Avoid cream soups such as cream of broccoli, Wisconsin cheese soup, clam chowder, or oyster bisque. Order French onion soup without the cheese on top or remove it at the table.



Select skinless chicken and lean cuts of beef and pork such as tenderloin, London broil, or filet mignon. Avoid ribs, prime rib, and other marbled meats. Ask the waiter to have your meats trimmed prior to cooking, if possible.

Eat seafood such as broiled or boiled shrimp with cocktail sauce instead of butter and tarter sauce.

Eat only a portion of the meat entrée; you may take the rest home for another meal. If you order a 12-ounce steak, eat only a third of it and bag the rest.

Try to avoid food covered with cheeses, cream or white sauce, and gravy. A “light” cream sauce may refer to its light color, not calorie content. When in doubt, **Ask**.

If you eat dessert, select a fresh fruit cup, small dish of ice cream, or sherbet, or angel food cake, if possible.

Cheesecake, pecan, and fruit pies, frosted cakes and brownies are loaded with calories. Share these desserts with someone else. Most waiters will gladly bring an extra plate and fork to the table.

Finally, when in doubt about a food’s preparation method or hidden fat calories, ask. The restaurant staff are there to serve you, so don’t hesitate to ask for substitutions and special preparation. Many restaurants will be glad to accommodate your request.





# WALKING FOR WELLNESS



Improving your health can be done by simply walking. Conditioning your heart and lungs with low intensity walking provides short and long term benefits. It can help lower your risk of heart disease by reducing high blood cholesterol, high blood pressure, high blood sugar, and even help you shed a few extra pounds. Regular physical activity such as walking gives you more energy, tones your muscles, burns off extra calories, helps to control your appetite, and makes you feel and look better. Beginning a walking program is a positive step toward taking control of your health and helping to prevent disease.

## HELPFUL HINTS TO START A WALKING PROGRAM

1. Make walking a habit. Try to walk 3 to 6 times per week, start as low as 5 minutes and gradually work up to 20 to 40 minutes.
  - Set up a specific time to walk during the day to establish a routine.
  - Keep a record of how far and how long you walk so that you keep improving.
  - Set goals to continue to exercise and reward yourself with non- food items.
2. Build flexibility and strength in your muscles.
  - Warm- up muscles to prevent injury by walking slowly for about 5 minutes.
  - Cool down after walking by allowing about 5 minutes of slow walking to bring down your heart rate to resting.

3. Make sure to have good form to prevent injury.
  - Don't slouch! Keep your back straight with your stomach slightly contracted.
  - Establish a walking rhythm that is comfortable for you.
  - Keep arm motion natural with your arms bent at right angles.
4. Increase speed, distance, and/or time.
  - Pace yourself, don't over exert yourself. You should be able to walk and talk at the same time.
  - If you feel you overdid it (soreness or excess fatigue), you may take a day off from walking. But remember to resume as soon as the soreness is tolerable!
  - Set goals to walk longer and faster than the day before.
5. Plan for variety in a walking plan.
  - Change speed and how long you walk from day to day.
  - A change of scenery will add variety to your workout. Walk at the mall, a store, or a park.
  - Have a friend walk with you to make it more fun.
6. Always consult with your physician before initiating any exercise program.

## ***Digesting the Food Label***

### *A Guide to Understanding Food Label Information*

<b>Whole Milk</b>	
Serving Size 8 fl oz (240mL)	
Servings Per Container 2	
Amount Per Serving	
<b>Calories 150</b>	<b>Calories from Fat 70</b>
% Daily Value*	
<b>Total Fat 8g</b>	<b>12%</b>
Saturated Fat 5g	25%
<b>Cholesterol 35mg</b>	<b>12%</b>
<b>Sodium 125mg</b>	<b>5%</b>
<b>Total Carbohydrate 12g</b>	<b>4%</b>
Dietary Fiber 0g	0%
Sugars 11g	
<b>Protein 8g</b>	
Vitamin A 6%	Vitamin C 4%
Calcium 30%	Iron 0%
	Vitamin D 25%
* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.	
	Calories: 2,000    2,500
Total Fat	Less than 65g    80g
Sat Fat	Less than 20g    25g
Cholesterol	Less than 300mg    300mg
Sodium	Less than 2,400mg    2,400mg
Total Carbohydrate	300g    375g
Dietary Fiber	25g    30g

**Serving Size:** All label information pertains to this amount of food.

**Calories:** Total amount of food energy present in the designated serving size.

**Calories from Fat:** Amount of total calories that come from fat. Try to keep below 30% of total calories. 1 gram of fat = 9 calories. Multiply #fat grams by 9 to get calories from fat.

**Total Fat:** Total amount of fat grams per serving.

**%Daily Value from Fat:** Foods that are less than 5% are usually low-fat choices.

**Saturated Fat:** Amount of saturated fat (cholesterol-raising fat) within the total fat grams. Keep intake to less than 10% of total daily calories.

**Cholesterol:** Mostly found in animal products. Keep intake to less than 300 mg/day.

**Sodium:** Implicated in high blood pressure. Keep intake below 2,400 mg/day. Any product over 450 mg is considered a high-sodium food.

**Total Carbohydrate:** Provides energy. 60% of your total daily calories should come from carbohydrates. Try eating complex carbohydrates such as whole grains, fruit and vegetables. 1 gram = 4 calories.

**Dietary Fiber:** Important for digestive health. Consume between 25-35 grams daily.

**Sugar:** Keep intake as low as possible. Purchase cereals with less than 6 grams per serving.

**Protein:** Needed for muscle repair. 15% of calories should come from protein. 1 gram = 4 calories

<b>Skim Milk</b>	
Serving Size 8 fl oz (240mL)	
Servings Per Container 2	
Amount Per Serving	
<b>Calories 80</b>	<b>Calories from Fat 0</b>
% Daily Value*	
<b>Total Fat 0g</b>	<b>0%</b>
Saturated Fat 0g	0%
<b>Cholesterol less than 5mg</b>	<b>1%</b>
<b>Sodium 130mg</b>	<b>5%</b>
<b>Total Carbohydrate 12g</b>	<b>4%</b>
Dietary Fiber 0g	0%
Sugars 11g	
<b>Protein 8g</b>	
Vitamin A 8%	Vitamin C 4%
Calcium 30%	Iron 0%
	Vitamin D 25%
* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.	
	Calories: 2,000    2,500
Total Fat	Less than 65g    80g
Sat Fat	Less than 20g    25g
Cholesterol	Less than 300mg    300mg
Sodium	Less than 2,400mg    2,400mg
Total Carbohydrate	300g    375g
Dietary Fiber	25g    30g

### ***Product A***

### ***Product B***

***Food Label Quiz:***

1. Which product contains more saturated fat?     A     B
2. Which product contains more cholesterol?     A     B
3. Which product would help to reduce dietary fat?     A     B

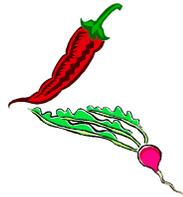




**LOW CALORIE SNACK SUGGESTIONS**

**“Free” Foods (less than 20 calories)**

Bouillon  
 Broth without fat  
 Cabbage (1 cup raw)  
 Carbonated water  
 Catsup (1 tbsp.)  
 Celery  
 Club soda  
 Coffee  
 Cucumber (1 cup)  
 Diet punch/lemonade  
 Diet soft drinks  
 Endive  
 Escarole  
 Fat free mayonnaise  
 Fat free salad dressing  
 Green onion  
 Horseradish  
 Hot peppers (1)  
 Lemon juice or vinegar  
 Lettuce (2 cups)  
 Low calorie whipped topping  
 Low salt seasonings/herbs  
 Molly McButter/Butter Buds  
 Mushrooms (1 cup raw)  
 Mustard  
 Radishes  
 Spinach (1½ cups raw)  
 Sugar free hard candy/gum  
 Sugar free jam/jelly (2 tsp.)  
 Sugar free Jell-O  
 Sugar free pancake syrup  
 Sugar free popsicles  
 Sugar substitutes  
 Taco sauce (1 tbsp.)  
 Tea  
 Unsweetened cocoa powder  
 Zucchini (1 cup raw)



**25-30 Calories**

1 cup raw vegetables  
 1/2 cup cooked vegetables  
 1/2 cup crisp or puffed cereal (unsweetened)  
 1/2 cup vegetable juice  
 1 cup plain air popped popcorn  
 12 goldfish crackers  
 2 slices melba toast



**50-60 Calories**

1 cup sugar free hot cocoa  
 1 cup “lite” microwave popcorn  
 1 oz. 95% fat free lunch meat  
 1 slice low calorie bread  
 1 small piece fresh fruit  
 1/2 banana  
 1/2 cup skim or 1% milk  
 1/2 cup unsweetened juice  
 1/2 plain baked potato  
 1/4 cup low fat cottage cheese  
 1/4 cup tuna packed in water  
 15 small grapes  
 2 gingersnaps  
 2 graham cracker squares  
 2 peach/pear halves (packed in own juice)  
 2 tbsp. raisins  
 3 dried prunes  
 3 triscuit crackers  
 3 vanilla wafers  
 4 saltines  
 6 wheat thin crackers



**80-100 Calories**

1 chicken drumstick (no skin)  
 1 cup broth-base soup  
 1 hard cooked egg  
 1 low fat granola bar  
 1 slice bread  
 1 slice low fat cheese  
 1 slice low fat or diet cheese  
 1 slice mozzarella cheese  
 1/2 bagel  
 1/2 cup low fat vanilla yogurt  
 1/2 cup sugar free pudding  
 1/2 English muffin  
 1/3 cup low fat frozen yogurt  
 1/4 cup sherbet  
 3/4 oz. pretzels



**ASK YOUR DIETITIAN ABOUT THE NUMBER OF TOTAL CALORIES THAT YOU NEED**

Nutrition & Food Service  
 SAVAHCS, Tucson, AZ  
 (6/04)

**Appendix I.**

**Visit Documentation Form**

**Does Step Count Feedback Enhance Nutritional Counseling for Weight Loss?**  
**Visit Documentation Form**

Site (circle one): Memphis Miami Oklahoma San Diego Topeka Tucson  
 Dietitian \_\_\_\_\_ Date \_\_\_\_\_ Randomization ID \_\_\_\_\_ Visit Number 2 3 4 5 6

Problems With Visit? No Yes \_\_\_\_\_  
 Weight: \_\_\_\_\_ Shoes Off? Yes No Height \_\_\_\_\_ BMI \_\_\_\_\_ Hx of HTN? Yes No  
 Was this visit audio taped? Yes No History of DM? Yes No If Yes, dispensed "Walking Safely with Diabetes" Yes No

**Physical Activity Counseling:**

Any new symptoms, chest pain / light-headedness during walking? No Yes \_\_\_\_\_  
 If yes, report to site PI, complete today's visit, participant suspended, no walking until medical clearance. Fax AE form to Ann Arbor.  
 Units (circle one): a) Minutes b) Digiwalker Steps c) Sportbrain Steps

	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Day of Wk							Yesterday
Date							
Walking							
Problems							

Total For Week \_\_\_\_\_ Daily Average \_\_\_\_\_ (if steps: +10% \_\_\_\_\_ +25% \_\_\_\_\_)  
 (if minutes: +5 min +10min)

Set new walking Goals: \_\_\_\_\_  
 \_\_\_\_\_

Planning Ahead for Walking: \_\_\_\_\_  
 \_\_\_\_\_

Comments or Problems: \_\_\_\_\_  
 Total time spent counseling about physical activity \_\_\_\_\_ minutes.

Walk to Wellness Handout used today? Y N

**Does Step Count Feedback Enhance Nutritional Counseling for Weight Loss?**  
**Visit Documentation Form**

Site (circle one): Memphis Miami Oklahoma San Diego Topeka Tucson  
 Dietitian \_\_\_\_\_ Date \_\_\_\_\_ Randomization ID \_\_\_\_\_

Visit Number 2 3 4 5 6

**Nutritional Counseling:** DIET GOALS ONLY. Exercise and walking goals should be recorded in previous section.

Dietary Stages of Change Form (circle one) Completed Today Updated Today Not Reviewed Today

Problems With SOCF ? \_\_\_\_\_

Goal	New?	Goal	Current Stage	Barriers / How and When / Successes
<b>1</b>	Review New		PC C P A M SOCF # _____	
<b>2</b>	Review New		PC C P A M SOCF # _____	
<b>3</b>	Review New		PC C P A M SOCF # _____	
<b>4</b>	Review New		PC C P A M SOCF # _____	
<b>5</b>	Review New		PC C P A M SOCF # _____	

Handouts discussed or given to participant during this visit (check all that were used):

<input type="checkbox"/> Suggested Behavior Changes	<input type="checkbox"/> Digesting the Food Label	<input type="checkbox"/> Restaurant Tips
<input type="checkbox"/> 20 Ways to Think THIN	<input type="checkbox"/> Eating at Home	<input type="checkbox"/> Low Calorie Snacks
<input type="checkbox"/> How Much Should I Eat?	<input type="checkbox"/> The Basics of Weight Loss	<input type="checkbox"/> Food Record
<input type="checkbox"/> How to Avoid Portion Distortion	<input type="checkbox"/> Recipe Modification Tips	
<input type="checkbox"/> Liquid Calories	<input type="checkbox"/> Tips on Reducing Kcals /Eating Out	<input type="checkbox"/> Other _____ (attach copy)

Total time spent counseling about diet and nutrition: \_\_\_\_\_ Minutes

**Appendix J.**  
**Patient Survey**

Enrollment ID# \_\_\_\_\_ 1

Date Completed (mm/dd/yyyy): \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

# VETERANS WALK FOR HEALTH



Dear Participant,

Thank you for agreeing to participate in this walking and nutrition study.

If you have questions or would like the study coordinator to read the questions to you, please don't hesitate to ask. This survey should take approximately 20 – 30 minutes to complete.

If we publish results from the study, your individual responses will not be published, nor will your name be revealed. However, if you feel uncomfortable answering any of the questions, even knowing that your name will not be revealed, please skip those questions.

Thank you for your help with this important study.

Sincerely,

# HEALTH STATUS

---

**Instructions:** The following items ask for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Please answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

H1. In general, would you say your health is:

- |                |   |                     |
|----------------|---|---------------------|
| Excellent..... | 1 |                     |
| Very good..... | 2 |                     |
| Good.....      | 3 | (Circle one number) |
| Fair.....      | 4 |                     |
| Poor.....      | 5 |                     |

H2. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

(Circle 1, 2, or 3 on each line)

	Yes Limited <u>A Lot</u>	Yes, Limited <u>A Little</u>	No, Not Limited <u>At All</u>
a. <b>Moderate activities</b> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.....	1	2	3
b. Climbing <b>several</b> flights of stairs.....	1	2	3

H3. During the **PAST 4 WEEKS**, have you had any of the following problems with your work or other regular daily activities **as a result of your PHYSICAL HEALTH?**

(Please answer YES or NO for each question by circling 1 or 2 on each line.)

	Yes	No
a. <b>Accomplished less</b> than you would like .....	1	2
b. Were limited in the <b>kind</b> of work or other activities .....	1	2

H4. During the **PAST 4 WEEKS**, have you had any of the following problems with your work or other regular daily activities **as a result of any EMOTIONAL PROBLEMS** (such as feeling depressed or anxious)?

(Please answer YES or NO for each question by circling 1 or 2 on each line.)

	Yes	No
a. <b>Accomplished less</b> than you would like .....	1	2
b. Did work or other activities <b>less carefully than usual</b> .....	1	2

H5. During the **PAST 4 WEEKS**, how much did **PAIN** interfere with your normal work (including both work outside the home and housework)?

Not at all.....	1	
A little bit .....	2	
Moderately .....	3	(Circle one number)
Quite a bit.....	4	
Extremely .....	5	

H6. These questions are about how you feel and how things have been with you during the **PAST 4 WEEKS**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

(Circle one number on each line)

	All of the <u>Time</u>	Most of the <u>Time</u>	Some of the <u>Time</u>	A Little of the <u>Time</u>	None of the <u>Time</u>
a. Have you felt calm and peaceful?.....	1	2	3	4	5
b. Did you have a lot of energy? .....	1	2	3	4	5
c. Have you felt downhearted and blue? .....	1	2	3	4	5

H7. During the **PAST 4 WEEKS**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

- All of the time..... 1
- Most of the time ..... 2
- Some of the time..... 3
- A little of the time..... 4
- None of the time..... 5

(Circle one number)

## STAGES OF CHANGE

---

Check the box that describes how you feel about each statement. Please be **very honest** about your responses so we can better serve you. If a statement does not apply to you or you do not understand it, skip it and go to the next question. Please choose one answer only for each question, and place an X in the appropriate box.

### How do you feel about the following.....?

	This has not crossed my mind.	I should be doing this, but do not.	I am ready to do this.	I do this, but not regularly.	I always do this.
C1. Avoiding junk food	1	2	3	4	5
C2. Making healthier food selections when eating out	1	2	3	4	5
C3. Eating at least 5 servings of fruits and vegetables daily	1	2	3	4	5
C4. Removing tempting snack foods from your environment	1	2	3	4	5
C5. Eating only when you are hungry	1	2	3	4	5
C6. Exercising regularly 3 or more times per week	1	2	3	4	5
C7. Limiting snacking in the evening	1	2	3	4	5
C8. Eating smaller portion sizes	1	2	3	4	5
C9. Writing down what you are eating daily	1	2	3	4	5
C10. Attending weekly weight loss classes	1	2	3	4	5
C11. Eating meals at regular times	1	2	3	4	5

## How do you feel about the following.....?

	<b>This has not crossed my mind.</b>	<b>I should be doing this, but do not.</b>	<b>I am ready to do this.</b>	<b>I do this, but not regularly.</b>	<b>I always do this.</b>
C12. Having salad dressings on the side	1	2	3	4	5
C13. Limiting the number of fast food meals you eat per week	1	2	3	4	5
C14. Keeping track of the number of servings you eat using the Food Guide Pyramid	1	2	3	4	5
C15. Preparing healthy meals to help you lose weight	1	2	3	4	5
C16. Resisting the desire to eat when you are bored	1	2	3	4	5
C17. Reading food labels in order to make healthier food choices	1	2	3	4	5
C18. Switching to low fat frozen desserts	1	2	3	4	5
C19. Cutting down your intake of pastries (donuts, danishes, cookies, cake, etc.)	1	2	3	4	5
C20. Decreasing your intake of high fat deli meats (salami, sausage, bologna)	1	2	3	4	5
C21. Reducing your intake of regular soda	1	2	3	4	5
C22. Switching to a lower fat milk	1	2	3	4	5
C23. Using regular mayonnaise less often	1	2	3	4	5

## How do you feel about the following.....?

	This has not crossed my mind.	I should be doing this, but do not.	I am ready to do this.	I do this, but not regularly.	I always do this.
C24. Cutting back on your use of fats (oil, butter, margarine, etc.)	1	2	3	4	5
C25. Using a low fat salad dressing.	1	2	3	4	5
C26. Participating in a supervised exercise program	1	2	3	4	5
C27. Incorporating more low fat foods in your diet	1	2	3	4	5
C28. Cutting down your intake of candy.	1	2	3	4	5
C29. Limiting your intake of ice cream.	1	2	3	4	5
C30. Limiting meat to 6 ounces per day	1	2	3	4	5
C31. Cooking with broth in place of oil	1	2	3	4	5
C32. Managing stressful situations without turning to food for comfort	1	2	3	4	5
C33. Limiting your intake when eating at buffets	1	2	3	4	5
C34. Avoiding "Super-sized" options at fast-food restaurants	1	2	3	4	5
C35. Balancing food intake throughout the day	1	2	3	4	5
C36. Baking or broiling instead of frying	1	2	3	4	5
C37. Counting calories to lose weight	1	2	3	4	5

## How do you feel about the following.....?

	This has not crossed my mind.	I should be doing this, but do not.	I am ready to do this.	I do this, but not regularly.	I always do this.
C38. Limiting intake of cream-based soups	1	2	3	4	5
C39. Involving those close to you to support your weight loss effort	1	2	3	4	5
C40. Making healthier snack choices	1	2	3	4	5
C41. Using nonfat cooking spray when sautéing or pan-frying	1	2	3	4	5
C42. Limiting your intake of fried foods (French fries, onion rings, etc.)	1	2	3	4	5

# PHYSICAL ACTIVITY

---

Physical activity or exercise includes activities such as walking briskly, jogging, bicycling, swimming, or any other activity in which the exertion is at least as intense as a brisk walk.

Please answer every question by marking the answer that indicates how confident you are that you could be physically active in each of the following situations.

E1. I can be physically active even when I am tired.

- Not at all Confident .....1
- Slightly Confident .....2
- Moderately Confident .....3           (Circle one number)
- Quite a bit Confident .....4
- Extremely Confident .....5

E2. I can be physically active even when I am in a bad mood.

- Not at all Confident .....1
- Slightly Confident .....2
- Moderately Confident .....3           (Circle one number)
- Quite a bit Confident .....4
- Extremely Confident .....5

E3. I can be physically active even when I feel I don't have time.

Not at all Confident .....1

Slightly Confident .....2

Moderately Confident .....3 (Circle one number)

Quite a bit Confident .....4

Extremely Confident .....5

E4. I can be physically active even when it is raining or snowing.

Not at all Confident .....1

Slightly Confident .....2

Moderately Confident .....3 (Circle one number)

Quite a bit Confident .....4

Extremely Confident .....5

# LEISURE TIME ACTIVITY

---

Please answer the questions below by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

P1. Over the **past 7 days**, how often did you participate in sitting activities such as reading, watching TV, or doing handcrafts?

<b>Never</b> <span style="float: right;">1</span>	<b>Seldom</b> <span style="float: right;">2</span> (1 - 2 Days)	<b>Sometimes</b> <span style="float: right;">3</span> (3 - 4 Days)	<b>Often</b> <span style="float: right;">4</span> (5 – 7 Days)
---	--	---	---



Go to Question P2.



**P1a. What were these activities?**

\_\_\_\_\_

**P1b. On average, how many hours per day did you engage in these sitting activities?**

Less than 1 Hour .....1

1 But Less Than 2 Hours .....2 (Circle one answer)

2 – 4 Hours .....3

More than 4 Hours .....4

P2. Over the **past 7 days**, how often did you take a walk outside your home or yard for any reason? For example, for fun or exercise, walking to work, walking the dog, etc.?

<b>Never</b>	1	<b>Seldom</b>	2	<b>Sometimes</b>	3	<b>Often</b>	4
		(1 - 2 Days)		(3 - 4 Days)		(5 - 7 Days)	



Go to Question P3.



**P2a. On average, how many hours per day did you spend walking?**

**Less than 1 Hour .....1**

**1 But Less Than 2 Hours .....2 (Circle one answer)**

**2 - 4 Hours .....3**

**More than 4 Hours .....4**

P3. Over the **past 7 days**, how often did you engage in light sport or recreational activities, such as bowling, golf with a cart, shuffleboard, fishing from a boat or pier or other similar activities?

<b>Never</b>	1	<b>Seldom</b>	2	<b>Sometimes</b>	3	<b>Often</b>	4
		<b>(1 - 2 Days)</b>		<b>(3 - 4 Days)</b>		<b>(5 - 7 Days)</b>	



Go to Question P4.



**P3a. What were these activities?**

\_\_\_\_\_

**P3b. On average, how many hours per day did you engage in these light sport or recreational activities?**

**Less than 1 Hour .....1**

**1 But Less Than 2 Hours .....2 (Circle one answer)**

**2 - 4 Hours .....3**

**More than 4 Hours .....4**

P4. Over the **past 7 days**, how often did you engage in moderate sport or recreational activities, such as double tennis, ballroom dancing, hunting, ice skating, golf without a cart, softball or other similar activities?

<b>Never</b>	1	<b>Seldom</b>	2	<b>Sometimes</b>	3	<b>Often</b>	4
		(1 - 2 Days)		(3 - 4 Days)		(5 - 7 Days)	



Go to Question P5.



**P4a. What were these activities?**

\_\_\_\_\_

**P4b. On average, how many hours per day did you engage in these moderate sport or recreational activities?**

Less than 1 Hour .....1

1 But Less Than 2 Hours .....2 (Circle one answer)

2 - 4 Hours .....3

More than 4 Hours .....4

P5. Over the **past 7 days**, how often did you engage in strenuous sport or recreational activities, such as jogging, swimming, cycling, singles tennis, aerobic dance, skiing (downhill or cross- country) or other similar activities?

<b>Never</b> 1	<b>Seldom</b> 2 (1 - 2 Days)	<b>Sometimes</b> 3 (3 - 4 Days)	<b>Often</b> 4 (5 - 7 Days)
----------------	---------------------------------	------------------------------------	--------------------------------



Go to Question P6.



**P5a. What were these activities?**

\_\_\_\_\_

**P5b. On average, how many hours per day did you engage in these strenuous sport or recreational activities?**

**Less than 1 Hour .....1**

**1 But Less Than 2 Hours .....2 (Circle one answer)**

**2 - 4 Hours .....3**

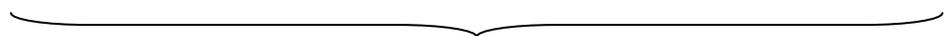
**More than 4 Hours .....4**

P6. Over the **past 7 days**, how often did you do any exercises specifically to increase muscle strength and endurance, such as lifting weights or pushups, etc?

<b>Never</b> 1	<b>Seldom</b> 2 (1 - 2 Days)	<b>Sometimes</b> 3 (3 - 4 Days)	<b>Often</b> 4 (5 - 7 Days)
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Go to Question P7.



**P6a. What were these activities?**

\_\_\_\_\_

**P6b. On average, how many hours per day did you engage in exercises to increase muscle strength and endurance?**

**Less than 1 Hour .....1**

**1 But Less Than 2 Hours .....2 (Circle one answer)**

**2 - 4 Hours .....3**

**More than 4 Hours .....4**

# HOUSEHOLD ACTIVITY

---

P7. During the **past 7 days**, have you done any light housework, such as dusting or washing dishes?

No .....1

Yes .....2

(Circle one number)

P8. During the **past 7 days**, have you done any heavy housework or chores, such as vacuuming, scrubbing floors, washing windows, or carrying wood?

No .....1

Yes .....2

(Circle one number)



You're more than halfway there!!

Keep up the good work!!

P9. During the **past 7 days**, did you engage in any of the following activities?

Please answer **YES** or **NO** for each item.

		<b><u>NO</u></b>	<b><u>YES</u></b>
<b>P9a.</b>	Home repairs like painting, wallpapering, electrical work, etc.	1	2
<b>P9b.</b>	Lawn work or yard care, including snow or leaf removal, wood chopping, etc.	1	2
<b>P9c.</b>	Outdoor gardening	1	2
<b>P9d.</b>	Caring for another person, such as children, dependent spouse, or another adult	1	2

# WORK-RELATED ACTIVITY

---

P10. During the **past 7 days**, did you work for pay or as a volunteer?

<b>NO</b>	1	<b>YES</b>	2
-----------	---	------------	---



Go to Question D1.

**P10a. How many hours per week did you work for pay and/or as a volunteer?**

\_\_\_\_\_ **HOURS**

**P10b. Which of the following categories best describes the amount of physical activity required on your job and/or volunteer work?**

Mainly sitting with slight arm movements.  
[**Examples:** office worker, watchmaker, seated assembly line worker, bus driver, etc.] 1

Sitting or standing with some walking.  
[**Examples:** cashier, general office worker, light tool and machinery worker.] 2

Walking, with some handling of materials generally weighing less than 50 pounds.  
[**Examples:** mailman, waiter/ waitress, construction worker, heavy tool and machinery worker.] 3

Walking and heavy manual work often requiring handling of materials weighing over 50 pounds.  
[**Examples:** lumberjack, stone mason, farmer or general laborer.] 4

## COMPUTER BACKGROUND

---

Please place an **X** in the box of the most appropriate response.

D1. How often do you use a computer in your home?

- [ 1 ] I **do not have a computer** in my home.
- [ 2 ] I have a computer in my home, but I **never** use it.
- [ 3 ] I use the computer in my home **less than once a month.**
- [ 4 ] I use the computer in my home **one to four times a month.**
- [ 5 ] I use the computer in my home **several times a week.**
- [ 6 ] I use the computer in my home **almost every day.**

D2. How often do you access the Internet from a home computer?

- [ 1 ] I **do not have Internet access** from a home computer.
- [ 2 ] I have Internet access in my home, but I **never** use it.
- [ 3 ] I use the Internet in my home **less than once a month.**
- [ 4 ] I use the Internet in my home **one to four times a month.**
- [ 5 ] I use the Internet in my home **several times a week.**
- [ 6 ] I use the Internet in my home **almost every day.**

D3. How often do you use a computer at work?

- [ 1 ] I do not currently work.
- [ 2 ] I **do not have a computer** at work.
- [ 3 ] I have a computer at work, but I **never** use it.
- [ 4 ] I use the computer at work **less than once a month.**
- [ 5 ] I use the computer at work **one to four times a month.**
- [ 6 ] I use the computer at work **several times a week.**
- [ 7 ] I use the computer at work **almost every day.**

D4. How often do you access the Internet from a work computer?

- [ 1 ] I **do not have Internet access** from a work computer.
- [ 2 ] I have Internet access at work, but I **never** use it.
- [ 3 ] I use the Internet at work **less than once a month.**
- [ 4 ] I use the Internet at work **one to four times a month.**
- [ 5 ] I use the Internet at work **several times a week.**
- [ 6 ] I use the Internet at work **almost every day.**

D5. Is there any other place that you use a computer with Internet access besides home or work?

- [ 1 ] **No.**
- [ 2 ] Yes, at the local public library.
- [ 3 ] Yes, at a friend or relative's house.
- [ 4 ] Yes, at \_\_\_\_\_

## OTHER INFORMATION ABOUT YOURSELF

---

Please place an **X** in the box of the most appropriate response.

D6. Do you currently have or have you ever had:

		YES	NO
D6a.	Angina or chest pain from heart disease	1	2
D6b.	Congestive Heart Failure	1	2
D6c.	Heart attack	1	2
D6d.	Parkinson's Disease	1	2
D6e.	Lung disease, emphysema, asthma or bronchitis	1	2
D6f.	Arthritis	1	2
D6g.	Osteoporosis or thin bones	1	2
D6h.	Depression, Anxiety, or an Emotional Problem	1	2
D6i.	Sleep problems such as insomnia or narcolepsy	1	2
D6j.	Chronic Pain	1	2
D6k.	A hip or knee joint replacement surgery	1	2
D6l.	Cancer other than skin cancer	1	2
D6m.	Diabetes	1	2
D6n.	Glaucoma	1	2
D6o.	Cataracts	1	2
D6p.	Stroke	1	2
D6q.	Hearing Problems	1	2
D6r.	High Blood Pressure	1	2
D6s.	High Cholesterol	1	2

D7. Do you have a health related disability that makes it difficult or impossible for you to work?

[ 1 ] **No.**

[ 2 ] Yes, Briefly describe the disability \_\_\_\_\_

D8. Do you currently smoke cigarettes?

[ 1 ] Yes, How many cigarettes a day? \_\_\_\_\_ packs or \_\_\_\_\_ cigarettes

[ 2 ] No, I am a former smoker. I quit \_\_\_\_\_ years ago.

[ 3 ] No, I have never smoked.

D9. What is your date of birth?

Month \_\_\_ \_\_\_ Day \_\_\_ \_\_\_ Year 1 9 \_\_\_ \_\_\_

D10. What is the highest level of formal education you have completed?

- [ 1 ] Less than 6<sup>th</sup> grade.
- [ 2 ] 6<sup>th</sup> grade to 11<sup>th</sup> grade.
- [ 3 ] High school graduate.
- [ 4 ] Some college
- [ 5 ] College graduate
- [ 6 ] Graduate school

D11. What was your total household income last year?  
Your household includes anyone in your family who lives with you.

- [ 1 ] Less than \$20,000
- [ 2 ] \$20,000 to \$40,000
- [ 3 ] \$40,000 to \$60,000
- [ 4 ] \$60,000 to \$80,000
- [ 5 ] \$80,000 to \$100,000
- [ 6 ] More than \$100,000

D12. What is your ethnicity?

- [ 1 ] Spanish, Hispanic, or Latino
- [ 2 ] **No**, not Spanish/Hispanic/Latino

D13. What is your race?

- [ 1 ] American Indian or Alaska Native
- [ 2 ] Asian
- [ 3 ] Black or African American
- [ 4 ] Native Hawaiian or Other Pacific Islander
- [ 5 ] White

**Thank you for completing this survey!**



All finished!!  
Thanks for your  
participation!!

# VETERANS WALK FOR HEALTH



Dear Participant,

Thank you for your participation in this walking and nutrition study.

If you have questions or would like the study coordinator to read the questions to you, please don't hesitate to ask. This survey should take approximately 10 – 20 minutes to complete.

If we publish results from the study, your individual responses will not be published, nor will your name be revealed. However, if you feel uncomfortable answering any of the questions, even knowing that your name will not be revealed, please skip those questions.

Thank you for your help with this important study.

Sincerely,

# **PARTICIPANT SATISFACTION**

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Please place an **X** in the box of the most appropriate response.

S1. When you had important questions to ask your dietitian, did you get answers you could understand?

- [ 1 ] Yes, always
- [ 2 ] Yes, sometimes
- [ 3 ] No
- [ 4 ] Didn't have questions

S2. Did you have confidence and trust in the dietitian treating you?

- [ 1 ] Yes, always
- [ 2 ] Yes, sometimes
- [ 3 ] No

S3. How would you rate the courtesy of your dietitian?

- [ 1 ] Poor
- [ 2 ] Fair
- [ 3 ] Good
- [ 4 ] Very Good
- [ 5 ] Excellent

S4. How would you rate the availability of your dietitian?

- [ 1 ] Poor
- [ 2 ] Fair
- [ 3 ] Good
- [ 4 ] Very good
- [ 5 ] Excellent

S5. Did you feel like you were treated with respect and dignity during your nutritional counseling sessions?

- [ 1 ] Yes, always
- [ 2 ] Yes, sometimes
- [ 3 ] No

S6. Did your dietitian explain recommended changes in your diet in a way you could understand?

- [ 1 ] Yes, completely
- [ 2 ] Yes, somewhat
- [ 3 ] No

S7. Did you have enough to say about your dietary treatment?

- [ 1 ] Yes, definitely
- [ 2 ] Yes, somewhat
- [ 3 ] No

S8. Did you find the nutritional counseling handouts helpful?

- [ 1 ] Yes, very helpful
- [ 2 ] Yes, somewhat helpful
- [ 3 ] No, not helpful
- [ 4 ] I did not get any nutritional counseling handouts.

S9. Did you feel that the nutritional counseling sessions helped you improve your diet?

- [ 1 ] Yes, helped a lot
- [ 2 ] Yes, helped somewhat
- [ 3 ] No

S10. Did your dietitian explain how to start a walking program in a way that you could understand?

- [ 1 ] Yes, completely
- [ 2 ] Yes, somewhat
- [ 3 ] No

S11. Did you have enough to say about your walking program including, setting walking goals?

- [ 1 ] Yes, definitely
- [ 2 ] Yes, somewhat
- [ 3 ] No

S12. Did you feel that the walking helped increase your overall level of physical activity?

- [ 1 ] Yes, helped a lot
- [ 2 ] Yes, helped somewhat
- [ 3 ] No

S13. Did anyone (family, friends, coworkers) who learned about your walking program start their own walking program?

- [ 1 ] Yes, several people – About how many? \_\_\_\_\_
- [ 2 ] Yes, at least one person
- [ 3 ] Not that I know of.

S14. Did you talk to a healthcare provider (a doctor or nurse) other than your dietitian about your walking program?

[ 1 ] No



Go to Question S15.

[ 2 ] Yes



<b><i>NAME OF PROVIDER</i></b>	<b><i>SPECIALTY</i></b>

**IF YOU DID NOT USE A PEDOMETER TO COUNT YOUR STEPS, SKIP TO QUESTION NUMBER S23 ON PAGE 9.**

S15. How comfortable was wearing the pedometer?

- [ 1 ] Very comfortable
- [ 2 ] Somewhat comfortable
- [ 3 ] Not comfortable

S16. Did you have trouble remembering to put the pedometer on in the morning?

- [ 1 ] Yes, often had trouble remembering
- [ 2 ] Yes, sometimes had trouble remembering
- [ 3 ] No

S17. Did you feel that the pedometer was accurately counting your steps throughout the day?

- [ 1 ] Yes, always
- [ 2 ] Yes, sometimes
- [ 3 ] No

S18. Did you have any problems using the pedometer?

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S19. What did you like most about using the pedometer?

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S20. How much money would you consider paying to continue using the pedometer for one more year?

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**IF YOU DID NOT USE A COMPUTER TO LOOK AT YOUR PEDOMETER RESULTS, SKIP TO QUESTION S23 BELOW.**

S21. How often did you upload your pedometer step- count data to a computer?

- [ 1 ] Almost every day or more often
- [ 2 ] A few times a week
- [ 3 ] Once a week
- [ 4 ] Less than once a week

S22. Did viewing your step- count data help you increase your walking?

- [ 1 ] Yes, helped a lot
- [ 2 ] Yes, helped somewhat
- [ 3 ] No

S23. How would you rate the overall quality of the nutritional counseling and walking program that you received as a part of this study?

- [ 1 ] Poor
- [ 2 ] Fair
- [ 3 ] Good
- [ 4 ] Very Good
- [ 5 ] Excellent

S24. Did you have any problems with or complaints about the nutritional counseling and walking program?

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S25. What was the thing you liked the most about the nutritional counseling and walking program?

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S26. If you could change one thing to improve the nutritional counseling and walking program, what would it be?

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**Thank you for completing this survey!**



All finished!!  
Thanks for your  
participation!!

# VETERANS WALK FOR HEALTH



Dear Participant,

Thank you for your participation in this walking and nutrition study.

If you have questions or would like the study coordinator to read the questions to you, please don't hesitate to ask. This survey should take approximately 20 – 30 minutes to complete.

If we publish results from the study, your individual responses will not be published, nor will your name be revealed. However, if you feel uncomfortable answering any of the questions, even knowing that your name will not be revealed, please skip those questions.

Thank you for your help with this important study.

Sincerely,

# HEALTH STATUS

---

**Instructions:** The following items ask for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Please answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

H1. In general, would you say your health is:

- |                |   |                     |
|----------------|---|---------------------|
| Excellent..... | 1 |                     |
| Very good..... | 2 |                     |
| Good.....      | 3 | (Circle one number) |
| Fair.....      | 4 |                     |
| Poor.....      | 5 |                     |

H2. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

(Circle 1, 2, or 3 on each line)

	Yes Limited <u>A Lot</u>	Yes, Limited <u>A Little</u>	No, Not Limited <u>At All</u>
a. <b>Moderate activities</b> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.....	1	2	3
b. Climbing <b>several</b> flights of stairs.....	1	2	3

H3. During the **PAST 4 WEEKS**, have you had any of the following problems with your work or other regular daily activities **as a result of your PHYSICAL HEALTH?**

(Please answer YES or NO for each question by circling 1 or 2 on each line.)

	Yes	No
a. <b>Accomplished less</b> than you would like .....	1	2
b. Were limited in the <b>kind</b> of work or other activities .....	1	2

H4. During the **PAST 4 WEEKS**, have you had any of the following problems with your work or other regular daily activities **as a result of any EMOTIONAL PROBLEMS** (such as feeling depressed or anxious)?

(Please answer YES or NO for each question by circling 1 or 2 on each line.)

	Yes	No
a. <b>Accomplished less</b> than you would like .....	1	2
b. Did work or other activities <b>less carefully than usual</b> .....	1	2

H5. During the **PAST 4 WEEKS**, how much did **PAIN** interfere with your normal work (including both work outside the home and housework)?

Not at all.....	1	
A little bit .....	2	
Moderately .....	3	(Circle one number)
Quite a bit.....	4	
Extremely .....	5	

H6. These questions are about how you feel and how things have been with you during the **PAST 4 WEEKS**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

(Circle one number on each line)

	All of the <u>Time</u>	Most of the <u>Time</u>	Some of the <u>Time</u>	A Little of the <u>Time</u>	None of the <u>Time</u>
a. Have you felt calm and peaceful?.....	1	2	3	4	5
b. Did you have a lot of energy? .....	1	2	3	4	5
c. Have you felt downhearted and blue? .....	1	2	3	4	5

H7. During the **PAST 4 WEEKS**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

- All of the time..... 1
- Most of the time ..... 2
- Some of the time..... 3
- A little of the time..... 4
- None of the time..... 5

(Circle one number)

## STAGES OF CHANGE

---

Check the box that describes how you feel about each statement. Please be **very honest** about your responses so we can better serve you. If a statement does not apply to you or you do not understand it, skip it and go to the next question. Please choose one answer only for each question, and place an X in the appropriate box.

**How do you feel about the following.....?**

	This has not crossed my mind.	I should be doing this, but do not.	I am ready to do this.	I do this, but not regularly.	I always do this.
C1. Avoiding junk food	1	2	3	4	5
C2. Making healthier food selections when eating out	1	2	3	4	5
C3. Eating at least 5 servings of fruits and vegetables daily	1	2	3	4	5
C4. Removing tempting snack foods from your environment	1	2	3	4	5
C5. Eating only when you are hungry	1	2	3	4	5
C6. Exercising regularly 3 or more times per week	1	2	3	4	5
C7. Limiting snacking in the evening	1	2	3	4	5
C8. Eating smaller portion sizes	1	2	3	4	5
C9. Writing down what you are eating daily	1	2	3	4	5
C10. Attending weekly weight loss classes	1	2	3	4	5
C11. Eating meals at regular times	1	2	3	4	5

## How do you feel about the following.....?

	<b>This has not crossed my mind.</b>	<b>I should be doing this, but do not.</b>	<b>I am ready to do this.</b>	<b>I do this, but not regularly.</b>	<b>I always do this.</b>
C12. Having salad dressings on the side	1	2	3	4	5
C13. Limiting the number of fast food meals you eat per week	1	2	3	4	5
C14. Keeping track of the number of servings you eat using the Food Guide Pyramid	1	2	3	4	5
C15. Preparing healthy meals to help you lose weight	1	2	3	4	5
C16. Resisting the desire to eat when you are bored	1	2	3	4	5
C17. Reading food labels in order to make healthier food choices	1	2	3	4	5
C18. Switching to low fat frozen desserts	1	2	3	4	5
C19. Cutting down your intake of pastries (donuts, danishes, cookies, cake, etc.)	1	2	3	4	5
C20. Decreasing your intake of high fat deli meats (salami, sausage, bologna)	1	2	3	4	5
C21. Reducing your intake of regular soda	1	2	3	4	5
C22. Switching to a lower fat milk	1	2	3	4	5
C23. Using regular mayonnaise less often	1	2	3	4	5

## How do you feel about the following.....?

	This has not crossed my mind.	I should be doing this, but do not.	I am ready to do this.	I do this, but not regularly.	I always do this.
C24. Cutting back on your use of fats (oil, butter, margarine, etc.)	1	2	3	4	5
C25. Using a low fat salad dressing.	1	2	3	4	5
C26. Participating in a supervised exercise program	1	2	3	4	5
C27. Incorporating more low fat foods in your diet	1	2	3	4	5
C28. Cutting down your intake of candy.	1	2	3	4	5
C29. Limiting your intake of ice cream.	1	2	3	4	5
C30. Limiting meat to 6 ounces per day	1	2	3	4	5
C31. Cooking with broth in place of oil	1	2	3	4	5
C32. Managing stressful situations without turning to food for comfort	1	2	3	4	5
C33. Limiting your intake when eating at buffets	1	2	3	4	5
C34. Avoiding "Super-sized" options at fast-food restaurants	1	2	3	4	5
C35. Balancing food intake throughout the day	1	2	3	4	5
C36. Baking or broiling instead of frying	1	2	3	4	5
C37. Counting calories to lose weight	1	2	3	4	5

## How do you feel about the following.....?

	This has not crossed my mind.	I should be doing this, but do not.	I am ready to do this.	I do this, but not regularly.	I always do this.
C38. Limiting intake of cream-based soups	1	2	3	4	5
C39. Involving those close to you to support your weight loss effort	1	2	3	4	5
C40. Making healthier snack choices	1	2	3	4	5
C41. Using nonfat cooking spray when sautéing or pan-frying	1	2	3	4	5
C42. Limiting your intake of fried foods (French fries, onion rings, etc.)	1	2	3	4	5

# PHYSICAL ACTIVITY

---

Physical activity or exercise includes activities such as walking briskly, jogging, bicycling, swimming, or any other activity in which the exertion is at least as intense as a brisk walk.

Please answer every question by marking the answer that indicates how confident you are that you could be physically active in each of the following situations.

E1. I can be physically active even when I am tired.

- Not at all Confident .....1
- Slightly Confident .....2
- Moderately Confident .....3           (Circle one number)
- Quite a bit Confident .....4
- Extremely Confident .....5

E2. I can be physically active even when I am in a bad mood.

- Not at all Confident .....1
- Slightly Confident .....2
- Moderately Confident .....3           (Circle one number)
- Quite a bit Confident .....4
- Extremely Confident .....5

E3. I can be physically active even when I feel I don't have time.

Not at all Confident .....1

Slightly Confident .....2

Moderately Confident .....3 (Circle one number)

Quite a bit Confident .....4

Extremely Confident .....5

E4. I can be physically active even when it is raining or snowing.

Not at all Confident .....1

Slightly Confident .....2

Moderately Confident .....3 (Circle one number)

Quite a bit Confident .....4

Extremely Confident .....5

# LEISURE TIME ACTIVITY

---

Please answer the questions below by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

P1. Over the **past 7 days**, how often did you participate in sitting activities such as reading, watching TV, or doing handcrafts?

<b>Never</b> 1	<b>Seldom</b> 2 (1 - 2 Days)	<b>Sometimes</b> 3 (3 - 4 Days)	<b>Often</b> 4 (5 - 7 Days)
----------------	---------------------------------	------------------------------------	--------------------------------



Go to Question P2.



**P1a. What were these activities?**

\_\_\_\_\_

**P1b. On average, how many hours per day did you engage in these sitting activities?**

Less than 1 Hour .....1

1 But Less Than 2 Hours .....2 (Circle one answer)

2 - 4 Hours .....3

More than 4 Hours .....4

P2. Over the **past 7 days**, how often did you take a walk outside your home or yard for any reason? For example, for fun or exercise, walking to work, walking the dog, etc.?

<b>Never</b> <span style="float: right;">1</span>	<b>Seldom</b> <span style="float: right;">2</span> (1 - 2 Days)	<b>Sometimes</b> <span style="float: right;">3</span> (3 - 4 Days)	<b>Often</b> <span style="float: right;">4</span> (5 - 7 Days)
---	--	---	---



Go to Question P3.



**P2a. On average, how many hours per day did you spend walking?**

**Less than 1 Hour .....1**

**1 But Less Than 2 Hours .....2 (Circle one answer)**

**2 - 4 Hours .....3**

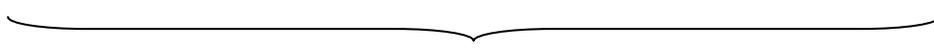
**More than 4 Hours .....4**

P3. Over the **past 7 days**, how often did you engage in light sport or recreational activities, such as bowling, golf with a cart, shuffleboard, fishing from a boat or pier or other similar activities?

<b>Never</b>	1	<b>Seldom</b>	2	<b>Sometimes</b>	3	<b>Often</b>	4
		<b>(1 - 2 Days)</b>		<b>(3 - 4 Days)</b>		<b>(5 - 7 Days)</b>	



Go to Question P4.



**P3a. What were these activities?**

\_\_\_\_\_

**P3b. On average, how many hours per day did you engage in these light sport or recreational activities?**

**Less than 1 Hour .....1**

**1 But Less Than 2 Hours .....2 (Circle one answer)**

**2 - 4 Hours .....3**

**More than 4 Hours .....4**

P4. Over the **past 7 days**, how often did you engage in moderate sport or recreational activities, such as double tennis, ballroom dancing, hunting, ice skating, golf without a cart, softball or other similar activities?

<b>Never</b>	1	<b>Seldom</b>	2	<b>Sometimes</b>	3	<b>Often</b>	4
		(1 - 2 Days)		(3 - 4 Days)		(5 - 7 Days)	



Go to Question P5.



**P4a. What were these activities?**

\_\_\_\_\_

**P4b. On average, how many hours per day did you engage in these moderate sport or recreational activities?**

Less than 1 Hour .....1

1 But Less Than 2 Hours .....2 (Circle one answer)

2 - 4 Hours .....3

More than 4 Hours .....4

P5. Over the **past 7 days**, how often did you engage in strenuous sport or recreational activities, such as jogging, swimming, cycling, singles tennis, aerobic dance, skiing (downhill or cross- country) or other similar activities?

<b>Never</b> 1	<b>Seldom</b> 2 (1 - 2 Days)	<b>Sometimes</b> 3 (3 - 4 Days)	<b>Often</b> 4 (5 - 7 Days)
----------------	---------------------------------	------------------------------------	--------------------------------



Go to Question P6.



**P5a. What were these activities?**

\_\_\_\_\_

**P5b. On average, how many hours per day did you engage in these strenuous sport or recreational activities?**

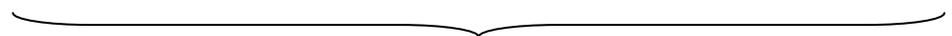
- Less than 1 Hour .....1
- 1 But Less Than 2 Hours .....2 (Circle one answer)
- 2 - 4 Hours .....3
- More than 4 Hours .....4

P6. Over the **past 7 days**, how often did you do any exercises specifically to increase muscle strength and endurance, such as lifting weights or pushups, etc?

<b>Never</b> 1	<b>Seldom</b> 2 (1 - 2 Days)	<b>Sometimes</b> 3 (3 - 4 Days)	<b>Often</b> 4 (5 - 7 Days)
----------------	---------------------------------	------------------------------------	--------------------------------



Go to Question P7.



**P6a. What were these activities?**

\_\_\_\_\_

**P6b. On average, how many hours per day did you engage in exercises to increase muscle strength and endurance?**

**Less than 1 Hour .....1**

**1 But Less Than 2 Hours .....2 (Circle one answer)**

**2 - 4 Hours .....3**

**More than 4 Hours .....4**

# HOUSEHOLD ACTIVITY

---

P7. During the **past 7 days**, have you done any light housework, such as dusting or washing dishes?

No .....1

Yes .....2

(Circle one number)

P8. During the **past 7 days**, have you done any heavy housework or chores, such as vacuuming, scrubbing floors, washing windows, or carrying wood?

No .....1

Yes .....2

(Circle one number)



You're more than halfway there!!

Keep up the good work!!

P9. During the **past 7 days**, did you engage in any of the following activities?

Please answer **YES** or **NO** for each item.

		<b><u>NO</u></b>	<b><u>YES</u></b>
<b>P9a.</b>	Home repairs like painting, wallpapering, electrical work, etc.	1	2
<b>P9b.</b>	Lawn work or yard care, including snow or leaf removal, wood chopping, etc.	1	2
<b>P9c.</b>	Outdoor gardening	1	2
<b>P9d.</b>	Caring for another person, such as children, dependent spouse, or another adult	1	2

# WORK-RELATED ACTIVITY

---

P10. During the **past 7 days**, did you work for pay or as a volunteer?

<b>NO</b>	1	<b>YES</b>	2
-----------	---	------------	---



Go to Question S1.

**P10a. How many hours per week did you work for pay and/or as a volunteer?**

\_\_\_\_\_ **HOURS**

**P10b. Which of the following categories best describes the amount of physical activity required on your job and/or volunteer work?**

Mainly sitting with slight arm movements.  
[**Examples:** office worker, watchmaker, seated assembly line worker, bus driver, etc.] 1

Sitting or standing with some walking.  
[**Examples:** cashier, general office worker, light tool and machinery worker.] 2

Walking, with some handling of materials generally weighing less than 50 pounds.  
[**Examples:** mailman, waiter/ waitress, construction worker, heavy tool and machinery worker.] 3

Walking and heavy manual work often requiring handling of materials weighing over 50 pounds.  
[**Examples:** lumberjack, stone mason, farmer or general laborer.] 4

## PARTICIPANT SATISFACTION

---

Please place an **X** in the box of the most appropriate response.

S1. When you had important questions to ask your dietitian, did you get answers you could understand?

- [ 1 ] Yes, always
- [ 2 ] Yes, sometimes
- [ 3 ] No
- [ 4 ] Didn't have questions

S2. Did you have confidence and trust in the dietitian treating you?

- [ 1 ] Yes, always
- [ 2 ] Yes, sometimes
- [ 3 ] No

S3. How would you rate the courtesy of your dietitian?

- [ 1 ] Poor
- [ 2 ] Fair
- [ 3 ] Good
- [ 4 ] Very Good
- [ 5 ] Excellent

S4. How would you rate the availability of your dietitian?

- [ 1 ] Poor
- [ 2 ] Fair
- [ 3 ] Good
- [ 4 ] Very good
- [ 5 ] Excellent

S5. Did you feel like you were treated with respect and dignity during your nutritional counseling sessions?

- [ 1 ] Yes, always
- [ 2 ] Yes, sometimes
- [ 3 ] No

S6. Did your dietitian explain recommended changes in your diet in a way you could understand?

- [ 1 ] Yes, completely
- [ 2 ] Yes, somewhat
- [ 3 ] No

S7. Did you have enough to say about your dietary treatment?

- [ 1 ] Yes, definitely
- [ 2 ] Yes, somewhat
- [ 3 ] No

S8. Did you find the nutritional counseling handouts helpful?

- [ 1 ] Yes, very helpful
- [ 2 ] Yes, somewhat helpful
- [ 3 ] No, not helpful
- [ 4 ] I did not get any nutritional counseling handouts.

S9. Did you feel that the nutritional counseling sessions helped you improve your diet?

- [ 1 ] Yes, helped a lot
- [ 2 ] Yes, helped somewhat
- [ 3 ] No

S10. Did your dietitian explain how to start a walking program in a way that you could understand?

- [ 1 ] Yes, completely
- [ 2 ] Yes, somewhat
- [ 3 ] No

S11. Did you have enough to say about your walking program including, setting walking goals?

- [ 1 ] Yes, definitely
- [ 2 ] Yes, somewhat
- [ 3 ] No

S12. Did you feel that the walking helped increase your overall level of physical activity?

- [ 1 ] Yes, helped a lot
- [ 2 ] Yes, helped somewhat
- [ 3 ] No

S13. Did anyone (family, friends, coworkers) who learned about your walking program start their own walking program?

- [ 1 ] Yes, several people – About how many? \_\_\_\_\_
- [ 2 ] Yes, at least one person
- [ 3 ] Not that I know of.

S14. Did you talk to a healthcare provider (a doctor or nurse) other than your dietitian about your walking program?

[ 1 ] No



Go to Question S15.

[ 2 ] Yes



<b><i>NAME OF PROVIDER</i></b>	<b><i>SPECIALTY</i></b>

**IF YOU DID NOT USE A PEDOMETER TO COUNT YOUR STEPS, SKIP TO QUESTION NUMBER S23 ON PAGE 28.**

S15. How comfortable was wearing the pedometer?

- [ 1 ] Very comfortable
- [ 2 ] Somewhat comfortable
- [ 3 ] Not comfortable

S16. Did you have trouble remembering to put the pedometer on in the morning?

- [ 1 ] Yes, often had trouble remembering
- [ 2 ] Yes, sometimes had trouble remembering
- [ 3 ] No

S17. Did you feel that the pedometer was accurately counting your steps throughout the day?

- [ 1 ] Yes, always
- [ 2 ] Yes, sometimes
- [ 3 ] No

S18. Did you have any problems using the pedometer?

---

---

---

S19. What did you like most about using the pedometer?

---

---

---

S20. How much money would you consider paying to continue using the pedometer for one more year?

---

**IF YOU DID NOT USE A COMPUTER TO LOOK AT YOUR PEDOMETER RESULTS, SKIP TO QUESTION S23 BELOW.**

S21. How often did you upload your pedometer step- count data to a computer?

- [ 1 ] Almost every day or more often
- [ 2 ] A few times a week
- [ 3 ] Once a week
- [ 4 ] Less than once a week

S22. Did viewing your step- count data help you increase your walking?

- [ 1 ] Yes, helped a lot
- [ 2 ] Yes, helped somewhat
- [ 3 ] No

S23. How would you rate the overall quality of the nutritional counseling and walking program that you received as a part of this study?

- [ 1 ] Poor
- [ 2 ] Fair
- [ 3 ] Good
- [ 4 ] Very Good
- [ 5 ] Excellent

S24. Did you have any problems with or complaints about the nutritional counseling and walking program?

---

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---

S25. What was the thing you liked the most about the nutritional counseling and walking program?

---

---

---

S26. If you could change one thing to improve the nutritional counseling and walking program, what would it be?

---

---

---

## MEDICAL HISTORY

---

Please answer YES or NO for each question by circling 1 or 2 on each line. If you are unsure about how to answer a question, please ask the study coordinator for help.

Have you ever been diagnosed or treated for any of the following health problems?

	<b>Yes</b>	<b>No</b>
M1. Angina or Chest Pain from heart disease .....	1	2
M2. Congestive Heart Failure .....	1	2
M3. Heart Attack .....	1	2
M4. High Blood Pressure .....	1	2
M5. High Cholesterol .....	1	2
M6. Diabetes .....	1	2
M7. Lung Disease, Emphysema, Asthma, or Bronchitis .....	1	2
M8. Arthritis .....	1	2
M9. Osteoporosis or thin bones .....	1	2
M10. Mental Health Problems (such as Depression, Anxiety Attacks, Manic-Depression, or Schizophrenia) .....	1	2
M11. Chronic Pain .....	1	2
M12. Hip or Knee Joint Replacement Surgery .....	1	2
M13. Cancer other than Skin Cancer .....	1	2
M14. Stroke .....	1	2
M15. Kidney Disease .....	1	2
M16. Liver Disease .....	1	2
M17. HIV/AIDS .....	1	2
M18. Any other major health problem .....	1	2
M18a. If yes to M18, what is the other major health problem?		

## **Appendix K.**

### **Diabetes and Exercise Handout**

[▶ Return to Web version](#)

## Diabetes and Exercise

### How can exercise help my diabetes?

Exercise can help control your weight and lower your blood sugar level. It also lowers your risk of heart disease, a condition which is common in people who have diabetes. Exercise can also help you feel better about yourself and increase your overall health.

### What kind of exercise should I do?

Talk to your doctor about what kind of exercise is right for you. The type of exercise you can do will depend on whether you have any other health problems. Most doctors recommend aerobic exercise, which makes you breathe more deeply and makes your heart work harder. Examples of aerobic exercise include walking, jogging, aerobic dance or bicycling. If you have problems with the nerves in your feet or legs, your doctor may want you to do a type of exercise that won't put stress on your feet. These exercises include swimming, bicycling, rowing or chair exercises.

No matter what kind of exercise you do, you should warm up before you start and cool down when you're done. To warm up, spend 5 to 10 minutes doing a low-intensity exercise such as walking. Then gently stretch for another 5 to 10 minutes. Repeat these steps after exercising to cool down.

When you start an exercise program, go slowly. Then gradually increase the intensity and length of your sessions as you become more fit. Talk to your doctor for specific advice.

### Are there any risks to exercising for people with diabetes?

Yes, although the benefits far outweigh the risks. Exercise changes the way your body reacts to insulin. Regular exercise makes your body more sensitive to insulin, and your blood sugar level may get too low (called hypoglycemia) after exercising. You may need to check your blood sugar level before and after exercising. Your doctor can tell you what your blood sugar level should be before and after exercise.

If your blood sugar level is too low or too high right before you plan to exercise, it's better to wait until the level improves. It is especially important to watch your blood sugar level if you exercise in really hot or cold conditions, because the temperature changes how your body absorbs insulin.

### How will I know if my blood sugar is too low while I'm exercising?

Hypoglycemia usually occurs gradually, so you need to pay attention to how you're feeling during exercise. You may feel a change in your heartbeat, suddenly sweat more, feel shaky or anxious,

or feel hungry. When you feel this way, you should stop exercising and follow your doctor's advice about how to treat hypoglycemia. Your doctor may suggest you keep candy or juice on hand to treat hypoglycemia.

## **What else should I do to exercise properly?**

Many people with diabetes have problems with the nerves in their feet and legs, sometimes without even knowing it. So it's important that you wear shoes that fit well and have plenty of room when you exercise. Otherwise you could develop blisters or other sores on your feet that can lead to infection and other problems. You should check your feet before and after you exercise to make sure there are no blisters or other sores.

## **Should I drink more fluids during exercise?**

Yes. When you're exercising, your body uses more fluid to keep you cool. By the time you feel thirsty, you may already be getting dehydrated. Dehydration (not enough fluid in your body) can affect your blood sugar level. Drink plenty of fluid before, during and after exercise.

## **Exercise checklist for people with diabetes**

- Talk to your doctor about the right exercise for you.
- Check your blood sugar level before and after exercising.
- Check your feet for blisters or sores before and after exercising.
- Wear the proper shoes and socks.
- Drink plenty of fluid before, during and after exercising.
- Warm up before exercising and cool down afterward.
- Have a snack handy in case your blood sugar level drops too low.

## **Other Organizations**

American Diabetes Association

<http://www.diabetes.org>

800-342-2383

*This handout was developed by the American Academy of Family Physicians in cooperation with the American Diabetes Association.*

Reviewed/Updated: 7/02

Created: 3/99

This handout provides a general overview on this topic and may not apply to everyone. To find out if this handout applies to you and to get more information on this subject, talk to your family doctor.

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**Appendix L.**

**Instructions to Site Coordinators and Principal Investigators:  
Patient Safety Information**

## Veterans Walk For Health Participant Safety

The Basics:

Every participant in the VWH trial is at high risk for having a heart attack. There is a very good chance that at least one participant will have a heart attack and die during the time they are participating in our study. Therefore, it is critical that all proper procedures have been followed in the recruitment, enrollment, safety screening, medical clearance, and informed consent process for every single participant.

**Adverse Event Reporting:** Whenever something bad, no matter how minor, happens to a participant, it **MUST** be reported to your site PI and to the Ann Arbor coordinating center as an adverse event!!! Whose job is it to report an adverse event? Whoever learns about it first. One of the primary jobs of the site coordinator will be to make sure all adverse events are reported appropriately.

Adverse Event Reporting Procedure (from recruitment site to Ann Arbor coordinating center)

- 1) Make sure the participant is safe or obtain emergency services immediately
- 2) Fill out an adverse event reporting form
  - available from your site coordinator
- 3) Submit the form to your site PI before the end of the day.
- 4) Fax the report to Ann Arbor: 734-761-2939 before the end of the day.

No participant identification information should be on the Adverse Event form when it is faxed to Ann Arbor, only site and study ID should identify the participant.

In Ann Arbor, all serious events will be classified according to three scales

- severity,
- expectedness
- relatedness to study interventions.

Unexpected, serious adverse events will be reported immediately to all 7 IRB's. This may result in immediate suspension of the study until the IRB gives approval to continue the study.

**Even minor adverse events (harms to the patient) must be reported.** There was a study at Johns Hopkins for in which the investigators gave a drug to healthy volunteers and several of the volunteers coughed a little after taking the drug. Finally, a healthy volunteer participant had such a severe asthmatic reaction to the drug that she died. The expert review panel found that if the minor adverse events of coughing had been reported, the pattern might have been recognized as potentially dangerous and the death of the healthy volunteer might have been prevented. Minor harms will not be reported immediately to the IRBs, however they will be reviewed monthly in the coordinating center to look for patterns that could lead to more serious problems. A summary of minor adverse reactions will be given to the IRBs each year for annual review. Contrary to what you might think, a long list of Adverse Events reported is actually seen favorably rather than unfavorably by the IRBs.

There are 5 expected adverse events, one of them serious. From the informed consent document:

- 1) Muscle and joint injuries are possible in a walking program. It is possible that you get an injury such as an ankle sprain, sore feet, sore legs or experience a fall as a result of increasing your walking. By gradually increasing your walking, walking in safe places, and wearing proper shoes, you can minimize these risks.
- 2) For most people, even those at high risk for having a heart attack, starting a walking program reduces the overall risk of having a heart attack. However, for a few individuals it might not be safe to start an exercise program. Therefore, prior to starting the walking program, your doctor must sign a form stating that it is ok for you to start a walking program. By gradually increasing your walking goals and by teaching you signs and symptoms that might indicate that you are having heart trouble, we will further decrease your risk of having a heart attack while walking.
- 3) If you have diabetes, a walking program is an important part of managing your blood sugar levels. However, walking can also increase your risk of very low blood sugar episodes and of problems with your feet. To reduce this risk, your dietitian will provide you with a copy of an "Exercising with Diabetes" handout and discuss with you how to exercise safely.
- 4) If you have high blood pressure, a walking program is an important part of managing your blood pressure. However, if your blood pressure is not well controlled, walking may increase your risk of having a heart attack or stroke. To reduce this risk we will check your blood pressure at each nutritional counseling visit and we will recommend that you talk to your doctor if your blood pressure is high.

There is also the possibility of loss of confidentiality, which means that someone not on the study team could obtain your data from the study. As described above, even if someone obtained your study data, they would not know your identity, because your name will not be included anywhere with your data. If someone was able to obtain the file linking your name with your study identification number, AND they were able to obtain your study data with your study identification number, then they could link your identity with your data. As described above, we will take many precautions to keep this from happening; so, it is very unlikely this will happen.

#### Additional Points:

Every member of the research team must have completed training in the Human Subjects Protection in research prior to assisting with recruitment, enrollment or data collection or any other aspect of the study. This includes all site coordinators, principle investigators and dietitians. If you have not completed the web-based training modules on Human Subjects Protection, please contact your site Principle Investigator to find out how to log on and complete this module.

Every member of the research team is responsible for protecting the participants in our study. Our participants are at particularly high risk for adverse cardiovascular events such as heart attacks and stroke. Any research staff person who has any reason for concern about the safety of a participant, no matter how small, must report the concern immediately to either the site principle investigator or to the study principle investigator. Every dietitian and site coordinator in the study has the authority to suspend participation until medical clearance has been obtained. Thus, any new symptoms of chest pain, shortness of breath, light headedness, passing out, swelling in the legs or any other concerning symptoms that might represent heart disease must be addressed immediately. Arrangements must be made for a medical evaluation by the patient's usual physician and the participant's nutritional counseling visits must be suspended until written medical clearance has been obtained. Any adverse cardiovascular events such as heart attack must be reported as an adverse event to the Human Subjects Protection or IRB committee at all participating sites. It is the responsibility the principle investigator in Ann Arbor to make sure that this happens, however, it is the responsibility of the site coordinators and dietitians to notify the site coordinators, site principle investigators and the Ann Arbor coordinating center.

## **Appendix M.**

### **Budget**

**(Please contact an Ann Arbor Investigator for this information)**

For budget information please contact the investigators  
(Caroline Richardson or Julie Lowery)

**Appendix N.**

**Responses to Reviewers' Comments**

**(Please Contact an Ann Arbor investigator for this information)**

April 28, 2004

Robert L. Ruff, M.D.  
Acting Director  
Rehabilitation Research & Development Service (122A)  
VA Central Office  
810 Vermont Avenue NW  
Washington, DC 20420

Dear Dr. Ruff:

Attached are responses to the reviewers' suggestions for our study, "Does Step-Count Feedback Enhance Counseling for Weight Loss?" (Proposal No. D3358R; Caroline Richardson, M.D., and Julie Lowery, Ph.D.). We appreciate the opportunity to respond; and we have made some modifications in response to the reviewers' recommendations, which we believe have greatly strengthened the study design. We thank the reviewers for their suggestions.

As a result of modifying the study design somewhat, the budget has increased from \$664,329 to \$691,842. Details regarding the changes making up this increase are included in our responses to the specific recommendations. A revised budget with justification is enclosed. (The justifications for the revised items are in italics.) We have also enclosed a biosketch for Hyungjin Myra Kim, Sc.D., who prepared the response to item #2 in the absence of Dr. Ronis, who is on medical leave.

Please do not hesitate to contact us if you need additional information.

Sincerely,

Caroline Richardson, M.D., Principal Investigator

Julie Lowery, Ph.D., Co-Principal Investigator

## Response to Reviewers’ Comments

### 1. Equate step count monitoring for all three groups.

We agree that this is a major concern that needs to be addressed. However, the solution suggested by the reviewers has some significant methodological concerns. We propose an alternate solution to the problem:

Rather than using the Sportbrain as both an outcome assessment tool and an intervention/feedback tool simultaneously, we propose to uncouple the measurement of the outcome and the intervention/feedback in arm 3 by using another device, an Actigraph accelerometer, to measure outcomes for all three arms. This frees us to use the Sportbrain in the intervention arm as intensively as we like without having to ask participants in the other two arms to wear the Sportbrain every day for 6 weeks without getting any feedback (as suggested in the reviewers’ summary statement). The Actigraph accelerometer is currently the gold standard for activity monitoring. Conveniently, the Actigraph accelerometer can measure two things simultaneously, step-counts and activity clicks. Activity clicks provide a good objective estimate of total energy expenditure, and step-counts will more directly assess adherence to the walking program in our intervention.

The Actigraph accelerometer is a relatively small activity monitor that can be worn on the hip, wrist or ankle. Similar to other accelerometers, it is an electronic sensor that measures both the quantity and intensity of movement, resulting in the collection and storage of daily patterns of physical activity. The Actigraph is a unidimensional accelerometer with a step counting function included. It is a much more precise and accurate instrument compared to the pedometer and has often been used to validate the pedometer (Bassett, 1996). These monitors have been validated in a variety of laboratory and field settings. In adults, the Actigraph has been shown to be related to metabolic measures with the correlation coefficients ranging from  $r = 0.66$  to  $r = 0.89$  (Melanson, 1995). Comparisons with oxygen consumption during treadmill exercise and self-selected speed on a track found that the Actigraph was highly related to both and was highly sensitive to change in speed but not changes in grade (Nichols, 2000). The Actigraph has been found to successfully detect bouts of moderate-intensity physical activity such as brisk walking (Masse, 1999). The Actigraph monitor can continuously store data for up to 6 weeks. Not only can it determine the time the physical activity occurred but it has the capability to break down each bout of activity, minute by minute. Data from the Actigraph monitor are downloaded to a computer so the potential for recording errors in the data are minimized. The accelerometer is one of the current “gold standards” in assessing physical activity levels and is often used to validate the much simpler, less expensive pedometer.

Given that we no longer need to be concerned about equating Sportbrain use across all three arms, we further propose the following modification to the study design. In our original proposal we had planned to give both Digiwalkers and Sportbrains to the Sportbrain group to help them monitor their step counts between visits to the dietitian. This makes the Sportbrain intervention complicated and confusing. To simplify the intervention for the Sportbrain arm of the RCT, we would like to give participants randomized to this arm the ability to use the Sportbrain web-

based feedback at home. This is the way the Sportbrain was designed to be used, with frequent feedback. This means we will give them the Sportbrain-enhanced pedometer as well as a Sportport that allows them to upload data over a phone line to the central Sportbrain computer. Participants do not need to have a computer or web access at home. They only need a regular phone line. We will, however, require that they have access to the Internet at least once a week to review their step-count data. They can use their own home computer, or a computer at work, at a friend's house, or at a local library or community technology center. Study coordinators at each site will be able to assist participants in finding Internet access. By allowing those randomized to the enhanced pedometer arm to use a single device—the Sportbrain—for all of their step-count monitoring, we are greatly simplifying the intervention. We also may be strengthening the intervention by increasing exposure to the detailed, time stamped-web based step-count feedback for this group.

We believe that these two modifications greatly strengthen the study design and we thank the reviewers for pushing us to resolve this issue. It will require some budget modification as we will need to purchase the Actigraphs and the Sportports. However, we will need fewer Sportbrains and fewer Digiwalkers so the marginal increase in cost should be within an acceptable range allowed by the reviewers in order to address this problem. The total additional funds for purchasing the revised configuration of pedometers and accelerometers is \$12,229. Funds for FedEx costs (for sending and returning the Actigraphs to patients) were also recalculated, for an additional cost of \$2400.

#### References for #1

Bassett DR, Jr., Ainsworth BE, Leggett SR, et al. Accuracy of five electronic pedometers for measuring distance walked. *Med Sci Sports Exerc.* 1996;28(8):1071-1077.

Melanson EL Jr. Freedson PS. Validity of the Computer Science and Applications, Inc. (CSA) activity monitor. *Med Sci Sports Exerc.* 1995;27(6):934-940.

Nichols JF, Morgan CG, Chabot LE, Sallis JF, Calfas KJ. Assessment of physical activity with the Computer Science and Applications, Inc. Accelerometer: Laboratory versus field validation. *Research Quarterly for Exercise and Sport* 2000;71:36-43.

Masse LC, Fulton JE, Watson KL, Heesch KC, Kohl HW, Blair SN, Tortolero SR. Detecting bouts of physical activity in a field setting. *Research Quarterly for Exercise and Sport* 1999;70:212-219.

## **2. Statistical analysis**

We have responded below to all of the statistical issues mentioned by the committee and by individual reviewers. Myra Kim, a ScD statistician at the Ann Arbor HSR&D, stepped in to help us with these responses as David Ronis, our original statistician, was hospitalized this month with a brain tumor. (We anticipate his return and have kept him in the budget for the study.) Dr. Kim's biosketch is attached.

### **2a. Using change scores**

For both outcomes of weight and walking, between group outcome comparisons will be done using change scores as suggested by the reviewers. Specifically, outcomes will be calculated as *weight loss* (change in weight calculated as baseline weight minus 6-month weight) and as the *step count gain* (change in average daily step counts calculated as 6-month minus baseline).

## **2b. Clustering by site**

In order to make between group comparisons while adjusting for potential within site clustering as well as for potential confounders, we will use a *linear mixed-effect model* with the change score (weight loss or step count gain) as the dependent variable (Laird, 1982). In addition to the two primary predictors of dummy variables representing the intervention arms and other potential confounders described in the original proposal, the linear mixed-effect model will include site as random intercept (to account for potential clustering within site) and baseline weight as independent variable (to further adjust for baseline differences). Including site as a random-effect rather than fixed-effect has an advantage of allowing for broader inferences from this study about other sites.

## **2c. Seasonal variation**

With the follow-up of 6 months, as the reviewers correctly pointed out, seasonal variation may result in potential bias in our assessment. Two things will be done to address this: (1) randomization will be done in blocks, and (2) the above described model will also utilize an indicator variable for warmer climate (Miami, Tucson, San Diego) and categorical dummy variables for season at baseline as independent variables. The inclusion of baseline season variables will be modified after further exploratory graphical analysis to see if differential seasonal pattern exists where, for instance, seasonal effect may be more or only prominent in sites from colder climates. The project statistician will be responsible for the randomization process, which will be done within each of the 6 sites and prepared ahead in sequenced and sealed envelopes for each consecutive participant. To further enhance the balance between the number of people in the three groups during the recruitment period and thus over the various seasons, blocked randomization will be done. To prevent potential bias from the study coordinator being aware of the group assignment toward the end of each block, block sizes will also vary randomly among 3, 6, and 9 where the order in which the group assignments are made in each block will be randomized.

## **2d. Missing data**

All efforts will be made to minimize missing data as described in the original proposal (Section 3.a.5.1). Sample size calculation was also done with 20% attrition in mind, which is a conservative estimate given all our efforts to reduce missing data. In terms of analysis, those who are missing final or baseline measures will not be included in the analysis because the outcome measurements are measured at only two time points, and the proposed analysis requires both. However, to assess whether any baseline differences exist between patients who are missing versus patients who are not missing 6-month outcome measures, their baseline values (such as baseline weight) will be compared using a two sample t-test. In case any statistical or clinical difference is found between these two groups, such as those missing final weight being heavier at baseline compared with those not missing final outcome, the final conclusion from the comparisons will be made carefully in light of this finding. Similar comparisons will be made

with other baseline potential confounding variables as well, and those variables found to be associated with missing data will be included in the final model.

## **2e. Recalculate sample size given clustering**

The *sample size* of 103 patients per group was selected to provide 80% power to detect a 3-pound difference in weight loss between pairs of conditions (e.g., control vs. simple pedometer) in the planned comparisons with alpha of 0.05, two-tailed. The sample size calculation assumed the standard deviation (SD) of weight change over a 6-month period of 6.8 pounds and 20% attrition. With the same proposed sample size, but with the potential within site clustering, the power will be smaller to detect the same effect size. The inclusion of the baseline values of the outcome variables (baseline weight) in the model, however, will likely reduce the standard errors and thus will increase the power. Hence, the statistical power of the study will remain approximately unchanged. Specific illustration is as follows: Since the assumed SD of 6.8 pounds was from pilot data of single site, the SD was essentially an estimate of within site SD. Thus, assuming the within-site SD in weight loss of 6.8, but with the assumed correlation of 0.7 between baseline weight and weight loss, the within-site SD is reduced to about 5.3. And with approximately 13 patients per site (= 82/6; complete data available from 82 patients per group) for each group and an assumed intra-cluster correlation coefficient (ICC) of 0.02, the cluster SD is expected to be 1.651. With these assumptions and 6 sites, the study will maintain 80% power to detect a between group difference in means of 3 pounds in weight loss with a two-sided 0.05 test. (Donner, 1987) Note that with a smaller ICC, the power will increase, but with a larger ICC, the power will decrease. No specific estimate of ICC for weight loss as the outcome is known, but most health study literatures including substance abuse and utilization have reported the ICC between 0.005 to 0.05, and thus the assumed ICC of 0.02 seems appropriate.

## **2f. Budget for statistical consultation**

There was an error in our originally submitted budget. We should have asked for 5%, 10%, and 10% time for the statistician over years 1, 2, and 3, respectively. Unfortunately, the 10% time for year 2 was inadvertently not included in the budget. Because this is a multi-site study, we will need a significant amount of statistical work in year 2 as well as in year 3 in order to present our interim results to the data monitoring committee. This has been added to our revised budget.

### References for #2

Laird NM, Ware JH. Random-effects models for longitudinal data. *Biometrics* 1982; 38: 963-74.

Donner A, Donald A. "An analysis of data arising from a stratified design with the cluster as the unit of randomization " *Statistics in Medicine* 1987; 6:32-43.

## **3. Rules for suspension of participation**

We agree that there should be explicit rules for suspending participation for individuals in the study who experience adverse health events during the course of the intervention. In particular, it would be inappropriate for dietitians to be making decisions about whether or not it is safe for a participant to continue in the study after an adverse health event. As a rule, any concerns by

the dietitian should result in suspension from the study until a physician treating the participant gives written medical clearance.

Criteria for temporary suspension from the study are as follows:

- Hospitalization or evaluation in the Emergency Room for any reason other than for a minor laceration or for a viral infection that has resolved, including but not limited to
  - i. cardiac evaluation for symptoms,
  - ii. syncope or TIA symptoms,
  - iii. adverse reaction to medications,
  - iv. bacterial infection on antibiotics,
  - v. Motor Vehicle Accident,
  - vi. problems with glucose control for patients with diabetes, or
  - vii. dehydration.
- outpatient cardiac evaluation for symptoms (i.e., chest pain or shortness of breath)
- any report of chest pain, shortness of breath or light-headedness when walking
- any injury or impairment that significantly limits ability to walk or increases risk for further injury while walking

At the beginning of each nutritional counseling session, dietitians will ask the participant about any of the above events. For any participant who has experienced one of the above events, the counseling session will be terminated and the participant will be informed that they have been suspended from the study. In order to be reinstated in the study, the participant will need to get written, signed medical clearance from their primary care physician or from a specialist evaluating the problem. The study coordinator at the participant's site will assist the participant in getting the written medical clearance.

If at any time the dietitian is concerned about the safety of a participant, he or she can contact the study principal investigator for guidance.

Additionally, all participants will receive a letter addressed generically to any physician who may treat the patient while the patient is enrolled in the study. The letter will describe the study emphasizing potential risks and precautions. The letter will give the treating physician the option of indicating in writing whether the illness or injury being treated should result in suspension from the study or of contacting the study coordinator, dietitians, or principal investigator directly to discuss the issues. Participants will be encouraged to present the letter to any treating physician they see during the course of the study.

Scheduled routine cardiac testing (such as an annual stress-test) for these high risk patients will not constitute grounds for study suspension in the absence of symptoms.

#### **4 and 5. Procedural/manualized steps for counseling behaviors and counselor training**

We do not completely agree that it is critical that every counselor use exactly the same techniques or methods. We are looking for an average effect in a variety of settings with different dietitian/patient relationships. One of the strengths of this type of intervention may be that it requires relatively little training for effective delivery. Contamination—i.e., dietitians

using techniques in the Sportbrain arm to motivate participants in the other arms—are less of a concern in this study because the Internet-based feedback simply will not be available for participants in the other arms. Nutritional counseling should be similar across all three arms so contamination is not an issue for nutritional counseling either.

However, we understand the concerns of the reviewers and note that several dietitians who participated in the pilot study requested more guidance with the intervention. As was mentioned by one reviewer, dietitians will not be blinded to treatment arm and thus there is the possibility that they will be more or less enthusiastic in their follow-up and motivational efforts for patients in one arm or another. Thus, we will focus our protocol development on clearly delineating the procedure for setting step-count (or time-based in the case of the control group) walking goals and for motivating participant who are not successful in achieving previously set goals or for those who fail to show up for a nutritional counseling session. Additionally, we will use a checklist to determine usual counseling practices for each of the study dietitians and in the analysis we will look for particular styles or techniques that enhance effectiveness of the intervention. A subset of dietitian/participant counseling sessions (8 per dietitian, 2 each for sessions 2,3,4,and 5) will recorded and transcribed for coding. This coding will serve to validate the checklist described above and to provide a richer source of data on the actual content of the counseling sessions. We have added a budget item for audio recorders to the budget at an additional cost of \$780.

In our pilot study, all training for dietitians was done by telephone. We had all participating dietitians wear the Sportbrain enhanced pedometers for one week so that they would get experience uploading data to the Sportbrain web site and navigating through the web based results. Dietitians were given explicit training in setting safe step-count goals using a 10% incremental approach and were discouraged from discussing anything related to the 10,000 steps target frequently used in public health walking messages. In the proposed randomized controlled trial, we have allocated funds for one dietitian from each site to travel to Ann Arbor for training that is more intensive. Weekly conference calls will be used to address any protocol issues that develop during the course of the study.

We plan to have IRB approval from all participating sites by October 1<sup>st</sup>, 2004, and at that time we hope to receive the funds to begin the study. Between May 1<sup>st</sup> and July 1<sup>st</sup>, we will work on the protocols described above. All protocols will be developed with input, oversight, and final approval from the Research Council of the VA's National Advisory Board for Nutrition and Food Services. The completed and approved, detailed protocols will be presented for your review in July, well before the proposed start of funding.

One more issue to address is the concern about equating contact time with nutritionists across the three treatment arms. The protocol will provide guidelines for total visit time for each of the six nutritional counseling sessions and total visit time should be similar across the three arms. This controls for attention to the issue of weight loss. Those in the intensive step-count monitoring groups may get slightly more time focused on walking, particularly in the first few sessions than those in the control group. However, those in the control group will get more exposure to conventional nutritional counseling. If attention to step-counts is more effective than attention to diet given the same amount of face-to-face counseling time, then it makes sense to employ the

objective step-counters and to take some of the counseling time away from dietary issues to focus on step-count goals. On the other hand, if conventional nutritional counseling alone without the assistance of step-counters results in equal weight loss and activity, there is no support for the use of pedometers in weight loss counseling interventions.

## **6. Standardization of weights**

We agree that a standardized procedure will be important for reducing measurement error. Dietitians will use the following protocols for weight and height measurement:

### **Measurement of weight**

Subjects will be weighed on an upright balance beam scale. Only one scale at each site will be designated the “study scale” and it will be used at each site for all study participants and all sessions. If the scale is moveable, it will be re-calibrated after each move. The main and fractional sliding weights will be placed at their respective zero positions and the zeroing weight should then be moved until the beam balances at zero. Subjects will be weighed with minimal clothing on and shoes removed. Jackets, heavy sweaters, and large belts will be removed prior to weighing along with removal of heavy items in pockets such as keys and/or wallets. The subject will stand with feet placed over the center of the platform and weight evenly distributed between both feet. Weight will be adjusted and recorded standing behind the beam to avoid reaching around the subject. Weight will be recorded to the nearest ¼ lb. Subjects who weigh greater than 350 lbs. present a problem as that is the limit for some scales. Weights for these participants can be recorded on an alternate scale, even possibly one at a different site, as long as the above procedure is followed and the measurement takes place within 24 hours before or after the nutritional counseling session.

### **Measurement of height**

The subject should stand erect with back to the vertical backboard of a stadiometer with weight equally distributed between both feet and heels together. The head, shoulder blades, buttocks and heels should touch the vertical backboard whenever possible. Arms should hang loose at sides with palms facing thighs. The subject should be instructed to look straight ahead with line of vision perpendicular to the body. The subject should be informed to take a deep breath holding that position while the horizontal headboard or lever is brought down firmly on top of the head. Stature should be measured at maximum inspiration. The measurer’s eyes should be level with the headboard to avoid parallax. The measurer may need to stand on a stool if necessary. Measurements should be recorded to the nearest 0.1 cm. The presence of spinal curvature should be noted.

### References for #6

Anne Grant, & Susan DeHoog. Nutritional Assessment & Support. 4<sup>th</sup> Ed. 1991

Nutritional Assessment of the Elderly through Anthropometry. The Ross Medical Nutrition System. Ross Laboratories, Columbus, Ohio, 1987

NHANES anthropometry Procedural Manual, 2000

CDC Body Measurement Manual, 1988.

**7. Clarify Hypothesis 5 - Psychological and behavioral characteristics can be used to predict participants who are more likely to benefit from the step-count feedback interventions.**

We will collect data on the following patient characteristics: number of comorbidities, income, education, work disability, age, smoking, social support, stress/ depression and experience using computers. These 9 baseline characteristics will be examined to see if any subgroups are more or less likely to respond to the different types of interventions either with increased walking or successful weight loss.

Additionally, baseline self-efficacy and stage of change for both diet and physical activity will be examined as potential predictors of success. Self-efficacy and stage-of-change are also a potential mediating construct and it will be measured at three sessions (session #1, session #4 and session #6) to see if self-efficacy mediates the effect of the interventions on weight loss and walking.

**8. Telephone contact reminders**

Calling participants to remind them to wear the pedometers is a good idea, but probably not practical in the real-world application of these pedometer-based interventions. We know that people wear the pedometer for at least 4 weeks (see our pilot data) and we will have a better idea of whether or not they are willing to wear the pedometer for a longer period of time at the end of this study. We will have the study coordinators at each site call the participants on day #2 of wearing the Actigraph for both the baseline activity measure and for the 6-month activity measure to make sure that the participants are wearing the device according to the protocol.