

D.5.1 Outcome Variables Definition and Measurement

The two primary outcome measures for this study are kilocalories expended per week and maintenance of PA. Each will be derived from self-report at baseline and each follow-up. Secondary outcomes include measures of the penetration of the intervention into the eligible target population, measures of intervention cost, and psychosocial factors associated with PA.

D.5.1.1 Kilocalories expended per week. Participants' expended kilocalories per week (kcal/wk) will be derived from their reported levels of PA as measured by the CHAMPS PA questionnaire¹²⁵ at baseline and all follow-ups. The CHAMPS questionnaire was developed specifically for use with older adults and has been demonstrated to be sensitive to change in PA in response to interventions geared toward increasing light to moderate intensity PA^{125, 131-133} (See Appendix D).

The CHAMPS questionnaire collects weekly frequency and duration of all physical activities in which study subjects participated. PA intensity is reflected by applying metabolic cost weights (METs – metabolic equivalents) to each activity, adjusted for body weight, which allows the estimation of weekly kilo-calories expended in each type of PA. Because we will obtain 6 measures of kcal/wk over the 24 month course of the study, we will be able to assess baseline expended kcal/wk as well as trends in expended kcal/wk to evaluate the efficacy of the intervention over time in promoting PA maintenance.

D.5.1.2 Maintenance of Physical Activity. Our second primary dependent variable, PA maintenance, will be derived from kcal/wk. PA maintenance is defined conceptually as expenditure of an equal or greater number of kcal/wk relative to baseline. Participants able to maintain (or increase) their baseline PA level will be said to have maintained PA, regardless of their absolute level of baseline caloric expenditure. Clearly, PA is likely to fluctuate over time and small decrements in PA at a follow-up should still be considered PA maintenance.

The point of intervention is to help participants maintain a PA level useful for health needs, not an arbitrary level of PA. We set a “floor” for PA maintenance based on the estimation that an individual expends about 300 kcal per 60 minutes of moderate PA. We define PA maintenance as follow-up kcal/wk \geq (baseline kcal/wk – 150), assuming kcal/wk remains \geq 300. Thus, maintenance is defined relative to each person's baseline but sets a minimum equal to the entry criteria (e.g. 2 bouts \geq 30m/wk). PA maintenance will be assessed at each of the follow-ups which should allow us to observe fluctuations in PA maintenance over time in study participants, while permitting reductions of up to 30 minutes of weekly PA without being considered in relapse.

D.5.2 Independent Variable Definition and Measurement

Because the study is a randomized trial, independent variables such as age, gender, race/ethnicity, educational level, marital status, obesity, smoking, Charlson scores, and comorbid conditions should be equally distributed across study arms. Each of these variables will be measured and analyzed to assure the adequacy of randomization, and to permit adjustment for unequal balance of these variables across study arms in the analysis, if necessary. Availability of

these data will also support secondary analyses, such as the characterization of participants and non-participants as discussed above with respect to recruitment.

D.5.2.1 Intervention/Control group assignment. The primary independent variable is assignment to intervention or control group. Recognizing that some individuals assigned to control may enroll in similar programs offered by CHP or other entities, we will assess treatment contamination by tracking enrollment in other PA interventions offered through the HP CHP. Enrollment in PA intervention programs outside of HP is expected to be low or non-existent, although participation in any such programs will be assessed via self-report.

D.5.2.2 Personal attributes. Personal attributes of participants will be assessed via self-report. Most of these attributes will remain stable over 24 months and will be used as covariates and in secondary analyses. *Demographic* data assessed at baseline include: age, gender, educational attainment, family income, race/ethnicity, gender and marital status. Self-reported body weight and height will be obtained at each survey point so that *Body Mass Index* may be calculated and used in the analyses. *Smoking status*, defined as daily use of cigarettes, will be assessed by self-report at each survey point and participants will be categorized as current, former, or never smokers using standard questions from the CDC BRFSS survey. A brief set of items will be used to gather data on subjects' *physical activity history* one, five, and ten years prior to baseline. *History of specific health conditions* will be assessed at baseline using standard BRFSS questions on personal history of diabetes, heart disease, hypertension, or hypercholesterolemia. At 12 and 24 months, participants will indicate whether they have been told in the last year by their physician or other health professional that they have any of these conditions. *Health-related quality of life* will be measured at each assessment point using the 12-item Health Status Questionnaire.¹³⁸ This instrument measures physical, social, and emotional well-being in diseased and non-diseased populations. A *modified Charlson Comorbidity* score will be computed from prior 12-month ICD-9-CM diagnostic codes from administrative databases.¹³⁹ A Charlson score over 3 has been associated with a 30% mortality rate in the following year.^{140, 141}

D.5.3 Potential mediators of PA

D.5.3.1 Sedentary Behavior. Leisure-time sedentary behavior will be assessed using a 1-week recall measure of 9 activities (e.g., TV watching, computer use, reading).⁷⁹ This measure has been shown to have high test-retest reliability and good concurrent validity.

D.5.3.2 Self-efficacy for overcoming barriers to physical activity. A 13-item scale measuring self-efficacy for overcoming barriers to PA will be used.¹⁴² This scale was designed to tap subjects' perceived capabilities to exercise in the face of commonly identified barriers to participation. This measure has been used to predict exercise behavior in diverse older adult populations.

D.5.3.3 Social support. The 10-item Social Support for Exercise Behavior Questionnaire¹⁴³ will be used to assess participants' perceived exercise-related social support from family, friends, and counselor. Participants will be asked to rate how often (1=never, 2=rarely, 3=a few times, 4=often, and 5=very often) their family, friends, and exercise counselor encouraged their participation in exercise. Separate scores for family, friend, and exercise counselor perceived support can be computed as well as an overall perceived social support measure. This measure has been shown to have adequate test-retest reliability and validity in older adults.⁷⁶

D.5.3.4 Perceived barriers to exercise. A 23-item questionnaire regarding self-perceived barriers to exercise¹⁰⁴ will be used. In addition to a total barriers score, the measure includes three sub-scales: Motivational Barriers, Negative Attitudes and Environmental Barriers. Sample items include: 1) It is difficult to motivate myself to exercise; 2) Often the amount of effort I need to put into exercising doesn't seem worthwhile; and 3) It is difficult for me to find good places to exercise.

D.5.3.5 Perceived benefits to exercise. A 12-item measure assessing perceived benefits to exercise adapted from Myers & Roth¹⁴⁴ for use in the PBH survey will be used. Domains assessed include: 1) health benefits; 2) appearance/body weight improvement; and 3) self-confidence. A 12-item measure of PA Enjoyment will also be modified for use in this study.⁷⁹ Activities are rated by level of enjoyment using a 5-point Likert scale (1=no enjoyment to 5=a lot of enjoyment) and include organized or structured activities such as jogging, aerobics or exercise classes and unstructured physical activities such as gardening, and raking leaves.

D.5.3.6 Injuries. To assess potential adverse effects of the intervention, participants will provide self-report data regarding injuries at each follow-up measure.

D.5.3.7 Process Evaluation Measures. To assess exposure to the intervention, we will collect on the number of lessons, phone calls, and self-monitoring records completed and the number of mailings sent to participants. Participants will also be asked to rate their satisfaction with the intervention and its components. The CHP routinely gathers such information and has systems in place to facilitate this data collection. We will also collect data regarding control participant's use of HP services and participation in other PA programs.