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Validity and Reliability of the Paffenbarger Physical Activity Questionnaire among Healthy Adults

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Validity and Reliability of the Paffenbarger Physical Activity Questionnaire among
Healthy Adults

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BS, University of Massachusetts Amherst, 2009

A Thesis

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Master of Arts Thesis

Validity and Reliability of the Paffenbarger Physical Activity Questionnaire among
Healthy Adults

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List of Abbreviations

Physical activity	PA
U.S. Department of Health and Human Services	USDHHS
Metabolic Equivalent	MET
Cardiovascular Disease	CVD
Cardiorespiratory Fitness	CRF
Paffenbarger Physical Activity Questionnaire	PPAQ
Physical Activity Index	PAI
Question Six	Q6
Body Mass index	BMI
High density lipoprotein	HDL
Question Eight	Q8
National Institutes of Health	NIH
The Effects of Statins on Muscle Performance	STOMP
Blood pressure	BP
Mean Arterial Pressure	MAP
Triglyceride	TG
Total Cholesterol	TC
Low density lipoprotein	LDL
Heart rate	HR
Waist Circumference	WC
Maximal Oxygen Uptake	VO ₂ max
Activity Energy Expenditure	AEE

Introduction

Regular participation in physical activity (PA) is an important component of health and quality of life for people of all ages. In general, individuals who are physically active live longer, healthier lives than those who are less physically active due to the numerous health benefits associated with PA (Table 1) (1-4). Therefore, increasing PA participation among those who are sedentary and maintaining PA participation among those who are already active is a major goal of researchers, health/fitness and exercise professionals, and health care providers.

Table 1. The Benefits of Habitual Physical Activity (3, 4)

-
- Reduces the risk of pre-mature all-cause mortality.
 - Reduces total body fat and, therefore, prevents and eliminates overweight and obesity.
 - Reduces the risk of developing chronic diseases such as cardiovascular and coronary heart disease, several types of cancer, type 2 diabetes mellitus, and osteoporosis.
 - Reduces and can even eliminate the presence of risk factors for chronic disease, such as high blood pressure and cholesterol.
 - Increases aerobic capacity, muscle strength, and endurance.
 - Increases an individual's ability to engage in activities of daily living, known as functional capacity.
 - Decreases anxiety and depression.
 - Reduces an individual's risk of injury.
 - Improves cognitive function.
-

In 2008, the United States Department of Health and Human Services (USDHHS) published the *Physical Activity Guidelines for Americans* (3). This publication aims to increase participation in PA by outlining the minimum PA recommendations necessary to maintain a healthy lifestyle (3). These recommendations follow the Frequency, Intensity, Time, and Type (FITT) principle of exercise prescription.

The intensity of different physical activities can be quantified using metabolic equivalents (METs) (14). METs express the intensity of an activity in comparison to resting energy expenditure, with one MET equal to the rate of energy expenditure at rest (3.5 mL of oxygen/kg/min or 1 kcal/kg/hr for an average adult). The intensity level of a given activity can be described simply as a multiple of 1 MET (14). Using METs, PA can be grouped or classified using the following classifications: light (< 3 METs), moderate (3-<6 METs), and vigorous (≥ 6 METs) intensity PA (14).

In the 2008 USDHHS PA guidelines, healthy adults age 18-64 yr are recommended to participate in at least 150 minutes (2 hours and 30 minutes) of moderate or 75 minutes (1 hour and 15 minutes) of vigorous intensity aerobic PA each week, or an equivalent combination of the two (3) (Table 2). Examples of moderate intensity PA include walking briskly, water aerobics, general gardening, bicycling (slower than 10 miles per hour), and ballroom dancing (3). Similarly, examples of vigorous intensity PA include speed walking, jogging, running, bicycling (faster than 10 miles per hour), and jumping rope (3).

For more extensive health benefits, such as losing and keeping off weight, the USDHHS PA guidelines recommend healthy adults participate in at least 300 minutes (5 hours) of moderate or at least 150 minutes of vigorous intensity aerobic PA each week

(3). The recommended aerobic PA should be performed in bouts of at least 10 minutes and, preferably, should be spread throughout the week (3).

In addition to aerobic PA, healthy adults are also encouraged to participate in activities designed to increase and maintain muscular strength and endurance. These activities should involve all the major muscle groups and should be performed on two or more days of the week (3).

Table 2. United States Department of Health and Human Services 2008 Minimum Aerobic Physical Activity Recommendations for Adults 18-64 yr (3)

Frequency	3- \geq 5 d/wk
Intensity	Moderate and/or Vigorous
Time	20-60 min/d to total 150 min moderate, or 75 min vigorous, or combination; continuous or accumulated
Type	Aerobic Resistance 2-3 d/wk Flexibility 2-3 d/wk

The positive relationship between participation in PA and health is well known. Physical activity, or a predominantly active lifestyle, is associated with a reduced risk for developing several chronic diseases and health conditions such as cardiovascular disease, type 2 diabetes mellitus, hypertension, and several forms of cancer including breast and colon cancer. Additionally, PA results in a reduced risk for increased body weight, thus preventing overweight and obesity (32, 42).

Despite efforts by the USDHHS to increase participation in PA, the number of adults and youth in the United States who are active on a regular basis remains low. Only

35% of American adults over the age of 18 yr meet the minimum PA recommendations set forth by the USDHHS (3, 5).

Along with low rates of PA, the number of people in the United States suffering from chronic diseases remains high. According to the Centers for Disease Control and Prevention, 133 million American adults suffered from at least one chronic disease in 2005 (44). This translates to almost 1 out of every 2 American adults (44). The American Heart Association estimates 36.3% of adults in the United States suffer from cardiovascular disease, 33.3% have hypertension, and 9.35% are diagnosed with type 2 diabetes mellitus (7). Further, an estimated 60% of adults in the United States over the age of 20 yr meet the criteria for overweight and obesity (defined as a BMI ≥ 25 kg/m²) (6, 8). Finally, cardiovascular disease, type 2 diabetes mellitus, and several forms of cancer constitute about 70% of all deaths in the United States (6).

These high rates of chronic disease pose numerous problems. First, chronic disease creates an enormous financial burden to society. In 2005, an estimated 75% of the United States' \$2 trillion medical care budget was devoted to the direct cost of caring for patients with chronic diseases (6). The presence of a chronic disease may also result in a significant loss of wages for the individual with the disease due to time spent away from work (6). In addition to the financial burden, chronic disease can result in a lower quality of life, a loss of independence, and decreased longevity (6). Finally, chronic disease can increase an individual's risk for developing mood disorders such as anxiety and depression (9).

Since participation in PA is known to reduce the risk for developing chronic diseases, researchers are currently examining the efficacy of different policies, strategies

and interventions aimed at increasing the number of people in the United States who participate in PA on a regular basis. However, in order to know whether or not a particular intervention is effective, reliable and valid tools for measuring and assessing PA are necessary.

Self-Report PA Questionnaires: Habitual participation in PA can be measured and assessed through a variety of methods including accelerometers, cardiorespiratory fitness (CRF), daily PA logs, and direct observation (32). Self-report PA questionnaires are currently one of the most practical and widely used methods for assessing PA (10). These questionnaires typically ask respondents to recall participation in certain activities over a specific period of time, and are often used in large epidemiological studies examining the relationship between PA and health outcomes (10, 11).

As is the case with other methods of assessing PA, there are both benefits and limitations associated with using PA questionnaires (Table 3). For instance, PA questionnaires are inexpensive, quick, and relatively easy to administer to large groups of people (1, 2, 12, 13). However, using PA questionnaires to assess participation in PA can result in a greater misclassification of PA habits than objective PA measures due to recall and social desirability biases (12, 15). Additionally, PA questionnaires that are currently available often differ in terms of mode of administration (i.e., self-administered/interview), complexity, length, and difficulty of scoring (28). These differences can have an impact on the efficacy of the questionnaire at measuring and assessing PA. Therefore, before a questionnaire is used to assess PA, it is imperative that it be validated against a criterion measure.

Table 3. The Benefits and Limitations of Self-Report Physical Activity Questionnaires (15)

Benefits	Limitations
<ul style="list-style-type: none">• Low Cost.• Easy to administer to large groups of people.• Easily adapted to fit the needs of a particular population or research question.• Possible to assess all of the dimensions of PA so behavior patterns can be examined.	<ul style="list-style-type: none">• Over reporting of PA often occurs due to social desirability response bias.• Recalling PA is a highly complex cognitive task, and children and older adults may have memory or recall skill limitations.• Researcher and respondent must share an understanding of ambiguous terms such as “physical activity,” “moderate intensity,” “vigorous intensity,” or “leisure time.”• Accuracy of results depends on the respondent’s ability to follow directions.

The Paffenbarger Physical Activity Questionnaire (PPAQ) is a short, self-administered questionnaire designed to measure participation in leisure time PA among young and older adults (29). The current form of the PPAQ consists of eight questions. The first four questions ask respondents to report the number of city blocks they walk and flights of stairs they climb on a typical day, as well as to list the frequency and duration of any sports or recreational activities they participated in over the past year (30). From the answers to these questions, a physical activity index (PAI) can be computed, providing an estimate of energy expenditure (30).

Question six (Q6) of the PPAQ asks respondents to report whether or not they engage in regular PA long enough to work up a sweat, get their heart thumping or get out of breath at least once a week. If the answer is yes, respondents are asked to report the frequency and the type of activity. Both the PAI and the PPAQ Q6 have been validated against CRF, accelerometers, daily PA logs, and various health outcomes, i.e. body mass index (BMI) and high-density lipoprotein (HDL) cholesterol and are believed to be good

measures of participation in moderate and vigorous intensity PA (13, 31, 43).

Question eight (Q8) of the PPAQ asks respondents to report the number of hours they spend on a typical day during the week and weekend sleeping, sitting, and participating in light, moderate, and vigorous intensity PA. Q8 is a useful component of the PPAQ because it assesses participation in sedentary and light activities as well as moderate and vigorous intensity activities, thus providing a more complete estimate of PA than the other components of the PPAQ can on their own.

Several studies have examined the validity of the PPAQ Q8 (32, 43). However, these studies used subject populations consisting of post-menopausal women and individuals of low socioeconomic status (32, 43), so the results may not be generalizable to other populations. Additionally, to the best of the author's knowledge, no study has examined the reliability of Q8. Therefore, a study investigating the validity and reliability of the PPAQ Q8 using a subject population of healthy men and women across the lifespan, regardless of socioeconomic status, is necessary.

Thus, the purpose of this study was to examine the criterion validity as well as the test-retest reliability of the PPAQ Q8. Criterion validity of a PA questionnaire is the degree to which PA measured by responses on the questionnaire match PA measured by a gold standard or a well accepted method of assessing PA (i.e. an accelerometer). There are two main types of criterion validity: concurrent and predictive. Concurrent validity is the degree to which PA measured by a questionnaire matches PA measured by a gold standard when the questionnaire and gold standard are administered at the same point in time. Predictive validity is the degree to which PA measured by a questionnaire matches PA measured by a gold standard when the questionnaire and gold standard are

administered at different time points. Finally, test-retest reliability of a PA questionnaire refers to the degree to which a subject's responses on the questionnaire match the same subject's responses on the questionnaire after a certain period of time. In other words, reliability refers to the stability of responses on the questionnaire over a certain period of time.

This current study utilizes data obtained from a larger National Institutes of Health (NIH) funded (1R01HL081893-01A2) study entitled, "*The Effects of Statins on Muscle Performance*" (STOMP). Therefore, this study is a sub-study of STOMP. STOMP examined the incidence rate of statin-induced muscle symptoms defined as myalgia, as well as the effects of statins on skeletal muscle strength, endurance and aerobic exercise performance in healthy men and women over 20 yr taking either 80 mg of Atorvastatin (Lipitor) or placebo daily for six months.

In this sub-study of STOMP, objectively measured PA from an accelerometer was used to examine the concurrent validity of the PPAQ Q8. Additionally, the predictive validity of the PPAQ Q8 was examined by comparing subject responses on Q8 with CRF, measured by $\text{VO}_{2\text{max}}$, and various health outcomes known to be associated with participation in PA including blood pressure (BP), mean arterial pressure (MAP), triglycerides (TG), total cholesterol (TC), HDL cholesterol, low-density lipoprotein (LDL) cholesterol, resting heart rate (HR), BMI, and waist circumference (WC). Finally, the test-retest reliability of the PPAQ Q8 was examined by comparing subject responses on the PPAQ Q8 at baseline with subject responses at three and six months following baseline.

Specific Aims and Hypotheses: The purpose of this sub-study of STOMP was to

examine the efficacy of the PPAQ Q8 as a tool for assessing PA by investigating its criterion and predictive validity as well as its test-retest reliability.

Specific Aim 1: To assess the concurrent validity of the PPAQ Q8 by examining the relationships among average self-reported hr/d spent in each PA intensity category on Q8 and measurements from an Actical accelerometer, including average daily steps (d^{-1}), activity counts (d^{-1}), energy expenditure (kcal/d), and average time (min/d) spent in each PA intensity category.

Hypothesis 1: Average self-reported hr/d spent participating in moderate and vigorous intensity PA on the PPAQ Q8 will be positively correlated with average daily steps (d^{-1}), activity counts (d^{-1}), and energy expenditure (kcal/d) measured with the Actical accelerometer. Additionally, average self-reported hr/d spent in each PA intensity category on the PPAQ Q8 will be positively correlated with average min/d spent in each PA intensity category measured with an Actical accelerometer.

Specific Aim 2: To determine the predictive validity of the PPAQ Q8 by examining the relationships among average self-reported hr/d spent in each PA intensity category on the PPAQ Q8 and CRF, measured by VO_{2max} .

Hypothesis 2: Average self-reported hr/d spent in vigorous intensity PA on the PPAQ Q8 will be positively correlated with VO_{2max} .

Specific Aim 3: To further determine the predictive validity of the PPAQ Q8 by examining the relationships among average self-reported hr/d spent in each PA intensity category on the PPAQ Q8 and several health outcomes including BP, MAP, TG, TC, HDL and LDL cholesterol, resting HR, BMI, and WC.

Hypothesis 3: Average self-reported hr/d spent engaging in vigorous and

moderate intensity PA on the PPAQ Q8 will show weak, negative associations with BP, MAP, TG, TC, LDL cholesterol, resting HR, BMI, and WC and weak, positive associations with HDL cholesterol.

Specific Aim 4: To examine the test-retest reliability of the PPAQ Q8 by comparing average self-reported hr/d spent in each PA intensity category on the PPAQ Q8 at baseline with average self-reported hr/d spent in each PA intensity category on the PPAQ Q8 three and six months from baseline.

Hypothesis 4: Average self-reported hr/d spent in each PA intensity category on the PPAQ Q8 at baseline will not be significantly different from average self-reported hr/d spent in each PA intensity category reported by the same subjects on the PPAQ Q8 three and six months from baseline.

Literature Review

Validation of Physical Activity Questionnaires: The validity and reliability of a PA questionnaire must be examined prior to it being used to measure and assess participation in PA. To do this, researchers commonly use accelerometers, CRF, and health outcomes known to be associated with participation in PA.

Accelerometers: Researchers often use data from accelerometers as a criterion measure to validate PA questionnaires. Accelerometers are objective PA monitors that allow researchers to examine the frequency, intensity, and duration of PA performed by individuals (21). Considerable research has been conducted to examine the ability of accelerometers to assess PA. Overall, accelerometers have been shown to provide accurate estimates of PA under laboratory conditions. Additionally, accelerometers are small in size, generally well tolerated by participants, and have long-term data storage capabilities (24). As a result, the use of accelerometers in epidemiological studies has become very common over the past several years (22, 23).

The Actical is a fairly new PA monitor currently on the market. It uses a single omni-directional accelerometer to detect motion in multiple directions. However, it is most sensitive within the vertical plane (25). The Actical is capable of detecting low frequency G-forces produced during human movement. Each time a force is detected, the Actical produces a voltage signal that varies in magnitude depending on the intensity of the detected force. This voltage signal is then amplified and digitized. The digitized values are then summed over a specified period of time, known as an epoch, between 15 sec and 1 min (24, 25). Since the data stored by the Actical are proportional to the magnitude and duration of the motions sensed by the accelerometer, they correspond to

the changes in energy expenditure that occurs during PA (24, 25).

Heil (2006) investigated the efficacy of the Actical accelerometer as a means of assessing PA (24). To do this, Heil (2006) fit 24 children and 24 adults with three Actical accelerometers and a small backpack containing a portable metabolic measurement system. Participants wore one Actical on their wrist, another on their ankle, and one on a belt around their hip. Volunteers then completed various activities in the lab including resting, sitting activities, household cleaning activities, walking, and jogging. The researchers used VO_2 measured by the portable metabolic measurement system to compute activity energy expenditure (AEE) (24).

Regression analysis was then used to create one regression (1R) and two regression (2R) models for predicting AEE using the Actical data output from each of the three accelerometers. The resulting 1R and 2R models were then incorporated into algorithms for computing AEE and time values corresponding to sedentary and light (AEE_{SL} , kcal; T_{SL} , min), moderate (AEE_{MOD} , kcal; T_{MOD} , min), and vigorous (AEE_{VIG} , min kcal; T_{VIG}) intensity PA. The AEE and time variables were computed based on minimum bout durations of 1, 3 and 5 min. The regression equations for each Actical location were statistically significant for adults ($R^2=0.14-0.85$, $p<0.008$) (24).

AEE derived from measures of VO_2 were then compared to the predicted values resulting from the 1R and 2R models. For adults, the predicted AEE values were not significantly different from the actual AEE values derived from VO_2 for all of the 1R algorithms and 2R algorithm for the hip-worn Actical (24). Mean values for AEE_{VIG} from the ankle ($M=5.2$ for the 1 min, $M=1.0$ for the 3 min, and $M=1.0$ for the 5 min minimum bout duration, $p<0.01$) and wrist ($M=2.9$ for the 1 min, $M=2.7$ for the 3 min,

and $M=2.2$ for the 5 min minimum bout duration, $p<0.01$) 2R algorithms were significantly lower than the actual mean AEE values ($M=43.9$ for the 1 min, $M=40.9$ for the 3 min, and $M=28.4$ for the 5 min minimum bout) (24).

Additionally, Heil computed the mean and standard deviation of the differences between the predicted values of AEE and the actual AEE values. The positive or negative mean differences represented a tendency of the algorithm to under or overestimate AEE. For adults, the 1R algorithms slightly overestimated most variables (residuals of +4.2 to +15.7 kcal for AEE_{SL} , AEE_{mod} , and AEE_{TOT}). In contrast, the 2R algorithms for adults were less likely to overestimate AEE (residuals of -0.7 to +7.1kcal) (24). As a result of these findings, Heil concluded the Actical accelerometer is a fairly accurate tool for assessing AEE and, therefore, adult PA when worn on the ankle, wrist, or hip (24).

Similarly, Eslinger et al. (2007) examined the validity of the step-count function of the Actical accelerometer by comparing it to two criterion measures. First, eight Actical accelerometers were activated and mounted to the surface of a shaker table. The shaker table was then set to oscillate at six different intensities. The shaker table oscillations per minute for each intensity condition were compared to the number of steps measured by the Actical to assess the ability of the Actical to record steps during each intensity condition. Second, 38 volunteers age 9-59 yr were given eight Actical and eight ActiGraph accelerometers to wear. After a warm up, the volunteers completed three 6 min exercise bouts on a treadmill: a slow walk ($50 \text{ m}\cdot\text{min}^{-1}$), a normal walk ($83 \text{ m}\cdot\text{min}^{-1}$), and a run ($133 \text{ m}\cdot\text{min}^{-1}$). A trained observer visually counted the steps taken by the volunteer during minutes 2 and 4 of each exercise bout using a handheld tally counter

(23).

The correlation between the number of steps detected by the Actical accelerometer and the number of shaker table oscillations per minute during each intensity condition was perfect ($r = 1.0$). Additionally, comparing the number of visually counted steps with the number of steps detected by each accelerometer resulted in near perfect agreement during the normal walk and the run conditions ($r = 0.99$ for both the Actical and the ActiGraph accelerometers). However, agreement between the number of visually counted steps and the number of steps detected by each accelerometer during the slow walk was lower ($r = 0.73$ and 0.52 for the Actical and ActiGraph accelerometers, respectively) (23). These results suggest both the Actical and ActiGraph accelerometers underestimate the number of steps taken during slow walking, but are capable of accurately measuring steps during normal walking and running (23).

The Actical accelerometer has been used in studies examining the validity of PA questionnaires. For instance, Wolin et al. (2008) examined the validity of the short version of the IPAQ in 142 African Americans age 24 to 70 yr. Subjects completed the short version of the IPAQ, which asks respondents to report time spent over the past 7 days participating in walking, moderate, and vigorous intensity PA across leisure time, work, domestic activities, and transportation. For scoring, the following MET values were used: light = 3.3 METs, moderate = 4.0 METs, and vigorous = 8.0 METs. Subjects were considered to have met the minimum PA recommendations if they reported participating in at least 150 min/week of walking, moderate, or vigorous intensity PA.

After completing the IPAQ, subjects wore an Actical accelerometer on their hip for 6 consecutive days. The raw activity data from the Actical accelerometer was

converted to minute-by-minute AEE using the 2R algorithm for the Actical worn on the hip. Activity counts and time spent within light, moderate, and vigorous intensity PA were averaged across the total time each subject wore the accelerometer. Finally, the AEE data were evaluated separately for two minimum bout lengths: 1 min and 10 min (25).

When using the 1 min bout definition, moderate agreement between the IPAQ and accelerometer determined activity counts was observed ($r=0.36$, $p<0.001$). This agreement was higher among men ($r=0.58$, $p<0.001$) and lower among women ($r=0.21$, $p<0.05$). Using the 10 min bout definition, the correlation between the IPAQ and accelerometer measured activity counts was fair ($r=0.26$, $p<0.002$) for the whole sample, moderate for men ($r=0.48$, $p<0.003$), and poor among women ($r=0.07$, $p=0.48$) (25).

The results of these studies suggest the Actical accelerometer is capable of accurately measuring PA levels. Therefore, the Actical accelerometer can be used as a criterion measure to assess the ability of a PA questionnaire to accurately estimate PA.

Cardiorespiratory Fitness: CRF refers to the ability of the circulatory and respiratory systems to deliver oxygen to skeletal muscles during exercise, as well as the ability of the muscles to absorb and use the oxygen to produce energy via cellular respiration (4). As a result, CRF is related to the ability to perform moderate to high intensity PA for prolonged periods of time (4). The gold standard measure of CRF is maximal oxygen uptake ($VO_2\text{max}$). Typically, $VO_2\text{max}$ is determined using indirect calorimetry on a treadmill or bicycle ergometer (16, 17).

$VO_2\text{max}$ is often used to validate PA questionnaires in addition to accelerometers (18). For instance, Aadahl et al. (2006) investigated the validity of a new self-report PA

questionnaire designed to measure PA on an average weekday. In this study, 102 healthy men and women age 35-65 yr described their habitual PA on a typical weekday by reporting the number of hours they spend participating in activities classified into nine different intensity levels. The intensity levels ranged from sleeping (0.9 METS) to vigorous PA (≥ 6.0 METS). From the subject responses, a 24-hr MET score was calculated. Subjects also rated their own physical fitness level as excellent, very good, good, fair, or poor. VO_2max was obtained from a standardized graded bicycle ergometer test with increasing workload until exhaustion (12).

The total amount of PA reported by subjects was not significantly associated with VO_2max ($r^2=0.69$, $p=0.098$). However, there was a strong, significant association between the amount of daily vigorous intensity PA and VO_2max ($r^2=0.76$, $p=0.0001$). Additionally, a significant trend across the self-reported physical fitness groups of excellent/very good, good, and fair/poor in relation to VO_2max was observed (P for trend <0.001) (12).

Richardson et al. (2001) investigated the validity of the Stanford 7-Day Recall (7-DR) by comparing self-reported PA measured by the 7-DR with PA records, Caltrac accelerometer readings, VO_2max , and percent body fat. Test-retest reliability was evaluated by comparing PA assessed by the 7-DR during two separate occasions. In this study, 28 healthy men and 50 healthy women age 21-59 yr completed the 7-DR during visits 10 and 11 of the National Heart, Lung and Blood Institute funded Survey of Activity, Fitness and Exercise (SAFE) study. These two study visits were separated by approximately 26 days (19).

The 7-DR asks subjects to report the number of hours they spent sleeping and

engaging in moderate (3.0-5.0 METs), hard (5.1-6.9 METs), and very hard (≥ 7 METs) PA during the previous seven days. The time subjects reported sleeping and engaging in moderate, hard, and very hard PA was subtracted from 24 hrs to determine time spent engaging in light activity (1.0-2.9 METs). For scoring, the following MET levels were assigned to each PA category: sleep = 1 MET, light = 1.5 METs; moderate = 4 METs; hard = 6 METs; and very hard = 10 METs. Results were reported as the product of the MET level and the duration of activity in minutes (MET-minutes \cdot day⁻¹) (19). For 48 hrs prior to SAFE study visits 10 and 11, subjects wore a Caltrac accelerometer and recorded the PA they performed during this time period in a PA log. VO₂max was measured using a maximal graded treadmill test and percent body fat was determined by hydrostatic weighing (19).

For men, total ($r=0.49$, $p<0.05$ at visit 10 and $r=0.54$, $p<0.01$ at visit 11) and very hard ($r=0.48$, $p<0.05$ at visit 10 and $r=0.62$, $p<0.01$ at visit 11) PA measured by the 7-DR during visits 10 and 11 were significantly correlated with VO₂max. For women, the correlations between total ($r=0.14$, $p>0.05$ at visit 10 and $r=0.47$, $p<0.01$ at visit 11) and very hard ($r=0.24$, $p>0.05$ at visit 10 and $r=0.42$, $p<0.01$ at visit 11) PA measured by the 7-DR and VO₂max were weaker and less consistent (19).

Kurtze et al. (2008) examined the validity of the short version of the IPAQ by comparing PA measured by the IPAQ to VO₂max and PA assessed by the ActiReg activity monitor. In this study, 108 Norwegian men age 20-39 yr were randomly selected from the Nord-Trøndelag Health Study (HUNT) to participate. VO₂max was measured for each subject in this study using a maximal graded treadmill test. Each subject then wore an ActiReg activity monitor for seven consecutive days. Following this, volunteers

completed the IPAQ, which consisted of seven questions pertaining to the PA they participated in during the previous seven days. These questions asked subjects to report the number of days, hours and minutes they spent engaging in vigorous intensity PA, moderate intensity PA, walking, and sitting during the previous week (20).

For scoring purposes, the following MET values were assigned to each activity category: vigorous intensity PA = 8 METs, moderate intensity PA = 4 METs, and walking = 3.3 METs. A total MET value for each activity category was calculated by multiplying the time spent in each category by the category's assigned MET value. Additionally, a total was calculated for each intensity category by computing an index of days, hours and minutes. Each subject completed the IPAQ a second time seven days following the first administration of the questionnaire. PA assessed by the IPAQ during the first administration of the questionnaire was compared to PA assessed by the second administration to determine test-retest reliability of the IPAQ (20).

Subjects in this study who reported participating in the highest amount of vigorous intensity PA over the previous seven days (4-6 hrs) also had the highest mean VO_2max ($49.2 \text{ ml}\cdot\text{kg}^{-1}\cdot\text{min}^{-1}$). VO_2max also showed moderately strong, significant correlations with total vigorous intensity PA, hours per week spent participating in vigorous intensity PA, and number of days per week subjects reported participating in vigorous intensity PA ($r = 0.41, 0.40, \text{ and } 0.36$ respectively, $p < 0.01$). Moderate intensity PA, walking and sitting were not significantly correlated with VO_2max (20).

The results of these studies suggest VO_2max is associated with the amount of time spent engaging in vigorous intensity PA. Therefore, VO_2max can be used to assess the ability of a PA questionnaire to accurately measure time spent in vigorous intensity PA.

However, since CRF is influenced by genetics, VO₂max cannot be the only method used to validate a PA questionnaire.

Health Outcomes: In addition to accelerometers and VO₂max, researchers often use health outcomes associated with participation in PA to validate PA questionnaires. For instance, Bowles et al. (2004) examined the validity of self-reported historical walking, running, and jogging activity by comparing subject responses to anthropometric measurements as well as CRF, BP, and serum lipids. In this study, 4,100 men 18-80 yr and 963 women 18-75 yr underwent a medical examination at least once between the years 1976 and 1985. During the medical examination, height, weight, BP, cholesterol, and TG concentrations were measured. In addition, CRF was measured during the examination by performance on a maximal treadmill test using a modified Balke protocol (26).

In 1986, each study participant completed a survey designed to assess the amount of walking, running, or jogging they completed each year during the previous decade. Each participant was classified as sufficiently or insufficiently physically active based on his or her responses on the survey. Men classified as sufficiently physically active had significantly lower TG levels (mean difference = 28.38, $p = 0.001$) and BMI (mean difference = 1.35, $p < 0.001$) and higher treadmill times (mean difference = -4.96, $p < 0.001$) than men classified as insufficiently physically active. Women classified as sufficiently physically active had significantly lower BMI (mean difference 0.80, $p < 0.001$) and higher treadmill times than women classified as insufficiently physically active (mean difference = -4.63, $p < 0.001$) (26).

Similarly, Graff-Iversen et al. (2007) examined the validity of the long version of

the IPAQ. In this study, 1068 men and 1372 women 31-67 yr living in the Oslo region of Norway completed the IPAQ. Investigators measured and recorded anthropometric and biological characteristics of each subject. Such characteristics included height, weight, WC, hip circumference, resting BP, HR, and serum cholesterol, glucose and TG. The anthropometric and biological characteristics of each subject were compared to the energy expenditure of each subject assessed by the IPAQ (27).

Correlations between energy expenditure determined by the IPAQ and the anthropometric and biological characteristics were weak but significant. For both men and women, the strongest correlations were found for vigorous leisure time PA and total vigorous PA. In men, diastolic BP ($r = -0.13$ and -0.11 , $p < 0.001$), waist/hip ratio ($r = -0.14$ and -0.12 , $p < 0.001$), TG ($r = -0.13$ $p < 0.001$, $r = -0.07$, $p < 0.05$), HDL cholesterol ($r = 0.12$ $p < 0.001$, $r = 0.08$ $p < 0.01$), and glucose ($r = -0.07$ and -0.07 , $p < 0.05$) were significantly correlated with both vigorous leisure time PA and total vigorous PA, respectively. BMI for men was only significantly correlated with vigorous leisure time PA ($r = -0.07$, $p < 0.05$). In women, diastolic BP ($r = -0.08$ and -0.07 , $p < 0.01$), BMI ($r = -0.09$ $p < 0.001$ and $r = -0.06$ $p < 0.05$), waist/hip ratio ($r = -0.09$ $p < 0.01$, $r = -0.06$ $p < 0.05$), TG ($r = -0.12$ and -0.12 , $p < 0.001$), HDL cholesterol ($r = 0.07$ $p < 0.05$, $r = 0.08$ $p < 0.01$) and glucose ($r = -0.12$ and -0.10 , $p < 0.001$) were also significantly correlated with both vigorous leisure time PA and total vigorous PA, respectively (27).

Washburn et al. (1991) examined the validity of the Harvard Alumni Activity Survey by comparing subject responses to HDL cholesterol and BMI. In this study, 645 men and women between 25-65 yr completed the Harvard Alumni Activity Survey in their home during a baseline interview and again during follow up interviews 7-12 wk

later. During the baseline interview, field researchers also obtained a series of physiologic measurements including BP, height and weight. A single, non-fasted blood sample was also obtained during the baseline interview for HDL and total cholesterol measurements. Test-retest correlations for daily energy expenditure reported at baseline and follow up was moderate ($r = 0.58$) for the sample as a whole. Pearson correlations between the natural log values of reported energy expenditure and HDL cholesterol and BMI were weak but statistically significant ($r = 0.14$ and -0.13 respectively, $p < 0.01$). These results suggest the Harvard Alumni Activity Survey is a valid and reliable tool for assessing habitual PA (28).

The results of these studies show weak but significant correlations between self-reported PA and health outcomes known to be associated with PA. As a result, health outcomes known to be associated with PA can be used, along with accelerometers and CRF, to assess the ability of a questionnaire to accurately estimate PA.

Paffenbarger Physical Activity Questionnaire: The PPAQ is an example of a questionnaire used in epidemiological studies to assess PA and, therefore, must be validated. The PPAQ, also commonly referred to as the College Alumni Questionnaire and the Harvard Alumni Questionnaire, was designed to measure leisure time PA in young and older adults (29). In its original form, the PPAQ asked respondents to report the number of city blocks they walk and the number of flights of stairs they climb on a typical day, as well as the frequency and type of any sports or recreational activities they participated in over the past year (30). Using subject responses to these questions, Paffenbarger et al. (1978) was able to estimate energy expenditure by calculating a PAI (30).

Since the development of the PPAQ, a number of studies have investigated the validity of the PAI as an estimate of energy expenditure and PA. For instance, Ainsworth et al. (1993) examined the validity of the PAI using a sample of 50 healthy women and 28 healthy men. This study consisted of 14 visits to the laboratory over a 12 month time period. Each study visit was separated by approximately 26 days. Participants completed the PPAQ during study visits 1, 8, and 9. Investigators computed the PAI for each subject and compared it to measures of CRF, body fatness, PA data from an accelerometer, and PA records (13).

In men, the PAI was significantly correlated with total and heavy intensity leisure time PA measured by the PA records ($r=0.60$ and $r=0.69$ $p<0.01$, respectively) and $VO_2\text{max}$ ($r=0.55$ $p<0.01$). In women, the PAI was also significantly correlated with total and heavy intensity leisure time PA measured by the PA records ($r=0.34$ and $r=0.65$ $p<0.01$, respectively) as well as $VO_2\text{max}$ and percent body fat ($r=0.53$ $p<0.01$ and $r=0.36$ $p<0.05$, respectively) (13). However, the PAI scores from the PPAQ were lower than the scores obtained from the PA records. This may be due to the fact that the PAI does not assess activities of daily living, which often includes sedentary and light intensity activities. The test-retest reproducibility of the PAI was highest after 1 month ($r = 0.72$) and lower after 8 and 9 months ($r = 0.35$ and 0.43 respectively, $p< 0.05$). These results suggest the PAI from the PPAQ is a moderately good tool for measuring habitual PA status and it has acceptable short-term repeatability (13).

The current form of the PPAQ includes the questions that make up the PAI as well as several additional questions regarding the frequency and intensity of PA the respondent participates in (Appendix A). There are several studies in the literature

examining the validity of the additional questions on the current form of the PPAQ. For instance, the PPAQ Q6 asks, “At least once a week, do you engage in regular activity akin to brisk walking, jogging, bicycling, swimming, etc. long enough to work up a sweat, get your heart thumping, or get out of breath?” If the answer is yes, respondents are asked to report the activity and the number of times per week they participate in the activity. If the answer is no, respondents are asked to provide a reason as to why not.

Siconolfi et al. (1985) examined the relationship between the frequency of participation in PA long enough to work up a sweat reported on the PPAQ Q6 and VO_2max in healthy men and women age 20-70 yr. The correlations for VO_2max and frequency of participation in activities long enough to work up a sweat obtained in this study were significant for men and the total group ($r = 0.54$ and 0.46 , respectively $p < 0.01$). These results suggest CRF can be assessed rapidly in epidemiologic studies using the PPAQ Q6 (31).

In addition to Q6, limited research is also available investigating the validity of the PPAQ Q8. The PPAQ Q8 asks respondents to report how much time they spend participating in PA of different intensities. Respondents are asked to report the number of hours they spend on a typical week day and weekend day sleeping, sitting and participating in light, moderate, and vigorous intensity PA.

Mahabir et al. (2006) examined the validity of the PPAQ Q8 as a tool for assessing PA in a group of 65 post-menopausal women over 50 yr. Volunteers in this study first completed the PPAQ Q8. The MET values assigned to the sleeping, light, moderate, and vigorous PA intensity levels were 1, 2, 4, and 6, respectively. An average METs/hr was calculated by multiplying the time (hrs) each subject reported sleeping and

engaging in light, moderate, and vigorous intensity PA by the assigned MET values, summing the four results, and dividing by the total hours in a week. Energy expenditure (kcal/day) was measured for each subject using the Doubly Labeled Water method. Daily energy expenditure estimated by the PPAQ Q8 was significantly correlated with energy expenditure measured by the doubly labeled water method ($r = 0.36$, $p < 0.05$). However, compared with the doubly labeled water method, the PPAQ Q8 overestimated energy expenditure (percent difference in the means was 62%) (32).

Similarly, Rundle et al. (2007) examined the validity of the PPAQ Q8 as a tool for assessing PA in a group of 192 men and women age 18-74 yrs who were enrolled in a larger study examining the effects of antioxidant micronutrients among cigarette smokers. All volunteers in this sub-study were of low socioeconomic status and smoked at least 10 cigarettes a day at the time of enrollment (43).

Volunteers in this sub-study completed the PPAQ Q8 during the 12-month visit of the larger antioxidant micronutrients study. The MET values assigned to the sleeping, sitting, light, moderate, and vigorous PA intensity categories were 0.9, 1, 3, 4.5, and 7, respectively. For each PA intensity category, the number of hours reported was multiplied by the corresponding MET value to get a MET×hr score for a typical day during the week and weekend. To estimate total weekly activity, the MET×hr score for weekday activity was multiplied by 5 and the MET×hr score for weekend activity was multiplied by 2, and the resulting quantities were summed. This resulted in an estimate of energy expenditure expressed in units of MET×hr per week. After completing Q8, each volunteer then had his or her BP measured. BMI (kg/m^2) was calculated for each subject using his or her height (m) measured at the time of enrollment and weight (kg)

measured during the 12-month visit (43).

After controlling for age, gender, and number of cigarettes smoked per day, weekly activity estimated by the PPAQ Q8 was significantly, inversely associated with BMI, systolic BP, and diastolic BP ($p=0.01$) (43).

The results of the studies done by Mahabir and Rundle suggest the PPAQ Q8 is a valid tool for assessing PA among men and women of low socioeconomic status, but overestimates PA among post-menopausal women (32, 43). However, little information is available regarding the validity and reliability of this question as a tool for assessing PA in healthy men and women across the lifespan.

Methods

STOMP Overview: This study investigated the validity and test-retest reliability of the PPAQ Q8 using data from a larger study entitled, “*The Effects of Statins on Muscle Performance*” (STOMP). STOMP was funded by the National Institutes of Health (NIH) (1R01HL081893-01A2) and was conducted by researchers at Hartford Hospital, the University of Massachusetts, Amherst, and the University of Connecticut, Storrs. The specific aims of STOMP were to investigate the incidence rate of statin-induced muscle symptoms, defined as myalgia, as well as the effects of statins on skeletal muscle strength, endurance, and aerobic exercise performance in healthy men and women taking either 80mg of Atorvastatin (Lipitor) or placebo daily for six months. The institutional review boards at all three of the study sites approved the experimental design of STOMP, which has been described in detail elsewhere (34).

STOMP consisted of six visits to the laboratory over a period of approximately six months (Figure 1). During study visit one (V1), subjects provided a blood sample in the

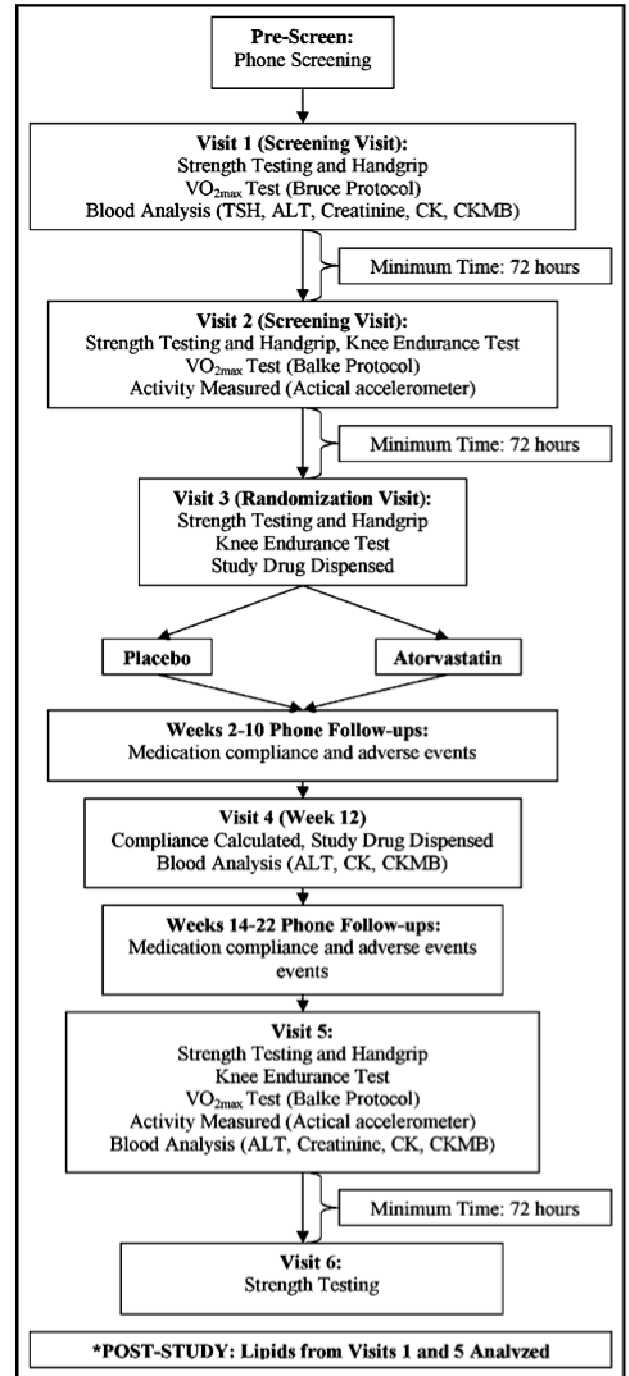


Figure 1: Overview of STOMP study (34)

fasted state. Subjects then completed several quality of life assessment forms, including the PPAQ, and performed a series of elbow and knee flexion/extension isometric and isokinetic strength tests using a Biodex System 3 isokinetic dynamometer (Biodex Medical, Shirley, NY). Finally, subjects underwent a brief physical examination as well as a physician supervised maximal graded treadmill test using a Bruce protocol with electrocardiographic monitoring.

Study visit two (V2) occurred at least 72 hrs following V1. During V2, subjects performed another series of elbow and knee flexion/extension isometric and isokinetic strength tests on the Biodex. CRF was measured using a modified Balke protocol maximal graded treadmill test. At the end of V2, subjects received an Actical accelerometer and were instructed to wear it for at least four consecutive days (96 hrs) including two days during the week and two days during the weekend.

Study visit three (V3) occurred at least 96 hrs following completion of V2. During V3, subjects returned the Actical accelerometer and performed another series of elbow and knee flexion/extension isometric and isokinetic strength tests on the Biodex. At the end of V3, subjects received a three-month supply of either Atorvastatin or placebo. Subjects were instructed to take two pills every evening for the next three months. During the three-month time period, subjects were contacted every other week by a study investigator to document the presence of any muscle symptoms associated with statins.

Study visit four (V4) occurred approximately three months following the completion of V3. During V4, subjects completed the PPAQ and provided a blood sample in a non-fasted state. At the end of V4, subjects received another three-month

supply of study medication and were instructed to continue taking two pills every evening. During the next three-month period, subjects were again contacted via telephone every other week by a study investigator to document the presence of any muscle symptoms associated with statins.

Study visit five (V5) occurred approximately three months following the completion of V4. During this visit, subjects provided another blood sample in the fasted state. Subjects then completed the PPAQ and performed another series of elbow and knee flexion/extension isometric and isokinetic strength tests on the Biodex. CRF was again measured using a modified Balke protocol maximal graded treadmill test. At the end of V5, subjects received an Actical accelerometer and were instructed to wear it for another four consecutive days (96 hrs) including two days during the week and two days during the weekend.

Study visit six (V6) took place at least 96 hrs following the completion of V5. During V6, subjects returned the Actical accelerometer. They then performed one last series of elbow and knee flexion/extension isometric and isokinetic strength tests on the Biodex.

PA measured by the Actical, CRF measured by VO_2max , and health outcomes associated with participation in PA collected during STOMP were used in this sub-study to determine the concurrent and predictive validity and test-retest reliability of the PPAQ Q8.

Subjects: Subjects for STOMP were recruited via study flyers, email announcements, and radio/newspaper advertisements. Volunteers in STOMP included equal numbers of men and women in the age groups 20-39, 40-54, and 55+ yr. Written informed consent

was obtained from all subjects prior to participating (Appendix B). Individuals with diabetes mellitus, hyper- or hypothyroidism, who had any kind of surgery or injury to the knees or hips that would prevent the individual from exercising vigorously on a treadmill, who were presently or had previously been treated with cholesterol-lowering medications, or who had a heart condition that required medication or a restriction of activity were excluded from participating in STOMP. Anyone with hepatic disease (alanine aminotransferase > 2x the normal limit) or renal disease (creatinine > 2mg/L), as determined by the fasted blood sample obtained during V1, or occult cardiac ischemia documented during the physician-supervised treadmill test using a Bruce protocol with electrocardiographic monitoring in V1 were also excluded from STOMP (34).

Individuals using hypertensive medications were included in the study so long as they had been on the medication for at least three months and their BP was stable (<140/90 mmHg). BP was monitored during V1 and V2 of STOMP to ensure each subject's eligibility. Women of childbearing age who participated in STOMP were given a urine pregnancy test at the start (V1) and conclusion (V5) of the study and were asked to use a type of contraception throughout the duration of their participation in the study (34).

Sub-Study Procedures

Paffenbarger Physical Activity Questionnaire: Subjects completed the PPAQ for the first time during V1. At the beginning of this visit, a STOMP study investigator gave the PPAQ to the subject and explained how to properly complete the questionnaire. Subjects were then instructed to take their time and complete the PPAQ to the best of their ability. Once the subject finished completing the questionnaire, the investigator

checked over the completed PPAQ to ensure there were no errors or omissions. If errors or omissions were detected, the investigator clarified them with the subject.

Although STOMP subjects were asked to complete the entire PPAQ, only their responses on Q8 were used in this sub-study. The PPAQ Q8 asks subjects to report the number of hours they spent sleeping and participating in sitting activities and PA of light, moderate and vigorous intensity on a typical day during the week and during the weekend. According to Q8, sitting activities include “eating, reading, desk work, watching TV, listening to the radio, etc.” Light intensity activities (<3 METs) are defined as “office work, driving car, strolling, personal care, standing with little motion, etc.” Moderate intensity activities (3-6 METs) are “housework, light sports, regular walking, golf, yard work, lawn mowing, painting, repairing, light carpentry, ballroom dancing, bicycling on level ground, etc.” Finally, vigorous intensity activities (>6 METs) include “digging in the garden, strenuous sports, jogging, aerobic dancing, sustained swimming, brisk walking, heavy carpentry, bicycling on hills, etc.” For this STOMP sub-study, the concurrent and predictive validity of PPAQ Q8 were examined by comparing subject responses on Q8 during V1 with measurements from an Actical accelerometer, VO_2max , and health outcomes.

V4 and V5 of STOMP occurred approximately three and six months following the completion of V3, respectively. During these two visits, STOMP subjects completed the PPAQ the same way they did during V1. For this sub-study, the test-retest reliability of the PPAQ Q8 was examined by comparing subject responses on the PPAQ during V1 with their responses during V4 and V5 in a sample of subjects ($n = 130$) who were randomized to receive the placebo during the STOMP study.

In most situations, PA data collected using the PPAQ was analyzed exactly as reported by the subject. However, in instances where a subject's response to a section on the questionnaire was not entirely clear, all study investigators used a set of strict standard procedures to appropriately interpret and correct the data (Appendix C).

Health outcomes of PA: During V1, blood samples were collected from the antecubital space on the arm of each subject. These blood samples were allowed to sit at room temperature for at least 10 minutes. They were then centrifuged at 3400 rpm for 15 minutes (VanGuard V6500, Hamilton Bell Co., Inc., Montvale, NJ, USA). After the blood samples were centrifuged, 1 mL aliquots of serum were obtained and shipped to Clinical Laboratory Partners in Hartford, CT for serum lipid (ml/dL) analysis including TC, TG, LDL and HDL cholesterol.

Following the blood draw during V1, subjects underwent a brief physical examination with a physician. During this examination, the subject's height and weight were measured and recorded. Prior to measuring height and weight, subjects were instructed to remove their shoes and any heavy or bulky clothing, such as a jacket or sweatshirt. Height was measured using a wall-mounted tape measure while the subject stood erect with their head in the neutral position. Height was initially measured in inches and then converted to centimeters by multiplying by 2.54. Weight was then measured using a calibrated balance beam scale. Weight was initially measured in pounds and then converted to kilograms by dividing by 2.2. From the height and weight measurements, BMI was calculated (kg/m^2).

Following the height and weight measurements, WC (cm) was measured using a Gulick spring-loaded tape measure. With the subject standing, arms at their sides, feet

together and abdomen relaxed, a horizontal measure was taken at the narrowest part of the torso (above the umbilicus and below the xiphoid process). The study investigator took two measurements. The average of the two measurements was used in this study, provided the measurements were within 5 mm of one another. If the two measurements were not within 5 mm of one another, the study investigator continued to take measurements until he/she obtained two measurements that were within 5 mm of one another.

Following the physical examination during V1, subjects completed a graded treadmill test using a Bruce protocol to exclude individuals with occult ischemic coronary artery disease. Prior to and at certain points during this treadmill test, BP (mmHg) and HR (b/min) were measured. Resting BP (mmHg) was measured via auscultation using a mercury sphygmomanometer (Trimline™, PyMaH Corp., Somerville, NJ, USA), a Trimline BP cuff (Omni Kuff®, Latex Free, Universally connection BALANCED® design, Trimline Medical Products, Somerville, NJ, USA) and a Cardiology stethoscope (3M™ Litman® Lightweight II SE, St. Paul, MN, USA) while the subject sat with their back and arms supported and their legs uncrossed. MAP (mmHg) was calculated from the resting systolic and diastolic BP readings ($MAP = Diastolic\ BP + 1/3(Systolic\ BP - Diastolic\ BP)$). Resting HR (b/min) was also measured while the subject was seated using a HR monitor (Polar Vantage NV™ HR Monitor, Polar Electro Inc., Port Washington, NY, USA).

Cardiorespiratory Fitness: CRF was measured during V2 and V5 of STOMP using a modified Balke maximal treadmill test (4, 36, 37). Only CRF measured during V2 was used in this study. VO_{2max} (ml/dg/min) was determined by breath-by-breath

analysis of expired gases via an open circuit respiratory apparatus (Parvomedics TrueOne 2400 metabolic cart, Parvomedics Corp, Sandy, UT, USA).

During the maximal treadmill test, subjects were asked to sit quietly for five minutes prior to the start of the treadmill test. Following five minutes of seated rest, subjects began the protocol by walking on the treadmill for two minutes at a speed of two miles per hour and a 0% treadmill incline. Following these initial two minutes, the speed of the treadmill was increased until the subject was running at a speed at which they could comfortably maintain their natural stride for at least 30 minutes. This treadmill speed remained constant throughout the remainder of the test. However, the incline of the treadmill was increased by 1% after every minute. Periodically throughout the test, the subject's BP was measured, their HR was recorded, and the subject reported how hard they were working using a rating of perceived exertion (RPE) from the 15 point Borg scale (41). Treadmill test termination criteria included: an overall RPE ≥ 18 , a plateau in oxygen uptake, a respiratory exchange ratio >1.1 , achievement of the age predicted maximum HR ($220 - \text{subject's age}$), and/or termination by the subject due to fatigue or discomfort (4).

Actical Accelerometer: Subjects wore an Actical accelerometer between V2 and V3 and again between V5 and V6. Only the Actical data collected between V2 and V3 was used in this study. At the end of V2, STOMP subjects received the Actical accelerometer (Mini Mitter Company, Bend, OR, USA). The Actical was securely fastened to a hip clip allowing the subjects to wear the Actical attached to their belt or the waistband of their pants. The device was set to record PA in 25-sec epochs and was initialized to begin recording data immediately. The subjects were instructed to wear the

Actical for at least four consecutive days (96 hrs; two days during the week and two days over the weekend) and were told to only take the Actical off when they were swimming, bathing, showering, or sleeping. If subjects removed the Actical to swim during the 96 hr time period, they were asked to record the intensity and duration of their swim.

Subjects returned to the laboratory for V3 at least 96 hr following completion of V2. During this visit, subjects returned the Actical accelerometer. The raw data from the Actical accelerometer was downloaded immediately to a computer using a telemetry-based receiver that connects to the computer via a serial port connection. A STOMP investigator quickly examined the raw data to ensure the accelerometer properly registered the subject's PA. If the Actical did not properly record a subject's PA or if the subject reported not wearing the Actical for 96 consecutive hrs, the subject was asked to wear the monitor for another four consecutive days.

If the Actical properly recorded the subject's PA, the raw data was then exported to Microsoft Excel for further processing and analysis. From the raw data obtained from the Actical, the average number of daily steps (d^{-1}), activity counts (d^{-1}), energy expenditure (kcal/day), and average daily time (min/d) spent being sedentary and engaging in light, moderate, and vigorous intensity PA was calculated.

Data Administration: Data collected during the STOMP study was compiled in an online master database, which was maintained by the study coordinator (BAP) at Hartford Hospital, Hartford, CT. Investigators from each of the three study sites manually entered STOMP data into the online database. Access to the database was limited to study personnel and was secured using confidential usernames and passwords.

Statistical Analysis: Prior to any statistical analysis, from the PPAQ Q8, the number of

hours subjects reported spending sleeping and sitting were added to obtain the number of hours on a typical day during the week and a typical day during the weekend subjects spend sedentary. For example:

$$(\# \text{ hrs sleeping on a weekday}) + (\# \text{ hrs sitting on a weekday}) = \# \text{ hrs sedentary on a weekday}$$

Then, for each PA intensity category on the PPAQ Q8, the number of hours reported for a typical day during the week and a typical day during the weekend were averaged to obtain the average number of hours subjects spend being sedentary and engaging in light, moderate, and vigorous intensity PA. For example:

$$[(\# \text{ hrs Vigorous Weekday}) + (\# \text{ hrs Vigorous Weekend Day})] \div 2 = \text{Average } \# \text{ hrs Vigorous}$$

Descriptive statistics were then calculated on all study variables and were reported as the mean \pm standard error of the mean (SEM).

Hypothesis 1 (Concurrent Validity): To determine the concurrent validity of the PPAQ Q8, Pearson product-moment correlation coefficients were calculated to assess the relationships among average self-reported time (hr/d) spent being sedentary and engaging in light, moderate, and vigorous intensity PA on the PPAQ Q8 during V1 and average daily steps (d^{-1}), activity counts (d^{-1}), energy expenditure (kcal/d), and time (min/d) spent in each PA intensity category measured with the Actical accelerometer. For any relationship that was significant, multivariable regression analysis was used to determine the influence of age, gender, and season during which the PPAQ Q8 was completed

during V1 on the relationship. All multivariable regression models were zero-centered to limit the likelihood of multicollinearity.

Hypothesis 2 (Predictive Validity): To examine the predictive validity of the PPAQ Q8, Pearson product-moment correlation coefficients were calculated to examine the relationships among average self-reported time (hr/d) spent being sedentary and in light, moderate, and vigorous intensity PA on the PPAQ Q8 during V1 and CRF, measured by VO_2max (ml/kg/min). For any relationship that was significant, multivariable regression analysis was used to determine the influence of age, gender, and season during which the PPAQ Q8 was completed during V1 on the relationship. All multivariable regression models were zero-centered to limit the likelihood of multicollinearity.

Hypothesis 3 (Predictive Validity): To further examine the predictive validity of the PPAQ Q8, Pearson product-moment correlation coefficients were calculated to examine the relationships among average self-reported time (hr/d) spent in each PA intensity category on the PPAQ Q8 during V1 and various health outcomes, including resting BP, MAP, TG, TC, LDL and HDL cholesterol, resting HR, BMI, and WC. For any relationship that was significant, multivariable regression analysis was used to determine the influence of age, gender, and season during which the PPAQ Q8 was completed during V1 on the relationships. All multivariable regression models were zero-centered to limit the likelihood of multicollinearity.

Hypothesis 4 (Test-Retest Reliability): To determine the test-retest reliability of the PPAQ Q8, Pearson product moment correlation coefficients were calculated to compare self-reported time (hr/d) spent in each PA intensity category on the PPAQ Q8

during V1 with self-reported time (hr/d) spent in each PA intensity category on the PPAQ Q8 during V4 and V5. Pearson product moment correlation coefficients were also used to compare average self-reported time (hr/d) spent in each PA intensity category on the PPAQ Q8 during V4 with average self-reported time (hr/d) spent in each PA intensity category on the PPAQ Q8 during V5. A repeated measures ANCOVA, with gender and season during which subjects completed the PPAQ Q8 during V1 as fixed factors and age as a covariate, was used to examine whether or not average self-reported time (hr/d) spent in each PA intensity category on the PPAQ Q8 was significantly different at three and six months.

All statistical analyses were performed with the Statistical Package for the Social Sciences (SPSS) Base 14.0 for Windows (SPSS Inc, Chicago, IL) with $p < 0.05$ established as the level of statistical significance.

Results

PPAQ Q8 Validity

Subject Characteristics: The sample for the validity portion of this sub-study ($n=240$) consisted of mostly young, healthy, Caucasian (85.8%) men ($n=118$) and women ($n=122$) (Table 4). Subjects were overweight with above optimal LDL cholesterol, optimal BP, desirable TC; and normal MAP, HDL cholesterol, and TG. Men were heavier ($p=0.000$) and had higher BP ($p=0.000$), WC ($p=0.000$), and TG ($p=0.005$), and a lower resting HR than women ($p=0.002$). Women, however, had higher HDL cholesterol than men ($p=0.000$) (Table 4).

Table 4. Subject Characteristics (Mean \pm SEM)

Characteristics	Total ($n=240$)	Men ($n=118$)	Women ($n=122$)
Age (yr)	39.6 \pm 0.9	40.1 \pm 1.4	39.1 \pm 1.3
Height (m)	1.7 \pm 0.1	1.8 \pm 0.1*	1.7 \pm 0.0
Weight (kg)	77.9 \pm 1.1	87.3 \pm 1.4*	68.9 \pm 1.2
BMI (kg/m ²)	26.3 \pm 0.3	27.4 \pm 0.4*	25.3 \pm 0.4
Systolic Blood Pressure (mmHg)	116.8 \pm 0.9	120.2 \pm 1.2*	113.5 \pm 1.1
Diastolic Blood Pressure (mmHg)	74.7 \pm 0.6	76.5 \pm 0.9 ψ	72.9 \pm 0.8
Mean Arterial Pressure (mmHg)	88.7 \pm 0.7	91.1 \pm 0.9*	86.5 \pm 0.9
Resting Heart Rate (b/min)	69.7 \pm 0.8	67.4 \pm 1.1 ψ	71.9 \pm 1.1
Waist Circumference (cm)	85.2 \pm 0.9	91.9 \pm 1.3*	79.1 \pm 1.1
VO ₂ max (ml/kg/min)	35.3 \pm 0.6	39.5 \pm 0.8	31.4 \pm 0.8
High Density Lipoprotein Cholesterol (mg/dL)	57.5 \pm 1.1	51.0 \pm 1.4*	63.3 \pm 1.6
Low Density Lipoprotein Cholesterol (mg/dL)	113.9 \pm 2.2	118.3 \pm 2.9	109.9 \pm 3.3
Total Cholesterol (mg/dL)	191.7 \pm 2.6	191.9 \pm 3.3	191.4 \pm 3.9
Triglycerides (mg/dL)	102.8 \pm 3.8	113.9 \pm 6.5 ψ	92.6 \pm 4.1

Men vs. Women: ψ $p<0.01$, * $p<0.001$

Specific Aim 1: The first specific aim of this STOMP sub-study was to assess the

concurrent validity of the PPAQ Q8 by examining the relationships among self-reported PA on the PPAQ Q8 during V1 and the Actical accelerometer measurements. The average min/d subjects spent being sedentary and engaging in light, moderate, and vigorous intensity PA measured with the Actical accelerometer by age group is shown in Table 5. Subjects spent the most amount of time (min/d) being sedentary, followed by light and moderate, and the least amount of time in vigorous intensity PA ($p=0.000$). Individuals in the youngest age group had a tendency to spend more min/d in moderate intensity PA than individuals in the oldest age group ($p=0.085$) (Table 5).

Table 5. Average Daily Time (min/d) (Mean \pm SEM) Spent in each Physical Activity Intensity Category Measured with the Actical by Age Group

Age Group (yr)	Sedentary* (1 – <1.5 METs)	Light Intensity* (1.5 – 3 METs)	Moderate Intensity* (3 – 6 METs)	Vigorous Intensity* (≥ 6 METs)
20-29	1088.8 \pm 11.4	202.3 \pm 6.8	143.9 \pm 5.7	5.0 \pm 0.9
30-48	1084.5 \pm 11.1	219.5 \pm 6.7	133.4 \pm 5.9	2.6 \pm 0.7
49-82	1103.1 \pm 11.9	206.5 \pm 7.4	126.5 \pm 5.7	3.9 \pm 1.1

*Sedentary vs. Light vs. Moderate vs. Vigorous $p=0.000$, independent of age

There was a positive association between average self-reported hr/d spent engaging in vigorous intensity PA on the PPAQ Q8 during V1 and average daily activity counts (d^{-1}) measured with the Actical ($p=0.022$). Additionally, average self-reported hr/d spent being sedentary and engaging in moderate and vigorous intensity PA on the PPAQ Q8 during V1 was positively associated with average min/d spent being sedentary and in moderate and vigorous intensity PA measured with the Actical accelerometer (sedentary $p=0.005$, moderate $p=0.000$, vigorous $p=0.045$, respectively). Age, gender,

and season during which the PPAQ Q8 was completed did not influence these relationships ($p>0.05$) (Table 6).

Table 6. Correlations among Intensity Categories on the Paffenbarger Physical Activity Questionnaire Question Eight Completed during Visit One and the Actical Accelerometer Measurements

Actical Measurements	Sedentary	Light Intensity	Moderate Intensity	Vigorous Intensity
Average Steps (day^{-1})	0.022	-0.147*	0.077	0.089
Average Activity Counts (day^{-1})	0.085	-0.192*	0.013	0.149*
Average Energy Expenditure (kcal/d)	0.032	-0.168**	0.072	0.096
Sedentary (min/d)	0.183**	0.143*	-0.306**	-0.177
Light Intensity (min/d)	-0.235	-0.066	0.313**	0.075
Moderate Intensity (min/d)	-0.089	-0.187**	0.233**	0.121
Vigorous Intensity (min/d)	0.070	-0.102	-0.045	0.130*

* $p<0.05$, ** $p<0.01$

Specific Aim 2: The second specific aim of this STOMP sub-study was to assess the predictive validity of the PPAQ Q8 by comparing self-reported hr/d in each PA intensity category on Q8 and CRF, measured by VO_2max . Average self-reported hr/d spent in vigorous intensity PA on the PPAQ Q8 during V1 was positively correlated with VO_2max ($r=0.134$, $p=0.026$).

Specific Aim 3: The third specific aim of this sub-study of STOMP was to further assess the predictive validity of the PPAQ Q8 by comparing self-reported PA on Q8 during V1 and various health measures. Weak, negative associations were observed between average self-reported hr/d spent in moderate intensity PA on the PPAQ Q8 during V1 and WC ($p=0.027$), systolic BP ($p=0.007$), MAP ($p=0.030$), and TG ($p=0.046$). Similarly, weak, negative associations were observed between average self-reported hr/d spent in vigorous intensity PA on the PPAQ Q8 during V1 and diastolic BP ($p=0.037$) and BMI ($p=0.004$). Weak, positive associations were observed between

average self-reported hr/d spent in moderate and vigorous intensity PA on the PPAQ Q8 during V1 and HDL cholesterol (moderate $p=0.005$; vigorous $p=0.000$) (Table 7).

Table 7. Correlations among Intensity Categories on the Paffenbarger Physical Activity Questionnaire Question Eight Completed during Visit One and Various Health Measures

Health Outcomes	Sedentary	Light Intensity	Moderate Intensity	Vigorous Intensity
BMI (kg/m ²)	0.128*	0.045	-0.122	-0.185**
Resting Heart Rate (b/min)	0.021	0.088	-0.056	-0.112
Waist Circumference (cm)	0.091	0.081	-0.150*	-0.109
Systolic Blood Pressure (mmHg)	0.180**	-0.024	-0.176**	-0.068
Diastolic Blood Pressure (mmHg)	0.142*	-0.020	-0.100	-0.135*
Mean Arterial Pressure (mmHg)	0.170**	-0.023	-0.141*	-0.116
High Density Lipoprotein Cholesterol (mg/dL)	-0.162*	-0.106	0.187**	0.275**
Low Density Lipoprotein Cholesterol (mg/dL)	-0.089	0.109	-0.003	0.005
Total Cholesterol (mg/dL)	-0.127	0.062	0.046	0.110
Triglycerides (mg/dL)	0.110	0.034	-0.134*	-0.070

$p<0.05^*$, $p<0.01^{**}$

Multivariable regression analysis examined the influence of age, gender, and season on the relationships among the health measures described above in specific aims 2 and 3 and average self-reported hr/d spent in each PA intensity category on the PPAQ Q8 during V1 (Table 8). Women who were older, had a lower BMI, and completed the PPAQ Q8 during the summer and fall months reported spending more hr/d in moderate intensity PA ($F=5.722$, $p=0.001$). Additionally, men and women who were older, had a higher VO₂max and a lower diastolic BP, and completed the PPAQ Q8 during the summer and fall months reported spending more time in vigorous intensity PA ($F=7.910$, $p=0.000$) (Table 8).

Table 8. The Influence of Age, Gender, and Season on the Relationships among Health Measures and Self-Reported Time (hr/d) Spent in Moderate and Vigorous Intensity Assessed with the Paffenbarger Physical Activity Questionnaire Question Eight

Moderate Intensity		β-value	<i>p</i>-value
Predictors			
	Age (yr)	0.459	0.017
	Body Mass Index (kg/m ²)	-0.673	0.001
	Season	0.273	0.003
	Overall Model	F=5.722	<i>p</i> =0.001
Vigorous Intensity		β-value	<i>p</i>-value
Predictors			
	Age (yr)	0.022	0.000
	VO ₂ max (ml/kg/min)	0.031	0.000
	Diastolic Blood Pressure (mmHg)	-0.013	0.052
	Season	0.149	0.002
	Overall Model	F=7.190	<i>p</i> =0.000

PPAQ Q8 Reliability

Subject Characteristics: Subjects (*n*=130) in the STOMP study who were randomized to receive the placebo participated in the reliability portion of this sub-study. Descriptive characteristics for these subjects are shown in Table 9, and they did not differ from those of the subjects participating in the validity portion of this sub-study (*p*>0.05). Similar to the subjects in the validity portion of this sub-study, men were heavier (*p*=0.007) and had a higher systolic BP (*p*=0.017), MAP (*p*=0.036), and VO₂max (*p*=0.000) than women. Women on the other hand were older than the men (*p*=0.043) (Table 9).

Table 9. Subject Characteristics (Mean \pm SEM)

Characteristics	Total (n=130)	Men (n=63)	Women (n=79)
Age (yr)	39.9 \pm 1.2	37.4 \pm 1.7 γ	41.9 \pm 1.5
Height (m)	1.7 \pm 0.1	1.8 \pm 0.1*	1.7 \pm 0.1
Weight (kg)	76.9 \pm 1.4	86.9 \pm 1.9*	69.0 \pm 1.4
BMI (kg/m ²)	26.2 \pm 0.4	27.3 \pm 0.6 ψ	25.3 \pm 0.5
Systolic Blood Pressure (mmHg)	115.1 \pm 1.0	118.2 \pm 1.7 ψ	112.6 \pm 1.2
Diastolic Blood Pressure (mmHg)	74.3 \pm 0.8	75.9 \pm 1.2	73.1 \pm 1.1
Mean Arterial Pressure (mmHg)	87.9 \pm 0.8	90.1 \pm 1.3 ψ	86.2 \pm 1.0
VO ₂ max (ml/kg/min)	34.1 \pm 0.8	40.4 \pm 1.1*	29.1 \pm 0.9

Men vs. Women, $\gamma p < 0.05$, $\psi p < 0.01$, $*p < 0.001$

Specific Aim 4: The fourth specific aim of this STOMP sub-study was to examine the test-retest reliability of the PPAQ Q8 measured at baseline and then again at three and six months. To achieve this aim, subjects completed the PPAQ Q8 during V1 (baseline) then again during V4 (three months) and V5 (six months). Pearson product moment correlation coefficients were calculated to examine the relationships among average self-reported hr/d spent in each PA intensity category on Q8 during V1 and V4, V4 and V5, and V1 and V5 (Table 10).

Moderately strong, positive associations were observed between V1 and V4, V4 and V5, and V1 and V5 for average self-reported hr/d spent being sedentary ($p=0.000$); and in light ($p=0.000$), moderate ($p=0.000$), and vigorous ($p=0.000$) intensity PA (Table 10).

Table 10. Correlations among Intensity Categories on the Paffenbarger Physical Activity Questionnaire Question Eight Completed during Visit One and Visit Four, Visit Four and Visit Five, and Visit One and Visit Five

Physical Activity Intensity Category	V1 vs. V4*	V4 vs. V5*	V1 vs. V5*
Sedentary	0.390	0.496	0.548
Light Intensity	0.390	0.384	0.369
Moderate Intensity	0.500	0.258	0.359
Vigorous Intensity	0.282	0.548	0.362

For all variables, $p < 0.001^*$

The average self-reported hr/d subjects spent in each PA intensity category on PPAQ Q8 during V1, V4, and V5 is shown in Table 11. A repeated measures ANCOVA showed there was no significant within-subjects effect on average self-reported hr/d spent being sedentary ($F=0.782$, $p=0.387$) and engaging in light ($F=0.021$, $p=0.884$), moderate ($F=0.004$, $p=0.950$), and vigorous ($F=0.633$, $p=0.428$) intensity PA on Q8 on V1, V4 and V5. Furthermore, there was no significant within-subjects effects of age, gender, and season on average self-reported hr/d spent being sedentary and engaging in moderate and vigorous intensity PA on PPAQ Q8 on V1, V4, and V5 (Table 11). There was, however, a significant within-subjects effect of age on average self-reported hr/d spent engaging in light intensity PA ($p=0.003$).

ANCOVA showed there was no significant between-subjects effects of age, gender, or season on average self-reported hr/d spent being sedentary and engaging in moderate and vigorous intensity PA on Q8 during V1, V4, and V5 ($p > 0.05$). However, there was a significant between-subjects ($p=0.003$) effect of age on average self-reported hr/d spent in light intensity PA on the PPAQ Q8 on V1, V4, and V5 such that as age

increased averaged self-reported hr/d spent engaging in light intensity PA increased (Table 11).

Table 11. Average Time (hr/d) (Mean \pm SEM) Spent in Physical Activity Intensity Category Reported on Question Eight on Visit One, Visit Four, and Visit Five

Physical Activity Intensity Category	Visit One (hr/d)*	Visit Four (hr/d)*	Visit Five (hr/d)*
Sedentary	12.9 \pm 0.3	13.0 \pm 0.3	12.6 \pm 0.3
Light Intensity	5.3 \pm 0.2	5.1 \pm 0.2	5.4 \pm 0.2
Moderate Intensity	4.3 \pm 0.2	4.2 \pm 0.2	4.5 \pm 0.3
Vigorous Intensity	1.5 \pm 0.1	1.6 \pm 0.1	1.7 \pm 0.1

For each PA intensity category V1 vs. V4 vs. V5, $p>0.05^*$

Discussion

The purpose of this STOMP sub-study was to examine the concurrent and predictive validity as well as the test-retest reliability of the PPAQ Q8 among healthy men and women across the lifespan. The results of this STOMP sub-study show significant associations among PA reported on Q8 and measurements from an Actical accelerometer, VO_2max , and various health outcomes. Furthermore, the results of this study show PA assessed by the PPAQ Q8 is consistent when measured three and six months from baseline.

PPAQ Q8 Validity

Specific Aim 1: The first specific aim of this STOMP sub-study was to examine the concurrent validity of the PPAQ Q8 by comparing subject responses on Q8 with PA measurements from an Actical accelerometer. The original hypothesis stated that self-reported time (hr/d) spent in moderate and vigorous intensity PA on the PPAQ Q8 would be positively correlated with average daily steps (d^{-1}), activity counts (d^{-1}), and energy expenditure (kcal/d) as measured by an Actical accelerometer. It was also hypothesized that self-reported time (hr/d) spent in each PA intensity category on the PPAQ Q8 would be positively associated with average min/d spent in each PA intensity category as measured by the Actical accelerometer.

A weak, positive association between self-reported hr/d spent in vigorous intensity PA on the PPAQ Q8 during V1 and average daily activity counts (d^{-1}) was observed ($r=0.149$, $p=0.022$). Moreover, weak positive associations ($r=0.130$ - 0.233) were also observed among average self-reported hr/d spent being sedentary and in

moderate and vigorous intensity PA on the PPAQ Q8 and min/d spent being sedentary and in moderate and vigorous intensity PA measured with the Actical accelerometer.

Although the observed associations are weak, previously published studies have reported correlations of similar magnitude between self-reported PA and PA measured with an accelerometer. Wolin et al (2008) found correlations ranging from $r=0.26-0.36$ among self-reported PA on the short version of the IPAQ and PA measured with an Actical accelerometer in a group of healthy African American men and women age 24-70 yr (25). Similarly, Strath et al. (2004) reported correlations among self-reported PA on the PPAQ PAI and PA measured using the simultaneous heart-rate motion sensor technique ranging from $r=0.20-0.47$ in a group of men and women in a slightly younger sample (20-56 yr) (1). Finally, Hagstromer et al. (2008) and Boon et al. (2010) reported fairly weak associations among self-reported PA on the IPAQ and PA measured by the Actigraph accelerometer ranging from $r=0.14 - 0.27$ and $r=0.19-0.30$, respectively (46, 47).

In this STOMP sub-study, the associations among self-reported PA on the PPAQ Q8 and the measurements from the Actical accelerometer (ranging from $r=0.130-0.233$) agree with the hypothesis and are consistent with the literature. This indicates the PPAQ Q8 has adequate concurrent validity among healthy men and women over the age of 20 yr.

Specific Aim 2: The second specific aim of this STOMP sub-study was to examine the predictive validity of the PPAQ Q8 by comparing subject responses on Q8 and CRF, measured by $VO_2\text{max}$ (ml/kg/min). The original hypothesis stated that self-

reported time (hr/d) spent in vigorous intensity PA on the PPAQ Q8 would be positively correlated with VO₂max (ml/kg/min).

As hypothesized, a positive association between self-reported time (hr/d) spent in vigorous intensity PA on the PPAQ Q8 and VO₂max (ml/kg/min) was observed ($r=0.134$, $p=0.026$). This association is in agreement with previously published studies. For instance, Aadahl et al. (2006) reported a strong, significant association between the amount of daily vigorous intensity PA reported on a newly developed and validated PA questionnaire and VO₂max ($r=0.87$, $p=0.0001$) in a group of 102 healthy men and women age 35-65 yr (12). Similarly, Richardson et al (2001) observed strong associations on the Stanford 7-day recall on two separate occasions between VO₂max and total PA as well as very hard (≥ 7 METs) PA in men (Total PA: $r=0.49$, $p<0.01$ and $r=0.54$, $p<0.01$; Very hard: $r=0.48$, $p<0.05$ and $r=0.62$, $p<0.01$) and women (Total PA: $r=0.14$, NS and $r=0.47$, $p<0.01$; Very hard: $r=0.24$, NS and $r=0.42$, $p<0.01$) aged 21-59 yr (19). Finally, Kurtze et al. (2008) reported a positive correlation of moderate strength between time spent in vigorous intensity PA reported on a PA questionnaire and VO₂max ($r=0.46$, $p<0.01$) in a group of men age 20-39 yr (20).

The association between self-reported hr/d spent in vigorous intensity PA and VO₂max ($r=0.134$, $p=0.026$) in this STOMP sub-study is consistent with the original hypothesis, but is weaker than what is reported in the literature. Therefore, this indicates acceptable predictive validity of the PPAQ Q8 among healthy men and women across the lifespan as compared to VO₂max. However, it must be noted that self-report questionnaires measure participation in PA, whereas VO₂max measures fitness. Fitness is determined to an extent by participation in vigorous intensity PA, but is also influenced

by genetics and environmental factors (49). Therefore, $\text{VO}_{2\text{max}}$ must be used to validate Q8 in conjunction with other validation methods.

Specific Aim 3: The third specific aim of this STOMP sub-study was to further examine the predictive validity of the PPAQ Q8 by comparing average self-reported hr/d spent in each PA intensity category on Q8 and various health outcomes. The original hypothesis was that negative associations would be observed between average self-reported time (hr/d) spent in moderate and vigorous intensity PA on the PPAQ Q8 and BMI, systolic and diastolic BP, WC, TG, TC, LDL cholesterol, and resting HR. It was also hypothesized that a positive association would be observed between average self-reported time (hr/d) spent in moderate and vigorous intensity PA on the PPAQ Q8 and HDL cholesterol.

As hypothesized, there were a number of significant negative associations observed for self-reported time (hr/d) spent in moderate and vigorous intensity PA and objective health outcome measures; specifically BMI, WC, systolic and diastolic BP, MAP, and TG, ranging from $r = -0.134$ to -0.185 . Furthermore, positive associations were observed between average self-reported hr/d spent in both moderate and vigorous intensity PA and HDL cholesterol ($r = 0.187$ and $r = 0.275$, $p < 0.001$), respectively.

The direction and magnitude of these correlations agrees with previously published studies. Graff-Iversen et al. (2007) reported weak yet significant correlations between self-reported PA on the long version of the IPAQ and health outcomes (BMI, HDL cholesterol, waist/hip ratio, TG, diastolic BP, and glucose) ranging from $r = -0.14$ - 0.12 in a group of men and women age 31-67 yr (27). Washburn et al. (1991) also found weak but significant associations between self-reported energy expenditure on the PPAQ

PAI and HDL cholesterol and BMI ($r=0.14$ and $r=-0.13$ $p<0.01$) in a group of men and women age 25-65 yr (28).

The associations between self-reported PA and health outcomes observed in this STOMP sub-study agree with both the hypotheses and the literature. These findings lend additional support that the PPAQ Q8 has acceptable predictive validity among healthy men and women across the lifespan.

PPAQ Q8 Reliability

Specific Aim 4: The fourth specific aim of this STOMP sub-study was to examine the test-retest reliability of the PPAQ Q8 measured at baseline and then again at three and six months. The original hypothesis was average self-reported time (hr/d) spent in each PA intensity category on the PPAQ Q8 during V1 would not be significantly different from average self-reported time (hr/d) spent in each PA intensity category on the PPAQ Q8 during V4 and V5.

Moderately strong correlations were observed between PA reported on Q8 during V1 and V4 (baseline and three months), V4 and V5 (three months and six months), and V1 and V5 (baseline and six months) for each PA intensity category, with values ranging from $r=0.282$ - 0.548 for reliability over a three month time period and $r=0.359$ - 0.548 for reliability over a six month time period.

The correlations between self-reported time in each PA intensity category on the PPAQ Q8 during V1, V4, and V5 agree with the results of other previously published studies. For instance, Ainsworth et al. (1993) reported similar reliability over an eight and nine month time period for the PPAQ PAI ($r=0.34$ and $r=0.43$ $p<0.05$) in a group of men and women of similar age to subjects in this STOMP sub-study (13). Likewise,

Richardson et al. (2001) reported similar observations on the test-retest reliability over a one month period of time of the Stanford 7-day recall in 78 healthy men and women ($r=0.60$, $p<0.01$ and $r=0.36$, $p<0.05$,) age 21-59 yr (19). In addition, the repeated measures ANCOVA demonstrated there was no significant difference between average hr/d spent in each PA intensity category reported by the same subjects on the PPAQ Q8 during V1, V4, and V5.

The correlations between self-reported PA on the PPAQ Q8 during V1, V4, and V5 and the results of the repeated measures ANCOVA are consistent with both the original hypothesis and the literature. The PPAQ Q8 demonstrated good test-retest reliability for PA assessments made at baseline, three and six months.

Study Significance

The purpose of this STOMP sub-study was to assess the validity and reliability of the PPAQ Q8. Questionnaires are a desirable tool to assess and measure participation in PA because they are relatively inexpensive and easy to administer to large groups of people (1,2,12,13). However, questionnaires must be shown to be valid and reliable before they can be used to assess PA. To the best of the author's knowledge, this is the first study performed which examined the criterion and predictive validity as well as the test-retest reliability of the PPAQ Q8 using a sample of healthy men and women across the lifespan.

The results of this study provide novel evidence that, among healthy men and women over the age of 20 yr, the PPAQ Q8 has adequate concurrent validity, acceptable predictive validity, and good test-retest reliability. These findings are significant because the PPAQ Q8 allows researchers and health/fitness professionals to assess PA in ways

that the other components of the PPAQ cannot. For instance, other components of the PPAQ (i.e., the PAI and Q6) are able to accurately measure participation in moderate and vigorous intensity PA, but are unable to accurately reflect participation in sedentary or light intensity PA (1). The PPAQ Q8 inquires about participation in PA of all intensities. This allows researchers and health/fitness professionals to examine participation in sedentary and light intensity activities as well as moderate and vigorous intensity PA, thus providing the clinician with a more complete representation of the individual's habitual PA.

Additionally, including Q8 in the PPAQ PA assessment battery allows clinicians to assess an individual's participation in PA using the complete FITT principle of exercise prescription. The other components of the PPAQ are capable of accurately assessing PA in terms of the frequency (Q6), intensity (Q7), and type (Q4 and Q6) components of FITT. Since the results of this sub-study show the PPAQ Q8 is both accurate and valid, it can be used to assess PA in terms of the Time component of the FITT. Ultimately, Q8 will help clinicians determine whether or not healthy adults are meeting the recommended 150 min/wk of moderate or 75 min/wk of vigorous intensity PA recommended by the USDHHS.

Potential Study Limitations

This STOMP sub-study is limited by several factors. The data used in this STOMP sub-study were collected at multiple test sites. This increased the chances of site and interpretation bias occurring during the data collection and entry processes. However, investigators at each of the three sites followed a strict standard protocol for collecting data as well as for interpreting subject responses on the PPAQ during data

entry (Appendix C). Investigators from each study site also attended a mandatory monthly staff meeting to discuss study progress and ensure investigators at each site were accurately following the study protocol, limiting the opportunity for bias during data collection and subsequent entry (34). These actions likely decreased the amount of site and interpretation bias that may have occurred.

Additionally, only individuals who were identified as “healthy,” according to the inclusion/exclusion criteria of the STOMP study, who could exercise vigorously on a treadmill, and who were willing to take either Lipitor or placebo for six months participated in STOMP. As a result, the sample used in this STOMP sub-study was self-selected as opposed to a true random sample. However, despite the fact that it was self-selected, the sample used in this sub-study is representative of the general population. Therefore, the results of this study are applicable to the general population.

Finally, one of the major limitations to using questionnaires to assess participation in PA is their increased tendency to misclassify PA compared with objective methods of assessing PA (15). Despite the evidence in specific aims 1-4 that PPAQ Q8 is both valid and reliable, a multivariable regression analysis used in this sub-study demonstrated that older subjects are more likely to report spending the most time in moderate and vigorous intensity PA ($p=0.000$). This contradicts the findings of previously published studies. For instance, in Healthy People 2010, the USDHHS reported that as age increased, participation in all types of PA decreased (46). Additionally, Macera et al. (2001) analyzed data from the 2001 Behavioral Risk Factor Surveillance System and reported that participation in both moderate and vigorous intensity PA decreased with increasing age (47). Furthermore, Ayabe et al. (2009) measured PA in both younger (18-29 yr) and

older (50-69 yr) adults with an accelerometer. They found younger adults spent the most time in moderate to vigorous intensity PA ($p<0.01$) when compared to the older adults, who spent more time in light intensity PA ($p<0.05$) (45). The disagreement between the multivariable regression analysis in this sub-study and the previously published literature illustrates the tendency of PA questionnaires to misclassify PA.

Study Strengths

There are several strengths to this STOMP sub-study. First, previously published studies assessing the ability of questionnaires to measure and assess participation in PA sometimes only focus on one dimension of validity, such as concurrent or predictive validity. Moreover, questionnaire validation studies often times neglect to examine the test-retest reliability of the questionnaire altogether (1, 2, 12, 27). This study focused on the concurrent and predictive validity as well as the test-retest reliability of the PPAQ Q8. Therefore, the results of this study provide more complete and accurate evidence that the PPAQ Q8 is indeed a valuable tool for assessing participation in PA.

Second, this STOMP sub-study utilized data collected from a large sample ($n=240$) of healthy men and women. The sample used in this study was larger and covered a wider age range (20-81 yr) than a number of other studies in the literature examining the validity and/or test-retest reliability of other PA questionnaires. The larger sample size and wider age range used in this study increases the accuracy of the results and allows the findings/conclusions to be generalized to a larger group of people.

Additionally, all measurements were obtained using either the gold standard for the specific test or well-accepted procedures often cited in the literature. For example, CRF was measured using $\text{VO}_{2\text{max}}$, BP was measured via auscultation, WC was

measured with a Gulick spring-loaded tape measure at the narrowest part of the torso, and PA was measured using an accelerometer for at least four days. All equipment used in this study, including BP cuffs, Actical accelerometers, and HR monitors were calibrated prior to their use. Furthermore, investigators from each testing site followed a strict standard operating procedure and frequently conducted quality control tests to ensure all measurements were accurate and reliable. The above quality control measures helped to minimize site and interpretation bias during the data collection processes.

Lastly, the STOMP study was conducted by a strong research team composed of internationally known experts in muscular and cardiovascular physiology and physical activity assessment from Hartford Hospital, the University of Massachusetts Amherst, and the University of Connecticut Storrs. Each investigator on the research team possessed extensive experience in designing and executing randomized control trials, increasing the likelihood that the results and conclusions of this STOMP sub-study are indeed accurate.

Conclusion/Future Directions

The results of this STOMP sub-study suggest that the current form of the PPAQ Q8 has adequate concurrent validity, acceptable predictive validity, and good test-retest reliability. However, as is the case with most self-report PA questionnaires, the associations among average self-reported hr/d spent in each PA intensity category on PPAQ Q8 and objectively measured PA and health/fitness measures were generally weak. This indicates that, although it is currently a valid and reliable tool, future research should be done to further improve its validity and reliability.

First, the first four questions on the PPAQ ask respondents to report the PA they participated in over a specific time period. For instance, question four of the PPAQ asks respondents to “List any sports or recreation you have actively participated in during the past year.” Stating a specific time period helps to ensure respondents are accurately reporting their current PA participation. Currently, the PPAQ Q8 states, “On a usual weekday and a weekend day, how much time do you spend on the following activities?” It does not specify over what time period subjects should be reporting their average daily activity. Specifying a time period might help to further improve the validity and reliability of PPAQ Q8. Therefore, future research should be done to examine whether or not re-wording the instructions on the PPAQ Q8 to include a time period, such as over the past week or over the past year, increases the validity and reliability of Q8.

Second, on the PPAQ Q8, examples are given for each PA intensity category. However, these examples do not take into consideration the fact that age has an impact on the intensity of an activity for a given person (48). For example, regular walking is used as an example of moderate intensity PA. This activity may be of moderate intensity for an older adult, but this same activity may constitute a lighter intensity for a younger adult and may cause confusion during reporting (48).

Future research should be done to develop different versions of the PPAQ Q8 for different age groups using specific and age appropriate examples of each PA intensity category. Creating these new age-specific versions of PPAQ Q8 may help individuals more accurately report the time they spend in each PA intensity category per day and, thus, help strengthen the ability of the PPAQ PA assessment battery to accurately measure and assess habitual PA participation.

Finally, the results of this STOMP sub-study show the PPAQ Q8 has adequate concurrent and predictive validity as well as good test-retest reliability among healthy men and women over 20 yr. Therefore, the PPAQ Q8 can be used, in conjunction with the other components of the PPAQ, to provide clinicians with a complete representation of habitual PA participation among healthy men and women across the lifespan.

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Appendix

A. The Paffenbarger Physical Activity Questionnaire

Paffenbarger Physical Activity Questionnaire

1. How many city blocks or their equivalent do you normally walk each day?

Blocks/day (Let 12 blocks = 1 mile)

2. What is your usual pace of walking? (Please check one)

- ☐ casual or strolling (less than 2 mph)
☐ average or normal (2 to 3 mph)
☐ fairly brisk (3 to 4 mph)
☐ brisk or striding (4 mph or faster)

3. How many flights of stairs do you climb up each day?

Flights/day (Let 1 flight = 10 steps)

4. List any sports or recreation you have actively participated in during the past year?

(Please remember seasonal sports or events)

Sport, recreation, or other physical activity	Number of times/year	Hours	Minutes	Years Participation

5. Which of these statements best expresses your view? (Please check one)

- ☐ I take enough exercise to keep healthy.
☐ I ought to take more exercise.
☐ Don't know.

6. At least once a week, do you engage in regular activity akin to brisk walking, jogging, bicycling, swimming, etc. long enough to work up a sweat, get your heart thumping, or get out of breath?

- ☐ Yes

How many times per week? _____

Activity: _____

- ☐ No

Why not? _____

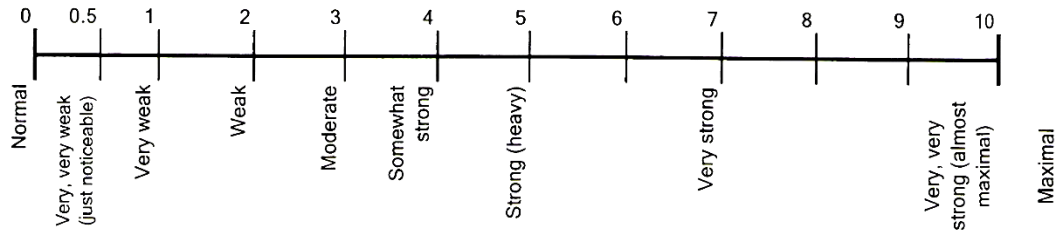
(turn over) ➡

Subject Code: _____

Date: ____/____/____

Paffenbarger Physical Activity Questionnaire

7. When you are exercising in your usual fashion, how would you rate your level of exertion (degree of effort)? *(Please circle one number)*



8. On a usual weekday and a weekend day, how much time do you spend on the following activities? *(Total for each day should add to 24 hours)*

	Usual Weekday Hours/Day	Usual Weekend Day Hours/Day
A. Vigorous activity (digging in the garden, strenuous sports, jogging, aerobic dancing, sustained swimming, brisk walking, heavy carpentry, bicycling on hills, etc.)		
B. Moderate activity (housework, light sports, regular walking, golf, yard work, lawn mowing, painting, repairing, light carpentry, ballroom dancing, bicycling on level ground, etc.)		
C. Light activity (office work, driving car, strolling, personal care, standing with little motion, etc.)		
D. Sitting activity (eating, reading, desk work, watching TV, listening to radio, etc.)		
E. Sleeping or reclining		
COLUMN TOTAL:		
MUST EQUAL:	24	24

Subject Code: _____

Date: ____/____/____

B. Informed Consent Document for “The Effects of Statins on Muscle Performance”
(STOMP) Study

INFORMED CONSENT FOR PARTICIPATION IN CLINICAL RESEARCH
UNIVERSITY OF CONNECTICUT

PRINCIPAL INVESTIGATOR: Dr. Paul Thompson, M.D., and Linda S. Pescatello, PhD.

DEPARTMENT: Preventive Cardiology (Hartford Hospital) Kinesiology (Univ of CT)

PHONE: (860) 545- 2899 (Dr. Thompson), (860) 486-0008 (Dr. Pescatello)

EXPECTED DURATION: approximately 6 months

SPONSOR (if applicable): National Institutes of Health (NIH)

- I. You have been asked to participate as a subject in the research study, **The Effects of Statins on Skeletal Muscle Function**. The purpose, procedures, and length of your involvement are stated below:

A. **Purpose** of research:

Statins (such as Lipitor) are cholesterol-lowering medications that lower cholesterol levels and also reduce the frequency of heart attacks, cardiac deaths, and strokes. Unfortunately, statins can cause muscle discomfort or pain called “myalgia” in patients treated with these drugs. These symptoms often cause patients who need these medications to stop taking the drug. Therefore, one of the goals of this study is to document how frequently people complain of muscle symptoms like aching and cramps. The cause of statin muscle discomfort is not known, but is often increased by exercise. As a result, this study will also determine the effect of 80 milligrams of Lipitor on muscular strength and endurance and aerobic exercise performance in comparison to a placebo (“sugar pill”).

B. **Procedures:** Your participation will involve the following procedures:

Prior to the start of the study, a detailed explanation of the study will be given and you will be interviewed to determine if you meet the qualifications necessary to participate.

You will have your blood pressure measured up to 3 times at each visit prior to the start of the study and during V1 and V2 to determine your eligibility based on your blood pressure. Regarding blood pressure measurements in the STOMP protocol, if you are on antihypertensive medication you must have a blood pressure of <140/90 mmHg or you will not be enrolled and will be referred to your physician. After 3 months, if

your blood pressure is <140/90, you may be eligible to enroll at that point. If you have mild hypertension, you will be informed of that during screening. You will be enrolled and monitored throughout the study. If your blood pressure remains elevated at the end of the study, you will be referred to your physician. If your blood pressure is 150/100 or greater, you will not be enrolled and will be referred to your physician.

If you do not qualify, the doctor or research staff will tell you why. If you do qualify, you will be asked to read and sign this informed consent prior to your first visit.

1. On Visit 1, you will report to the Human Performance Lab (Gampel Pavilion, 2095 Hillside Rd, room 112). You will be asked to complete a physical activity survey, pain symptom questionnaire, and two psychological questionnaires. You will then be escorted to our Exercise Physiology Laboratory for the following strength and exercise assessments:

- The strength of your hands will be measure by asking you to squeeze a handgrip device. We will measure each hand 3 times to get a good estimate of your strength.
- The strength of your biceps (upper arm) muscle will be measured using a Biodex dynamometer. It looks like a universal weight lifting machine. You will be seated on the machine and a Velcro strap will secure you to the seat at the hips and across your upper body to prevent extra movement throughout the testing. Your wrist will be placed snugly between two padded supports and a wide strap placed across the lower arm. You will warm up by performing 10 biceps curls at a light intensity and 10 curls at a moderate intensity. The actual test will consist of 3 sets of 3 biceps curls with a 5-minute rest between each set.
- The strength of your thigh muscle will also be measured using the Biodex machine. You will be seated with your arms folded across your chest and you will be secured by Velcro straps at the thigh, hips, and upper body to prevent extra movement during the testing. You will warm up by performing 10 knee extensions (like kicking a ball) at a light intensity and 10 knee extensions at a moderate intensity. The actual test will consist of 3 sets of 3 extensions with a 5-minute rest between each set.

2. On visit 2 you will report to the exercise physiology lab at Hartford Hospital (85 Jefferson Street, Suite 704) having fasted (no food or beverage other than water. You will have blood taken from one of your arm veins for analysis. Blood tests will be performed for liver safety assessments, as well as cholesterol levels, muscle proteins, and vitamin D. If your TSH (thyroid

test) or other lab results are outside of the study limits, they will be repeated to confirm the initial results at another date, prior to performing any additional study procedures. This will require an additional study visit. Some of the blood taken during the study will be saved and stored (archived). One of the tubes of blood drawn will be used for DNA analysis to compare the variation and patterns in genes in your sample with that in samples from other people, including subjects with other conditions or diseases. All information indicating that the sample came from you (such as your name, birth date and social security number) will be removed. Next, your vital signs (blood pressure, heart rate, breathing rate), height, weight, and waist circumference will be measured. You will then undergo a maximal aerobic test on a treadmill to determine your fitness level. You will wear electrodes on your chest to monitor your heart rate and the electrical activity (electrocardiogram-“ECG”) of your heart. You will also breathe through a snorkel-like mouthpiece, so that your breath can be collected and analyzed for oxygen and carbon dioxide. During the test you will be asked to exercise until you cannot go any further.

3. Based on your health history and/or the initial maximal aerobic test results on visit 2 our staff may require the presence of a medical doctor for your second and third maximal aerobic tests (visits 3 and 6). If this is the case, those tests may be scheduled at Hartford Hospital or the Human Performance Lab at Gampel Pavilion depending on physician and equipment availability. All other testing will still take place at the Human Performance lab, as listed below.
4. On visit 3, you will report to the Human Performance Lab in Gampel Pavilion. You will repeat the muscular strength tests from visit 1 and perform a knee endurance test on the Biodex machine. For this test you will perform 30 consecutive maximal knee extensions (like kicking a ball). You will undergo a maximal exercise test on a treadmill to determine your aerobic fitness level (note- as mentioned above, this test may be scheduled at Hartford Hospital, if it than it would be visit 4). This test will be similar to visit 2 except no electrodes will be attached to your body. You will still breathe through a snorkel-like mouthpiece, so that your breath can be collected and analyzed for oxygen and carbon dioxide. During the test you will be asked to exercise until you cannot go any further. You will be given a special watch to wear, called an activity monitor. It will monitor your movements for the next 24 hours. The research coordinator will show you how to use it.
5. Visit 4 will take place at the Human Performance Lab. You will repeat the arm and leg strength testing including the knee endurance test on the Biodex machine. You will be given a cholesterol lowering diet handout and asked to follow this diet as best possible during the study. At this visit you will receive your randomly (similar to that of a flip of a coin) assigned study

medication to take daily at bedtime for 3-months. This is a double-blind study, which means that neither you nor the doctor will know if you are assigned to take a placebo (like a “sugar pill”) or 80 milligrams of Lipitor. The capsules will look identical. Your study drug assignment can be found out if medically necessary. Please note, if you performed your second maximal aerobic test at Hartford Hospital, then this would be visit 5.

6. Someone from our research staff will contact you twice per month to monitor your use of the study drug and to ensure that you have not experienced any health issues. If you have had any problems that the study doctor considers clinically significant, you will be asked to return to the clinic for blood testing within 48 hours. Throughout the study, you will be instructed to call our 24-hour beeper in case of an emergency.
7. If at any time you experience muscle discomfort or aching (“myalgia”) related to the study medication, you may be invited to participate in another optional part of this study. This additional part of the study requires that Dr. Thompson or the Preventive Cardiology Fellow, both medical doctors, perform a needle biopsy on one of your legs. This is done after giving local anesthesia to the skin and muscle with Novocain. A small incision will be made in the skin of the upper thigh. A needle, the size of a lead pencil, will be inserted into the muscle and a small “plug” of tissue (about the size of three grains of rice) will be removed. The muscle samples will be frozen and analyzed for gene activity. This type of gene analysis does not reveal anything significant about your genetic profile or that of your family. This will be performed at Hartford Hospital.

You may also be invited to participate in this additional part of the study if you have *not* had such muscle problems to serve as a “control”, or comparison subject. Your biopsy sample would be compared to samples from participants who did experience muscle discomfort. The procedure for the biopsy is the same as described above. This part of the study is not a requirement; it is completely voluntary.

8. Visit 5 will take place after 3 months. You will report to the Human Performance Lab at Gampel Pavilion to have blood drawn for liver and muscle safety testing. If any of the blood work results are high and the study doctor considers them clinically significant, you will be asked to return to the clinic for blood testing within 48 hours. You will bring in any unused study medication and empty bottles to measure your pill compliance. You will be given another 3-month supply of the study medication. Please note if you performed all of your maximal aerobic tests at Hartford Hospital, then this is visit 6.

9. Again, someone from our research staff will contact you twice per month for the remainder of the study to monitor your use of the study drug and to ensure that you have not experienced any health issues.
10. Visit 6 will take place after 3 months (a total of 6 months after you entered the study). You will report the Human Performance lab at Gampel Pavilion having fasted (no food or beverage other than water) for at least 12 hours. We will measure your vital signs, height, weight, and waist circumference. You will then have blood taken from one of your arm veins for analysis. You will complete the physical activity survey and pain symptom questionnaire. You will then repeat the arm and leg strength testing, including the knee endurance test. You will repeat the maximal treadmill exercise test as in visit 3 (please note, as described in item 3 above, if you performed both maximal aerobic tests at Hartford Hospital, then your third one must also occur at Hartford Hospital, if so, then this is visit 7 and the maximal aerobic test would be visit 8). If you are performing your maximal aerobic test at Hartford Hospital, then vital signs, height, weight, and waist circumference, as well as the blood draw will occur then, not at the Human Performance Lab. After the exercise testing, you will wear the activity watch for 24 hours.
11. Visit 7 is your final visit; it will take place at the Human Performance Lab in Gampel Pavilion no less than 72 hours after visit 6. You will repeat the arm and leg strength testing on the Biodex machine, without the knee endurance test. You will also return the activity monitor. You will bring in any unused study medication and empty bottles to measure your pill compliance. Please note- if you completed all three of your maximal aerobic treadmill tests at Hartford Hospital, your total visits will be 9, as opposed to 7.
12. Altogether, during the study, approximately 4.5 tablespoons of blood (45 ml) will be taken. This is approximately one fourth the amount taken when someone “gives blood”.
13. You will be contacted, by phone, 2 weeks after your final visit to monitor any changes in your health status
14. You may be invited to participate in another *optional* part of this study. The purpose of this sub-study is to gather pilot data on statin patients. In this sub-study, the cognitive function sub-study, you will be asked to complete a series of cognitive tests and an MRI scan at the end of the study (while you are still on the STOMP study drug or placebo) as well as two months after you have been off of study drug or placebo following study completion. If you participate in this sub-study, an additional 4 teaspoons of blood will be drawn at your STOMP Visit 5 and again after you have been off of the study drug for 2 months. Conducting this study will help us to understand the chronic effect of statins on cognitive function. Your agreement to participate

is optional and entirely up to you. You will receive the same treatment and care under the main study whether or not you decide to participate in the Cognitive Function Sub-Study. You will be compensated \$200 for your time and effort associated with this study. You will receive the \$200 in the form of a check 6-8 weeks after your last study visit. If you stop your participation for a medical reason deemed important by the study doctor, your time will be compensated \$50 for each visit that you have completed. You will not receive compensation for your time and effort if you do not complete the study for other reasons.

Of the item(s) listed above, the following is/are **experimental**:

Lipitor is an approved drug and one of the most prescribed medicines in the whole world. Maximal treadmill tests are done commonly in medicine. Nevertheless, this entire study is experimental because none of this would be done to you if you were not participating in the study.

- C. **Duration** of Participation: This study will take place in both the Human Performance Lab in Gampel Pavilion at the University of Connecticut and the Preventive Cardiology Department at Hartford Hospital. Your participation will last approximately 6 months and you will be asked to participate in a total of 7-9 study visits.

- II. The possible **risks**, discomforts and side effects of the procedures are described below, including safeguards to be used for your protection:

1. Atorvastatin is an FDA approved drug for reducing high cholesterol and is in a class of drugs called “statins.” Atorvastatin is generally well tolerated. Side effects commonly reported are: Constipation, gas, upset stomach, abdominal pain, headache, muscle pain, joint pains, rash, loss of strength and abnormal increases of liver blood tests. If you suffer from any of these symptoms, or any other symptoms, you should report them to the STOMP Research Team by contacting Health/Fitness Research lab during normal business hours at 486-2812. Additionally, you will be given a phone number that you may call outside of normal business hours if symptoms are severe and/or intolerable such as severe muscle cramps, flu symptoms, or black or brown urine. The member of the STOMP research team that receives your call will record your symptoms and immediately contact Dr. Thompson who will contact you promptly and advise you.
2. Statins (such as Lipitor) may cause severe muscle problems called rhabdomyolysis, which is a breakdown of muscle leading to muscle pain, kidney failure requiring dialysis and even death. This problem happens once in every 10 million prescriptions. This risk may be increased by exercise,

but this should not happen in this study because of the close medical attention you will receive.

3. Statins can also cause abnormalities in tests of liver function. This is really a measurement, and not a medical problem, that usually goes away without stopping the medicine, and almost never leads to a long-term problem.
4. Other side effects that are not known at this time could occur during your treatment. This could include allergic reaction. A severe allergic reaction can be life threatening. You will be informed of any changes in the way the trial is done and of any newly identified risks to which you may be exposed. You will be informed in a timely manner if other information becomes available that may be relevant to your willingness to continue your participation in this trial.
5. Exercise and exercise testing can cause a heart attack and even sudden death. This happens once in 10,000 tests in people with heart disease and much, much less in healthy people. The research staff will observe you closely during the exercise testing sessions to minimize the possibility of injury and a clear explanation of all procedures and equipment will be given to you.
6. You will almost certainly become sore and tired and possibly weak from the exercise sessions. These feelings should go away in 5-6 days. If you do not perform strenuous exercise for 3 days following the exercise, the tiredness will go away faster. If the symptoms do not go away after 7 days or if you experience black or brown urine, contact Dr. Pescatello's team immediately with the cell phone number provided to you. The team member who takes your call will contact Dr. Thompson who will promptly contact you to advise you.
7. The risk of serious injury (such as a muscle pull or strain) is very small, but can happen.
8. During the collection of blood samples you will feel pain where the needle is inserted and you may have bruising at the puncture site. There is also the risk of infection, but this is very rare. Dizziness and/or fainting sometimes occur during or shortly after blood is drawn. A person trained in taking blood will draw your blood sample to minimize these risks.
9. Fasting (nothing to eat or drink except water) for 12 hours before each visit could cause dizziness, headache, stomach discomfort and rarely fainting.
10. There are no known side effects associated with ECGs, other than possible skin irritation where the ECG patch was applied.

III. You may get no personal **benefits** out of participating in this study although:

1. Study medication may lower your LDL (bad cholesterol) level.
2. You may contribute to our knowledge of how Lipitor and exercise affect muscle.

IV. This is a study and not a **treatment** for a condition that you may have. Consequently, you are only deciding whether or not to participate in how the cholesterol drug called Lipitor along with exercise affect muscle. If you want to find a treatment for any health problem, you should discuss this with Dr. Thompson or your own doctor and not volunteer for this study.

V. Dr. Thompson, Dr. Pescatello and their staff are willing to answer any **questions** you may have concerning the procedures herein described. You should not sign this consent until all of your questions about the study have been answered. If you have questions about the research in general, you can call the University of Connecticut Institutional Review Board at (860) 486-8802, or Dr. Laurine Bow, Vice President for Research at Hartford Hospital, at (860) 545-2893.

If you have questions about the treatments during the research project or if you have a research-related injury or emergency, you should call Dr. Paul Thompson, M.D. at (860) 545-2899.

If you have questions about your rights as a research subject you may call the University of Connecticut Institutional Review Board at (860) 486-8802 or the Institutional Review Board at Hartford Hospital at (860) 545-2893 and speak to an IRB representative.

If you have any confidential issues to discuss, such as problems or complaints, you may call Patients Relations at Hartford Hospital (860) 545-1400 and talk to someone who is not connected with the research.

VI. Your **participation is voluntary** and you may refuse to participate and/or withdraw your consent and discontinue participation in the project at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate will not affect your future medical care at the Cholesterol Management Center or any other program at Hartford Hospital. Your decision will also not affect how Dr. Pescatello or her staff feels about you since they realize that participation in such projects is totally voluntary.

VII. You will be reimbursed up to \$720 for your time and effort at the end of the study. You will receive your payment in the form of a check within 6-8 weeks of completing the study. This will be reported to the Internal Revenue Service as income received. If you stop your participation for a medical reason deemed

important by Dr. Thompson your time will be compensated in full. You will not be reimbursed for your time and effort if you do not complete the protocol for other reasons.

VIII. Your **confidentiality** will be guarded to the extent possible. Your records will be maintained in accordance with applicable state and federal laws. However, private identifiable information about you may be used or disclosed for purposes of this research project. You may request that your records be released to your own doctor. Your blood samples will be stored in small tubes labeled only with an identification number. Therefore, your identity will never be revealed to anyone or be connected with genetic information from your samples. They will be stored in a locked freezer until all study testing has been completed. Only Dr. Thompson and members of his research staff will have access to this freezer.

The cells, blood, or other specimens resulting from this study may be valuable for scientific research. May the University of Connecticut, and collaborating sites Hartford Hospital, and University of Massachusetts Amherst retain your specimens after the end of this research project with identifying information for use in future research?

_____ YES my samples may be saved for future research without identifying information.

_____ NO my samples must be destroyed at the end of this research project.

The information that may be used or disclosed as part of the research includes the following:

1. Your study records

This information may be used or disclosed by:

1. Dr. Thompson and researchers working under his supervision.

The information may be disclosed to:

1. The Hartford Hospital Department of Research Administration
2. The Hartford Hospital Institutional Review Board
3. The University Human Subjects Review Committee of the University of Massachusetts
4. Researchers working under the direction of Dr. Hoffman at Children's National Medical Center.
5. Researchers working under the direction of Dr. Benjamin Levine and Dr. Ronald Haller at the University of Texas Southwest Medical Center.
6. The U.S. Food and Drug Administration

7. The Data Safety Monitoring Board

The purpose(s) of the use or disclosure of this information is (are):

1. To answer the research questions
2. To ensure the study is being conducted properly and that your rights as a participant are protected.

The use or disclosure of the information is permitted until completion of the study and analysis and publishing of the results.

By signing this consent you are agreeing to the use or disclosure of your protected health information as described above. If you do not agree to the use or disclosure of the information as described and therefore do not sign this consent, you cannot be in the study.

If, after signing the consent, you change your mind, you have the right to revoke your consent, in writing. However, you may be withdrawn from the study.

Once private information is disclosed, it is subject to redisclosure by the recipient, and no longer can be considered protected.

You may obtain a copy of the Hartford Hospital Privacy Notice for a complete description of the Hospital's privacy practices for protected health information. You have the right to review the Notice before signing this consent.

The results of this research trial may be presented at meetings or in publications; however, your identity will not be disclosed in these presentations.

- IX. In case of any injuries as a direct result of taking part in this research project, you will receive help in the following way:

If you have medical insurance, the hospital will collect fees for medical treatment from your insurance company. If you are not fully covered or are uninsured, Hartford Hospital will cover these expenses. The hospital will not pay medical expenses at other hospitals or pay for pain and suffering, travel, lost wages, or other indirect costs of taking part in this project.

X. Signatures

I have been given a copy of this informed consent form to keep. I have read it, and I hereby voluntarily agree to participate in the research study, **The Effects of Statins on Skeletal Muscle Function**, and consent to the performance of the above procedures upon me.

Participant's Signature // Date

Legally authorized healthcare representative // Date

Person Obtaining Consent // Date

Witness (person observing the explanation of the above information to the participant) - optional unless consent is presented orally.

C. Paffenbarger Physical Activity Questionnaire Data Entry Protocol

Before entering the data from the questionnaire first walk through each question to be sure everything has been entered.

Fill in any blanks. Use the guidelines below to aid you in filling in the most accurate response. "Protocol" refers to this document.

<u>Question</u>	<u>Possible solution</u>
Question #1	Post questionnaire
Question #2	Question #7, post questionnaire
Question #3	Post questionnaire
Question #4 (see data entry log below for more)	Question #6-8, protocol
Question #5	Post questionnaire
Question #6	Post questionnaire
Question #7	Question #6, 8, post questionnaire
Question #8 (see data entry log below)	Question #1-7, post questionnaire, protocol

Any changes that need to be made should be written on the original questionnaire. Do not cross out or erase any existing data. Just note what was entered on the database, an explanation for the change, your initials, and the date. This information will also go on the data entry log sheet. See examples listed under "Examples of problems encountered when examining questionnaires" at the end of this document.

Data entry site:

Enter the link below into your web browser; it will take you to the data entry page.

<http://10.239.3.35:95/login.aspx>

The data entry page mimics the actual Paffenbarger Physical Activity Questionnaire. So each item on the Questionnaire has a corresponding box to enter to on the web data entry page.

Additional data entry guidelines:

All subject ID's should be entered in the following format:

Site location (UC, UM, or HH) followed by a dash “-” then the number. For example UC-312. Do not leave out the dash. Note there are no spaces between the dash and the location or number.

For question #1

If nothing is entered or a note is written by the subject akin to “walk to and from class 3d/wk the default will be 12 blocks.

For question #3

If the amount of flights/day is greater than 40, we will assume the subject misunderstood the question and answered in steps, as 10 steps is equal to 1 flight. We will correct it by dividing the answer by 10, so 50 flights would be 5 flights. If the question is left blank, the default will be 1 flight.

For question #4:

The drop down list may not contain all activities that are written on the questionnaire. Many of the common “missing” activities are listed in table 1, use the substitutions listed when encountering them on a questionnaire. Substitutions for activities not listed should be brought to the lab meetings for discussion.

Activities that appear on the web entry for #4 with light, moderate, vigorous options but where the questionnaire does not specify refer to question #7 and use the following guidelines to determine which intensity to enter.

<3 – Light
3-5 – Moderate
5> - vigorous

If a questionnaire lists amount of times per year, or how long as a range, for instance 35-40x per yr or 35-45 minutes, then enter the average, so 37.5x/yr and 40 minutes for those two examples.

For activities listed that have an options such as low impact or hi-impact aerobics and no indication is given as to which it is then split the times per year and enter both activities. See example 4 below.

For question #7

If the subject marks the RPE chart in between 2 numbers, rather than circling the

most appropriate number then:

If the preceding number is odd, round up, if it is even, round down. For example if the questionnaire indicates intensity between 3 and 4, you would enter 4 on the database.

If the question is left blank, look at question 6, if the subject answered “yes” to engaging in activity long enough to break a sweat, get your heart thumping, or get out of breath, then we will consider the effort to be vigorous, circle 6. If they answered no, then use question 2 to estimate an answer.

If Question 2=	then ...
a	Choose 0.5
b	Choose 2
c	Choose 3
d	Choose 5

for question 7.

For question #8

Both columns, weekday and weekend day should each add up to 24 hours. If they do not, examine questions #1, 2, 3, 4, 5, 6 to find out how active this person is, for instance, how many blocks, flights do they cover/day (#1-2), what activities do they do and how often (#4). Do they think they get enough exercise, what activities they do daily that gets their heart pumping, and brings on a sweat (#6). Use these to make your best judgment on where to add or subtract hours (depending if the total was < or > 24).

To be most consistent, we can generally assume, if the columns total is <24, the extra hours should be added to light, or sitting. This is the most likely activity that goes unnoticed by the individual. The only time extra hours should go into moderate, or even vigorous is if:

- 1) Vigorous and/or moderate hours are blank AND the individual indicates regular participation in sports on questions 4 and 6.
- 2) The amounts entered in vigorous and/or moderate are less than what is indicated in question 4.

For example, subject X indicates in question 4 that they play soccer 150 times per year for 2 hours each bout, and run 200 times per year, 45 minutes each bout. In question 8, vigorous hours during the week are blank, and weekend is 1. According to question 4, 150 times per year is roughly 3 days per week, and running 200 times per year is nearly 4 times per week. So, on average they are spending 9 hours per week (2 hr x 3 + 45min x 4) in moderately vigorous activity. In this case, enter 1 hour in the vigorous weekday column. The running however, may or may not be vigorous per se but because the PPAQ MET ranges from 4 to 10, we can justify adding another hour to the vigorous

weekend column, thus the total per week, on average would be 9.

Most importantly, make sure to fill out the data entry log for each subject entry, any judgment you make on questions #4 or #8 must be written into the notes section, as well as any notes written on the hard copy. Anytime a change or clarification is made on the original hard copy, circle the change, so it is clear what to enter into the database. For example, if a subject writes 8-10 blocks per day for question #1, you should cross it out with a single line and write 9, with a circle around it. See example 3 below.

Examples of problems encountered when examining questionnaires

Example 1:

Subject XX enters an 8 on question #7 (when you exercise, how hard do you work, circle on following scale). Yet, the subject listed no activities or exercise in question 4 or 6 and listed zero hours per week doing vigorous activity for question 8.

It is likely that the subject did not fully understand the question. If this subject spends little or no time doing vigorous activity and did not list any exercise in #4 or #6 it is likely they are sedentary and do not exercise or exert themselves very much. In this case a 3 for #7 would be more appropriate. Circle a 3 and then write a brief note such as:

Subject listed 8 (vigorous) but did not list any exercise #4, #6, or time spent performing vigorous activity in #8, so I entered a 3 in the database, MK 6/26/07.

*note this info will also be written on the data entry log sheet.

Example #2:

Subject XY lists "running" 2-3 time per week for question #6, yet nothing is listed in question #4. Since this activity is something the subject performs regularly it should be listed in #4, so we must figure out the name, intensity, number of times/yr, and hours/minutes performed. For type of activity, we list running. Times per year would be 130 (2.5 times/wk x 52 wk/yr). For intensity we can examine question #7. The subject circled a 6 (according to our protocol this is vigorous). Estimates of hours and/or minutes performed should come from question #8. Note how many hours/wk is spent doing vigorous exercise. In this case the person listed 1 hour/day during the week and .5/day on the weekends. It is likely, since no other activities are listed anywhere on the questionnaire that time listed in the vigorous category primarily pertains to the subject's running. Though the subject indicated 2-3x per week in #6, 30-60 minutes daily is too much, (there are some other activities, perhaps done intermittently that were not borne out on the questionnaire); since the questionnaire is a general indication, we must estimate. We will not concern ourselves with the extra vigorous activity on the days the subject does not run.

In this case on days the subject runs it is for 30 or 60 minutes of vigorous exercise, so 45 minutes is a fair estimate to put for time in #4. Leave “years participation” blank.

The entry for #4 should read:

<u>Sport, recreation, or other physical activity participation</u>	<u>number of times/ year</u>	<u>hours</u>	<u>minutes</u>
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a. Running (vigorous)	130	45	
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The notation you write on the questionnaire should resemble the following:

Question 4 was blank but question six listed running as a regular activity. I listed running from #6, vigorous intensity from number #7, 130 times/yr from #6 (2-3/wk x 52 wk/yr), and 45 minutes from #8 (subject indicated 30-60 min vigorous activity/day), MK 6/26/07

This case is an example, it would have been more difficult to predict if the hours listed for vigorous exercise was considerably higher (for instance 3-4 hours/day) or if question #7 was also entered incorrectly (in this case see example 1 above). In such cases, follow the protocol as best as you can, make your best estimate; note the change and how/why you did it. In the case where the hours/min for cardio exercise cannot be estimated with reasonable accuracy (walking, running, biking, swimming< etc), enter 30 minutes as a default.

Example #3:

Question 8 was not correctly filled out, as both weekday and weekend hours did not total 24. See below.

	Usual weekday hrs/day	Usual weekend hrs/day
a. Vigorous	3-4	1
b. Moderate	2-3	1
c. Light	5	2
d. Sitting	5	2
e. Sleeping or reclining	8	8

Total	23-27	14
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In this case, we can take the middle values for the range of the Vigorous and Moderate during the week numbers. This way the total adds to 24. The subject indicates considerably less Vigorous and Moderate activity on the weekend than during the week, as both are 1 hour, compared to 3.5 and 2.5. Since sleeping is 8 hours for both weekday and weekend, we will assume the subject purposely sleeps 8 hours a day regardless if it is a weekend or not. So we can assume that the extra 10 hours needed to make the weekend column total 24 can be put into light and sitting activity. In both columns the subject put the same values for light and sitting activity, so we can assume that they spend the same amount of time doing both, so the remaining 10 can be split equally between the two (5 and 5). See below. Note the notation.

	Usual weekday hrs/day	Usual weekend hrs/day
a. Vigorous	3-4 3.5	1
b. Moderate	2-3 2.5	1
c. Light	5	2 7
d. Sitting	5	2 7
e. Sleeping or reclining	8	8
Total	24	24

Note that in spite of the examples given, there will inevitably be some instance where it is not clear how to proceed. These instances can always be brought to the attention of the lab group for discussion.

Example 4:

Subject XY enters aerobics as the lone activity for question #4, 300 times/year, for 35 minutes. The options in the web drop down menu are hi- or low-impact. There is no indication in question #4, 5, or 6 as to which type of aerobics was performed. Check question 7, if they indicate a degree of exertion 5 or greater, we will assume hi-impact aerobics, if degree of exertion is lower than 5, assume low impact. In the rare case that question 7 is not clear, we should split this into two entries, one for low- and one for hi-impact aerobics, each for 150 times/yr for 35 minutes.

Addendum

Note, as of 8/9/07, any notation to changes made in any questionnaire, that are covered in the protocol can be written as:

Q#(1-8) adjusted according to protocol. (your initials) (date you entered it).

Table 1

Paffenbarger PA data entry substitutions on question #4 for activities not listed

Activity from questionnaire	Substitution to enter into database
Running (with no intensity listed)	See Q #7, anything <3 use running/jogging 3-5 use 8 min/mile, >5 use <7 min/mile
Running – light	running/jogging
Running – moderate	running 8 min/mile
Running - hard/heavy/vigorous	running <7 min/mile
Biking/cycling (with no intensity listed)	See Q#7, follow protocol for question #4
Billiards/pool	Croquet (2.5 METS)
Snowboarding	Downhill skiing
Rollerblading	Roller-skating
Team sport not listed (ultimate Frisbee, European team handball)	Soccer
Cardio	Health Club
Cheerleading	Gymnastics
Motorcycle racing (not riding but off road/dirt track racing)	Horseback riding
Paintball	Soccer
Tae Bo	Hi-impact aerobics
Dance Dance Revolution (DDR)	Hi impact aerobics
Elliptical training	Bicycling moderate (8 METS)
Skiing	Downhill Skiing
Workout at gym	Health club
Marching band (1 fall season = 48 times/yr, 3 hours)	Walking
Dodgeball	racquetball
Colorguard	dancing
Spinning	vigorous or moderate bicycling
Broomball	hockey
Step aerobics	low-impact aerobics

Kickball

Any sport, intramurals

Hurling

Camogie

Baseball

Soccer

Lacrosse