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Effects of Short-Term Protein Supplementation on Muscle Work Efficiency in Elderly Adults

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EFFECTS OF SHORT-TERM PROTEIN SUPPLEMENTATION ON MUSCLE WORK EFFICIENCY IN ELDERLY ADULTS

by

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Approved by

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ABSTRACT

Objective: This study assessed the effect of increased dietary protein intake on adaptation of energy expenditure and skeletal muscle function at rest and during low-intensity physical activity in elderly adults.

Methods: Using a randomized, crossover design, 12 adults (7 F, 5 M), aged 82 ± 7 y (mean ± SD) completed two 6-day periods of consuming fruit-smoothie beverages twice daily (with breakfast and lunch) containing 230 kcal and 25 g whey protein (WPro) or 25 g corn-derived glucose polymer (CHO) (total 460 kcal/day and 50 g/day WPro or CHO).

Results: On day 7 of each period, fasting blood urea nitrogen was 28 ± 9% higher in WPro vs. CHO (P=0.003), consistent with higher total protein intake. Fasting state energy expenditure and respiratory ratio at rest and while exercising on a stationary cycle at 1, 10, 20 watts were not different between WPro and CHO. Gross mechanical efficiency of skeletal muscle progressively increased from 1 to 10 to 20 watts, but this response was not different between WPro and CHO.

Conclusion: Short-term supplementation with either whey protein or glucose polymer does not differentially influence fasting state whole body substrate utilization or skeletal muscle work efficiency in elderly adults.

ACKNOWLEDGMENTS

I would like to thank Dr. Wayne Campbell for his patience and guidance throughout this project. His encouragement and support helped me accomplish my first of hopefully many more research studies. Thank you Jan Green for guiding us through recruitment, screening, and test day procedures. Also thank you Doug Maish, EMT-P, for all your help with our clinical laboratory services. Dr. Shirley Rietdyk, Dr. Jeffrey Haddad, and Dr. Steven McKenzie were also all instrumental in this research project and I sincerely appreciate all the help and guidance they provided regarding our exercise protocols. Finally thank you so much to all the volunteers and employees at University Place, without whom this project could not have been completed.

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LITERATURE AND RATIONALE

From previous research we know protein is critical for maintaining muscle size and function [3, 18]. This is particularly relevant for old adults who experience a progressive decline in muscle mass, referred to as sarcopenia. Old adults also experience a decline in substrate utilization [1, 3, 5, 18, 20]. One way of measuring substrate utilization is through oxygen consumption at rest and during low levels of exercise [7, 11, 14]. At low levels of exercise, measuring the volume of oxygen consumed (VO_2) presupposes a change in pulmonary VO_2 predicts changes in muscular VO_2 [4, 7, 13, 14].

Other predictors of muscle function besides substrate utilization as measured by VO_2, include balance and gait. Physiological declines of aging, including sarcopenia, are factors in decreased balance, gait speed, and stride length [17]. All of these factors are well-researched due to their correlation with fall risk in the elderly [17, 21].

A previous study from our lab indicated that a short-term inadequate protein diet (0.5 $g \bullet kg^{-1} \bullet d^{-1}$) caused a down-regulation of 35 of 38 gene transcript profiles involved with energy metabolism in skeletal muscle in old adults [18], compared to when they consumed an iso-energetic diet with 1.2 g of protein $\bullet kg^{-1} \bullet d^{-1}$, representing a 0.7 $g \bullet kg^{-1} \bullet d^{-1}$ difference between groups protein intakes. Decreased transcripts from inadequate protein intakes imply an adaptive response in muscle by an increase in the efficiency of substrate utilization to preserve muscle function. This adaptive response would precede physiological changes of accommodation such as muscle wasting [18].

Consumption of an energy restricting diet lead to increased skeletal muscle efficiency in a 2003 study of weight perturbation and the effects of muscle function [14]. The energy restricting diet decreased subject's energy and protein intakes by 10%. One could attribute the

decrease in protein intake as a component of the cause for an increase in skeletal muscle efficiency. This increase is muscle efficiency accounts for decreased non-resting energy expenditure associated with energy restriction, demonstrating an adaptive change in skeletal muscle. Muscle efficiency in this study was quantified by Gross Mechanical Efficiency which is defined as the ratio of power generated to the change in energy expenditure above resting [14]. Low levels of physical activity were used to calculate GME in this study to account for the sedentary lifestyles of their subjects.

The primary aim of our study was to investigate the effects of short-term increases in dietary protein on adaptive changes in skeletal muscle, such as the efficiency of substrate utilization in old adults. From previous research mentioned above we know decreasing protein by 0.7 $g \bullet kg^{-1} \bullet d^{-1}$ will lead to changes in muscle transcripts. We hypothesize we will also see an adaptive change in the efficiency of substrate utilization. Also from past studies mentioned above, we know weight loss will lead to increased efficiency of substrate utilization in skeletal muscle. Old adults are in a comparable state to weight loss populations because both involve the loss of muscle mass [16]. We also hypothesize that increased protein intake in old adults will lead to decreased muscle efficiency of substrate utilization.

Our secondary aim was to evaluate other indicators of muscle function such as gait speed and balance. We hypothesize that there will be no effect of protein supplementation on gait and balance, since we will use a short term dietary intervention.

In this study, we measured substrate utilization efficiency in skeletal muscle in twelve elderly volunteers (7F, 5M) following 6 days of protein and carbohydrate supplementation. Low levels of exercise were selected to represent the sedentary lifestyle of older individuals. Their gait and balance were also measured as muscle function predictors.

METHODS

Volunteers

Potential volunteers were recruited from University Place Retirement Community in West Lafayette, Indiana. All participants obtained physician approval prior to starting the study. The exclusion criteria for the study are listed below:

- Diagnosis of diabetes mellitus.
- Status post myocardial infarction (MI) or coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA) within 6 months and/or a documented ejection fraction of less than 50% .
- Acute upper respiratory infection.
- Acute symptoms suggestive of cardiovascular disease.
- Acute symptoms suggestive of acute congestive heart failure.
- Uncontrolled hypertension at rest (systolic blood pressure greater than or equal to 160 mm Hg and or diastolic blood pressure greater than or equal to 100 mm Hg).
- Lower extremity conditions (such as osteoarthritis or peripheral vascular disease), which preclude the subject from peddling a stationary cycle at 20 watts.
- Cognitive conditions or limitations that preclude the subject from being able to understand, comprehend, or interpret instructions, fatigue or symptoms.
- Routine use of supplemental oxygen during rest or exercise.

Volunteer characteristics are included in Table 2. Twelve volunteers completed the study, seven female and five male.

All study procedures were approved by the Purdue University Biomedical Institutional Review Board, and all the volunteers were informed of the purpose, procedures, and potential

risks of the study prior to signing the informed consent document. There was no monetary compensation for participation.

Experimental Design

We utilized a randomized, cross-over design for this study (Figure 1). Each volunteer was tested following two six-day interventions. Between each intervention there was a 7-day washout period where volunteers returned to their normal diet with no supplementation. During the last three days of each intervention volunteers recorded all dietary intake on dietary record forms which were reviewed by a research assistant on test day to ensure completion.

There were two test days on study day 7 and day 21. On each test day, volunteers arrived in the morning having been fasted overnight for at least 8 hours. Testing lasted approximately 3 hours and included resting and non-resting energy expenditure, gait, balance, a blood draw, and body composition measurements. Before exercise protocol, volunteers completed a readiness to exercise questionnaire (Par-Q Survey) to ensure there were no medical changes recently that would prevent them from performing the exercise safely.

All test day procedures were explained and practiced by the volunteers prior to beginning the study to allow for equipment acclimation.

The clinical phase of this study was completed from May 2012 to August 2012.

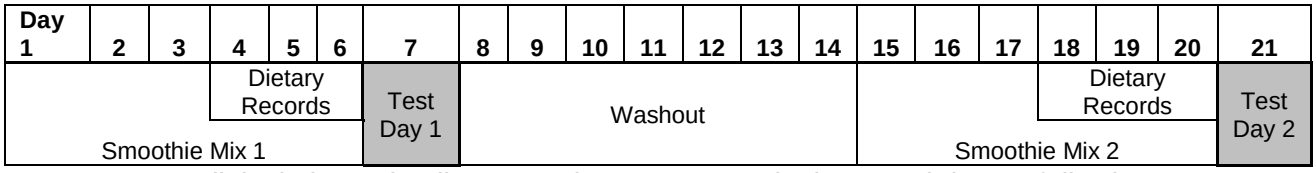

FIGURE 1. Clinical phase timeline. Test days are on study day 7 and day 21 following a randomized cross-over design of treatments that lasted 6 days each. The washout period had no treatment.

Treatments

Volunteers were provided shake supplements to consume twice daily, once at breakfast and once at lunch during each of the interventions. Each supplement contained 230 kcal of energy from mixtures of carbohydrates, fat, and protein (total energy per day was 460 kcal). The two interventions had different supplements, given in a random crossover design, that differed in the amounts of macronutrients, but not total energy (Table 1). One supplement was the placebo, which contained 22 grams of polydextrose, a corn derived glucose polymer (CHO). The other supplement was the high-protein supplement, which contained 22 grams of whey protein (WPro). Both supplements contained the same amount of fat.

Table 1. Total Macronutrient Composition Smoothies During WPro and CHO interventions

	WPro Smoothie	CHO Smoothie Mix
Energy, kcal	225	237
Fat, g	0.3	0.5
Carbohydrates, g	56.7	33.4
Protein, g	2.5	25.8

Each smoothie was consumed twice daily during each intervention. Values reported above include 22 grams of added whey protein or polydextrose.

Volunteers were given the supplements frozen and pre-prepared prior to the start of each intervention. Volunteers were instructed to keep the smoothies frozen until the consumption of each one. All volunteers were also instructed to consume the smoothies with breakfast and lunch meals, and were told to compensate within their normal diet to account for the smoothies to achieve satiation at each meal time.

During each treatment volunteers completed dietary records during the last three days prior to testing day. This allowed for dietary acclimation for the addition of the supplement. The results of the dietary records were analyzed using the Nutritional Data System for Research (NDSR) which is a computer based dietary analysis program. We analyzed total energy intake

(kcal), total protein intake (g), and total carbohydrate intake (g) during WPro and CHO interventions, as well as pre-study for each volunteer.

Resting Energy Expenditure

Volunteers were rested and acclimated to room temperature for at least thirty minutes prior to testing. A neoprene hood was placed over the subject's head and resting energy expenditure was measured using indirect calorimetry for thirty minutes. We utilized a TrueOne® 2400 Metabolic Measurement System by Parvo Medics (Sandy, Utah, U.S.A.) to measure O_2 and CO_2. The last twenty minutes of data were used for analysis to provide acclimation time for the volunteer during the first ten minutes.

Blood

A fasting blood sample was obtained from an antecubital vein after the volunteer had rested in a seated position for 15 minutes to obtain a clinical chemistry panel, pre-albumin and complete blood count with differential.

Non-Resting Energy Expenditure

Fasting non-resting energy expenditure was recorded during a low level cycle egrometer protocol using indirect calorimetry during each test day. We utilized a TrueOne® 2400 Metabolic Measurement System by Parvo Medics (Sandy, Utah, U.S.A.) to measure O_2 and CO_2, which was also used in resting energy expenditure.

During this test, the volunteer wore a plastic headpiece, which had a rubber mouthpiece with a 2-way valve attached to it. A plastic breathing tube was connected from the mouthpiece to

the pneumotach. The analyzer module measured gas composition from the pneumotach and processed it to the computer.

Exercise protocol was low resistance to represent the sedentary lifestyle of most old adults. Volume of oxygen consumed and CO_2 produced were recorded and energy expenditure was estimated using the Weir Equation [7].

To begin the test, the volunteer began by cycling for 2 minutes at 0 watts (no resistance on the peddles) for a warm up. Volunteers continued peddling at 1 watt for an additional four minutes after the warm up. The next stage was 10 watts of power for four minutes, followed by the last stage of 20 watts of power for an additional four minutes of peddling. Finally, there was a two-minute cool down period at 0 watts again. The entire test lasted 16 minutes, and data were collected for analysis during the last three minutes of each stage of power (1, 10 and 20 watts). During pre-study, while the volunteers were acclimated to the cycle they were instructed to find a comfortable pace, or rotations per minute (rpm), for peddling. The rpm they selected was recorded and on both test days volunteers were monitored by a research assistant to ensure they peddled at this same pace.

Gait

Volunteers were instructed to walk at a normal pace over a pressure-sensing walkway, the GAITRite® system by CIR Systems Inc (Clifton, NJ) . The GAITRite® measured temporal and spatial gait parameters such as step length, step width, and gait speed at a frequency of 80 Hz and transferred data to a computer with GAITRite® Gold, Version 3.4 software. The volunteer had at least twenty-five footsteps recorded by the GAITRite® during test days. Means for stride length, time in double support, cadence, and gait speed were calculated for each volunteer.

Balance

Standing balance was assessed using the Biodex Balance System SD™ by Biodex Medical Systems, Inc. (Shirley, NY). Three 20 second trials were performed with the volunteer standing on a steady platform force plate on each test day. The average of the three trials was reported by the machine in three parameters: overall stability index, anterior-posterior balance, and medial-lateral balance. These indices were then recorded onto a computer for each volunteer.

Body Composition

Body composition measurements were made in the fasting state on testing days using a bioelectric impedance machine which recorded weight (kg), and percent body fat (%). Fat-free mass (FFM) was calculated from weight and percent body fat for each volunteer as well.

Calculations

Gross mechanical efficiency (GME) calculations were performed using non-resting energy expenditure (NREE) and resting energy expenditure (REE) data [14]. REE was subtracted from NREE (on the cycle egrometer). NREE and REE were corrected for by the ratio of oxygen consumption and carbon dioxide expiration, or the respiratory exchange ratio (RER), of each volunteer during rest and each workload. This determined the amount of energy being expended per minute of cycling. The power generated during cycling at 1, 10, and 20 Watts was converted to kilocalories (kcal) per minute by the equation 1 W = 0.01433 kcal/min. GME was then calculated as the ratio of power generated in kcal/minute to the change in energy expenditure above resting [14].

Statistical Analysis

Statistical analysis were preformed using SPSS. Values are reported as means ± standard deviations in tables and means ± standard error of the mean in figures. All measured outcomes were analyzed by a repeated measures analysis between treatments. Statistical significance was defined as a P-value ≤ 0.05.

RESULTS

Volunteer characteristics are presented in Table 2 below. During the study percent body fat and weight did not change across treatments from pre-study measurements.

Table 2. Pre-Study Volunteer Characteristics

Age, years	82 ± 7
Weight, kg	72.14 ± 11.23
Percent Body Fat, %	33.28 ± 8.76
Fat-Free Mass, kg	48.16 ± 9.73
Resting Energy Expenditure, kcal/min, kcal/day	0.850 ± 0.149 (1223 ± 214)

Values are reported as mean ± standard deviation. N=12 volunteers (7 female, 5 male).

Effect of Carbohydrate and Protein Intervention on Diet and Blood

Volunteers consumed the same amount of total energy during WPro and CHO interventions (Table 3). However, volunteers consumed significantly less energy during pre-study measurements.

Table 3. Energy Intake Changes Associated With WPro and CHO Interventions

	Pre-Study	WPro	CHO
Energy intake ($kcal \bullet d^{-1}$)	1658 ± 367 [a]	1945 ± 394 [b]	1945 ± 393 [b]
Protein ($g \bullet kg^{-1} \bullet d^{-1}$)	0.95 ± 0.24 [a]	1.63 ± 0.25 [b]	0.90 ± 0.35 [a]
Carbohydrate ($g \bullet kg^{-1} \bullet d^{-1}$)	3.12 ± 0.61 [a]	3.42 ± 0.72 [a]	3.83 ± 1.40 [b]

Superscripts that vary in letters are significantly different ($p \leq 0.05$).

Total protein intake was higher during the WPro intervention versus the CHO intervention and pre-study measurements. The difference in average protein intake between WPro and CHO was 0.73 $g \bullet kg^{-1} \bullet d^{-1}$.

Total carbohydrate intake was higher during the CHO intervention compared to the WPro intervention and pre-study measurements. During the CHO intervention volunteers were consuming on average 0.41 $g \bullet kg^{-1} \bullet d^{-1}$ more carbohydrates then during the WPro intervention.

The reported change in total protein intake during each of the treatments is supported by the change in blood urea nitrogen (Figure 2). The WPro group had a 28% higher blood urea nitrogen (mg/dL) than the CHO group.

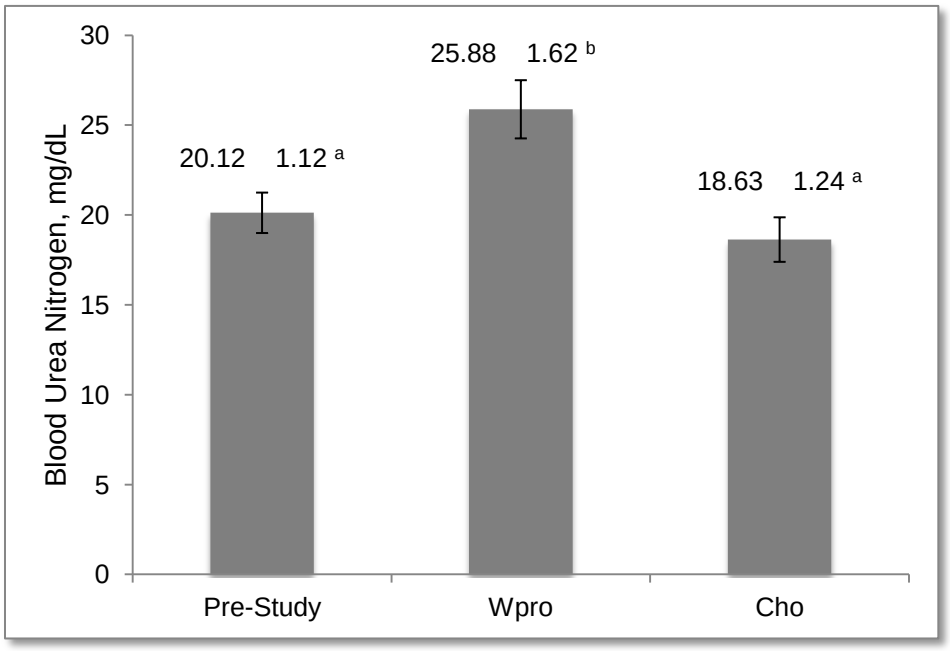

FIGURE 2. Blood urea nitrogen during the WPro and CHO interventions. Values are reported as mean ± standard error of the mean. Superscripts that vary in letters are significantly different (p-value ≤ 0.05).

Pre-albumin concentration was not different between treatments ($p \geq 0.05$). Pre-albumin was 25.5 ± 3.0 mg/dL for the WPro group and 24.9 ± 3.7 mg/dL for the CHO treatment.

Effect of Protein Intervention on Substrate Utilization

The figure below represents the percent of fat, carbohydrate, and estimated protein utilized during resting and cycling protocol (Figure 3). At rest volunteers were utilizing 64.2% and 58.0% fat and 21.8% and 28.0% carbohydrate during WPro and CHO treatments respectively. Fat and carbohydrate utilization was not significantly different between treatments.

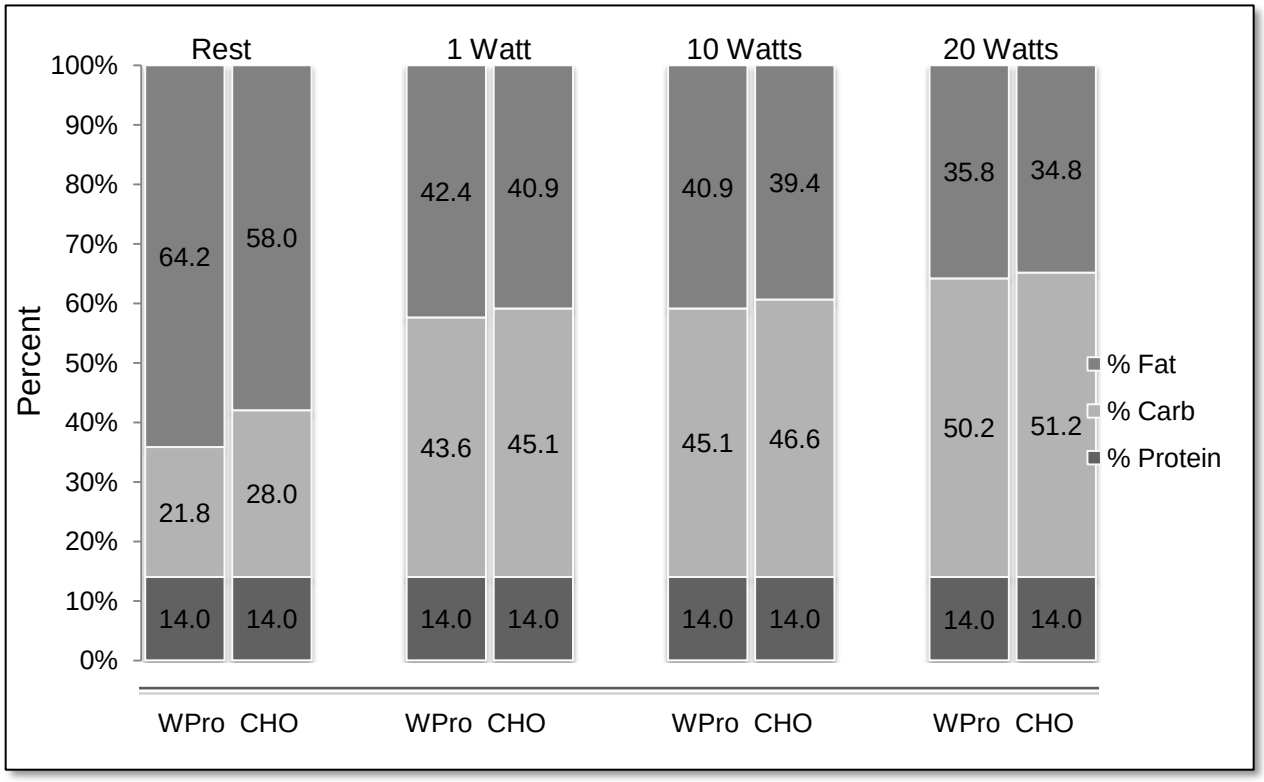

FIGURE 3. Macronutrient utilization during the WPro and CHO interventions at rest and at low levels of exercise. Percentages were determined from respiratory quotient (RQ) from indirect calorimetry.

During exercise, fat utilization decreased from 1, to 10, to 20 watts, and carbohydrate utilization increased, these responses were not different between WPro and CHO.

It should be noted that our methods did not allow for accurate calculations of protein utilization. Therefore, protein utilization was set at 14% for both interventions at rest and during

exercise. Previous research in our lab has determined this to be a reasonable assumption for protein utilization**.**

Effect of Protein Intervention on Muscle Efficiency

GME increased from 1, to 10, to 20 watts indicating an exercise response. This response was not different between WPro and CHO interventions.

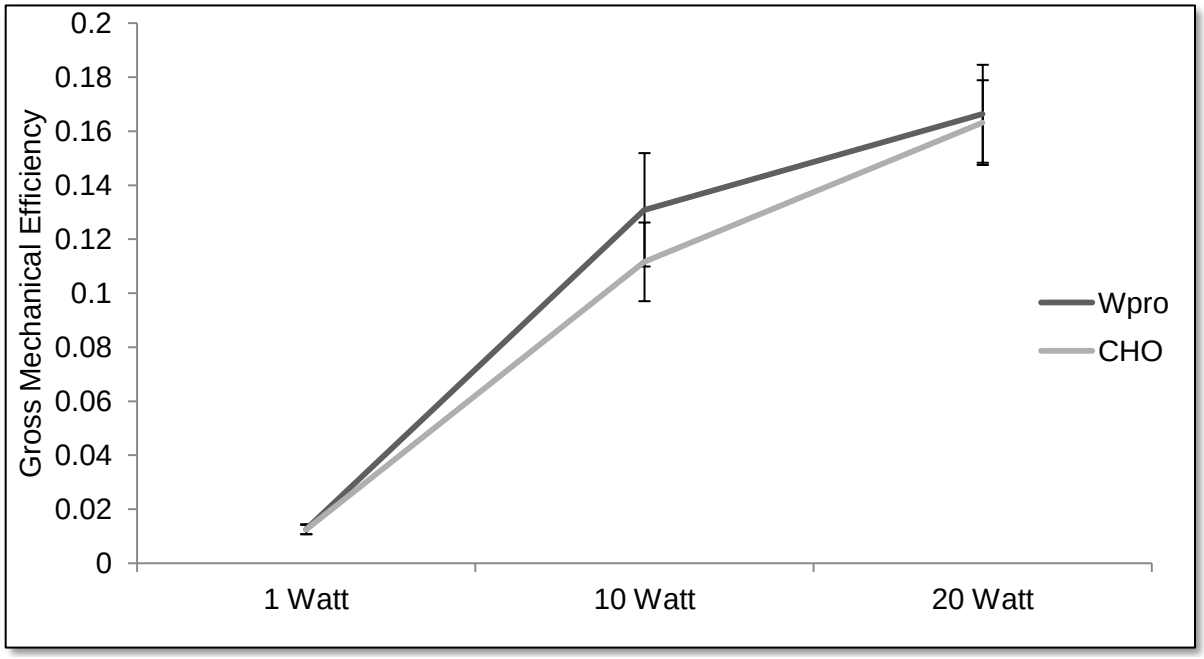

FIGURE 4. Gross Mechanical Efficiency (GME) during the WPro and CHO interventions. Values are reported as mean ± standard error of the mean. There were no significant changes between treatments (p-value ≥ 0.05).

Effect of Protein Intervention on Gait and Balance

Overall stability index showed no significant differences between treatments (Table 4). anterior-posterior balance and medial-lateral balance were not significantly changed between treatments as well.

Table 4. Balance Index between WPro and CHO Treatments

	Overall stability index	Anterior-posterior balance	Medial-lateral balance
WPro	0.725 ± 0.230	0.408 ± 0.131	0.458 ± 0.207
CHO	0.692 ± 0.264	0.392 ± 0.173	0.467 ± 0.206

All values are expressed as mean ± standard deviation. There were no significant differences between treatments in OBI, APB, or MLB (p-value ≥ 0.05).

Supplementation with WPro or CHO did not influence gait characteristics including time in double support and stride length in either foot. Gait speed and cadence did not show significant differences between treatments either (Table 5).

Table 5. Gait Characteristics between WPro and CHO Treatments

	WPro		CHO	
	Right Foot	Left Foot	Right Foot	Left Foot
Double Support (sec)	0. 36 ± 0.08	0.36 ± 0.08	0.33 ± 0.08	0.33 ± 0.08
Stride Length (cm)	108.83 ± 20.61	108.37 ± 20.68	112.36 ± 21.91	111.83 ± 22.34
Cadence (steps/min)	110.65 ± 10.76		113.66 ± 12.07	
Gait Speed (cm/s)	100.19 ± 23.39		106.36 ± 25.65	

All values are expressed as mean ± standard deviation. There were no significant differences between treatments in any gait characteristics measured (p-value ≥ 0.05).

DISCUSSION

The first aim of this study was to investigate the effects of supplementation of protein or carbohydrate on efficiency of substrate utilization in skeletal muscle. We know that inadequate intakes of protein, or energy restriction accompanied by protein restriction, will increase efficiency [14, 18]. Using this information, we had hypothesized that efficiency would decrease with an increase of dietary protein. This study found no evidence of protein supplementation affecting the efficiency of substrate utilization as measured by gross mechanical efficiency compared to carbohydrate supplementation.

Previous research has identified adaptive changes in muscle transcript levels involved with substrate utilization from similar short-term changes in protein (Δ= 0.7 $g \bullet kg^{-1} \bullet d^{-1}$). We had expected to see changes from an opposite effect of high protein as well [18]. The lack of the adaptive response indicates short term protein supplementation may not elicit adaptive changes in muscle, and therefore may have no effect on long term physiological outcomes of accommodation. In contrast, in short-term inadequate protein intake diets, adaptation markers are evident and precede accommodation responses of muscle wasting [18].

Our secondary aim was that protein supplementation would not affect gait or balance characteristics of our volunteers. Gait data such as stride length, time in double support, cadence, and gait speed were not altered between interventions, nor were balance indices. These responses were predicted because gait and balance are long term indicators of muscle function and would most likely not be influenced by short term supplementation.

This study was unique because it investigated short-term high protein intakes for elderly adults (1.6 $g \bullet kg^{-1} \bullet d^{-1}$) and subsequent muscle outcomes. Previous research focused on energy or protein restricting diets in elderly or sedentary individuals who are experiencing muscle wasting,

and its effect on muscle function. Since dietary protein is so critical in maintaining muscle size and function, research focused on supplementation is also necessary for old populations.

This study was also novel because it investigated muscle efficiency at very low powered stationary cycle ergometry. Rosebaum et at in 2003, found that changes in muscle work efficiency are most prevalent at low levels of physical activity [14]. Also, this study reported that using a cycle ergometer can be a surrogate for activities of daily living [14]. Their subjects were not comparable in age to ours, but they were confined to a research facility and considered sedentary. A sub-maximal test, as used in previous research on muscle function in old people may not be appropriate. Utilizing low powered exercise such as in the present study may be more representative of the activities of daily living of old people.

This study was limited in statistical power due to the small number of subjects that participated. This study was also limited because it was not a complete dietary intervention, rather just a supplementation. Our results show increases in total energy intake during supplementation from pre-study measurements due to lack of complete compensation. We know from previous research that increases in energy intake will influence resting and non-resting energy expenditure, so it is important to keep volunteers on an iso-caloric diet while manipulating their protein and carbohydrate intake [14].

Future research should be aimed at investigating the effects of protein supplementation for longer interventions in elderly adults. It would be especially important for a longer intervention to have maintained weight of volunteers by having them consume an iso-caloric diet as mentioned above. Also future research should focus on comparing inadequate versus supplemental protein intakes. The present study included a group with supplemental protein during WPro (1.63 $g \bullet kg^{-1} \bullet d^{-1}$), but the CHO control group also consumed adequate protein too

(0.9 g•kg^{-1}•d^{-1}). Since we know inadequate protein leads to adaptive changes in muscle, having a low protein group could serve as a control for the protein supplemented group.

In conclusion, the present study represented two groups of elderly individuals who consumed short-term diets of adequate protein intakes, and high protein intakes. No adaptive changes in muscle occurred between high protein (WPro) or adequate protein (CHO) intakes as measured by substrate utilization at rest and during exercise. The exercise protocol was low intensity, which represented activities of daily living for old people. This could be indicative that supplementation of protein to already adequate protein intakes may not elicit any later changes of accommodation in elderly individuals.

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APPENDIX

Appendix 1: Recruitment Flyer

Men and Woman Age 65 and Older Needed For Research Study

Dr. Wayne Campbell in the Department of Nutrition Science, Stone Hall, Purdue University, West Lafayette, IN is conducting a research study to assess diet and muscle function in adults 65 years and older. This study will be conducted at University Place Senior Living Community.

This study includes 2 parts, over a period of 26 days.

Part 1 of this study will last approximately 5 Days with 1 Test Day

Part 1 and 2 of this study will last approximately 26 Days with 3 Test Days

Measurements Will Include:

- Resting Energy Expenditure
- Exercise Energy Expenditure (Stationary Bike Exercise)
- Body Composition(lean and non-lean body tissue)
- Blood Chemistry Profile
- Diet Analysis
- Physical Energy Level Questionnaires
- You Will Be Asked To Consume A Dietary Supplement In Part 2

Are you 65 or older and in general good health, non-smoking, do not have diabetes, or acute heart or lung diseases? Are you physically able to ride on a stationary bike at an easy pace for up to 16 minutes? If so, please contact:

Kristen Clark at clarkk@purdue.edu Or Kathryn Sands at 765-496-6480

Appendix 2: Screening Consent Form

RESEARCH PARTICIPANT SCREENING
CONSENT FORM

Diet and Muscle Function in Older Adults

Professor Wayne W. Campbell, Ph.D.
Purdue University
Department of Nutrition Science

Purpose of Research
The purpose of this study is to assess if your diet, body composition, and physical abilities affect how many calories your body burns at rest and while doing low-intensity exercise.

Specific Procedures
The information you will provide during screening may also be used for the study. You have been asked to fill out a Medical History Questionnaire and give your doctor a form to send back to us that determines your eligibility. You will then return that information back to the Department of Nutrition Science at Purdue University. We will then schedule a meeting to review your information and describe the study in detail. Once you have a good understanding of what we are asking you to do and if you agree, then we can start the study.

Screening measurements: *# OF DAYS: 1 TOTAL ESTIMATED TIME: ~ 1 hour*

Medical History Questionnaire, Physician's Clearance Form:
You have provided (to the best of your knowledge) a complete history of all of your medical disorders during the screening process. To the best of your knowledge, you are free from disease that might make participation in this study unsafe. You will let Professor Campbell know all of the medications, drugs, and/or supplements that you currently take. You have also provided your physician's clearance form allowing you to participate in this study. If requested by Professor Campbell, you will agree to stop taking some or all of these medications, drugs, and/or supplements two weeks before and during this study. **You will not be asked or required to change any of your prescription drug intake without the authorization of your personal physician.** It is expected that you will not take any new medications, drugs, and/or supplements during this study. It is expected that you will not change the dose of medications that you keep taking during the study. If you find that you must change the dose of your medications, you will contact Professor Campbell before the medication change or as soon as possible immediately afterward.

Duration of Participation
Screening procedures will take approximately 1 hour to complete.

Benefits to the Individual
There is no direct benefit for participating in this study. However, you may benefit from the information given to you concerning your general overall health.

Risks to the Individual
There are no known risks when completing questionnaires. There is a risk of breach of subject confidentiality but safeguards are in place to minimize this risk as outlined above.

Compensation
You will not be paid for completing this screening process.

Injury or Illness
Purdue University will not provide medical treatment or financial compensation if you are injured or become ill as a result of participating in this research project. This does not waive any of your legal rights nor release any claim you might have based on negligence.

Confidentiality
The project's research records may be reviewed by the Purdue University Institutional Review Board, Office of Human Research Protections, and by departments at Purdue University responsible for regulatory and research oversight. All records will be kept confidential in locked cabinets/rooms for at least three years and after the close of the study. The data will be kept indefinitely and may be used for future studies. All records, data, and specimen will only be available to the principle investigator or his designee for analysis purposes.

Voluntary Nature of Participation
You do not have to participate in this screening evaluation. If you agree to participate you can withdraw your participation at any time without penalty.

Contact Information
If you have any questions about this research project, you can contact Professor Wayne W. Campbell at (765) 494-8236. If you have concerns about the treatment of research participants, you can contact the Institutional Review Board at Purdue University, Ernest C. Young Hall, Room 1032, 155 S. Grant St., West Lafayette, IN 47907-2114. The phone number for the Board is (765) 494-5942. The email address is irb@purdue.edu

Documentation of Informed Consent

I HAVE HAD THE OPPORTUNITY TO READ THIS PARTICIPANT SCREENING CONSENT FORM AND HAVE THE RESEARCH STUDY EXPLAINED. I HAVE HAD THE OPPORTUNITY TO ASK QUESTIONS ABOUT THE RESEARCH PROJECT AND MY QUESTIONS HAVE BEEN ANSWERED. I AM PREPARED TO PARTICIPATE IN THE SCREENING EVALUATION FOR THE RESEARCH PROJECT DESCRIBED ABOVE. I WILL RECEIVE A COPY OF THIS CONSENT FORM AFTER I SIGN IT.

_____ _____

Screening-Participant's Signature Date

_____ _____

Researcher's Signature Date

Please check only one of the two boxes below

☐ You agree to allow the use of your data and/or specimens collected during this screening evaluation to be used for future research that is unrelated to this study.

_____ _____

Screening-Participant's Signature Date

☐ You request your data and/or specimens collected during this screening evaluation to NOT be used for any future research that is unrelated to this study.

_____ _____

Screening-Participant's Signature Date

Appendix 3: Study Consent Form

RESEARCH PARTICIPANT STUDY CONSENT FORM

Diet and Muscle Function in Older Adults

Wayne W. Campbell, Ph.D.
Purdue University
Department of Nutrition Science

Purpose of Research

This is a two-part project to improve our scientific understanding of diet, body composition and energy use in older adults. Part 1 will assess if your diet, body composition, and physical abilities affect how many calories your body burns at rest and while doing low-intensity exercise. Part 2 will assess how dietary protein intake affects muscle energy use and your daily perceived vigor.

Medical History Questionnaire, Physician's Clearance Form

You have provided (to the best of your knowledge) a complete history of all of your medical disorders during the screening process. To the best of your knowledge, you are free from disease that might make participation in this study unsafe. You will let Professor Campbell know all of the medications, drugs, and/or supplements that you currently take. You have also provided your physician's clearance form allowing you to participate in this study. If requested by Professor Campbell, you will agree to stop taking some or all of these medications, drugs, and/or supplements two weeks before and during this study. You will not be asked or required to change any of your prescription drug intake without the authorization of your personal physician. It is expected that you will not take any new medications, drugs, and/or supplements during this study. It is expected that you will not change the dose of medications that you keep taking during the study. If you find that you must change the dose of your medications or a new medication, you will contact Professor Campbell before the medication change or as soon as possible immediately afterward.

Procedures To Be Used

This study includes two parts. Part 1 is shown on the study table (next page) as study days one through five (1-5). Part 2 will consist of days 6-26 on the study table below.
After participating in Part 1, if you are interested in continuing with our research study, you can participate in Part 2.

	Part 1				Part 2						
Description	**Day 0**	**Day 1**	**Days 2-4**	**Day 5**	**Days 6-8**	**Days 9-11**	**Day 12**	**Days 13-19**	**Days 20-22**	**Days 23-25**	**Day 26**
Screening	X										
Study and Equipment Review		X									
Diet Supplement					X	X			X	X	
Wash out Period								X			
Body Composition				X			X				X
Blood Sample				X			X				X
Energy Expenditure				X			X				X

Bicycle Test				X			X				X
Physical Ability Test				X			X				X
Dietary Records			X			X				X	
Energy Level Survey			X			X				X	

Part 1: The study will consist of one test day. Prior to the test day, you will be asked to record everything you eat, how it was prepared, and the quantity consumed throughout the days on a 3-Day food record sheet, which will be provided. Also during these three days, you will be asked to complete an energy-level survey with each meal. This survey will have you rate your daily perceived energy level.

Part 2: You will continue to consume your normal diet with the addition of a daily nutritional supplement. At the beginning of the supplementation, you will be asked by our research team to consume 2 supplements/day. One will be consumed at the first eating occasion of the day (i.e., breakfast) and the second one will be consumed at the second eating occasion of the day (i.e., lunch). You will be asked to consume these supplements for two 6-day interventions (total of 12 days). Between these interventions, there will be a washout period of no supplements to be consumed lasting from Day 13-19. The supplements will be composed of dietary carbohydrates, protein and fat (total of 500calories/day). The supplements for each intervention will differ in the amount of protein, consisting of either a high protein or low protein shake.

During these interventions, on the last three days you will be asked to record everything you eat, how it was prepared, and the quantity consumed throughout the days on a 3-Day food record sheet provided. Also during these last three days both interventions you will be asked to complete an energy-level survey with each meal. This survey will have you rate your daily perceived energy level.

Test Days

Test days include days 5, 12, and 26. All three of these test days will be identical. Each test day will last approximately 3.5 hours. You will need to be in a fasted state. You will be asked questions about any recent changes in your health. You will also be asked to complete the following tests conducted by a member of our research staff:

A. **Body Composition:**
   Your height and weight will be measured. The amount of lean to non-lean tissue will be determined by stepping on a scale for about 10-15 seconds while barefoot. You may hold on to handle bars for balance.
B. **Blood sample:**
   You will have about 4 teaspoons of blood drawn from a vein in the crook of your arm using a needle. The sample will be used to measure clinical indicators of your health, including liver and kidney functions, risk of diabetes, acute illness, and if your body has adequate protein.
C. **Energy Expenditure:**
   You will lie on a bed in a reclining position for a total of 60 minutes. During the first 30 minutes, no measurements will be taken and you will simply lie quietly and relax. After 30 minutes, a large clear plastic hood will be placed over your head and the amount of oxygen you breathe in and out will be measured for the next 30 minutes.

You will be able to breathe normal room air, which is continually flowing into the hood during the procedure. This test is used to measure how many calories of energy you are burning while resting.

D. Bicycle Test:

This test measures how many calories you are using during easy-paced exercise on the stationary bike. You will pedal for approximately 16 minutes including a warm up and cool down session. During the test, a plastic headset will be worn to hold the mouthpiece and tubes for the air measurements. You will breathe through a mouthpiece attached to plastic tubes. Room air will always flow through the tubes. We will measure how fast and how much air you are taking in and breathing out. Periodically, you will be asked to rate how hard you are exercising. A heart rate monitor will be used to measure your heart rate before, during, and after exercise.

After the bicycle test, you will receive a snack and beverage before continuing with any further testing.

E. Physical Ability Tests*:*

A series of tests will be done to determine your physical abilities.

Postural Stability

You will simply be required to fit a square object through an opening of varying size while reaching movements and posture are monitored while standing on the force plate.

Walking Gait

You will walk across a pressure-sensing walkway. The GaitRight measures gait parameters such as step length, step width, and gait speed.

There is a hierarchy of gait tasks. In the first level, you will be seated. In the second level, you will walk over a walkway with no obstacles. In the third level, obstacles will be placed on the walkway where you must step over and continue walking. In the fourth level, you will walk and step over obstacles while carrying a tray with four plastic cups.

F. Dietary Food Record:

A member of Prof. Campbell's research staff will review your 3-Day food records with you to make sure the information is complete and accurate.

Duration of Participation

The study will take a minimum of 5 days to complete, but may take longer depending on your availability for testing for Part 1. If you participate in Part 1 and Part 2, the study will take a minimum of 26 days to complete, but may take longer depending on your availability for testing.

Benefits to the Individual

There is no direct benefit of participating in this study. However, you may perceive a benefit from knowing your body composition, how many calories you burn, and the results of the blood analyses.

Risks to the Individual

The following risks exist:

- Blood Draw
  You may experience discomfort and the development of a small bruise and/or infection at the puncture site on your arm where the blood is drawn. You may also feel lightheaded and there is a slight risk of fainting. The amount of blood drawn is about four (4) teaspoons (two-thirds of a fluid ounce or 20 milliliters) and is small enough that it should present no hazard to your physical well-being.
- Energy expenditure
  There is a risk of a feeling of claustrophobia occurring when clear plastic hood is placed over your head. If this occurs, you can always remove the hood or signal to the attendant and he or she will remove it for you.
- Bicycle Testing
  The cycling exercise should feel easy to moderately hard. During exercise, we will monitor your heart rate and stop the test at any time if your heart rate goes above an acceptable level for submaximal exercise based on age. If you feel discomfort, you can stop peddling at any time during the test. The bicycle seat could potentially be uncomfortable as well. Risks include shortness of breath, uncomfortable fit of mouthpiece, muscle and joint soreness, cardiac arrest, or death. Qualified responders will be on hand to provide assistance if the need arises.
- Functionality Tests:
  There is a risk of falling. If you should feel any discomfort, fatigue, lightheadedness, or chest pains the tests can be stopped.
- Supplement (Part 2 only):
  You may experience some gastro-intestinal discomfort with the supplement used in the study.

There is risk of breach of confidentiality. There are no known risks associated with: weight and height measurements, fat body tissue measurements and completing questionnaires and surveys.

Compensation

You will not be paid any money for doing this research study.

Injury or Illness

Purdue University will not provide medical treatment or financial compensation if you are injured or become ill as a result of participating in this research project. This does not waive any of your legal rights nor release any claim you might have based on negligence.

Confidentiality

The project's research records may be reviewed by the Purdue University Institutional Review Board, Office of Human Research Protections, and by departments at Purdue University responsible for regulatory and research oversight. All records will be kept confidential in locked cabinets/rooms for at least three years and after the close of the study. The data will be kept indefinitely and may be used for future studies. All records, data, and specimen will only be available to the principle investigator or his designee for analysis purposes.

Voluntary Nature of Participation

You do not have to participate in this study. If you agree to participate you can withdraw your participation at any time without penalty.

Human Subject Statement:

If you have any questions about this research project, you can contact Professor Wayne W. Campbell at (765) 494-8236. If you have concerns about the treatment of research participants, you can contact the Institutional Review Board at Purdue University, Ernest C. Young Hall, Room 1032, 155 S. Grant St., West Lafayette, IN 47907-2114. The phone number for the Board is (765) 494-5942. The email address is irb@purdue.edu.

Documentation of Informed Consent

I have had the opportunity to read this consent form and have the research study explained. I have had the opportunity to ask questions about the research project and my questions have been answered. I am prepared to participate in the research project described above. I will receive a copy of this consent form after I sign it.

Participant Consent for Part 1 of our research:

_____	_____
Participant's Signature	**Date**
_____	_____
Printed Name	**Date**
_____	_____
Researcher's Signature	**Date**

Participant Consent for Part 2 of our research (to be signed after completion of Part 1):

_____	_____
Participant's Signature	**Date**
_____	_____
Printed Name	**Date**
_____	_____
Researcher's Signature	**Date**

☐ Please check only one of the two boxes below:

I agree to allow the use of my data and/or specimens collected during this research project to be used for future research that is unrelated to this study.

_____ _____

Participant's Signature **Date**

☐ I request my data and/or specimens collected during this research project to NOT be used for any future research that is unrelated to this study.

_____ _____

Participant's Signature **Date**

Appendix 4: Physician Clearance Form

Physician Clearance Form

To Whom It May Concern:
Patient, _____, has expressed interest in participating in a two part research study being conducted at University Place Senior Community. The study is being conducted by Professor Wayne Campbell in the Department of Nutrition Science at Purdue University.
Part 1.) The purpose of the this study is to determine the metabolic effects of using low intensity exercise to represent the recreational lifestyle of adults 65yrs and older.
Part 2.) The purpose of this study is to investgate the effects of a normal or high dietary protein intake (supplemented through a nutritional shake) on muscle function in adults 65yrs and older. We are also investigating chronic fatigue in this population.

During the study the following parameters will be measured:

Resting Metabolic Rate *Blood Lipids* *Blood Glucose* *Body Wt* *Dietary Intake*
Body Composition (fat and lean mass) *Blood Clinical Chemistry Panel (including kidney& liver functions)*
Physical Function test

Energy Expenditure during low intensity exercise using a Stationary Cycle:

Each participant will sit on a stationary cycle and pedal against very light to moderate resistance for up 16 minutes.
Heart rate and preceived exertion will be monitored. As well, medical emergency services are available at University Place Senior Community if needed.

Cycle protocol will include the following:

A 2 minute warm up period at 0 **(very light)** resistance, 4 minutes of cycling at 0 **(very light)** resistance , 4 minutes of cycling at 10**(light)** watts of resistance, 4 minutes of cycling at 20 **(moderate)** watts of resistance, and a 2 minute cool down period at 0 **(very light)** watts resistance.

The exclusion criteria are as follows:

- Age < 65 years
- Diagnosis of diabetes mellitus.
- Post myocardial infarction (MI) or coronary artery bypass graft (CABG) surgery within 16 weeks
- Post percutaneous transluminal coronary angioplasty (PTCA) within 4 weeks.
- Acute upper respiratory infection, symptoms suggestive of cardiovascular disease and symptoms suggestive of acute congestive heart failure.
- Uncontrolled hypertension at rest (systolic blood pressure greater than or equal to 160 mm Hg and or diastolic blood pressure greater than or equal to 100 mm Hg).
- Lower extremity conditions (such as osteoarthritis or peripheral vascular disease), which preclude the subject from peddling a cycle at 20 watts.
- Cognitive conditions or limitations that preclude the subject from being able to understand comprehend or interpret instructions, fatigue or symptoms.
- Routine use of supplemental oxygen during rest or exercise.
- Lactose Intolerant

This study has the approval of the Institutional Review Board at Purdue University. As part of the protocol, physicians' clearance is required. Please sign and date this form if you agree that this patient is suitable to participate in this study. If you need more information or have any question regarding this study please call.
Thank You, Wayne Campbell, Ph.D., Professor, Dept of Nutrition Science, Purdue University, 765-496-6342

Physician Comments:

☐ I have reviewed the information and in my professional opinion, the described study activities are not contraindicated for this patient.

_____	_____	_____
Physician Name	**Date**	**Physician Name (Printed)**

You may return this form by fax to our office of Nutrition Science at Purdue University at 765 494 0674.

Appendix 5: Volunteer Medical History Questionnaire

Department of Nutrition Science
Wayne W. Campbell, Ph.D.

MEDICAL HISTORY QUESTIONNAIRE

The following questions are designed to obtain a thorough preliminary medical history. The information you provide will help us to make the best determination about your eligibility for a particular study. Please answer all questions and provide as much information as you possibly can. This questionnaire, as well as any other medical information you provide will be kept confidential and will not be shared with any unauthorized person or organization unless you specifically request us to do so.

Name: _____

Street Address: _____

City, State, Zip: _____

Telephone number: Home ( )_____ Work ( )_____

Date of Birth: _____ Age: _____
mm-dd-yy

Sex: M _____ F _____

Height _____ Weight _____

Personal Physician's Name: _____Phone_____

Address: _____

_____

Last grade completed in elementary or high school: _____

Education completed since leaving elementary or high school:

_____ None
_____ Vocational School
_____ Community or Junior College
_____ Four Year College
_____ Graduate School
_____ Professional School

Occupation

Current occupation or occupation at retirement:

_____

Marital Status

_____ Married _____ Single, never married
_____ Divorced _____ Separated
_____ Widowed

Living Situation

_____ Alone
_____ With family member(s)
_____ With non-family members(s)

Do you have any pets? No _____ Yes _____ (please describe)

_____

Race

____Caucasian (white) ____Hispanic
____ African American ____American Indian
____ Asian/Pacific Islander ____Other, please indicate

Personal Health History

Have you ever been hospitalized or had surgery? Yes _____ No _____

Please list all hospitalizations and surgeries to the best of your recollection

Hospitalized for Disease/Operation	Duration	Age when Hospitalized

List any disease or illness you have had not listed on the previous page (e.g., mumps, measles, broken bones, etc.)

_____
_____
_____
_____
_____

Are you allergic, sensitive or intolerant of any foods or medications? Yes___ No___
If yes, please describe:
Food:_____
Medication:_____
Other:_____

Are you currently seeing a doctor or other health care provider for any reason?

Yes _____ No _____
If yes, please explain: _____
_____

Do you have, or have you <u>ever</u> had any of the following conditions?

Alteration of your ability to remember Yes _____ No _____

Recurring headaches Yes _____ No _____

Recent changes in your vision Yes _____ No _____

Numbness of an arm or leg Yes _____ No _____

Weakness of an arm or leg Yes _____ No _____

Difficulty in speaking or slurred speech Yes _____ No _____

Fainting or dizziness Yes _____ No _____

Difficulty in walking (staggering) Yes _____ No _____

Shortness of breath Yes _____ No _____

Lung or Respiratory Disease Yes _____ No _____

Rheumatism or arthritis Yes _____ No _____

Pain in joints Yes _____ No _____

Osteoporosis Yes _____ No _____

Osteopenia Yes _____ No _____

Heart disease Yes _____ No _____

Epilepsy Yes _____ No _____

Tumors Yes _____ No _____

Mental illness Yes _____ No _____

Bleeding or clotting disorders Yes _____ No _____

Risk for infectious diseases Yes _____ No _____
(AIDS, IV drug use, blood transfusions, hemophilia, hepatitis)

Skin: rashes, lumps, moles, itching, eczema Yes _____ No _____

Nose, sinuses: frequent colds, sinus trouble Yes _____ No _____
nose-bleeds, deviated septum

Neck lumps, swollen glands, pain or stiffness Yes _____ No _____

Breasts: lumps, nipple discharge, pain Yes _____ No _____
or discomfort
For women: Date of last mammogram _____

High blood cholesterol Yes _____ No _____
Date of last reading _____

Stomach: chronic indigestion, ulcer, hiatal hernia, heartburn, trouble swallowing, vomiting. Yes _____ No _____

Intestine: constipation, diarrhea, change in bowel habits, irritable bowel disorder, colitis, polyps. Yes _____ No _____

Rectum: hemorrhoids, bleeding, polyps Yes _____ No _____

Liver, gallblader: hepatitis, gallstones Yes _____ No _____

Urinary: frequent urination, urgency, burning, pain, blood in urine, infection, kidney stones Yes _____ No _____

Incontinence: Loss of bladder or rectal control Yes _____ No _____

Do you use adult undergarment products such as Depends? Yes _____ No _____

Have you ever had any form of cancer, skin or other?

Yes _____ No _____ If yes, what kind: _____

Do you have diabetes mellitus (high blood sugar)?

Yes _____ No _____

If yes, when and what kind of treatment did/do you receive:

Insulin _____ Diet _____ Pills _____ No treatment _____

Is there a family history of diabetes mellitus?
Yes _____ No _____

Have you ever had or been told that you had high blood pressure?

Yes _____ No _____

If yes, when and what kind of treatment or medicine did/do you receive:

_____

Do you have any chronic illnesses?

Yes _____ No _____

If yes, please explain:
_____

Do you have any problems with constipation or diarrhea?
Yes _____ No _____

If so, how do you usually remedy it?
_____

Have you ever been treated for an eating disorder?
Yes _____ No _____

If yes, when and what type? _____

List all the prescribed medications you are currently taking:

Medicine Cause of Medication

_____
_____
_____
_____

List all the over-the-counter Physician recommended medications you are currently taking:

Medicine Cause of Medication

_____
_____
_____
_____

List all the over-the-counter medications you are currently taking:

Medicine Cause of Medication

_____
_____
_____
_____

Would you be willing to have your Physician give written approval for you to discontinue **only** your Physician recommended and self-prescribed medications for the duration of the study?

If yes, please have your Physician sign and date the bottom of this page indicating his/her approval.

_____ _____
Physician Name Date

_____ _____
Volunteer Name Date

Physician Comments:

_____
_____

For Females Only

Do you currently have menstrual periods? Yes _____ No _____

If yes, is your cycle regular? Yes _____ No _____

What is the typical length of your menstrual cycle? _____ days

What is the typical length between menstrual periods? _____ days

When was your last menstruation? _____

Do you or have you ever had menstrual problems, vaginal discharge, irregular bleeding, sexually transmitted illness.
Yes _____ No _____

If yes, please explain: _____

Are you sexually active? Yes _____ No _____

If yes, what type of contraceptives do you use? _____

Age of menopause if applicable: _____

Type of menopause: _____ natural _____surgical _____ other

Estrogen replacement: Yes _____ No _____

If yes, please explain:
_____

Last PAP smear: _____
Number of pregnancies: _____
Number of births: _____
Type of delivery: _____
Your age at time of birth (s): _____
Date of Hysterectomy (if applicable): _____
Reason: _____

Dietary Information

Are you currently taking any vitamins, minerals or health food supplements at least once per week on a regular basis? Yes _____ No _____ If yes, please describe:

Supplement Amount How often How long Reason
_____
_____

Would you be willing to stop your vitamins, minerals or health food supplements if needed while participating in a study? Yes _____ No _____

Are you currently following a special diet (i.e., vegetarian, diabetic, low fat, lactose free)?

Yes _____ No _____ If yes, what kind? _____

Has this diet been prescribed by your health care provider? Yes ____ No ____

If accepted for a study, are you willing to follow a diet that may vary from your current food intake?
Yes _____ No _____

Have you had a weight loss or gain in the last 6 months? Yes _____ No _____

If yes, how much? _____lbs. Gain _____ Loss _____ (check one)

How do you describe your appetite? Poor _____ Fair _____ Good _____

When required during the study, would you be willing and able to eat only the items provided by the Nutrition Laboratory, Purdue University?

Yes _____ No _____

Do you have problems eating high-fat foods? Yes _____ No _____

Do you have any food allergies/intolerance? Yes _____ No _____

If so, please explain:
_____
_____

Do you drink caffeinated beverages? (coffee, tea, soda) Yes _____ No _____

If yes, how many caffeinated beverages do you drink in an average day? _____/day

If required during a study, would giving up caffeine cause any problems for you?

Yes _____ No _____

Do you drink alcoholic beverages? Yes _____ No _____

If yes, how many alcoholic beverages do you consume in an average week? _____/wk

Can you forego drinking alcoholic beverages for the duration of a research study?

Yes _____ No _____

Do you have a problem drinking milk or eating dairy products?

Yes _____ No _____
If yes, what happens?
_____

How many meals to you typically eat in a day? _____

Please list the typical times that you eat throughout the day (meal #1 is the first meal of the day; only list the times for the meals that you eat):

Meal #1: _____

Meal #2: _____

Meal #3: _____

Meal #4: _____

Meal #5: _____

Meal #6: _____

Meal #7: _____

Exercise History

What kind of work are you engaged in? _____

How long have you been engaged in this type of work? _____ years.

In terms of physical demands, how would you rate your position?

very active active slightly active sedentary

In which of the following positions do you spend most of your time at work?

sitting sitting and standing walking and standing

About how much time on the job do you spend sitting?

all more than 1/2 about 1/2 less than 1/2 almost none

Do you lift and carry heavy things in your work? frequently sometimes infrequently

Do you take walks in good weather? frequently sometimes infrequently

Do you do manual work at home (e.g., painting, repairing, etc.)

frequently sometimes infrequently

Do you mow your lawn or work in your garden? frequently sometimes infrequently

Do you take part in sports during their season? frequently sometimes infrequently

List the sports and/or exercise that you engage in and the number of times per week:

_____
_____

In the past, were you a regular sport or exercise participant?

frequently sometimes infrequently

When and why did you cease participating?

Approximate date: _____
Reason for quitting: _____

Do you have any condition that would prevent you from being physically active?
Yes _____ No _____
If yes, please explain:_____

Smoking History

Do you smoke cigarettes at present? Yes _____ No _____

If yes, how many packs per day?
less than 1/2 pack
1/2 to 1 pack
1 to 2 packs
more than 2 packs

Do you inhale? Yes _____ No _____

How long have you been smoking?
less than 1 year
1 to 5 years
more than 5 years

Did you smoke cigarettes in the past and quit permanently? Yes _____ No _____

If yes, how many packs per day did you smoke?
less than 1/2 pack
1/2 to 1 pack
1 to 2 packs
more than 2 packs

Did you inhale? Yes _____ No _____

When did you quit?
less than 1 year
1 to 5 years
more than 5 years

Do you smoke cigars at the present? Yes _____ No _____

If yes, how many cigars per day?
less than 2
2 to 5
more than 5

Did you smoke cigars in the past and quit permanently? Yes _____ No _____

Do you smoke a pipe at present? Yes _____ No _____

If yes, how many pipefulls do you smoke per day?
less than 2
2 to 5
more than 5

Did you smoke a pipe in the past and quit permanently? Yes _____ No _____

Appendix 6: Pre-Exercise Questionnaire

Pre-Exercise Questionnaire

Subject Name: _____

Date: _____ Time: _____

Has your health status changed since the last time we saw you?

No Changes

YES (please describe)

Have your medications (types or dosages) changed since the last time we saw you?

No Changes

YES (please describe)

Have you experienced any injuries or illness since the last time we saw you?

No

YES (please describe)

Have you experienced any symptoms of illness including, but not limited to, dizziness, nausea, lightheadedness, fatigue, gastrointestinal distress, diarrhea, shortness of breath, chest pain or fever within the past 48 hours?

No symptoms

YES (please describe)

Subject Initials: _____
Investigator Name: _____

Appendix 7: Food Record Forms

Indiana Clinical and Translational Sciences Institute

Completing Multiple Day Food Records

General Instructions for Keeping Records

- Please use ink and write clearly.
- Please complete the food records for the **number of days** and **specific days of the week** (i.e. weekend days vs. weekdays) that were specified by the dietitian or study coordinator.
- Remember to **not** change your eating habits.
- Record **everything** you eat and drink in a 24 hour period, from midnight to midnight, preferably right after it's consumed.
- Write each food, beverage, or ingredient on a **separate line**.
- Start each **new day** on a **new page**. If you need more than one page per day, please mark the pages.
- Fully describe foods & beverages, including **brand names**, when possible. If the item is cooked, please **describe how it is prepared** (e.g. boiled, broiled, grilled, baked, fried, etc.)
- Estimate the **portion sizes** of everything you consume. Refer to page 2, "Seven Ways to Size up your Servings," for help with estimating portion sizes.
- Include items you add at the table. List them on separate lines. (e.g. margarine on a baked potato)
- You may attach copies of recipes.

Breads

- Indicate if whole wheat, white, etc.
- Record number, size, & portion.
- Include sandwich condiments & additions (e.g. lettuce, tomato, mustard)

Beverages

- List the type of milk – whole, 2%, etc.
- List whether fruit juice is fresh, frozen, sweetened, and if calcium fortified.

Cereals

- Record cooked cereal in portions of cup and amount eaten after cooking.
- Record dry cereal in level portions of cup.
- Note if milk, fruit, sugar, etc are added and the amounts (e.g. 1 tsp brown sugar).

Cheese

- Record the size in inches or weight in oz.
- Describe fat content – skim, 1%, 2%, whole.

Desserts

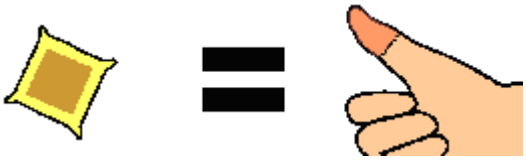
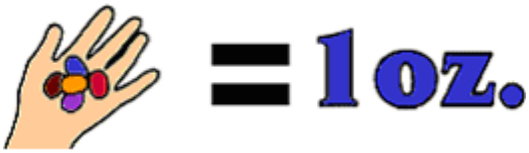
- List commercial brand or homemade.
- Record portion size of cakes, pies, and cookies by indicating thickness, diameter, width or length (e.g. brownie 2" x 2")
- Candy - # of pieces or size in ounces

Fruits

- Indicate if fresh, frozen, dried, or canned.
- If whole, record # eaten and size (1 apple, 3" diameter).

Meats, Fish, Poultry

- Record size in inches or weight in ounces, without bone, after cooking.
- Indicate leanness (e.g. % fat ground beef).
- Describe how meat was prepared.

Remember:		
1	3 ounces of meat is about the size and thickness of a deck of playing cards or an audiotape cassette.	
2	A medium apple or peach is about the size of a tennis ball.	
3	1 ounce of cheese is about the size of 4 stacked dice.	
4	1/2 cup of ice cream is about the size of a racquetball or tennis ball.	
5	1 cup of mashed potatoes or broccoli is about the size of your fist.	
6	1 teaspoon of butter or peanut butter is about the size of the tip of your thumb.	
7	1 ounce of nuts or small candies equals one handful.	

Participant ID#:_____
Day of Week: _____
Date:___/___/___

MEAL B = Brkfast L = Lunch D = Dinner S = Snacks	PLACE PREPARED H = Home R = Restaurant O = Other	TIME CONSUMED	METHOD OF PREPARATION e.g. Baked, Broiled, Fried, Raw, Canned etc.	FOODS & BEVERAGES (Include brand names, if known)	AMOUNT & / OR SIZE (e.g. cups, oz, tsp, Tbsp, inches)