Effects of the USDA Daily Recommended Intake for Protein and Strength Training on Physical Function, Body Composition, and Strength in Older Men

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ABSTRACT

Background: Aging adults experience significant declines in muscle mass and function. These can be reversed with strength training (ST). However, the combined effect of ST with the DRI for protein intake (0.8 g/kg/d) has not been determined.

Objective: To examine the combined effects of ST and protein DRI in older men.

Design: Seven healthy men (69-78y) were admitted to the Human Nutrition Research Center on Aging at Tufts University, Boston, MA for 13 ½ weeks. After 5 ½ weeks of diet equilibration at the DRI level, protein intake was maintained and subjects were randomized to high-intensity ST+DRI 3x/wk (n=3) or the DRI only group (n=4) for 8 ½ weeks of intervention. Physical function, muscle strength, body composition, leucine turnover and resting energy expenditure were measured at different phases of the intervention.

Results: Isokinetic knee flexion strength (240º/s) increased by 23% with ST+DRI and did not change in the DRI only group (p=0.03, time-by-group interaction). Leucine balance was negatively correlated with leucine oxidation (r=1.0, p<0.001) and remained negative with ST as compared to the DRI only group (p=0.10). No significant findings were observed for all other measures.

Conclusions: These data suggest that the DRI for protein may not be adequate to maintain protein balance or muscle strength when combine with high-intensity strength training. Additional studies are needed to confirm these findings.
CHAPTER 1
INTRODUCTION

The elderly are the largest growing segment of the population in the United States and world-wide (Kruskall, 1998; Mazzeo, Cavanaugh, Evans, Fiatarone, Hagberg, McAuley, et al., 1998). Adults over the age of 65 make up 18% of the U.S. population, an amount that will more than double by the year 2030 (Federal Interagency Forum on Age Related Statistics (Aging Statistics, 2006).

Approximately 40% of community dwelling older adults have at least partial limitation in their ability to perform activities of daily living (ADLs), also referred to as functionally impaired. More than 95% of older adults who reside in assisted living settings are functionally impaired (FAO/WHO, 1991; Aging Statistics, 2006). These impairments are largely due to sarcopenia (Borst, 2004; Evans, 1998; Fiatarone, O’Neill, Ryan, Clements, Solares, Nelson, et al., 1994; Keys & Brozek, 1950; Fujita & Volpi, 2004; Libow 1974).

Sarcopenia, taken from the Greek word meaning ‘poverty of flesh’, is defined as the age-related loss of skeletal muscle mass (Evans, 1998, 2004). Over a third of muscle mass may be lost by the age of 80 (Borst, 2004). Much of this muscle loss can be prevented with physical activity and proper nutrition (Borst, 2004; Castaneda et al., 1995; CDC, 2007; Esmark, Anderson, Olsen, Richter, Mizuno & Kjaer, 2001; Evans, 2004; Fiatarone et al., 1994; Fielding, 1995; Kruskall, 1998).
While benefits of strength training have been demonstrated in numerous studies, few have evaluated protein status as a potential mediator of physiologic benefits expected. Proper protein intake plays a critical role in neuromuscular function, muscle protein metabolism, and maintenance of muscle tissue (Campbell, Barton, Cyr-Campbell, Davey, Beard, Parise, et al., 1999; Castaneda et al., 1995; Delbono, 2003; Esmarck Anderson, Olsen, Richter, Mizuno, & Kjaer, 2001; Evans, 1998; Lemon, 2001, Tarnopolsky, Atkinson, MacDougal, Chesley, Phillips & Schwarcz, 1992; Fern, Bielinski, & Schutz, 1991). Thus, physical function may be affected by alterations in these physiologic parameters if protein intake is not adequate.

The USDA provides literature to older adults suggesting that 0.8g/kg is adequate protein intake for all adults to maintain both physiologic and physical function, whether individuals are sedentary or active (DHHS, 2004; Aging Statistics, 2006; Kruskall, 1999). However, there is no scientific research to support this claim in a population of older adults participating in strength training. In the same venues that provide information on proper nutrition, older adults are encouraged to practice strength training as a means to attenuate the loss of muscle mass and function experienced with aging. However, it is still questionable whether strength training is an effective means for enhancing muscle mass and function if an older adult consumes the USDA daily recommended intake (DRI) for protein. Using accurate and reliable tools to measure physical function, body composition, and muscular strength will best evaluate the association between the DRI for protein and the physiological effects strength training produces in an older adult population at risk of sarcopenia.
Purpose of the Study

The following are the primary purposes of the study:

1. To examine the effect of strength training and the DRI for protein on physical function, as measured by the Margaria-Kalaman stair climb test and timed sit-to-stand, in elderly men.

2. To examine the effect of strength training and the DRI for protein on fat mass and lean body mass (LBM) in elderly men.

3. To examine the effect of strength training and the DRI for protein on muscle strength, as measured by one repetition maximum and 60- and 240 °/s isokinetic testing, in elderly men.

4. To assess the effects of strength training and the DRI for protein on resting energy expenditure and protein synthesis, oxidation, and balance.

Delimitations

Healthy Caucasian men, ages 65 and older, having no active medical problems were recruited for the study. Only subjects who had normal hematology, chemistry, urinalysis and physical examination were accepted for the study. Subjects taking blood pressure medications other than beta blockers (due to suppressive effects of this drug class on the metabolic system) were eligible. Individuals with certain chronic conditions were excluded from the study. Individuals engaging in more than 30 minutes a day of strenuous physical activity on 3 or more days of the week were excluded. Additionally, those who reported a diet with less than 10%, or greater than 20% of energy intake from protein were excluded (Appendix A). All subjects read and signed informed consent
forms approved by the Tuft’s University Institutional Review Board (Appendix A). Additionally, this thesis was approved by the Northeastern Institutional Review Board (Appendix A).

**Limitations**

Protein metabolism varies with certain medical conditions and medications. The study included only apparently healthy older adults, limiting its applicability to the total population of older adults. In addition, all subjects were Caucasian men, limiting the ability to generalize results to women and other ethnic groups. Due to the required residency and extensive testing required, this was a small sample size. However, this is an exploratory study that may warrant further study in a larger sample. The strength training intervention was 8.5 weeks in duration; therefore, this may not have been long enough to achieve significant changes in lean mass and function with such a small sample size, however previous study has observed significant improvements in lean mass and REE within this time period (Westcott, 2007).

To limit cost, a control group consuming the average protein intake of elders was not used. Consequently, it is possible that results may be due to living in the metabolic unit of the Human Nutrition Research Center on Aging at Tufts University (Tufts-HNRC), preventing the ability to conclude whether effects are due to the diet and not the environment. To control for this, subjects’ activity levels were measured upon entering the study and visits to the exercise lab were assigned in order to maintain this level of activity throughout the study’s duration. Results from preceding research in which protein was of a self-selected diet will act as a control for qualitative comparison.
Also, a preliminary phase, (Phase 1), was included to provide a two-week equilibration period in which subjects consumed 1.1g/kg protein in the metabolic unit as a means to ensure all participants begin from the same baseline intake. Therefore the well-controlled specific aims will be evaluated.

**Hypotheses**

For the purpose of this study the following hypotheses were put forth:

1. Physical function will not change significantly in a group of elderly men participating in high-intensity strength training while consuming the DRI for protein over an 8 ½ week period when compared to a control group receiving the same diet and no strength training.

2. Body composition will not change significantly in a group of elderly men participating in high-intensity strength training while consuming the DRI for protein over an 8 ½ week period when compared to a control group receiving the same diet and no strength training.

3. There will be a significant increase in strength in a group of elderly men participating in high-intensity strength training while consuming the DRI for protein over an 8 ½ week period when compared to a control group receiving the same diet and no strength training.

4. Resting Energy expenditure and leucine metabolism (namely synthesis, oxidation and balance) will significantly increase in a group of elderly men participating in high-intensity strength training while consuming the DRI for protein over an 8 ½ week period when compared to a control group receiving the same diet and no strength training.
**Definition of Terms**

1. **Activities of Daily Living (ADLs):** activities performed on a daily basis, including getting out of bed, bathing, dressing, toileting, eating, and getting around inside. Further, Instrumental ADLs include light housework, laundry, meal preparation, shopping for groceries, getting around outside, managing money, taking medications, and telephoning (Aging Stats, 2006)

2. **Body composition:** the relative percentage of body mass that is fat mass and lean body mass (ACSM, 2006)

3. **Frailty:** state of being weak in health or body (Weber, 2002)

4. **Physical function:** the ability to carry out activities of daily living (Aging Stats, 2006)

5. **Functional impairment:** limitation in the ability to independently carry out activities of daily living (Aging Stats, 2006)

6. **Lean Body Mass:** all tissue excluding fat within the body (ACSM, 2006)

7. **Muscle mass:** metabolically active tissue responsible for movement of the body (NSCA, 2000)

8. **Muscular strength (1RM):** the ability of a muscle to generate force through a full range of motion one time in good form.

9. **Nitrogen balance:** a method of assessing overall body protein status by measuring the difference between nitrogen intake and output (El-Khoury, 1999)

10. **Older adult/Elderly:** adults over 65 years of age (Aging Stats, 2006)
11. **Strength training**: training in which a muscle generates force against a load, resulting in increased muscle size and strength (Evans, 1998)

13. **Protein metabolism**: the synthesis and degradation of proteins in the body (El-Khoury, 1999).
CHAPTER 2

REVIEW OF LITERATURE

Significance

Over 18% of the U.S. population is over 65. Of that 18%, nearly 70% currently experience limitations in their ability to perform tasks of everyday living, otherwise referred to as functional ability (Fig 1.) (http://www.cdc.gov/nchs/agingact.htm).

![Percentage of Medicare enrollees age 65 and over with functional limitations, by residential setting, 2003](http://www.cdc.gov/nchs/agingact.htm)

**Fig 1.** Breakdown functional limitations among Medicare enrollees by residential setting (Adapted from Aging Stats, 2006)

Functional limitation, the inability to perform a task of everyday living, is strongly correlated to frailty, falls, and hospitalizations. The loss of muscle mass and strength observed with aging is greatly responsible for functional limitations and the
morbidities associated with them (American College of Sports Medicine (ACSM), 2002; Borst, 2004; Campbell et al, 2001; Delbono, 2003; Esmarck et al., 2001; Evans, 2004; Frontera, Meredith, O’Reilly, Knuttgen, & Evans, 1988; Kruskall, 1998; Starling, Ades, & Poehlma, 1999). Reduced physical activity observed with aging accelerates the rate of muscle loss and leads to greater declines in physical function (Borst, 2004; Fiatarone, O’Neill, Ryan, Clements, Solares, Nelson et al., 1994; Fujita & Volpi, 2004).

Nutrition deficiency in older adults, particularly inadequate protein intake, further accelerates the loss of skeletal muscle mass and occurrence of frailty, falls and hospitalizations (Castaneda, Dolnikowski, Dallal, Evans, & Crim, 1995; Campbell et al., 2001; El-Khoury, 1999; Fiatarone et al, 1994; Fujita & Volpi, 2004; Morley, 1997; Starling et al., 1999). Over 85% of adults over 65 do not meet criteria for a good diet based on the food guide pyramid recommendations for daily intake (Aging Statistics, 2006).

Medical costs for older adults make up over 30% of the U.S. medical expenditures (Fig 2.). Medical costs increase exponentially as the amount of functional limitation increases; those with 3 or more limitations have greater than four times the expense of their healthy counterparts (National Center for Health Related Statistics (NCHS), 2007).
Currently, an estimated 38 million older adults have at least one functional limitation (Aging Statistics, 2006). With the projected population increase of this age group, there will be 58.5 million older adults with at least one functional limitation by the year 2050 if interventions do not advance to prevent it (see Fig 3.).

With the increasing number of older adults living longer lives, maintaining strength and functional ability is of primary concern, not only to help our elders’ live full, independent lifestyles, but also to limit the strain on the healthcare system (Aging Stats, 2006).
Aging and the Neuromuscular System

Aging is a natural process in which remarkable changes in body composition are observed (Evans, 1998, 2004). Sarcopenia, defined as the age-related loss of skeletal muscle mass, is considered a hallmark of aging. Nearly 20 years ago, Lexell, Taylor, & Sjostrom performed computerize tomography (CT) scans on whole vastus lateralis muscle of 43 cadavers of previously physically healthy men, ages 15 to 83. They found that decreases in muscle cross-sectional area (CSA), total fiber number, size, and type 2 muscle fibers began at approximately age 25, and loss accelerated from age 50 through the remainder of life (Lexell et al., 1988). Subsequent work by several other investigators has confirmed this finding (Lindle, Meter, Lynch, Fleg, Fozard, Tobin, et al., 1997; Starling, et al., 1999). Research by Lindle and colleagues (1997) measured fat free mass and muscle quality, defined as strength per unit of muscle, in 654 men and women aged 20-93 years. Regression analysis exhibited muscle mass and quality was significantly decreased in all older adults when compared to young counterparts. Starling et al. (1999)
compared total appendicular skeletal muscle mass of men aged 49-85 years. With graphical analysis, the researchers displayed an inverse correlation between age and appendicular skeletal muscle mass (Fig 4.).

In a summary by Delbono (2003), neural changes were discussed as partial contributors to the observations described above. With aging, the atrophy of fast-twitch motor neurons leads to atrophy of the fast twitch muscle fibers they innervate. These fibers are responsible for power and force production (Delbono, 2003; Larsson, 1993). The non-innervated muscle fibers may be re-innervated by the sprouting of neighboring slow-twitch motor nerves, those responsible for low-force, endurance activities. The addition of more slow-twitch fibers, in combination with an accumulation of fibers that are not re-innervated, leads to great declines in the ability to produce force and power, thereby limiting the ability to perform functional activities. The ability to re-innervate
muscle fibers depends on the local environment, including certain proteins, nutrients and hormones, along with stimulation of motor units through physical activity (Delbono, 2003).

**Sarcopenia Prevention**

Though once believed to be a natural by-product of aging, sarcopenia is not inevitable (Borst, 2004; Fielding, 1995; Kirtgaard, Mantoni, Schiaffino, Ausoni, Gorza, & Laurent-Winter, 1990; Kruskall, 1998). Physical inactivity and nutrition status are modifiable factors found to pay a large contribution to age related skeletal muscle loss (Borst, 2004; Castaneda et al., 1995; CDC, 2007; Esmarck et al., 2001; Evans, 2004; Fiatarone et al., 1995; Fielding, 1995; Kruskall, 1998). Over a decade ago, Klitgaard and colleagues measured muscle mass, by means of CT scan, of the thigh and upper arm, and maximal strength, by means of one repetition maximum testing (1RM). Older adults who had strength trained between 12 and 17 years before testing (70-90% one repetition maximum, 3 days per week) had muscle cross-sectional areas and strengths similar to the young controls, while older adults who did not have a history of strength training had significantly lower cross-sectional area and strength (Klitgaard et al., 1990). The current position of the American College of Sports Medicine and Centers for Disease Control and Prevention holds that participation in a strength training program is an effective mean to reduce, or even prevent muscle loss and functional declines associated with aging (ACSM, 2006; Kamimoto et al., 1999; Mazzeo et al., 1998).

**Sarcopenia and Strength Training**

The decreases in muscle mass and strength observed with aging mirror those seen with prolonged inactivity (Fielding, 1995). Muscle disuse due to inactivity causes a
reduction in muscle mass and strength, termed muscle atrophy (ACSM, 2006; Borst, 2004; NSCA, 2000). As a result of inactivity, protein breakdown exceeds synthesis, and muscle fibers size is decreased (El-Khoury, 1999; Fujita & Volpi, 2004; Kruskall, 1998). Fortunately, strength training has proven effective in reversing muscle atrophy across all population groups (ACSM, 2006; Bamman et al., 2003; Lindle, 1997; NSCA, 2000; Yarasheski et al., 1993).

Strength training improves motor control, improves endocrine function (Fiatarone Singh, MA, Ding, W, Manfredi, TJ, Solares, GS, O’Neill, EF, Clements, KM, et al., 1999; Fleck & Kraemer, 1987), induces muscle hypertrophy, increases cross sectional area, and increases strength (ACSM, 2006; Borst, 2004; Charette, McEvoy & Pyka 1991; Evans, 2004; Fiatarone et al., 1994; Frontera et al., 1988; Mazzeo et al., 1998; NSCA, 2000; Welle, 1998; Yarasheski, Zachwieja, & Bier, 1993). Further, increased motor control, muscle mass and strength observed with strength training enhances functional ability (Delbono, 2003; Fiatarone, 1994; NSCA, 2000).

It is widely accepted that increases in strength within the first six to eight weeks of strength training are largely due to neurological adaptation (Fleck & Kraemer, 1987; Kraemer, 1999; NSCA, 2000). However, in as little as two weeks of training, changes in muscle composition can be observed (Kraemer, 1999; Seynnes, 2006; Staron, 1994). Protein turnover increases after just one strength training session (Kraemer, 1999). Increases in both protein synthesis and oxidation create an environment in which contractile proteins are rapidly replaced, thereby enhancing the quality of contractile fibers and ridding the muscle of damaged fibers (Volpi, 2007). Rate of strength increases and strength gains relative to body mass are similar across gender and age groups when
individuals perform strength training at a moderate to high intensity for 3-5 sets of 8-12 repetitions, 3 days per week (ACSM, 2002; Evans, 2004; Esmarck et al., 2001; Fiatarone et al., 1994; Frontera et al., 1988). Improvements in physical function follow improvements in muscle mass and strength, and are correlated with the degree of muscle mass and strength increases made (Fiatarone et al., 1990, 1994; Fielding, 1995).

Among the major strength training studies conducted on older adults, identified in Table 1, the average strength increase following training is about 85%, though increases range from 20% to 180%. Though each study applied very similar training protocol of moderate-high intensity strength training 3 days per week, the majority of these studies did not control for dietary intake, functional limitation at baseline, and/or baseline physical activity. It should be noted that some studies investigated elders residing at nursing homes (Evans, 2004; Fiatarone et al., 1990; Fiatarone et al, 1994), while others investigated community dwelling elders (Bamman, Hill, & Adams, 2003; Brose, Parise, & Tarnopolsky, 2003; Connelly & Vandervoort, 2000; Esmarck et al., 2001, Evans, 2004; Ferri, Scaglioni, Pousson, Capodaglio, Van Hoecke, & Narici, 2003; Frontera et al., 1988; Lexell et al., 1988; Vincent, Braith & Feldman, 2002). Though the prevalence of significant improvements in strength for each population demonstrates strength training is effective in both healthy older adults and those with functional limitation, it does not allow for fair comparison between the two groups, as other extraneous variables were not controlled. Those who are more active would theoretically show less improvement than those who were more sedentary, as there is a greater window of improvement for those who had very low baseline activity levels. However, Table 1 indicates results are not predictable based on baseline activity level alone (Fiatarone et
al., 1994; NSCA, 2000). A much deeper evaluation of each research group’s methods and results is necessary to determine what factors may be responsible for such variability.
<table>
<thead>
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<td>M/F</td>
<td>69</td>
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<td>Ferri et al., 2003</td>
<td>RCT</td>
<td>M</td>
<td>68</td>
<td>3x/w @ 85% 1RM 1 set</td>
<td>16w</td>
<td></td>
<td>↑27% 1RM</td>
<td>U</td>
</tr>
<tr>
<td>Frontera et al., 1988</td>
<td>RCT</td>
<td>M</td>
<td>66</td>
<td>3x/w @ 80% 1RM 3 sets 8 reps</td>
<td>12w</td>
<td></td>
<td>↑107% 1RM</td>
<td>U</td>
</tr>
<tr>
<td>Frontera et al., 1993</td>
<td>RCT</td>
<td>F</td>
<td>74</td>
<td>3 sets 8 reps 3x/w @ 85% 1RM</td>
<td>12w</td>
<td></td>
<td>↑39% 1RM, ↑12% MM</td>
<td>U</td>
</tr>
<tr>
<td>Fiatarone et al., 1990</td>
<td>RCT</td>
<td>M/F</td>
<td>90</td>
<td>3 sets 8 rep 3x/w @ 80% 1RM</td>
<td>8w</td>
<td></td>
<td>↑174% 1RM</td>
<td>U</td>
</tr>
<tr>
<td>Fiatarone et al., 1994</td>
<td>RCT</td>
<td>M/F</td>
<td>87</td>
<td>3 sets 8 rep 3x/w @ 80% 1RM</td>
<td>10w</td>
<td></td>
<td>↑37-178% 1RM</td>
<td>U</td>
</tr>
<tr>
<td>Lexell et al., 1995</td>
<td>RCT</td>
<td>M/F</td>
<td>74</td>
<td>3x/w @ 85% 1RM</td>
<td>11w</td>
<td></td>
<td>↑163% 1RM</td>
<td>U</td>
</tr>
<tr>
<td>Vincent et al., 2002</td>
<td>RCT</td>
<td>M/F</td>
<td>68</td>
<td>1 set 8 rep 3x/w @ 80% 1RM WB</td>
<td>24w</td>
<td></td>
<td>↑18% 1RM</td>
<td>Obs</td>
</tr>
<tr>
<td>*Age is taken from mean of subjects in study</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RCT: Randomized Control Trial</td>
<td>U: Uncontrolled</td>
<td>comm.: community dwelling amb: ambulatory</td>
<td>hab. act.: habitual activity</td>
<td>1RM: one repetition maximum</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CrM: Creatine supplement</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Isokinetic: measure of peak torque for a given velocity</td>
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<tr>
<td>Euenergetic: maintained energy balance</td>
<td></td>
<td></td>
<td></td>
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</table>

*Age is taken from mean of subjects in study
Many of the above studies implemented strength training of just one or two muscle groups, and conducted the 1-RM strength testing on the same machines as used throughout the intervention, without secondary measures of strength or functional improvements (Bamman, Hill, & Adams, 2003; Charette McEvoy, Pyka, Snow-Harter, Guido, Wiswell, 1991; Connelly & Vandervoort, 2000; Lexell et al., 1995). This limits the relevance of results, as much of the strength gain may be due learned motor pathways, and may or may not be transferable to functional activities in which motor activation varies. Once more, the lack of data on muscle mass improvements leaves question as to if strength gain was strictly from improved motor function, or a combination of muscle mass gain and motor function improvements (Connelly & Vandervoort, 2000; Vincent et al., 2002).

Frontera et al. (1988) was the first to demonstrate the effectiveness of high-intensity strength-training in an older adult population (Frontera et al., 1988). Twelve subjects performed knee extension and flexion exercises 3 days/week for 12 weeks at 80% 1RM. Results showed over 100% increased in strength, as well as 12% increased muscle cross-sectional area (Frontera et al., 1988). Subsequent work supported the correlation between muscle strength and mass increases (Lexell et al., 1995; Bamman et al., 2003; Brose et al., 2003; Esmarck et al. 2001; Ferri et al., 2003).

Though the Frontera et al. (1994) study helped prove the effectiveness of strength training in the older population, it is limited by its lack of exploration of variables that may contribute to the results seen, as did its successors (Bamman et al., 2003; Brose et al., 2003; Esmarck et al., 2001; Ferri et al., 2003; Lexell et al, 1995). Though the Frontera study did not control total energy intake and nutrient levels, nutrition status was identified
as an influential variable. A nutrition supplement of 560kcal (43% carbohydrate, 40% fat, 17% protein) was given to subjects. Those that received the supplement experienced greater increases in mid-thigh cross-sectional area, suggesting dietary intake influences the magnitude of increases in muscle mass and subsequent strength produced. Brose et al. (2003) also considered nutrition status as a moderating factor. The group observed greater increases in strength and muscle mass when a creatine supplement was given post-exercise. Brose and colleagues (2003) observed strength gains of 36- to 66 percent, about half of that observed by Frontera et al. (1988). Physical activity level, baseline nutrition status and caloric intake, and changes in daily caloric intake with the supplementation may have differed among the two studies, as that information was not determined.

In the large study of very frail older adults conducted by Fiatarone and colleagues (1994), 100 frail older men and women participated in hip and knee flexion and extension exercises at 80% 1-RM 3 days a week for 10 weeks. Baseline fitness and activity level were assessed as moderating variables, yet energy balance and nutrient levels were not. Strength increases varying from 37-178% were observed. Subjects who had weaker baseline strength, yet larger reserves of muscle mass than other subjects, had the largest gain in muscle strength. This study displayed the strong correlations between muscle strength and cross-sectional area, the latter of which increased 2-7%. The significant relationship between strength and functional ability was also demonstrated. Gait speed, stair climbing power, and spontaneous physical activity increased 48%, 28% and 35% respectfully. Reports of falls significantly decreased over the time period, and four
subjects requiring a walker prior to beginning the study were not using one following the intervention (Fiatarone et al., 1994).

The study by the Fiatarone group is considered a landmark study in the effectiveness of strength training in improving strength and functional capacity in the older population, yet the neglect of control for nutrition status limits the ability to determine the role nutrition level had on the functional improvements shown. Though energy and protein balance were not controlled, energy intake was monitored. Those who received a nutrition supplement of 360kcal (60% carbohydrate, 23% fat, 17% soy-based protein) improved more than those who did not receive the supplement. The supplement given in the Fiatarone study supplied a fraction of the calories and fat given in the Frontera study, and more than that given in the study by Esmarck, et al. (2001), which produced more modest increases in strength and muscle mass than both the Frontera and Fiatarone groups. The amount of calories and percentage of nutrients in the supplements may explain much of the variability in strength results observed.

Once more, the Fiatarone study observed that those who did not participate in strength training but received the supplement spontaneously decreased daily caloric intake. Both the Fiatarone study and the Esmarck study noted that those who performed strength training and received supplementation increased daily caloric intake (Esmarck et al., 2000; Fiatarone et al., 1994). The observation that dietary intake was altered during these studies warranted further study of the effects of strength training on the older adult population in an environment in which dietary intake is controlled.
**Aging and Protein intake**

Proteins are needed for structural stability of muscle tissue, conductivity of motor neurons, and building of muscle fibers (Delbono, 2003). Therefore, protein intake has an effect on the neuromuscular system and the ability to build muscle mass. Inadequate protein intake alters strength and functional ability (Castaneda et al., 1995; Delbono, 2003; Dreyer & Volpi, 2004; El-Khoury, 1999 Fujita & Volpi, 2004; Morley, 1997). As individuals age, physical, psychological and economic factors influence protein intake.

Changes in taste sensation, and dentition, along with high costs of living and low income, social isolation and depression, alter food choices (see Fig 5.). Older adults tend to shift to a diet higher in fats and carbohydrates and lower in protein (Dreyer & Volpi, 2004, El-Khoury 1999; Morley, 1997).

Two similar, yet independent, studies performed tracer studies (as described later) to examine alterations in protein synthesis with age as a possible factor in the development of sarcopenia. Injections of a bolus of essential amino acids (dietary
proteins not able to be made by the body itself) in both older adults and young controls were traced with $^{13}$C. Both studies found that muscle protein synthesis was stimulated similarly in both young (18-30) and old (65-85) age groups with injection (Dreyer & Volpi, 2004; Fujita & Volpi, 2004). The Dreyer group subsequently examined oral administration of the same amount of amino acids. Though protein synthesis was stimulated in both groups following the oral administration of the amino acids, effects on muscle synthesis appeared to have less of an effect in the older adults (Dryer & Volpi, 2004). There is a higher extraction of protein at the liver in and longer time for digestion at the stomach in older adults; thus decreasing the amount of protein available for muscle synthesis in older adults consuming the same amount of dietary protein as their younger counterparts (Dreyer & Volpi, 2004; Fujita & Volpi, 2004). In addition, many older adults consume fewer calories than required to maintain energy balance. This causes an increase in protein used as fuel for bodily processes, and limits the availability of protein to build skeletal muscle (Morley, 1997).

Although protein needs may be greater in older adults in order to supply the same amount of amino acids to skeletal muscle, it has been shown by the Dreyer group (2004), and several other research groups, that once amino acids are available, protein anabolism at the muscle is similar to that of young adults (Dreyer & Volpi, 2004; Paddon-Jones, Sheffield-Moore, Zhang, Volpi, Wolf, Aarsland, et al., 2003; Volpi, Mittendorfer, Wolf & Wolf, 1999). Therefore, lack of skeletal muscle anabolism in older adults may not specifically due to a loss in the ability to build muscle as once thought, but rather due to an increased rate of breakdown that is not balanced with an increase in synthesis, largely due to a lack of available amino acids to metabolize into muscle. Interestingly, the Food
and Nutrition Board suggests that protein comprise 10-35% of the energy consumed daily. This corresponds to a similar value as the DRI value when considering caloric intakes of younger adults, but when considering the decreased caloric intake of elders, 10-35% of caloric intake from protein comprises 1-3.3g/kg BW per day, a value much greater than the DRI level, and perhaps more conducive to skeletal muscle maintenance.

**Protein Recommendations**

In a report published by the Federal Interagency on aging related statistics, only 15% of non-institutionalized older adults consume a good diet based on the USDA food guide pyramid, and only 30% meet the DRI for protein, set at 0.8g/kg body weight (BW) (2006).

The studies used to determine the DRI for protein intake did not measure body composition or functional status, but rather nitrogen balance. The nitrogen balance technique is based on the knowledge that all protein sources contain nitrogen, whereas all other macronutrients (fat and carbohydrates) do not. Therefore, if the amount of nitrogen taken in matches the nitrogen lost by the body, one is at nitrogen balance, and therefore protein balance. When the amount of nitrogen excreted is greater than that ingested, there is a negative balance (Campbell et al., 2001; El-Khoury 1999; USDA, 2007). Nitrogen balance is the accepted technique to determine protein requirements because there is no alternative technique considered superior; yet, it has limitations (Castaneda et al., unpublished protocol).

The majority of studies conducted to determine the DRI value were done on young subjects, yet less is known about the utility of the nitrogen balance method in determining requirements for older adults, as physiological functions change with aging.
The studies that did assess nitrogen balance on older adults were contradictory; three identified the DRI value as sufficient (Cheng, Gomez, Bergan, Lee, Monckeberg & Chichester 1978; Zanni, Calloway & Zezulka, 1978; Bunker, Lawson, Stansfield, & Clayton, 1987) and two identified the value as too low (Uauy, Scrimshaw, & Young, 1978; Gersovitz, Motil, Munro, Scrimshaw & Young, 1982). Not only were these studies conducted in an outpatient basis, suggesting questionable adherence to the given diets, but the studies also lacked control of extraneous variables that may potentially affect protein requirements, such as physical activity, baseline protein intake and total caloric intake (USDA, 2007). Subsequent studies have shown the DRI level is too low for the older adult population (Campbell et al., 1999; Campbell et al., 2001; El-Khoury, 1999).
<table>
<thead>
<tr>
<th>Reference</th>
<th>Study Type</th>
<th>Sex</th>
<th>Age mean</th>
<th>Intervention</th>
<th>Duration</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bunker et al., 1987</td>
<td>observational</td>
<td>M/F</td>
<td>76</td>
<td></td>
<td>5d</td>
<td>comm. Dwelling N bal@ .97g/kg BW housbnd@ neg N bal@ .67g/kg BW</td>
</tr>
<tr>
<td>Campbell et al., 2001</td>
<td>no control grp, comm. dwelling</td>
<td>M/F</td>
<td>66</td>
<td>0.8g/kg BW</td>
<td>14w</td>
<td>↓ muscle mass</td>
</tr>
<tr>
<td>Castaneda et al., 1995</td>
<td>RCT, comm. dwelling</td>
<td>F</td>
<td>72</td>
<td>P1 1.2g/kg BW</td>
<td>9w</td>
<td>↓ muscle mass</td>
</tr>
<tr>
<td>Cheng et al., 1978</td>
<td>RCT, own control grp, nurse home</td>
<td>M</td>
<td>64</td>
<td>PA 0.8g/kg BW</td>
<td>11d</td>
<td>55% sub. Pos</td>
</tr>
<tr>
<td>Gersovitz et al., 1982</td>
<td>no control grp, inpatient, comm. dwelling</td>
<td>M/F</td>
<td>77</td>
<td>0.8g/kg</td>
<td>30d</td>
<td>7 of 15 @</td>
</tr>
<tr>
<td>Uauy et al., 1978</td>
<td>RCT, comm. dwelling</td>
<td>M/F</td>
<td>71</td>
<td>3 groups: 0.52, 0.65 or .8g/kg F</td>
<td>10d</td>
<td>N balance at .83g/kg F</td>
</tr>
<tr>
<td>Zanni et al., 1979</td>
<td>RCT, own control grp, comm. dwelling</td>
<td>M</td>
<td>70</td>
<td>P1 protein fast</td>
<td>17d</td>
<td>N balance at</td>
</tr>
</tbody>
</table>

com= community  BW= body weight  neg.= negative  grp= group  BCM= body cell mass  pos= positive  N= nitrogen
In the study of Bunker et al. (1987), subjects consumed a self-selected diet and nitrogen balance was assessed on healthy older adults and housebound individuals with chronic illness. Although the results showed that community dwelling subjects were at nitrogen equilibrium, the average intake for community dwelling individuals was close to 1.0g protein per kg body weight. The housebound individuals averaged 0.67g protein per kg body weight and were at a negative balance. Though conclusions on the adequacy of the DRI value can not be drawn from the study’s results, as few subjects observed were actually at the DRI value for protein, it may help explain why resistance training studies did not see significantly higher increases in strength in housebound older adults when compared to more active counterparts as would be expected due to lower baseline fitness levels in housebound individuals (see Sarcopenia and Strength Training page 13).

In the study of Cheng et al. (1978), results showed that nitrogen balance was achieved at 0.8g/kg of body weight (BW) for 4 of 7 subjects. The Cheng group attempted to control for energy intake, yet assigned each subject to a diet of 40 calories per kilogram of body weight, a value that may be too high for such a population. Positive energy balance may allow for more energy sources, such as carbohydrates and fats, to be used as fuel, sparing amino acids. Despite this, the protein intake may still not be sufficient to maintain muscular mass and function (Castaneda et al., unpublished protocol).

Conversely, in the studies by Uauy et al. (1978) and Gersovitz et al. (1982) energy intake of subjects was kept at 31-32kcal/kg BW. Assumptions that negative nitrogen balance observed in these studies was due to low protein intake may not be valid due to the contribution of low energy intake. Hypocaloric states lead to the utilization of
protein as an energy source. Increased protein breakdown without sufficient synthesis leads to a negative nitrogen balance. In these trials, the cause of the negative balance cannot be concluded, as it may be from lack of proper energy intake as well as lack of sufficient protein intake (Castaneda et al., 1995; Evans, 2004).

In the study of Zanni et al. (1979), nitrogen balance was achieved at 0.46g/kg BW; however, all subjects were put on a 17-day protein-free equilibration period prior to the experimental phase. This could have increased protein retention in the subjects, leading to a decreased protein requirement once protein was returned to the diet. In opposition to effects this may cause, the subjects were assigned low calorie diets which may increase protein needs. These methodological errors contribute to the observation that the standard deviation for protein balance in fact equaled the protein level suggested to be adequate for protein balance (0.45). It would be of interest to know if the subjects of these experiments experienced declines in functional status or muscle mass; as it is apparent the nitrogen balance method was not a valid reflection of protein status in these settings.

**Isotope Tracer Studies**

With the knowledge that nitrogen balance studies have many faults, recent studies have used isotope tracer methods to more specifically evaluate protein kinetics at different protein intakes. These studies suggest that a higher level of protein intake is needed than levels that appear to be sufficient when using nitrogen balance analysis (El-Khoury et al., 1994; Lemon, 2000; Tarnopolsky et al., 1992). The most validated and widely used tracer is \([1^{-13}C]\)leucine. With this method, the amount of \(^{13}\)C-leucine entering the physiologic amino acid pool and leaving is can be measured, along with the
amount oxidized (El-Khoury, 1999). In normal, healthy adults consuming an adequate-protein diet, leucine balance strongly correlates with nitrogen balance; however, when protein consumption is below adequate, the two methods diverge, and leucine tracing detects changes in protein metabolism that may be unnoticed by nitrogen balance methods (Castaneda et al., unpublished protocol). Once measures of oxidation and intake are calculated using the leucine tracer method, the amount that has “disappeared” into protein synthesis can be estimated, thereby giving more specific information of the protein balance and utilization at muscle tissue, as the metabolism of the traced leucine reflects metabolism of total amino acids in the body. This also enables investigators to compute first-pass extraction of leucine at the liver, a concern with the older adult population that goes unaddressed when using the nitrogen balance method (El-Khoury, 1999).

**Protein Intake and Accommodation**

Nearly 40 years ago, JC Waterlow (1968) described an adaptation that occurs with alterations in protein intake. He explained that adaptation is a phenomenon that occurs when the body reaches a new steady state of nitrogen excretion without physiological impairment. Conversely, accommodation occurs when the amount of nitrogen consumed is too low. Nitrogen excretion cannot reach steady state, and physiological impairment results (Young & Marchini, 1990). Evans (2004) stated that the majority of accommodation occurs due to sacrifice to muscle protein synthesis; however, the research used to determine the DRI for protein neglected to measure any physiological outcomes.
Insufficient supply of essential amino acids down-regulates protein synthesis, or inhibits steps in translation of contractile proteins (Dreyer & Volpi, 2004). The original studies on nitrogen balance were short studies, limiting the evaluation of long term effects at the designated protein levels. Though declines in nitrogen excretion may appear to be within balance, the isotope tracer method may detect subtle changes, which may have great effects on muscle mass and function over time (Campbell et al., 2001; Castaneda et al., unpublished protocol).

With consideration of Waterlow and Young & Marchini’s deliberations, successive research assigned different amounts of protein to older adults and measured the effects this had on muscular strength and function, which are expected to decline following the impairment of the physiologic parameters described (Castaneda et al., 1995; Campbell et al., 2001; Evans, 1998). Campbell and colleagues (2001) compared the mid-thigh circumference, 1-RM strength, and nitrogen balance in a group of 10 healthy older adults. The group consumed 0.8g/kg BW protein over a 14-week period. At the end of the intervention, there was a decrease in muscle area and nitrogen excretion, yet no change in muscle strength. Though the study was conducted on an outpatient basis, it raises interesting questions as to how to interpret nitrogen balance as compared to functional impairment. The decreases in nitrogen excretion continued throughout the study, rather than reaching a new steady state, as would be expected to occur with adaptation. The subjects appeared to be in a state of accommodation. Had the study continued, accommodation may have lead to further functional impairment, as the correlation between muscle mass and function is very strong (Bamman et al., 2003; Brose
et al., 2003; Esmark et al. 2000; Ferri et al., 2003; Fiatarone et al., 1995; Lexell et al., 1995).

Castaneda et al. (1995), examined the effects of a 0.45g/kg protein diet on muscular mass and function in older women, using both leucine turnover and nitrogen balance analysis. In response to the low protein diet, subjects suffered declines in muscle mass and functional capacity. Subjects consuming 0.9g/kg BW protein did not suffer any decreases in function. Leucine oxidation decreased continually throughout the study in the low protein group, yet not in the adequate protein group. Interestingly, protein synthesis did not show decreases in the low protein group, in contrast to subsequent research (El-Khoury, 1999). Researchers concluded that protein oxidation is more sensitive to low protein diet. Protein oxidation was no longer correlated to intake in the low protein group, indicating an imbalance between the two, which may have caused the decrease in muscle mass.

The decrease in leucine oxidation correlated strongly with nitrogen excretion. Nitrogen balance appeared to be improving as the studied continued, as excretion decreased, yet knowledge of decreased muscle mass indicated the decrease in excretion was not due to an adaptation, but to accommodation. It is evident that at more extreme decreases in protein intake muscular function is impaired, despite an apparent adaptation to the reduced protein level observed by the Nitrogen balance technique. However, it has yet to be concluded if functional impairments are occurring, yet at a slower rate, when protein ingestion is at the DRI value.

In the only known controlled trial that evaluated the interaction of protein intake and strength training in older adults, Campbell and colleagues (1994) monitored nitrogen
balance in a group of older adults participating in high-intensity strength training at the DRI for protein or twice the DRI. Nitrogen excretion decreased 10-15% in the subjects upon initiation of the training intervention and continued to decrease for the 12-week study period. It was concluded that with strength training protein retention is improved, thus lowering the required amount of dietary protein needed in older adults. However, muscle mass, as measured by urinary creatinine excretion, was unchanged following the intervention despite the anabolic stimulus of strength training. Leucine kinetics were assessed, yet only in the fed state; this limited application of results seen, as protein synthesis is stimulated by protein intake in a dose-response relationship (Volpi, 2007), and the quantity of protein intake differed between groups. Values were higher in the high protein group, and even after strength training the lower protein group did not reach the rate of synthesis that the higher protein group had at baseline. Interestingly, oxidation rates decreased in the 0.8g/kg protein group, similar to results observed by the Castaneda et al group (1995). Muscle Strength and physical function were not measured during this study, limiting clinical interpretation of observed results.

**Protein Intake and Strength Training**

It is believed that with the development of proper exercise and nutrition interventions, much of the muscle loss and functional limitations experienced with increasing age may be attenuated (ACSM, 2006; CDC, 2007; Evans, 2004; Kruskall, 1998; Fiatarone et al., 1994; Kruskall, 1998; National Institute on Aging, 2004). What is less clear is what combination of the two provides the proper intervention.
Though the USDA does not provide separate protein recommendations for athletes or individuals participating in strength training, no scientific literature to date has supported the assumption that needs are not increased with training (Lemon, 2000). However, it has been shown in many studies that the DRI for protein is not sufficient to attain maximum strength gains in healthy young adults performing heavy strength training (Fig 6.). (Lemon, 1992; NSCA, 2000; Phillips, 2005; Tarnopolsky, Atkinson, MacDougall, Chesley, Phillips, & Schwarcz, 1991).

Fern and colleagues (1991) randomly assigned 12 young men to a protein supplement group, providing a total of 2g/kg BW when combine with a self-selected dietary protein intake, and a control group consuming 1.3 g/kg BW protein from a self-selected diet. After 4 weeks of a whole-body, high intensity strength training, the supplement group improved lean muscle mass by 2.8kg, whereas the control group improved lean mass by 1.5 kg. Synthesis and breakdown of protein increased 20 and 22% respectively in the control group, and 105 and 159% respectively in the supplemented protein group. Despite the blunted physiologic improvements among the control subjects, nitrogen balance went unchanged, appearing to be at nitrogen balance.
In a study conducted almost a decade later, Tarnopolsky and colleagues (2000) examined effects of protein intake on strength training young adults at 0.86, 1.40, or 2.40g protein/kg BW. Those at the two higher protein intakes increased protein synthesis significantly more than the low protein group (fig. 7). No change in elbow flexor strength or lean muscle mass was observed, which may be due to the selection of athletes, who were already participating in a regular strength training regimen. This study reveals the need for greater protein intakes for young individuals participating in strength training. Due to the observation that greater oral protein intake is needed to stimulate protein synthesis in older subjects (Dreyer & Volpi, 2004; Fujita & Volpi, 2004), it is only logical the conclusions drawn from the Tarnopolsky et al. (2000) study will also apply to older adults.

In the only known combination strength training and protein intake study with older adults, Campbell et al (2002), maintained protein intake at 0.8g/kg BW the current and conducted a total body strength training intervention 3 days per week at 80% 1RM in older men and women (n=29, 54-78 years of age) over a 12 week period. The group observed a modest increase in muscle strength compared to other studies of strength training in the older adult population (32%). The Campbell study, which did not maintain total daily energy expenditure at baseline values during strength training intervention,
found no difference between groups for lean body mass, percent lean mass, or percent body fat following the intervention. Oxidation decreased significantly, though half that of a control group. Balance significantly improved half the extent of the control group.

Synthesis during the high-intensity strength training remained unchanged for both fasting and fed state, indicative of a blunted anabolic response to the strength training intervention. This was supported by the group’s inability to display a change in REE following the intervention. Physical function of subjects at baseline and following intervention were not measured (Campbell, 2002).

It appears that muscle hypertrophy and strength gains occur to a greater degree when protein supply is increased, until a ceiling amount of protein synthesis is reached (see Figure 6). If muscular activity increases without sufficient protein supply, it seems logical that anabolic activity will not increase to its full potential, therefore muscle hypertrophy and strength gains will be blunted. No research to date has normalized all subjects to a DRI protein intake, maintained physical activity consistent with baseline levels throughout intervention, and measured muscular strength, physical function and both quantitative and physiologic parameters of body composition (lean body mass, fat mass, and protein metabolism respectively) in an inpatient controlled trial to monitor the affects of total body resistance training on muscular strength and function at the DRI for protein intake for older adults.
CHAPTER III

PROCEDURES

Subject Selection

Prior to data analysis, this researcher acquired certification from the Office for Human Research Protections/Public Responsibility in Medicine and Research (Appendix A). This study received prior approval from the Tufts-New England Medical Center Institutional Review Board (IRB) and all subjects provided informed consent (Appendix A). Further, this thesis was approved in the exempt category by the Northeastern Institutional Review Board (Appendix A).

Adults over 65 years of age were recruited for a 13 ½ week study examining the effects of the DRI for protein on several physiological parameters (namely nitrogen balance and protein metabolism, immune function, muscle mass, body composition, physical function and muscle strength).

Inclusion Criteria. Healthy men, ages 69-78, having no active medical problems (as listed below) were recruited. The subjects went through a screening interview, physical exam by a physician, and screening laboratory tests including complete blood count, urinalysis, and serum sodium, potassium, bicarbonate, testosterone, BUN and creatinine. Subjects had normal hematology, chemistry, urinalysis and physical examination. Additionally, a Block food questionnaire (Block et al., 1986)
was administered; those who reported consuming a diet with less than 10% or greater than 20% of energy intake from protein were excluded.

**Exclusion Criteria.** Individuals with the following conditions were excluded: diabetes mellitus, cancer, AIDS, chronic renal failure, respiratory or cardiovascular disease, abnormal thyroid status and any other disease that is known to affect protein status, smokers, amputees, those on medications known to affect protein status, glucocorticoids, estrogen, progesterone, any other steroid, growth hormone, insulin, laxatives, and immunosuppressives. Athletes and individuals engaging in more than 30 minutes a day of strenuous physical activity on 3 or more days of the week were excluded as well. Older subjects taking blood pressure medications other than beta blockers (due to suppressive effects to the metabolic system) were eligible (see Appendix A).

**Experimental Design**

Subjects arrived at the HNRCA on day 0, the night before the study began. Subjects stayed at the HNRA through the duration of the study and food was provided. The study was divided into three phases; Phase 1 (P1) was a 2-week period of weight equilibration on a 1.1g/kgBW protein diet in order to ensure all subjects began the following phases at the same protein level, and also to provide a period to obtain energy requirements when there is no weight loss due to negative nitrogen balance. Phase 2 (P2) was a 3-week N-balance period at .8g/kgBW. Subjects were randomly assigned to a strength training plus DRI group (ST+DRI) or to a DRI only group (DRI) on day 33 (3 days prior to the beginning of Phase 3). At this point, the study’s baseline data was collected. Phase 3 (P3) was an 8 ½-week strength training intervention during which dietary intake was maintained at 0.8g/kg BW.
Strength Training Program

Strength training sessions were performed on Keiser pneumatic resistive exercise equipment (Keiser Sports Health Equipment Company, Fresno, CA) three times per week at 80% 1-RM. Three sets of 8 repetitions were performed for the following exercises: lateral pull-down, chest press, knee extension, knee flexion, and leg press (Appendix C, pp.95-96). Subjects were asked to report their rating of perceived exertion on the Borg RPE scale (Appendix D) during all strength sessions. Resistance was increased to maintain an intensity of 17-19 throughout the study (ACSM, 2006).

Measurement Techniques

Resting Energy Expenditure. Resting energy expenditure (REE) was measured on four occasions (P1, beginning and end of P2, and end of P3) in order to accurately calculate energy needs and assess potential changes due to diet. Subjects were attached to the metabolic cart (Deltatrac, Sensormedics, Palo Alto, CA) for 40 minutes while still in bed, after 12 hour fast. Prior to the test the cart was calibrated using gases of known composition (Appendix C).

Activity Level. Caltrac monitors (Caltrac, Muscle Dynamics Fitness Network, Torrence, CA) were used to measure daily physical activity. All subjects were given instructions on how to use the activity monitors (Muscle Dynamics, 1993). Monitors were attached to subjects at waistline/belt just above the right thigh and worn throughout the day, including during activity. Calories expended were recorded on an activity log (Appendix D). Subjects wore monitors for a 10-day period at baseline, as well as 10 days during P3, to assure activity levels were matched baseline values throughout the study (Castaneda et al., unpublished protocol). To maintain activity level, subjects were asked
to walk on a treadmill or cycle ergometer each day for sufficient time to expend the
 calories expended before subjects were admitted (Appendix C). Subjects were matched
by season in order to control for seasonal changes in activity level.

**Food Intake Measurements.** Before admission, each subject’s usual dietary
intake of calories and protein was estimated by seven nonconsecutive days of food
records and Block questionnaire (Block, et al., 1986) administered by a registered
dietician and assessed for macronutrient and calorie content using the Minnesota Nutrient
Data System software (Food database version 2.7, University of Minnesota, MN).
Throughout the study, all food was provided by the Tufts-HNRC lab, consisting of
breakfast, lunch, a snack and dinner. Animal-based proteins in the form of egg and milk
products were used for all protein consumed.

During P1, protein intake was set at approximately 1.1g/kg BW and calories
provided based on the DRI for energy (as calculated from body weight and age). Subjects
were allowed to leave food if full or request more if hungry. During P2 and P3 the
subjects received the DRI for protein, 0.8g/kgBW. Three daily menus were rotated
throughout the remainder of the study (Appendix B). All food items were consumed
completely. During P2, compliance was monitored by using para-amino benzoic acid
(PABA) excretion (Roberts et al., 1991). If subject had less than 92.6% PABA retrieved
from tested samples he was considered at noncompliance. If trends in body weight were
noted and continued over a seven day period, non-protein food items were supplemented
to maintain stable body weight (see Appendix C)
Tracer Studies. To examine changes in protein kinetics at each phase, leucine infusions were preformed during P1, at the beginning and end of P2, and at the completion of the study (P3).

A sham infusion was done the day before each infusion to account for baseline dietary $^{13}\text{C}$, the tracer used to track leucine turnover. During the sham infusions, breath samples were collected and subjects were fed under the same schedule as the true infusions, but no blood was drawn. For both the true and sham infusions, subjects were fed a casserole customized to contain $0.8 \pm 0.04$ g/kg N with an appropriate balance of diet components to maintain the individual’s energy balance. This method has been used successfully before and allows for feedings of $1/10^{th}$ of the days energy and protein hourly for 10 hours rather than using a supplement with varying $^{13}\text{C}/^{12}\text{C}$ ratios. An aliquot was saved, frozen and analyzed for N content (Campbell et al, 1994).

For the infusions, participants had their last regular meal at 1500h on the day of the infusion. At 1800h the infusion began, with subjects sleeping from midnight to 0600h. Between the hours of 0600 and 1500h, subjects were given $1/10^{th}$ of the isoenergetic, isonitrogenous casserole every hour. The infusion ended at 1800h, so there were 12 hours of fed and 12 hours of fasting state. A retrograde 20g IV was placed in the dorsum of the contralateral hand used for blood sampling. The hand was kept in a warming box to arterialize samples. Whole body protein metabolism was determined using a primed-constant infusion of $^{13}\text{C}$-leucine (Cambridge Isotope Laboratories, Andover, MA). To measure leucine flux, oxidation and non-oxidative disappearance, loading boluses of $[1-^{13}\text{C}]$sodium bicarbonate (0.8µmol/kg) and $^{13}\text{C}$-leucine (4.2µmol/kg) were administered prior to infusion of $^{13}\text{C}$-leucine (.0466µmol/kg/min). Blood was
sampled before the infusion at 30-, 15- and 5 minutes, and then at 30-minute intervals for the 24 hour infusion. This method has been used successfully by this lab in previous research (Castaneda et al, 1995). Exhaled breath samples were collected in 15mL evacuated tube (Terumo Medical) at 30-minute intervals while subjects were awake. During sleep, CO₂ enrichment was determined from blood bicarbonate (El-Khoury et al, 1994). VO₂ and VCO₂ were measured by indirect calorimetry, as described for resting energy expenditure, for 20 minutes during hours 0, 3, 12 and 23. Procedures for analysis have been described in great detail in earlier publications. For detailed explanation of analysis procedures for leucine flux, leucine uptake into protein synthesis, and liberation of leucine from protein breakdown, see Matthews et al., 1982. For explanation of leucine oxidation, bicarbonate retention, and ¹³C enrichment, see El-Khoury et al., 1994.

**Physiologic Parameters**

**Physical Function.** Strength and power of the knee extensors were measured by the Margaria-Kalaman Stair Test (Margaria, Aghemo, & Rovelli, 1966). Sit-to-Stand, the time taken to rise 5 consecutive times from a chair, was recorded (Appendix C). This measures functional status and will be used as a comparison baseline to post-intervention (Guralnik, Simonsick, Ferrucci, Glynn, Berkman, Blazer, et al. 1994). All measures were timed to the hundredth second. Stair climb speed and power, and chair stand time are excellent predictors of disability and nursing home admissions due to functional limitations (Csuka & McCarthy, 1985; Guralnik et al., 1994; Fiatarone et al., 1994). In the Tufts lab the test-rested correlation for chair stands is 0.88, with a CV of 8.2%. For stair power, the test-retest correlation is .95-.98 with a CV of 5% (Castaneda et al., unpublished protocol).
**Peak Torque of Extensors and Flexors of the Knee.** Change in muscle strength of the knee extensors and flexors was assessed under standard protocol with a Cybex II isokinetic dynamometer (Appendix C). Peak torque at speeds of 60°/s (corresponding to dynamic strength training at a rate of 2 seconds per concentric and eccentric motion) and 240°/s were recorded (Appendix C). After a period of warm-up and familiarization, subjects were encouraged to exert maximal force for five repetitions at 60°/s, followed by a two-minute rest period. Next the subjects were asked to perform 25 maximal contractions at 240°/s. The peak torque and its corresponding angle were recorded as the maximal effort. The right and left side were taken separately, and largest torque recorded was taken as peak torque. There was no meaningful test-re-test correlation or coefficient of variance (CV) calculable for this method. Due to the potential for a learning effect, tests were repeated several days after the first test at the beginning of P2. Tests were repeated at the end of P3 (Castaneda et al., unpublished protocol).

**Total Body Strength.** The 1-RM test is the standard for dynamic strength assessment. Subjects completed 1RM testing on each of the five listed machines used for strength training. Prior to beginning, the subject was familiarized on the Borg Rating of Perceived Exertion (RPE) scale (Appendix D). Subjects warmed up by completing four to eight repetitions at a weight predicted to be near 50% of 1-RM on KEISER brand strength equipment. Rate of perceived exertion was asked after each trial. Weight was increased between each trial by 2.5 to 20 kg until the subject could not complete the selected repetitions through a full range of motion. The final weight lifted successfully was recorded as the 1-RM (Appendix C). Testing was done at the beginning of P2 and
repeated on a separate day to control for learning effect; this measurement was considered the baseline strength value. Testing was done again at the end of P3.

**Physical Parameters**

**Anthropometric Measurements.** Body weight was monitored daily to ensure weight maintenance. Subjects were weighed without clothing to the nearest 0.1kg, and gown weight subtracted. A Toledo Weight-Plate (model 8138; Sauter Scale Co, Cambridge, MA) was used (Castaneda et al., unpublished protocol).

**Body Composition.** Body density was measured by underwater weighing with a Sauter scale (model K120; Denshore Scale, Holbrook, MA) at the beginning of P2 and end of P3. Subjects were asked to exhale maximally and were submerged underwater for approximately 30 seconds until the scale equilibrated. Lean mass was determined by the Siri equation (ACSM, 2006). Fat mass percentage was determined by total body mass-lean body mass/total body mass. LBM percentage was determined by total body mass-percent fat mass. Lung residual volume was determined by nitrogen dilution prior to hydrostatic measurement (Castaneda et al., 1995).

Urinary Creatinine was employed as a marker for muscle mass at baseline and changes observed during the intervention. Creatinine is created by a non-enzymatic chemical reaction occurring almost entirely in skeletal muscle at a nearly constant rate within the body, provided the body is at equilibrium (Crim & Munro, 1994; Gibson, 1990). The 3 week nitrogen balance period (P2) prior to the intervention assures equilibration was achieved before strength training began (Lukaski, 1996).

Urinary creatinine excretion of older adults is 60% of young counterparts, therefore muscle mass was be estimated assuming 18.5kg of muscle per gram of urinary
creatinine (Gibson, 1990). Measurements were made at the beginning of P1, the beginning and end of P2, and the end of P3. Subjects’ urine was collected for a 24-hour period; aliquots were saved and analyzed in the HNRC Lab for creatinine content.

**Statistical Methods**

Data was be analyzed both graphically and numerically. Paired t-tests was be run for each measurement of strength, body composition, physical function and protein turnover to analyze within-group changes pre- and post intervention. For strength, physical function, protein turnover, REE and muscle mass measurements, between-group differences for pre-P2, end-P2 and post-intervention values and group-by-time interactions was analyzed by repeated measured ANOVA. Hydrostatic weighing data will be analyzed for difference pre and post intervention by independent student’s t-test. Data was shown as mean and standard (SD). If dependent variables appear to be associated, linear regression analysis was done using Pearson correlation coefficient to express the strength of the relationship between variables. Statistical analyses was performed using SPSS software version 14.0 (SPSS Inc., Chicago, IL). Results was considered statistically significant with a two-tailed p-value <0.05.
CHAPTER IV

RESULTS AND DISCUSSION

This study investigated whether older men participating in strength training while consuming the USDA’s daily recommended intake for protein (ST+DRI) would be able to improve physical function, muscle mass, and strength, protein metabolism and resting energy expenditure compared to those on the DRI only group (DRI). This chapter presents the results of statistical analyses preformed on the data collected, as well as a discussion of these results.

Results

Twenty-two older men completed screening for the study. Of these, ten men were unable to participate due to time constraints, and three were excluded due to health conditions meeting exclusion criteria. Of the nine men enrolled, seven completed the trial; three in the strength training plus DRI group (ST+DRI) and four in the DRI only group (DRI). These seven healthy older men were housed in the metabolic ward at the HNRC for 13½ weeks. During this time, dietary intake, daily energy expenditure and protein intake per kilogram body weight were controlled and measured periodically to maintain each subject’s weight and normal activity level throughout the study. Physical function assessments, muscular strength, body composition, protein turnover, and resting energy expenditure were measured before and after completion of the study to assess effects of the diet and/or exercise over time within and between groups. Of those who completed the study, body composition was missing for one subject in the ST+DRI
group. Data on pre and post values for physical function tests and post intervention 1RM leg press data was not available for one subject.

**Baseline Subject Characteristics.** There were no significant differences between groups in the baseline characteristics of age, body weight, and body composition, resting metabolic rates, strength, protein kinetics or Margaria-Kalaman stair time (Table 3). However, body mass index (BMI) was significantly higher in the DRI group at baseline. This indicated the DRI group was at a heavier weight for their height than the ST+DRI group, though none reached the threshold for obesity classification (range 21-29kg/m²) and the lack of significant difference in body composition between groups indicates the DRI group was proportionally similar to the ST+DRI group. Sit-to-stand time was significantly higher in the DRI group at baseline (p=0.04). This indicates baseline functional ability may have been lower in the DRI group and attention must be given to the impact this has on post intervention values and between group relationships.

**Study Compliance.** Dietary compliance was ensured by the fact that subjects were residents in the metabolic ward at the HNRCA where diet was maintained throughout the study’s duration. Adherence to exercise sessions was 87%, averaging 2.5 sessions per week.

**Physical Function.** There were no significant between group differences for Margaria-Kalaman stair climb or sit-to-stand time following the intervention (Table 4). There were no significant within group changes in Margaria-Kalaman stair time or sit-to-stand time pre-to post intervention (Table 4).
### Table 3

**Baseline Subject Characteristics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>ST+DRI n=3</th>
<th>DRI n=4</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>70.0±0.0</td>
<td>72.3±2.4</td>
<td>0.46</td>
</tr>
<tr>
<td>Weight</td>
<td>78.0±18.2</td>
<td>84.25±8.1</td>
<td>0.62</td>
</tr>
<tr>
<td>BMI</td>
<td>23.3±3.5</td>
<td>28.6±1.0</td>
<td>0.02*</td>
</tr>
<tr>
<td>Fat Mass %</td>
<td>30.0±0.8</td>
<td>31.1±1.4</td>
<td>0.36</td>
</tr>
<tr>
<td>Lean Mass %</td>
<td>70.0±1.1</td>
<td>68.4±2.7</td>
<td>0.14</td>
</tr>
<tr>
<td>Lean Mass, kg</td>
<td>59.0±14.5</td>
<td>56.7±5.2</td>
<td>0.86</td>
</tr>
<tr>
<td>REE</td>
<td>1274.0±395.0</td>
<td>1309.5±101.4</td>
<td>0.89</td>
</tr>
<tr>
<td>RQ</td>
<td>0.86±0.06</td>
<td>0.87±0.06</td>
<td>0.74</td>
</tr>
<tr>
<td>1RM Leg Press, kg</td>
<td>93.0±25.5</td>
<td>79.3±11.6</td>
<td>0.66</td>
</tr>
<tr>
<td>1RM Chest Press, kg</td>
<td>54.5±27.5</td>
<td>72.25±24.9</td>
<td>0.41</td>
</tr>
<tr>
<td>Isokinetic peak torque 240d/s leg flexion, Nm</td>
<td>58.8±39.6</td>
<td>34.8±22.6</td>
<td>0.42</td>
</tr>
<tr>
<td>Isokinetic peak torque 240d/s leg extension, Nm</td>
<td>64.2±44.3</td>
<td>48.0±15.3</td>
<td>0.60</td>
</tr>
<tr>
<td>Margaria-Kalaman, s†</td>
<td>2.7±0.3</td>
<td>3.2±1.1</td>
<td>0.41</td>
</tr>
<tr>
<td>Sit-to-Stand, s†</td>
<td>8.2±0.8</td>
<td>11.6±2.1</td>
<td>0.04*</td>
</tr>
<tr>
<td>Leucine synthesis, umol/kg/h (fasting)</td>
<td>59.0±6.7</td>
<td>59.5±7.2</td>
<td>0.47</td>
</tr>
<tr>
<td>Leucine balance, umol/kg/h (fasting)</td>
<td>-10.8±1.0</td>
<td>-9.2±1.6</td>
<td>0.23</td>
</tr>
<tr>
<td>Leucine oxidation, umol/kg/h (fasting)</td>
<td>10.8±1.0</td>
<td>9.2±1.6</td>
<td>0.23</td>
</tr>
</tbody>
</table>

* Between group statistical significance assessed by independent t-test
† n=2
**Muscle Strength.** There were no significant between group differences in 1RM strength measurements for leg press, chest press, leg flexion, leg extension, or lateral pulldown following the intervention (Table 4). There was no significant within group change in any of the 1RM strength measurements between phases 2 and 3 (see Table 4). Isokinetic knee flexion peak torque at 240°/s was significantly higher in the ST+DRI group following the intervention (Table 4). A significant within group change in peak torque at 240°/s was also observed in the ST+DRI group. There was virtually no change in peak torque for the DRI group at either 60°/s or 240°/s, nor in the ST+DRI group at 60°/s (Table 4). When strength was expressed relative to body weight, no additional significance was found.

**Body Composition.** There was no significant between-group difference in lean muscle mass, lean mass percentage or fat mass percentage following the intervention. There were no significant changes in lean mass, lean mass percentage or fat mass percentage between phases 1 and 3 for the ST+DRI or DRI group (Table 5).

There was no significant between-group difference in muscle mass, as calculated from 24-hour urinary creatinine excretion, following intervention. There were also no significant changes within groups following intervention (Table 6).
<table>
<thead>
<tr>
<th>Measure</th>
<th>ST+DRI P2</th>
<th>DRI Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Function, s Margaria-Kalaman stair climb</td>
<td>2.7±0.3</td>
<td>3.2±1.1</td>
</tr>
<tr>
<td>Sit-to-Stand</td>
<td>8.2±0.8</td>
<td>11.6±2.1</td>
</tr>
<tr>
<td>1 RM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leg Press</td>
<td>93.0±25.5</td>
<td>79.3±11.6</td>
</tr>
<tr>
<td>Chest Press</td>
<td>34.7±12.5</td>
<td>32.8±11.3</td>
</tr>
<tr>
<td>Leg Flexion</td>
<td>53.3±23.1</td>
<td>49.8±8.2</td>
</tr>
<tr>
<td>Leg Extension</td>
<td>65.3±18.5</td>
<td>50.75±13.4</td>
</tr>
<tr>
<td>Lat. Pulldown</td>
<td>47.72±22.6</td>
<td>52.7±12.0</td>
</tr>
<tr>
<td>Isokinetic knee flexion, Nm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>60° /s</td>
<td>95.2±42.4</td>
<td>66.3±12.9</td>
</tr>
<tr>
<td>240° /s</td>
<td>58.8±39.6</td>
<td>34.8±22.5</td>
</tr>
<tr>
<td>Isokinetic knee extension, Nm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>60° /s</td>
<td>144.0±72.1</td>
<td>111.1±22.1</td>
</tr>
<tr>
<td>240° /s</td>
<td>64.2±44.3</td>
<td>48.0±15.3</td>
</tr>
</tbody>
</table>

†P2= phase 2 weight equilibration period 1.1g protein/kg BW. P3=phase 3 intervention period + 0.8g protein/kg BW continued
** Between group p values were assessed by repeated measures ANOVA
* Within group p values were assessed by paired t-test
### Table 5

**Body Composition Outcomes**

<table>
<thead>
<tr>
<th>Measure</th>
<th>ST+DRI</th>
<th>DRI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>P1</td>
<td>P3</td>
</tr>
<tr>
<td>Lean Mass, kg</td>
<td>59.0±14.5</td>
<td>58.4±17.5</td>
</tr>
<tr>
<td>Lean Mass, %</td>
<td>70.0±1.1</td>
<td>70.8±1.4</td>
</tr>
<tr>
<td>Fat Mass, %</td>
<td>30.0±0.8</td>
<td>29.2±1.4</td>
</tr>
</tbody>
</table>

† P1= phase 1 nitrogen equilibration period 0.8g protein/kg BW. P3=phase 3 intervention period + 0.8g protein/kg BW continued

** Between group p values were assessed by independent students t-test

*Within group p values were assessed by paired students t-test

### Table 6

**Muscle Mass Outcomes**

<table>
<thead>
<tr>
<th>Measure</th>
<th>ST+DRI</th>
<th>DRI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>P1</td>
<td>P2</td>
</tr>
<tr>
<td>Muscle Mass, kg</td>
<td>22.6</td>
<td>23.9</td>
</tr>
</tbody>
</table>

† P1= phase 1 nitrogen equilibration period 0.8g protein/kg BW. P2=phase 2 nitrogen equilibration period 0.8g protein/kg BW
P3=phase 3 intervention period + 0.8g protein/kg BW continued

§ Muscle mass calculated by following formula: Muscle mass=Urinary creatinine excretion (g/24h)*18.5

** Between group p values were assessed by repeated measures ANOVA

*Within group p values were assessed by paired students t-test
**Protein Metabolism.** Following strength training, there were no significant differences between groups for fasting- or fed-state leucine balance, synthesis (Figure 8), oxidation, flux or breakdown (Table 7). Both the ST+DRI and the DRI group showed no change in any of the above parameters of leucine metabolism over time among phases 1, 2 and 3. There was an inverse relationship between fasting leucine oxidation and fasting leucine balance over the three study phases \( r=1.0, \ p<0.001 \), as shown in Figure 9.

![Synthesis](image)

**Figure 8.** Leucine synthesis rates ST+DRI versus DRI for both fed and fasting states at P1, P2 and P3.
Figure 9. The relationship of fasting leucine oxidation and leucine balance. Squares indicate P1, triangles P2 and circles P3. C data is shown in open shapes and ST in closed shapes. This data shows balance improved towards baseline from P1 to P2 as oxidation decreased, but fell lower again in P3 when oxidation in ST increased.

Energy Intake and Expenditure. There were no differences between groups for resting energy expenditure (REE), respiratory quotient (RQ) daily caloric expenditure, or energy intake (Table 8). REE, RQ, and daily caloric expenditure did not change significantly for either group among phases 1, 2 and 3 of the intervention. Intake values post-intervention were unavailable for analysis.
### Table 7

**Leucine Metabolism Outcomes**

<table>
<thead>
<tr>
<th>Measure (umol/kg/h)</th>
<th>ST+DRI</th>
<th>DRI</th>
<th>Within Group *</th>
<th>Between Group**</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>P1</td>
<td>P2</td>
<td>P3</td>
<td>P1</td>
</tr>
<tr>
<td><strong>Balance</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fasting</td>
<td>-15.6±4.0</td>
<td>-</td>
<td>-11.4±0.5</td>
<td>0.38</td>
</tr>
<tr>
<td>Fed</td>
<td>44.5±2.1</td>
<td>34.5±2.3</td>
<td>33.9±2.1</td>
<td>0.35</td>
</tr>
<tr>
<td><strong>Synthesis</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fasting</td>
<td>68.4±20.4</td>
<td>59.0±6.7</td>
<td>56.8±5.5</td>
<td>0.78</td>
</tr>
<tr>
<td>Fed</td>
<td>72.3±18.8</td>
<td>62.7±5.0</td>
<td>60.1±7.2</td>
<td>0.74</td>
</tr>
<tr>
<td><strong>Breakdown</strong></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Fasting</td>
<td>84.0±24.4</td>
<td>70.0±6.6</td>
<td>68.2±5.0</td>
<td>0.81</td>
</tr>
<tr>
<td>Fed</td>
<td>27.8±20.8</td>
<td>28.2±7.3</td>
<td>26.3±5.0</td>
<td>0.81</td>
</tr>
<tr>
<td><strong>Oxidation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fasting</td>
<td>15.5±4.0</td>
<td>10.8±1.0</td>
<td>11.4±0.5</td>
<td>0.38</td>
</tr>
<tr>
<td>Fed</td>
<td>20.5±2.1</td>
<td>12.7±2.3</td>
<td>13.3±2.1</td>
<td>0.36</td>
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<tr>
<td><strong>Flux</strong></td>
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<td></td>
</tr>
<tr>
<td>Fasting</td>
<td>83.9±24.4</td>
<td>69.8±6.7</td>
<td>68.2±5.0</td>
<td>0.83</td>
</tr>
<tr>
<td>Fed</td>
<td>92.73±20.8</td>
<td>75.4±7.3</td>
<td>73.4±5.1</td>
<td>0.80</td>
</tr>
</tbody>
</table>

**Between group p values were assessed by repeated measures ANOVA**

* Within group p values were assessed by paired students t-test

† P1= phase 1 weight equilibration period 1.1g protein/kg BW. P2=phase 2 nitrogen equilibration period 0.8g protein/kg BW

P3=phase 3 intervention period + 0.8g protein/kg BW continued
### Table 8

**Metabolic Outcomes**

<table>
<thead>
<tr>
<th>Measure</th>
<th>ST+DRI</th>
<th>P1</th>
<th>P2</th>
<th>P3</th>
<th>Within group * P value P3-P2</th>
</tr>
</thead>
<tbody>
<tr>
<td>REE, kcal/d</td>
<td></td>
<td>1399.3±293.0</td>
<td>1274.0±395.0</td>
<td>1248.7±196.1</td>
<td>0.92</td>
</tr>
<tr>
<td>RQ</td>
<td></td>
<td>0.86±0.06</td>
<td>0.86±0.06</td>
<td>0.89±0.2</td>
<td>0.81</td>
</tr>
<tr>
<td>Kcal expenditure/d</td>
<td></td>
<td>1260.94±377.7</td>
<td>----</td>
<td>1326.8±341.3</td>
<td>0.29</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Measure</th>
<th>DRI</th>
<th>P1</th>
<th>P2</th>
<th>P3</th>
<th>Within group * P value P3-P2</th>
<th>Between Group ** P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>REE, kcal/d</td>
<td></td>
<td>1488.0±262.8</td>
<td>1309.5±101.4</td>
<td>1319.5±133.3</td>
<td>0.85</td>
<td>0.86</td>
</tr>
<tr>
<td>RQ</td>
<td></td>
<td>0.85±0.05</td>
<td>0.87±0.06</td>
<td>0.85±0.1</td>
<td>0.74</td>
<td>0.67</td>
</tr>
<tr>
<td>Kcal expenditure/d</td>
<td></td>
<td>1504.2±181.1</td>
<td>----</td>
<td>1385.1±206.2</td>
<td>0.18</td>
<td>0.80</td>
</tr>
</tbody>
</table>

**Between group p values** were assessed by repeated measures ANOVA

* Within group p values were assessed by paired students t-test

† P1= phase 1 weight equilibration period 1.1g protein/kg BW. P2=phase 2 nitrogen equilibration period at 0.8g protein/kg BW. P3=phase 3 intervention period + 0.8g protein/kg BW continued
Discussion

The primary observation of this study is that older men did not improve physical function, body composition, muscle strength, protein metabolism, or resting energy expenditure when participating in a high intensity, progressive strength training program while ingesting the DRI for protein over an 8½ week period, compared to subjects receiving the DRI for protein only.

Physical Function. The primary aim of the present study was to determine if, when consuming the DRI for protein, physical function could be increased significantly with 8½ weeks of high-intensity strength training in older men. There was no change observed for sit-to-stand time or Margaria-Kalaman stair-climb time post intervention. There is a considerable lack of literature describing changes in physical function when both strict control of dietary protein and strength training is initiated in older adults, although it has been shown that physical function declines when protein intake is drastically reduced (Castaneda et al., 1995; Fiatarone et al., 1994).

It is unlikely that the lack of significant improvement observed was due to a high baseline fitness level creating a ceiling for potential improvement in function. Baseline subject characteristics are comparable to that of the literature describing that older adults who participate in high intensity strength training 2-3 days per week over a 6-24 week period, with no control for dietary intake, show significant improvements in sit-to-stand time and/or stair-climb time, indicative of improved physical function (Fiatarone et al., 1994; Henwood & Taaffe, 2006; Vincent et al., 2002).

In a study of healthy community dwelling older adults, Vincent, et al. (2002) observed a significant improvement in time to ascend 23 steps following a 24-week total
body strength training program of similar frequency and intensity (3x/w@80%1RM) as the current study. Vincent et al. revealed a significant inverse correlation between stair time and all lower body 1RM strength values (leg press -0.67, leg curl -0.78, and leg extension -0.64). This confirmed the observations made by Fiatarone et al. (1994) who studied frail nursing home patients over 10 weeks of hip and knee flexor strength training (3x/w@80% 1RM). Fiatarone et al. observed an improvement in stair climbing twice as great as that observed in the current study, with the largest improvements occurring in subjects who with the greatest increases in lower body strength. The subjects with the greatest improvements in stair climb time and lower body strength also made the largest improvements in muscle mass. This is consistent with cross-sectional data showing greater functional ability in individuals with higher muscle mass and strength (Misic, Rosengren, Woods, Evans, 2007; Rolland, Lauwers-Cances, Cournot, Nourhashemi, Reynish, Riviere, et al., 2003; Lindle et al., 1997; Klitgaard et al., 1990).

This may in part explain why significant improvements were not observed in the current study. The lack of significant increases in muscular strength and mass may have limited ability to demonstrate improvements in the Margaria-Kalaman stair climb time. With an increase in muscular mass, there are more potential contractile sites within a muscle fiber. As a result of the increased number of contractile sites, more force can be generated and strength increases. Therefore, time to ascend stairs decreases as an indirect function of increase in muscle mass (Kraemer et al., 2002; NSCA, 2000). Once more, the lack of significant difference in sit-to-stand time post-intervention, despite a significant difference at baseline, may be due to slight improvement in sit-to-stand time for the DRI group (p>0.05), while the ST+DRI time remained unchanged. Due to the lack of changes
in all variables observed, small sample size appears to be a threat to external validity that cannot be ignored.

**Body composition** The second aim of this study was to assess whether quantity of muscle mass and lean body mass improves when older men participate in strength training and consume the DRI for protein. The current study found no significant change in muscle mass or lean body mass for either group following the intervention. Similar to the present study, Campbell et al. (2002) found no difference between the strength training (3x/w@80% 1RM at DRI) and protein only (DRI) groups for lean body mass, percent lean mass, or muscle mass following an intervention of 12 weeks. This supported the only other known study investigating effects of the combination of the DRI for protein and whole body strength training in an older adult population conducted over a decade ago (Campbell, 1994).

Though not significant changes, both trials found that lean body mass decreased in both groups similarly. In both trials urinary creatinine excretion changes were statistically insignificant with the intervention, but quantitatively decrease at an amount equal to 1-2kg of muscle mass. These observations are consistent with results of accommodation to protein intake (Young & Marchini, 1990; Waterlow, 1968).

Castaneda et al. (1995) observed that when older women consumed a low-protein diet (0.46g/kg BW), they experienced a 2.3kg loss of muscle mass (p<0.05) assessed by 24-hour urinary creatinine. Lean mass decreased nearly 5% (p<0.05), accounted for by the 1.4kg decrease in skeletal muscle mass assessed by muscle biopsy (75-100% accountable). Both the current study and that of Campbell and colleagues (2002) lack the
assessment of skeletal mass by invasive methods, yet resemble Castaneda et al.’s evidence of accommodation to inadequate protein intake.

After 12 weeks of high intensity strength training (3x/w@80% 1RM), lean mass is expected to increase 3-4kg and muscle mass 1-2kg (Fiatarone Sing, Wescott & Guy, 1996). It must be taken into consideration that the current study was 8 ½ weeks. However, previous literature not only supports that strength training is a powerful anabolic stimulus, but that muscle morphology can change as early as 6 weeks in older adults (Frontera et al., 1988). Therefore, results of the current study may not be consistent with past trials of longer duration. However, observable changes would be expected within an 8 ½ week period of strength training.

**Muscular Strength.** The third aim for this study was to examine the degree to which strength improvements could be achieved with 8 ½ weeks of strength training if protein intake was strictly controlled at the DRI value.

The lack of significant improvements in 1RM values observed is surprising in view of the literature. It has been well established that neural adaptation to strength training contributes significantly to improvements in strength and functional ability among previously sedentary older adults. Reasoning behind this lies in the inactivity correlated to older age. The disuse of motor neurons causes neural atrophy; this decreases muscle fiber activation, causing atrophy of the corresponding muscle fibers in the motor unit. Strength training has proven to increase motor function and activate previously disused muscle fibers (Delbono, 2003; Fiatarone, 1994; Kraemer et al., 2002; NSCA, 2000). All subjects did increase 1RM values individually, though perhaps the variability within the group prevented statistically significant changes due to the small sample size.
Previous research of frail renal patients on low protein diets has observed significant increases in strength within 12 weeks of strength training while muscle mass and body weight remained unchanged (Castaneda et al., 2001).

Fiatarone et al., (1994) showed that strength training for 10 weeks increased subjects’ 1RM lower body strength regardless of age, sex, baseline functional ability or medical diagnosis. Strength changes ranged from 37-178%, averaging 113%. These results have been confirmed for both frail and healthy active older adults (Bamman et al., 2003; Campbell et al., 2002; Charette et al., 1991; Frontera et al., 1988; Frontera et al., 1993; Lexell et al., 1995). Frontera et al. (1988) observed improvements in strength progressively throughout the 12-week interventions (hip and knee flexion 3x/w@80%1RM) among the group’s twelve healthy older men. Strength was significantly improved by week 2 and continued to increase throughout the trial, averaging over 3% increase per training day. Campbell et al (2002), who maintained protein intake at 0.8g/kg BW similarly to the current trial, and conducted total body strength training in older men and women over a 12 week period, observed a modest increase in muscle strength compared to other studies of strength training in the older adult population, which would average to less than 1% increase per training session. The current study produced a 1.5% increase per training day, similar to the results of Campbell et al. although not statistically significant. The only significant improvement in strength measurements observed in the ST+DRI group of the current study was in isokinetic knee flexion peak torque at 240 °/s (p=0.04). Ferri and colleagues (2003), proposed that due to the inability of elders to develop strength at high velocities, the increases observed at higher isokinetic speeds may be due to familiarization with the
technique, or increased skill to perform the movement. The current study did familiarize
subjects with the testing prior to measuring baseline values, reducing the confounding
variable of retest familiarization.

Frontera et al. (1988), observed increases in strength in all muscle groups trained
after a 12-week high intensity strength training trial of 12 men and women. However, the
group observed greater changes at 60°/s versus 240°/s, and improvements were nearly
one-tenth that of 1RM improvements. Because neural firing frequency is specific to the
rate of movement, it would be expected that strength measurements using isokinetic
testing would show greater increases at speeds most similar to the training protocol.
Motor neurons increase firing frequency when larger force is needed, and when faster
speed of movement is required, therefore the improved motor neuron efficiency would be
specific to the exercises preformed at that, or similar, speed (Ferri et al, 2003; NSCA,
2000). The strength training preformed in the current intervention was more closely
associated to an isokinetic testing speed of 60°/s rather than 240°/s (equivalent to about
2 seconds each for concentric lifting and eccentric lowering). Therefore, strength
improvements similar to Frontera et al. should be expected. Due to the lack of increase in
1RM strength and isokinetic strength at 60°/s, one may assume the statistical
significance observed at 240/s was due to a multiple analysis effect, as no other viable
explanation is clear.

**Protein Metabolism.** The lack of significant increases in lean mass observed
after strength training was confirmed by the data collected for protein metabolism
parameters. There was no increase in protein synthesis with training, nor was there a
significant increase in oxidation. Breakdown did not decrease, protein balance was not
improved, and thus muscle mass was not increased. This is in agreement with observations of Castaneda et al. (1995) who examined protein metabolism by means of leucine isotope tracing in older women consuming protein intakes of half- or twice the DRI. Castanada et al. (1995), observed a significant decrease in oxidation rate in subjects ingesting protein at 0.46g/kg BW. The Castaneda study reported a significant correlation between leucine oxidation and urinary nitrogen excretion; as urinary nitrogen excretion decreased over time to reach a new steady state nitrogen balance, oxidation rates decreased linearly. No significant changes in leucine synthesis or breakdown occurred over the duration of the study by Castaneda et al. This indicated that oxidation was more sensitive to changes in protein intake than synthesis or breakdown. The study suggested that the body accommodates to low protein intakes by altering oxidation rates in an attempt to reach a new steady state of protein balance. Interestingly, the current study supports this theory. There was a statistically significant linear correlation between leucine oxidation rate and leucine balance (r= -1.0, p<0.001). Data displayed a decreased oxidation rate directly correlated to improvement in balance towards equilibrium. However, during Phase 3 of the study oxidation in the ST+DRI group did not continue to decrease, but rather began to increase, as expected with strength training. This correlated with a decrease in leucine balance when compared to the non-exercising DRI group. This suggests that the body began to adapt with decreased oxidation during Phase 2 of the study prior to exercise training, but with initiation of strength training (during Phase 3) the body was unable to continue to do so, thus hindering the body’s ability to compensate for the implicit lack in dietary protein.
The inability to maintain protein balance in the ST+DRI group did not cause the same dramatic decrease in physical function than that observed by Castaneda et al. (1995). However, the outcomes of the current study suggest that optimal physical function, muscle mass and strength gains were not achieved when older men perform strength training while consuming the given quantity of protein (namely the DRI).

Results from the current study contrast those expected with strength training. With dynamic strength training, the stress imposed on muscle contractile fibers during eccentric loading causes an increase in protein oxidation. This destruction initiates protein synthesis in order to repair the fibers to a stronger state than that prior to the strength training bout (Yarasheski et al., 1993; Powers et al., 2003; Evans, 2004). Over time, protein breakdown is also slowed down, as more protein is retained within the muscle in order to increase size and strength (Hartmen, Moore, & Phillips, 2006). Increased synthesis occurs after just one session of high intensity strength training (Kraemer et al., 2002). However, protein intake sets the stage for this anabolic effect (Fujita & Volpi, 2004; Padden-Jones et al., 2003; Tarnopolsky et al, 1992).

In the only other known study to investigate both fed and fasting protein metabolism with an strength training intervention in older adults consuming the DRI for protein, oxidation decreased significantly, though half that of a control group. Balance significantly improved half the extent of the control group. Synthesis during the high-intensity strength training remained unchanged for both fasting and fed state, indicative of a blunted anabolic response to the strength training intervention. The observations of the current study are in agreement with Campbell and colleagues, suggesting that the
dietary component of both trials was a limiting factor on the anabolic stimulus of strength training.

**Energy Intake and Expenditure.** The present study did provide adequate energy intake to maintain body weight to all subjects, in the form of carbohydrate, fat and good-quality protein. Compliance to the diet was checked routinely; with PABA measures indicating all subjects adhered to the specific diet assigned. Thus, it is improbable that insufficient energy intake, quality of protein source, or non-compliance caused the lack of body composition changes observed.

The present study observed a non-significant decrease in REE, similar to Campbell et al. (2001). REE is expected to increase with initiation of strength training due to the increased protein synthesis that occurs with strength training-induced oxidative stress. Among older adults, REE has been observed to increase by up to 1.5kcal/kg/day when strength training is preformed three times per week at 80% 1RM (Westcott, 2007). However, with low protein intake REE decreases (El-Khoury, 1999).

Research has shown that at protein intake of 0.5g/kg BW, protein synthesis is down-regulated in older men and women (Thalacher-Mercer, Fleet, Craig, Carnell & Campbell, 2007). Though the exact mechanisms responsible for this metabolic alteration were not determined, it was noted that transcripts related to whole body metabolism were down-regulated, including those for fat utilization, ATP production and cell protein proliferation. Transcripts for inflammation and negative control of cell protein proliferation were increased (Thalacker-Mercer et al., 2007). Proliferation transcripts are responsible for the production of satellite cells that proliferate into mature muscle cells for skeletal muscle repair after resistance training. This may explain the decrease in lean
body mass as well as the inability to build muscle mass in the current study, as well as in the Campbell et al (1995, 2002) research. This finding raises concern not only for the effect this may have on physical function in older adults, but the immune system as well.
CHAPTER V

SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

Summary

This study investigated whether older men participating in strength training while consuming the USDA’s DRI for protein intake would be able to gain significant muscle mass and strength as means to increase functional ability, compared to subjects receiving the DRI for protein only. Seven apparently healthy older men were kept in residence in a metabolic ward at the HNRC for 13½ weeks. During this time, dietary intake, daily energy expenditure and protein intake per kilogram body weight were controlled and monitored to maintain each subject’s weight and normal activity level throughout the study. Physical function assessments, muscular strength, body composition, protein metabolism, and resting energy expenditure were measured before and after completion of the study to assess effects of the diet and exercise within and between strength training (ST+DRI) and DRI only (DRI) groups.

Results indicated significant improvement in peak torque of the knee flexors at 240º/s in the ST+DRI group, yet no other statistically significant changes in physical function, lean body mass or muscular strength were observed within or between groups. Leucine synthesis and breakdown were unchanged with training, thus protein attrition was not attained and muscle mass did not increase. Leucine balance was negatively correlated to oxidation, therefore balance was not improved in the presence of strength
training due to strength training’s oxidative effects. There were no changes observed within or between groups for measures of physical function, muscle strength, body composition and resting energy expenditure.

**Conclusions**

Based on the results of the analysis of the data and according to the stated hypotheses the following conclusions seem warranted when comparing the ST+DRI vs. DRI groups:

1. Older men were not able to increase physical function after participating in a total body strength training regimen 3 days per week for 8 ½ weeks while consuming the DRI for protein.

2. Older men were unable to increase lean body mass or muscle mass after participating in a total body strength training regimen 3 days per week for 8 ½ weeks while consuming the DRI for protein.

3. Older men were unable to increase muscle strength after participating in a total body strength training regimen 3 days per week for 8 ½ weeks while consuming the DRI for protein.

4. Older men did not experience increases in protein synthesis, oxidation or balance after participating in a total body strength training regimen 3 days per week for 8 ½ weeks while consuming the DRI for protein.

**Recommendations for Further Study**

The small trial presented here serves as a pilot study focused on the public health message that elders can participate in strength training as a means to improve their physical function, thereby decreasing the occurrence of frailty, falls, hospitalization and morbidity. Recommendations that suggest older adults should engage in moderate to high
intensity strength training as a means to improve functional ability, muscle strength and
muscle mass should not be given without reference to proper nutritional intake. The DRI
value for protein used as the guideline to maintain physical function in order to prolong
independent living may not be optimal for older adults interested in improving physical
function through strength training. Therefore, further research is needed to determine
what level of protein intake is necessary to provide the greatest functional gains with
strength training. Future trials should incorporate both lower and higher intakes of protein
to determine what level produces the greatest gains in functional ability, muscle mass and
strength with strength training. Furthermore, diverse populations should be studied in
order to apply results to the broader older U.S. population. Incorporation of such
measures as muscle biopsy and computerized tomography scanning would be optimal for
determining even small changes in lean mass as well as detecting divergence of
improvement between fiber types.

Strength training investigation among the older population is shifting towards
high-velocity training as a more effective exercise prescription for improving physical
function. Incorporating multiple training protocols to determine the interaction of protein
with training may lead to a shift in the way strength training programs are designed for
older populations. Additionally, multiple strength-testing sessions should be utilized
throughout the protocol to determine if protein intake affects the rate at which
improvements in strength are achieved.

Moreover, investigation into the effects that the combination of strength training
and a low protein intake exerts on immune function is warranted, as the affect of low
protein on inflammatory markers may be deleterious to older adults.
APPENDIX A
Investigator Forms and Subject Forms
NOTICE OF IRB APPROVAL - CONTINUING REVIEW

Castanedo-Scoppa, Carmen MD
711 WASH
NEPS
HNRC

IRB #: 4560

Title: Effects of Age and Resistance Training on Protein Requirements

Date of IRB Review: 9/24/2007
Date of IRB Approval: 9/24/2007

Protocol approved: undated version received 12 September 2007
- as closed to subject enrollment

The above referenced research was reviewed and approved using expedited review procedures in accordance with 45 CFR 46.110(b)(8).

PLEASE NOTE: THE IRB NOW REQUIRES NOTIFICATION REGARDING LENGTH OF PATIENT FOLLOW-UP ON ALL CLOSED TO PATIENT ENTRY STUDIES. PLEASE SUBMIT A LETTER OF EXPECTED LENGTH OF FOLLOW-UP AND INCLUDE SUCH INFORMATION ON ALL FUTURE FORM V SUBMISSIONS.

Informed Consent Form(s): N/A

Human Protection Form for Funding Agency: not required

Regulations regarding your research protocol:
1. The approval is valid for one (1) year from the date of review. (Unless otherwise stipulated by the IRB).
2. Unanticipated or serious adverse reactions/adverse reactions encountered in this study must be promptly reported to the IRB within five (5) days. Deaths are reportable immediately.
3. Any changes or modifications in the study protocol or consent form must be reviewed and approved by the IRB prior to implementation.
4. You may not use the ICF or any other study document until it has been approved and validated by the IRB.
5. If you are subject to HIPAA, the Security Rule applies to your research. If you create, store, or transmit electronic PHI, you must meet institutional Security Rule standards. For more information, please contact your HIPAA Privacy Officer for Research.

THIS NOTICE MUST BE RETAINED WITH YOUR RESEARCH FILES.

9/24/07

Signature of Chair/Vice-Chair
Institutional Review Board (IRB)
Northeastern IRB Approval Form

Date: December 7, 2007

IRB No: 07-12-92

Principal Investigator: William J. Gilcap

Department: Health Sciences

Address: 316 Robinson, Northeastern University

Title of Project: Effects of the USDA Daily Recommended Intake for Protein on Strength Training Improvement of Body Composition, Strength and Physical Function in Older Adult Men

Approval Status: Approved

DHHS Review Category: Exempt, Category 1/1

Steve Roberts, DNSc, Vice Chair
Northeastern University Institutional Review Board

Dan C. Regina
Director, Research Integrity

This approval applies to the protection of human subjects only. It does not apply to any other university approvals that may be necessary.

Northeastern University FWA: 4630
Institutional Review Board

Investigator 101
Certificate of Completion

This is to certify that ___________________________ (Name)

has successfully completed the Mandatory Educational Requirement Investigator 101 course.

by the Office for Human Research Protection/Public Responsibility in Medicine and Research (OHRP/PROMAR).

Please note: The recipient of this certificate is responsible for retaining this documentation.

Please ensure that you can produce this certificate if requested.

[Signature]

OHRP Representative

Date 9/01/2007
HUMAN NUTRITION RESEARCH CENTER AT TUFTS UNIVERSITY

PREADMISSION SCREENING CONSENT FORM

Principal Investigator: Carmen Castaneda Sceppa, MD, PhD

Co-Investigator(s): Ronen Roubenoff, MD, MHS, Joseph Kehayas, PhD, Virginia Hughes, MS,
Jennifer Layne, MS, Mona Foldvari, MS, Susan Roberts, PhD.

Protocol: Effects of age and resistance training on protein requirements

You understand that you have been asked to participate in a research study at the Human Nutrition Research Center at Tufts University. In order to assess your eligibility to participate in this research study, you must go through a screening process.

1. First, you will have a 5-10 minute telephone interview by an interviewer who will ask questions about your health, medications, and lifestyle.

2. You will then be invited to the Nutrition Center for a day to go through the following steps. You understand that because of your travel distance you may be asked to remain at the Human Nutrition Research Center for up to three days.

   A. A physician will obtain a detailed medical history and perform a physical examination to determine your eligibility to participate in the research study. You may be asked to do some tasks that involve remembering things and making calculations. These procedures may be waived at the discretion of the above-named physician investigator or his/her designee.

   B. A registered Dietitian will obtain detailed information about your diet. You may be asked to taste test any special foods or formulas used on the research study for which you are being considered to participate. You may be asked to keep a record of your usual food intake, and/or you may be given instructions on following a specific diet on your own. You will be given specific directions on how to do this at this time. These procedures may be waived at the discretion of the above-named physician investigator or his/her designee.

   C. In addition, you will have 0.85 oz. (6.8 taps.) of blood drawn from your vein (venipuncture) for various routine blood measurements (e.g. complete blood count). There may be a slight discomfort during blood drawing and there is the possibility of a small bruise forming at the puncture site. There is also the remote possibility of a superficial inflammation (phlebitis) of the vein. This step may be waived at the discretion of the above-named physician investigator or his/her named designee. You will also give a urine sample for a routine urinalysis.

   D. An electrocardiogram (EKG) will be done to evaluate your heart. This may be waived if you have had an EKG in the past year. If you are less than 50 years of age, an EKG will be done at the discretion of the physician. This is a painless, 5-minute procedure that involves lying down and having rubber straps attached to your arms, legs, and chest.

   E. A pregnancy test may be done if it is thought necessary by N/A. The effects of dietary research on pregnant women is not known. You understand that you should avoid pregnancy while participating in this research study. This test will be done within 7 days of admission to the research study. This involves taking one teaspoon of blood from your vein (venipuncture). The risk of this is the same as for blood drawing in Part C.
F. Other special tests which will be done include:

**Oral Glucose Tolerance Test (OGTT)**
The OGTT assesses how well your body metabolizes a large sugar drink. You will be asked to drink a concentrated sugar solution and have blood samples drawn at the beginning and 2 hours later.

**Maximal Oxygen Consumption and Graded Exercise Testing**
The maximal oxygen consumption test determines how much oxygen your body can consume during a maximal exercise effort, and gives an indication of your level of physical fitness. You will be asked to walk and/or run on a treadmill while breathing into a snorkel-like valve, which will measure the content and volume of the air you breathe out. During the test, you will be wearing a nose clip so all of your breathing is done through the mouth. While you exercise, the speed and incline of the treadmill will get progressively harder, and will start feeling like you are climbing a steep hill. You will be able to stop the test when you feel exhausted, which usually happens within 6-10 minutes. During the test, your heart function will be monitored by an ECG and your blood pressure will be checked by the attending physician. If at any time, the monitoring indicates the test should be stopped, or if you suffer any pain or symptoms beyond those expected, the physician will stop the test. Additionally, you may terminate the test at any time.

**Questionnaire on Sexual Functioning**
You will be asked to complete a short questionnaire (3-4 questions) on sexual functioning. This is to assess the impact of health problems on sexual functioning. These questions may cause discomfort and you may choose not to answer them. All information will be kept confidential.

The risks of these tests include:
1. The OGTT may cause slight discomfort of venipuncture site and possible bruise.
2. The exercise tests may cause your muscles to feel tired or achy.
3. You may also feel some muscle soreness for 2-3 days after the test because of the exercise.
4. You may feel light-headed or short of breath at the end of the test.
5. The risks of carefully monitored exercise tests are very low, but do rarely include:
   a. Irregular heartbeats requiring immediate treatment (in less than 1 out 30,000 tests)
   b. Death (in less than 1 out of 150,000 tests).

While this screening procedure may be of no direct benefit to you, you may receive some benefit since the results of this medical testing (physical examination and laboratory results) may be made available to you and/or your physician for follow-up. If any abnormalities are discovered as a result of the physical examination and laboratory results, you will be notified and referred to your doctor. The results of this screening procedure may or may not qualify you to be admitted into the research study.

If you have any questions concerning this screening, you can call Dr. Ronenn Roubenoff at 617-556-3172.

You understand that you are being screened to participate in the above research study. If for some unforeseen reason the research study does not commence, the HNRC is not obligated to provide you with financial compensation for the research study. In such a case, the HNRC staff will attempt to identify an alternative research study for which you qualify and approve.
Preadmission Screening Consent Form
Page 3

VOLUNTEER STATEMENT

I understand that the screening process may be discontinued at any time by the staff of the HNRC. I also understand that, if for any reason I refuse to participate or discontinue my participation in this process at any time, I will be free to do so and this will have no effect upon continuation of any care or treatment I may be receiving from physicians at the New England Medical Center Hospitals.

I understand the importance of correct medical and psychosocial information in the determination of my eligibility for participation, for my own safety and benefit. I, therefore, agree to answer all questions put forth to me during this screening process accurately and to the best of my knowledge.

I understand that my medical records and data will be kept confidential, except as required by law.

I understand that, in the event I become ill or injured as a result of participating in this screening process, medical care will be provided to me. However, such medical care will not be provided free of charge even if the injury or illness is a direct result of this research study. I understand that no funds to provide financial compensation for research-related injury or illness are available.

I understand that I will be paid a stipend of $15.00 for completing the screening process. This stipend is provided to defray my travel/parking costs.

I have been fully informed of the above-described plan with its possible risks and benefits and I hereby consent to the plan set forth above. I have received a copy of this consent form.

__________________________  __________________________
Date  Participant’s Signature

__________________________
Address

__________________________
Telephone

I have explained to __________________________ the nature and purpose of the screening process and the risks that are involved in its performance. I have answered all questions to the best of my ability.

__________________________  __________________________
Date  Principal Investigator or Representative

__________________________
Date  Witness
Please complete the attached questions and return to the Center

Study # 1450: Effects of Age and Resistance Training on Protein Requirements

Volunteer Name ___________________________ Date ___________________________

1. Are you willing to be randomized into either a control group or exercise group? (for older men only)
   Yes____ No____

2. Are you willing to live at the Center for a total of 14 weeks?
   Yes____ No____

3. What is your current height in inches and weight in pounds?
   Height: _________ Weight: _________

4. Do you exercise on a regular basis?
   Yes____ No____
   If yes, please indicate type of exercise, duration each time and number of times per week.
   What type? _________ How long each time? _________ How often? _________

5. Do you lift weights?
   Yes____ No____
   If yes, please indicate the type and number of times per week. _________

6. Please list all daily vitamin and mineral supplements. ___________________________

(Please detach and return to the Center for consideration for study enrollment.)
SEXUAL FUNCTIONING

These next questions are about the way health problems might interfere with your sex life. These questions are personal, but your answers are important in understanding how health problems affect people’s lives.

CARD H

1. How much of a problem was each of the following during the past 4 weeks?

<table>
<thead>
<tr>
<th></th>
<th>Not A Problem</th>
<th>Little of a Problem</th>
<th>Somewhat of a Problem</th>
<th>Very Much of a Problem</th>
<th>NOT APPLICABLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Lack of sexual interest</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>99</td>
</tr>
<tr>
<td>b. Inability to relax and enjoy sex</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>99</td>
</tr>
<tr>
<td>c. Difficulty in becoming sexually aroused</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>99</td>
</tr>
</tbody>
</table>

MEN ONLY:

d. Difficulty getting or keeping an erection | 1 | 2 | 3 | 4 | 99 |
<table>
<thead>
<tr>
<th>Meds, first study, none in first line, if no meds</th>
<th>Meds, first follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sum</td>
<td>med1 avg</td>
</tr>
<tr>
<td>1</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Antidepressants</td>
</tr>
<tr>
<td>1</td>
<td>Antihypertensive</td>
</tr>
<tr>
<td>1</td>
<td>Beta blockers</td>
</tr>
<tr>
<td>1</td>
<td>Diuretics</td>
</tr>
<tr>
<td>1</td>
<td>HRT</td>
</tr>
<tr>
<td>1</td>
<td>Insulin</td>
</tr>
<tr>
<td>1</td>
<td>Nsaids, asa, tylenol for joint pain</td>
</tr>
<tr>
<td>1</td>
<td>Prednisone</td>
</tr>
<tr>
<td>1</td>
<td>Cholesterol lowering</td>
</tr>
<tr>
<td>1</td>
<td>Cardiac</td>
</tr>
<tr>
<td>1</td>
<td>Hypertension</td>
</tr>
<tr>
<td>1</td>
<td>Peripheral Vascular</td>
</tr>
<tr>
<td>1</td>
<td>Respiratory</td>
</tr>
<tr>
<td>1</td>
<td>Gastrointestinal</td>
</tr>
<tr>
<td>1</td>
<td>Hepatic</td>
</tr>
<tr>
<td>1</td>
<td>Renal</td>
</tr>
<tr>
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<td>Musculoskeletal</td>
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<tr>
<td>1</td>
<td>Cancer</td>
</tr>
<tr>
<td>1</td>
<td>Endocrine</td>
</tr>
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<td>Diabetes</td>
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<td>Osteoporosis</td>
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<td>1</td>
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</tr>
<tr>
<td>1</td>
<td>Thyroid</td>
</tr>
<tr>
<td>1</td>
<td>CHF</td>
</tr>
</tbody>
</table>

**Physact limitation**

- yes
- no
Informed Consent Form – Older Men
Effects Of Age And Resistance Training On Protein Requirements
PI: Carmen Castaneda Scoppa, MD, PhD

JEAN MAYER USDA HUMAN NUTRITION RESEARCH CENTER
ON AGING
TUFTS UNIVERSITY

INFORMED CONSENT FORM

Title: Effects of Age and Resistance Training on Protein Requirements – Older Men

Principle Investigator: Carmen Castaneda, MD, PhD

Co-investigators: Ronenn Roubenoff, MD, MHS
Virginia Hughes, MS
Jennifer Layne, MS
Mona Foldvari, MS
Joseph Kehayas, PhD
Susan Roberts, PhD

Physician: Ronenn Roubenoff, MD, MHS

Purpose of Study

You are being asked to participate, as a volunteer, in a study at the Human Nutrition Research Center (HNRC) on Aging at Tufts University. The purpose of this study is to investigate whether protein requirements change as we get older and with exercise. Both young and old male subjects will be enrolled in the study.

You have been provided, to the best of your knowledge, a complete history of your entire medical problems, medications, and vaccination history. To your knowledge you are free from any serious medical disorder including insulin dependent diabetes, active cancer or AIDS. You will avoid taking any new medications, vitamins, or nutritional supplements during this study without informing the study physician.

Study Procedures

If you choose to participate, the study will last for 13 ½ weeks and is divided into three study phases. The study requires residency at the HNRC for a minimum of 8 weeks although you may reside at the HNRC during the entire study if you so wish. Throughout the study you will be expected to continue your usual activity patterns and will be able to pursue your normal lifestyle except for during periods of metabolic testing when you need to remain at the HNRC. You will report to the HNRC at the dates and times designated by the investigators.
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Pr: Carmen Castaneda Scooppa, MD, PhD

**Phase 1: 14 days**

Over the course of 14 days I will consume only food provided by the HNRC and will try to neither gain nor lose weight. The food provided by the HNRC will consist of usual meals and snacks. You will be resident at the HNRC during this phase.

**Phase 2: 21 days**

During this phase you will be a resident in the HNRC and will continue to be provided food by the HNRC and you must eat this food and no other. The food will be in the form of solid foods. During this phase you will undergo various testing procedures to determine your resting energy expenditure, body composition, microscopic properties of the thigh muscle, muscle strength, immune function, and the way you metabolize protein in my body. For the latter you will make complete collections of urine and stools throughout the 21 days and you will be instructed about ways to collect what are called ‘insensible’ losses of protein from your body. Specifically these will include body hair, beard, nails, sweat and skin. You will be asked to exercise by walking for a total time of one hour on four days for sweat and skin collection. In addition, at the beginning and the end of this phase, you will undergo a 24-hour infusion procedure to determine protein metabolism (as described below).

**Phase 3: 8 weeks**

During this phase you will continue to be provided with food from the HNRC. You will be resident a minimum of 15 days during this phase, including the last 12 days. You may live at home on the days that residency is not required; however, you will be required to eat a minimum of two meals each day at the HNRC. You will be able to take out one meal each day if you so choose. The series of tests conducted in Phase 2 will be repeated. In addition, you understand that during this phase, only the group of older participants will be randomly assigned to either 1) a control group for which there will be no exercises involved or, 2) an exercise group for which weight lifting exercises will be performed three times per week at the HNRC. The exercises will include both upper and lower muscle groups, and will be performed in about 5 or 6 different pieces of equipment. Each exercise session will last between 45 and 60 minutes. Regardless of the group for which you are allocated, you keep my usual activity level.

The study procedures are described below.

1. **DIET**

Throughout the study the MRU kitchen will provide all your food. You must eat all the food without any other food or beverage that is not provided by the kitchen. You will be asked to rinse and scrape all dishes and glasses given to me at each meal. The diet will provide enough calories so that you will not lose or gain any weight, and the diet calories will be adjusted regularly based on your daily weights. The diet you will be receiving is not deficient in any nutrient. You will be taking a vitamin-mineral supplement tablet provided by the investigator.
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daily throughout the study. Some of the foods you consume will contain very small quantities of a substance refer to as PABA, which is used as a marker. However, side effects of PABA when given at higher concentrations include allergy, anorexia, nausea, fever and rash. These are infrequent and subside with omission of the drug.

During Phase 1 of the study, a registered dietician will obtain information about your diet and usual food intake.

2. ANTHROPOMETRIC MEASUREMENTS
A daily record of your weights will be kept at the MRU by weighing me every day of the study. This will be done first thing in the morning, after an overnight fast, before breakfast, and after voiding. You will be wearing a light gown, which has been weighed. You will be asked to keep a record of your bowel movements during the days you are not doing stool collections.

3. URINE AND FECAL COLLECTIONS
You will collect your urine for two 24-hour periods (two days) during Phase 1 and this sample will be used to evaluate your compliance with food consumption. You will collect my urine and stool 24 hours per day during Phase 2 (21 days) and end of Phase 3 (10 days) of the study. During the time that you are collecting the stool you will receive inactive dye tablets that will be excreted in your bowel movements. The purpose of this substance is to mark the beginning and end of each stool collection.

4. INSENSIBLE PROTEIN LOSSES
Some of the protein you eat is needed to replace losses in skin, hair, breath and other routes that are normally not measured. To determine these losses you will undergo the steps described below. These will take place for one week during Phase 1, two weeks during Phase 2 and one week during Phase 3.

a) Hair that collects in my comb, hairbrush, and shower will be collected. You will wear a surgical cap at night. Your hair will be cut at the beginning of Phase 2 and again at the beginning of Phase 3, at a hair salon in Boston, near to the HNRC, specifically for that purpose.

b) Hair removed during shaving will also be collected. You will be asked to shave every other day during this period. For this you will use an electric shaver provided to me at the HNRC. You will be instructed to collect your beard shaving for analysis for one week during Phase 1 in addition to the collections in Phases 2 and 3.

c) Loss of your nails will be determined by having your nails cut and collected in the middle of Phase 2 and again at the beginning of Phase 3.

d) Toothbrush rinses will be collected for a total of 8 days during Phases 2 and 3. You will be asked to brush your teeth first thing in the morning after getting up.
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e) At the beginning and end of Phase 2 and once during Phase 3, you will wear loose garments provided by the investigators continuously for 48-hours. Before putting these garments on, you will take a shower. After 48 hours (not before) you will remove the garments and wash thoroughly your entire body in 4 liters of water with a soap solution provided to you by the investigators. Both the garments and the tub water will be saved for analysis. You will exercise by walking for a total time of 1 hour on the days while you are wearing the garments.

5. BLOOD SAMPLING
You will have a total of 670 ml of blood drawn from your vein (venipuncture) during the course of the 13-week study period for measurement of nutritional biochemistries, cell blood count, protein metabolism, hormone and growth factor levels.

6. RESTING ENERGY EXPENDITURE
After an overnight fast, you will be asked to lie in bed and have a clear plastic hood placed over my head. Fresh air will be constantly flowing through this box and all of the air that you breathe out will be collected and analyzed. This measurement will take between 15-30 minutes and will be repeated several times throughout the study. This test measures your energy expenditure at rest.

7. INFUSION PROCEDURE
This procedure will help the investigators to understand any changes in your protein status at the tissue level. This infusion procedure will start at 6 p.m., 3 hours after your last meal by 3 p.m. that day, and will last until 6 p.m. the following day (a total of 24 hours).

During this time your activity level will be limited to either sitting down or lying down, as you wish and walking would be limited to only using the bathroom when needed. You will be able to sleep for about 5 hours during the night. This procedure will be done 3 times during the study, at the beginning and end of Phase 2 and at the end of Phase 3.

Two intravenous catheters or needles will be placed, one in the forearm, for the constant injection of a non radioactive isotope labeled amino acid (leucine) and bicarbonate that allows the investigators to evaluate protein metabolism, and the other one in the hand for blood sampling. You will be asked to blow into a bag every so often in order to collect breath samples. Four measurements of resting energy expenditure will be done during the infusion period.

During this 24-hour period you will receive 10 small meals between 7 a.m. and 4 p.m. Each meal will provide 1/10 of your daily energy and protein needs for the day, and will be provided in the form of selected solid food items.

During the infusion procedure, blood will be drawn at baseline, and every hour for 24 hours. In addition, five 15-minute blood draws will take place at the 11th hour from the start of the infusion and the 5th hour of feeding time during the infusion. A total of 12 tablespoons will be
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taken from your blood circulation stream. This is not a volume that is expected to cause
problems for you such as anemia or weakness.

A sham infusion with only the meals and the breath samples will be performed before each of
the three infusion procedures.

The risks involved in an infusion procedure are related to the venipuncture and the mechanical
effect of the catheters or needles causing allergic reactions, redness, and sometimes fever.
Infection is rarely seen because of the sterile conditions of the procedure. Blood sampling is
not a risk because the total amount of blood drawn is lower than the volume considered
harmful and it is drawn at intervals over time, not all at once.

8. TOTAL BODY POTASSIUM
The measurement of total body potassium is done by a whole-body counting technique. You
will be asked to lie on your back on a padded table and pillow while being scanned by two
detectors for about 40 minutes. The room where the measurement takes place is completely
isolated but you will be able to communicate with the technician outside the room through a
TV camera and intercom.

There are no harmful effects or radiation hazards involved in this procedure, since this is a
measurement of natural radiation that comes from my body. This measurement will be done
twice during the study.

9. COMPUTERIZED TOMOGRAPHY (CT SCAN) OF THE THIGH MUSCLE
You will be asked to lie down on a bed while the CT scan of your non-dominant thigh is done
for approximately 20 minutes. This x-ray technique will be used to obtain a picture of my
thigh muscles and will be done at New England Medical Center. The effective whole body
dose of radiation during the CT scan will not exceed the individual background whole body
dose received every three months by all people due to natural background radiation. This
measurement will be done twice during the study.

10. HYDROSTATIC WEIGHING
This test will measure the amount of lean (muscle, bones, organs, blood, connective tissue
etc.) and fat tissue that your body contains. You will sit in a tank of warm water (similar to a
Jacuzzi) with the water up to your shoulders. You will fully expire all the air from your lungs
as you put your head below water. Once under the water you will need to hold your breath for
a count of about 3 seconds. This procedure will be repeated about 6 times (no more than 10
times). Later that day, in order to determine the volume of air remaining in my lungs after a
full exhalation, you will be asked to breathe, with a mouthpiece and nose clips, into a machine
for several minutes. This measurement will be done twice during the study.

11. MUSCLE BIOPSY
A muscle biopsy will be taken to permit biochemical and microscopic evaluation. The
muscle biopsy procedure will be performed in your left thigh under sterile conditions. After a
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local numbing medicine, similar to that used in dentistry, is injected at the level of the mid-thigh where the incision will be made, a muscle biopsy needle will be inserted and the muscle specimen will be taken. The incision will be properly covered with a sterile dressing and an elastic bandage. The dressing will remain in place for 24 hours. You will not be able take a shower for 48 hours after the biopsies. This procedure may involve some discomfort such as redness, sensation of pressure in the area, soreness, and bruising. In this research group's experience, this has not been a harmful procedure. Rarely, infection, prolonged discomfort or numbness may occur. There is a small risk of bleeding, infection, and scarring of the skin. A total of 2 biopsies will be done during the study.

12. MUSCLE FUNCTION
The following muscle function measures will be done twice during the study.

a. Dynamic muscle strength (1RM).
You will be asked to lift and lower, with your legs and with your arms, using different machines that work different muscles in your body: chest press, leg extensors, knee extensors and flexors, and latissimus pull down muscles of your back and arms. The maximum weight that you can possibly lift without any extreme discomfort or pain, other than a strenuous effort while lifting, will be recorded. Biweekly and used to set the weight load for the different machines during the training sessions if you are allocated in the exercise group.

b. Adductor pollicis muscle function.
The function of a specific muscle in your right hand will be determined by using an electrical stimulus that is routinely used by physicians and physical therapists to assess contraction-relaxation patterns of different muscles. For this test, your right hand will be subjected to electrical pulses through a needle that touches your skin for a very short period of time (less than 1-2 seconds). During the test you will feel the electrical stimulus and the needle on your skin. The stimulus will not be painful but will definitely be perceptible, so you will experience a sensation of discomfort while doing the test. This procedure will be done 4 times throughout the study.

c. Leg Power Output
You will be asked to rapidly and forcefully give one push to a pedal attached to a machine to measure leg power with each of your legs. You will be asked to repeat this push up to 10 times with rest periods in between.

d. Isokinetic strength test (Cybex test)
You will be asked to exercise different muscles of your legs in a specially designed chair that resists movements of the joints. You will be asked to apply as much force as possible. You will determine the intensity of the muscle contraction so there is little danger of straining or hurting your muscles. At the end of the test your muscles will be fatigued. While the risks of this test are minimal, they might include muscle tightness, soreness and fatigue, and rarely muscle strain.
The overall risks involved with the muscle function tests are muscle tightness, soreness, and fatigue, and rarely pulled muscles. All of these risks however will be minimized with proper warm-up and cool-down procedures.

13. MOBILITY TESTS
You will be observed and timed while you perform simple maneuvers including walking at your usual pace and a fast pace walk for 20 feet, standing up from a chair ten times as fast as you can, and climbing 7 stairs as fast as you can. There is no risk to these procedures other than you might slip and fall. The examiner will be close to your side while you perform the tests so that you may be seated if necessary. These measures will be done twice during the study.

14. PHYSICAL ACTIVITY MONITORS
An activity monitor will be given to you when you start the study to keep track of the amount of normal physical activity you do. The monitor is a small device worn snugly around the waist. You will wear the monitor for a total of 18 days during Phases 1 and 3 of the study, except when you are sleeping, changing clothes, bathing or participating in water sports. You will keep a log of the times and the activities performed when the monitor is worn.

15. IMMUNE FUNCTION
This is a test to determine your immune status by applying 3 intradermal injections in your forearm, each one with a different allergen (substances that are recognized as foreign and to which the body reacts) mumps, candida albicans, and PPD. After 24 and 48 hours the area of placement will be evaluated for redness, induration, and tenderness surrounding the area, just like small lumps like mosquito bites. This is not a harmful procedure and the reaction goes away after few days. Rarely, severe reactions can occur. This test will be done twice during the study.

RISKS
Blood tests: with venipuncture there may be a slight discomfort during blood drawing, and there is the possibility of a small bruise forming at the puncture site. Muscle function tests: the overall risks involved with the muscle function tests may be muscle tightness, soreness, and fatigue, and rarely pulled muscles. Total body potassium test: there are no harmful effects or radiation hazards involved in this procedure, since this is a measurement of natural radiation that comes from my body. CT scan of the thigh: The average radiation dose to my thigh is approximately the same as the normal background radiation received by an individual in three months. Infusion procedures: the risks involved in an infusion procedure are related to the venipuncture, the mechanical effects of the catheters or needles causing allergic reactions, redness, sometimes fever. Infection is rarely seen because of the sterile conditions of the procedure. Blood sampling is not a risk because the total amount of blood drawn is lower than the volume considered harmful and it is drawn at intervals over time, not all at once. Muscle biopsy procedure: it involves some discomfort such as redness, sensation of pressure in the area, soreness, and bruising. In this research group's experience, this has not been a harmful procedure. Rarely, infection, prolonged discomfort or numbness may occur.
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There is a small risk of bleeding, infection, and scarring of the skin. PARA: given at higher concentrations include allergy, anorexia, nausea, fever and rash. These are infrequent and subside with omission of the drug.

BENEFITS
You have been told of the medical and scientific merits of this study. If you are assigned in the exercise group, there may be direct benefit to you as a result of the exercise program. You may get stronger, your muscles may become more developed, and your appetite may increase. You may benefit from knowing a resistance exercise training routine that you could continue on your own. In addition, your contribution may help provide a better understanding of aging and its physiological adaptations to people like you who are fed a low protein diet. If you are assigned in the non-exercise group, you will be offered the exercise training program after completion of the study with few training sessions, so you can continue exercising on your own.

You have been told that you may reach the Principal Investigator or the co-investigators of the study at any time of the day or night during the study period if you have any questions or problems related with it. The telephone numbers are:

Dr. Carmen Castaneda (617) 556-3081 office (781) 335-2518 home
Dr. Ronenn Roubenoff (617) 556-3172 office (617) 636-5114 (x2900) beeper
Dr. Susan Roberts (617) 556-3238 office (617) 244-0951 home

STIPEND
You will be paid $2,500.00 ($800.00 at weeks 4 and 8, and $900.00 at week 13) for completing this 13-week study. You may discontinue your participation in this study at any time. If this should occur, you will be paid up to the day you withdraw, an amount proportional to the time you have spent on the study.

PARTICIPANT’S STATEMENT

I have read this consent form and have discussed with Dr. Castaneda Sceppa or her representative the procedures described above. I have been given the opportunity to ask questions, which have been answered to my satisfaction. I understand that any questions that I might have will be answered verbally, or if I prefer, with a written statement.

I understand that I will be informed of any new findings developed during the course of this research study. I understand that my participation is voluntary and that I may refuse to participate in this study. I also understand that if, for any reason, I wish to discontinue my participation in the process at any time, I will be free to do so, and this will have no effect on my future care or treatment by my physicians or this hospital.
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I understand that if I discontinue my participation in the study, I will be paid up to the day I withdraw, and the amount will be proportional to the time I have spent in the study.

Also, the Investigator or the Institution may decide, at any time and for any reason, that my participation in this study may be terminated. In this event, I will be paid up to the day of termination and the amount will be proportional to the time I have spent in the study.

I understand that in the event I become ill or I am injured as a result of participating in this research study, medical care will be provided to me. However, such medical care will not be provided free of charge, even if the injury or illness is a direct result of this research study. I understand that no funds to provide financial compensation for research-related injury or illness are available.

If I have any questions concerning my rights as a research subject in this study, I may contact the Human Investigation Review Committee at (617) 636-7512.

I have been fully informed of the above-described plan with its possible risks and benefits, and I hereby consent to the procedures set forth above. I have received a signed copy of this consent form.

I understand that as a participant in this study my identity and my medical records and data relating to this research study will be kept confidential, except as required by law, and except for inspections by the study sponsor.

_________________________  ___________________________
Date  Participant

I have fully explained to _____________________________ (Participant) the nature and purpose of the above-described procedure and the risks that are involved in its performance. I have answered all questions to the best of my ability.

_________________________  ___________________________
Date  Principal Investigator or Representative

_________________________  ___________________________
Date  Witness
APPENDIX B
Protocol
### Distribution of measurements

<table>
<thead>
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<th>Measure</th>
<th>Pre-Study</th>
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<th>P2 (15-35)</th>
<th>P3 (36-95)</th>
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<td>E</td>
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<td>Food Block</td>
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* Weight was monitored on a daily basis
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<th>Item</th>
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<td>Orange juice w/calcium</td>
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<td>White bagel</td>
<td>57.0</td>
<td>Thy breast,ckd 38.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cream Cheese</td>
<td>20.0</td>
<td>Broccoli fzn 50.0</td>
<td>Carrots raw 50.0</td>
<td></td>
</tr>
<tr>
<td>Jam</td>
<td>22.0</td>
<td>Onion raw 20.0</td>
<td>Egg raw 50.0</td>
<td></td>
</tr>
<tr>
<td>Skim milk</td>
<td>244.0</td>
<td>1450 Cherries 25.0</td>
<td>ITEM</td>
<td>AMOUNT</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mushrooms cnd 50.0</td>
<td>Canola oil 26.7</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pineapple 50.0</td>
<td>Bread crumbs 13.5</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Olive oil 20.6</td>
<td>Parmesan chs 15.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sour Cherries 45.0</td>
<td>Salt 0.5</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Soy Sauce 30.0</td>
<td>White Roll 30.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>White Rice,ckd 300.0</td>
<td>Margarine, soy 5.6</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Angel Food cake 34.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cranberry jc 240.0</td>
<td>Choc syrup 20.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Peach cnd 400.0</td>
<td>Strawb fzn 200.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>White Sugar 13.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cranberry jc 240.0</td>
<td></td>
</tr>
<tr>
<td>Rinse &amp; scrape</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>100% consume</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distilled h20</td>
<td>no</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BREAKFAST</td>
<td></td>
<td>LUNCH</td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------</td>
<td>----------------</td>
<td>-----------------------</td>
<td>------------</td>
<td></td>
</tr>
<tr>
<td>ITEM:</td>
<td>AMT:</td>
<td>Tuna Salad:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orange juice</td>
<td>120.0</td>
<td>Celery, chgd.</td>
<td>15.0</td>
<td></td>
</tr>
<tr>
<td>w/calium</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total cereal</td>
<td>30.0</td>
<td>Tuna wtr pack</td>
<td>102.5</td>
<td></td>
</tr>
<tr>
<td>Raisins, 2s/2c</td>
<td>20.0</td>
<td>White rice, ckd</td>
<td>175.0</td>
<td></td>
</tr>
<tr>
<td>Skim milk</td>
<td>244.0</td>
<td>Lemon juice</td>
<td>6.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chopped onion</td>
<td>21.6</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Olive oil</td>
<td>10.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Farsley, dried</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Salt</td>
<td>0.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Black pepper</td>
<td>0.2</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>AMOUNT</th>
<th>ITEM</th>
<th>AMOUNT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saltine crax</td>
<td>4 ea</td>
<td>Beef-veg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>soup</td>
<td>See recipe</td>
</tr>
<tr>
<td>Lorna Doones</td>
<td>3 ea</td>
<td>1450 cheese</td>
<td>1 biscuit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>biscuit</td>
<td></td>
</tr>
<tr>
<td>Cran. juice</td>
<td>200.0</td>
<td>Cran juice</td>
<td>200.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1450 Prune cobbler</td>
<td>See recipe</td>
</tr>
</tbody>
</table>

|                |        | FM Snack:   |        |
|                |        |            |        |
APPENDIX C
Investigator Instruction and Sheets
Instructions for Use of the Deltatrac Indirect Calorimeter

Turn on the Deltatrac and printer at least 30 minutes prior to calibration. The names in brackets [ ] below refer to the modes represented on the keypad of the Deltatrac. The following four modes need to be checked and adjusted before the measurement is begun (sequence does not matter):

1. [SET-UP]

Check settings and press the number keys corresponding to "increase" or "decrease" as needed to adjust the values on the screen; press "next" to move to the next parameter. These should be as follows:

<table>
<thead>
<tr>
<th>TIME</th>
<th>hr min sec (should be current time)</th>
</tr>
</thead>
<tbody>
<tr>
<td>START DELAY:</td>
<td></td>
</tr>
<tr>
<td>Respirator</td>
<td>0 -mins</td>
</tr>
<tr>
<td>Canopy</td>
<td>5 -mins</td>
</tr>
<tr>
<td>UNIT OF ENERGY</td>
<td></td>
</tr>
<tr>
<td>kcal</td>
<td>kJ</td>
</tr>
<tr>
<td>cm</td>
<td>ft, in</td>
</tr>
<tr>
<td>kg</td>
<td>lb</td>
</tr>
<tr>
<td>Height</td>
<td></td>
</tr>
<tr>
<td>Weight</td>
<td></td>
</tr>
<tr>
<td>MODE</td>
<td></td>
</tr>
<tr>
<td>Respir.</td>
<td>Canopy</td>
</tr>
<tr>
<td>ARTIFACT SUPPR.</td>
<td></td>
</tr>
<tr>
<td>on</td>
<td>off</td>
</tr>
<tr>
<td>AVERAGING</td>
<td></td>
</tr>
<tr>
<td>on</td>
<td>off</td>
</tr>
<tr>
<td>VT ALARM</td>
<td></td>
</tr>
<tr>
<td>off</td>
<td>on</td>
</tr>
<tr>
<td>PRINTER OPERATION</td>
<td></td>
</tr>
<tr>
<td>num</td>
<td>at request</td>
</tr>
</tbody>
</table>

[RETURN TO MONITOR]

2. [PATIENT DATA]

<table>
<thead>
<tr>
<th>SEX</th>
<th>female</th>
<th>male</th>
</tr>
</thead>
<tbody>
<tr>
<td>WEIGHT</td>
<td>70 kg</td>
<td></td>
</tr>
<tr>
<td>HEIGHT</td>
<td>170 cm</td>
<td></td>
</tr>
<tr>
<td>AGE</td>
<td>40 yrs</td>
<td></td>
</tr>
<tr>
<td>NITROGEN EXCRETION</td>
<td>g/24 hr</td>
<td></td>
</tr>
</tbody>
</table>

Shown above are the default values. Enter appropriate data for the subject being tested by using the "up/down" and "next" keys; nitrogen excretion can be ignored. Predicted BMR and body surface area are calculated from these values; however they do not affect the data produced in any way.
has been going on. The measurement duration cannot be set, and will continue until the investigator chooses to stop it.

At the completion of each measurement segment, press

[STOP] (remove hood from patient at this point),
[END],
[3] - END REPORT,
[3] - CLEAR,
[2] - CLEAR SAME PATIENT.

[SILENCE ALARM] as soon as alarm goes off; this indicates no breathing.

Deltatrac is now ready for next measurement.

When study is completely finished, turn off the Deltatrac and printer; when alarm sounds (indicating a loss of power) press in the small button underneath the on/off switch in the back and hold in for 2 or 3 seconds.
Weight Log: Sample

<table>
<thead>
<tr>
<th>Date</th>
<th>Weight</th>
<th>Comments</th>
<th>Date</th>
<th>Weight</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>4/14</td>
<td>49.0</td>
<td></td>
<td>5/14</td>
<td>48.6</td>
<td></td>
</tr>
<tr>
<td>4/14</td>
<td>49.6</td>
<td></td>
<td>5/15</td>
<td>48.4</td>
<td></td>
</tr>
<tr>
<td>4/15</td>
<td>49.5</td>
<td>diet starts</td>
<td>5/16</td>
<td>48.5</td>
<td></td>
</tr>
<tr>
<td>4/15</td>
<td>49.4</td>
<td></td>
<td>5/17</td>
<td>48.8</td>
<td></td>
</tr>
<tr>
<td>4/16</td>
<td>49.7</td>
<td></td>
<td>5/18</td>
<td>48.5</td>
<td></td>
</tr>
<tr>
<td>4/17</td>
<td>49.0</td>
<td></td>
<td>5/19</td>
<td>48.6</td>
<td></td>
</tr>
<tr>
<td>4/18</td>
<td>49.2</td>
<td>ret</td>
<td>5/19</td>
<td>48.9</td>
<td></td>
</tr>
<tr>
<td>1/19</td>
<td>48.8</td>
<td>collar</td>
<td>5/11</td>
<td>48.6</td>
<td></td>
</tr>
<tr>
<td>4/20</td>
<td>49.0</td>
<td></td>
<td>5/12</td>
<td>48.7</td>
<td></td>
</tr>
<tr>
<td>4/21</td>
<td>48.8</td>
<td></td>
<td>5/13</td>
<td>49.0</td>
<td></td>
</tr>
<tr>
<td>4/22</td>
<td>49.0</td>
<td></td>
<td>5/14</td>
<td>48.7</td>
<td></td>
</tr>
<tr>
<td>4/23</td>
<td>48.5</td>
<td></td>
<td>5/15</td>
<td>48.7</td>
<td></td>
</tr>
<tr>
<td>Mean 4/14-4/19 = 49.3</td>
<td></td>
<td>5/16</td>
<td>49.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5/14</td>
<td>48.5</td>
<td>vmax</td>
<td>5/17</td>
<td>48.8</td>
<td></td>
</tr>
<tr>
<td>1/25</td>
<td>48.7</td>
<td></td>
<td>5/18</td>
<td>48.7</td>
<td></td>
</tr>
<tr>
<td>4/26</td>
<td>48.5</td>
<td></td>
<td>5/19</td>
<td>49</td>
<td></td>
</tr>
<tr>
<td>4/27</td>
<td>48.3</td>
<td></td>
<td>5/20</td>
<td>48.8</td>
<td></td>
</tr>
<tr>
<td>4/28</td>
<td>48.5</td>
<td></td>
<td>5/21</td>
<td>48.8</td>
<td></td>
</tr>
<tr>
<td>4/29</td>
<td>48.4</td>
<td></td>
<td>5/22</td>
<td>49.1</td>
<td></td>
</tr>
<tr>
<td>4/30</td>
<td>48.5</td>
<td></td>
<td>5/23</td>
<td>49.1</td>
<td></td>
</tr>
<tr>
<td>5/1</td>
<td>48.6</td>
<td></td>
<td>5/24</td>
<td>49</td>
<td></td>
</tr>
<tr>
<td>5/2</td>
<td>48.3</td>
<td></td>
<td>5/25</td>
<td>49</td>
<td></td>
</tr>
<tr>
<td>5/3</td>
<td>48.7</td>
<td></td>
<td>5/26</td>
<td>49</td>
<td></td>
</tr>
<tr>
<td>5/27</td>
<td>48.7</td>
<td></td>
<td>5/27</td>
<td>49</td>
<td></td>
</tr>
</tbody>
</table>
NEPS SOP: Isokinetic Cybex Equipment

Jean Mayer USDA Human Nutrition Research Center on Aging, Nutrition, Exercise Physiology and Sarcopenia Laboratory
Standard Operating Procedures
Cybex

1. Introduction

The Cybex II Dual Channel Dynamometer and Instrumentation System with Data is an electrical powered apparatus for testing isokinetic joint movements. Isokinetic (iso=same, kinetic=movement or speed) helps to assess the maximum muscle tension throughout a range of joint motion, while set at a constant velocity. The Cybex equipment controls the speed of joint rotation (°/sec) as well as the ability to test movement around various joints and measures peak rotational force or torque. The NEPS Lab primarily tests knee flexion and extension, although other joint movements can be tested.

The Cybex is attached to the HUMAC Direct Interface V7.01a computer software, which allows to set the dynamometer speed from the computer using the automatic speed control system.

There is a high correlation between peak slow speed torque and lean body weight. Aerobic capability, fast-speed torque, and power-endurance are not highly correlated with lean body mass.

References

ACSM's Guidelines for Exercise Testing and Prescription. Lippincott Williamson and Wilkins, 5th


McArdle, Katch, Katch, Exercise Physiology: energy, nutrition, human performance, 1996, Ch. 22.

Isolated Joint Testing and Exercise... ...a handbook for using the Cybex II and the UBXT (upper body exam table) (orange book in room 1319)

A Handbook for Using the Cybex Data Reduction Computer (gray pamphlet in room 1319)

Cybex Service and Parts Manual (blue binder in room 1319, with photos)

Cybex Data Reduction Computer pamphlet (blue pull-out sheet explaining meaning of printout)
NEPS SOP: Isokinetic Cybex Equipment

2. Principles of Operation

To test strength, power, and endurance using the isokinetic cybex equipment primarily for knee flexion and extension.

The Cybex is located in Room 1319. When testing, open the room and turn on the machines about 5 minutes before you start so that the generator and heat coils on the recorder have time to warm up. You need to turn on the computer, monitor, and Cybex II Speed Selector.

3. Supplies and Parts

Epson LQ-850 supplies: Hartford Catalog
- Fabric Ribbon EPS7753
- Continuous Printout Paper TOP-5507 (3500ct) or TOP-5557 (1000ct)

Refer to the blue binder in Room 1319 for parts and supplies

4. Safety Issues

Warm up and stretching helps to augment blood flow, reduce the susceptibility to musculoskeletal injury by increasing connective tissue extensibility, and improving joint ROM and function. Warm up also decreases the occurrence of ischemic ST-segment depression, threatening ventricular arrhythmias, and transient global left ventricular dysfunction.

5. Subject Preparation

Positioning:

LEG Flexion and Extension:
- Ask the subject to sit in the chair with the leg to be tested closest to the lever arm.
- Stabilize shoulders and torso by looping Velcro straps through side bars.
- Make thigh and shin pad straps as tight as comfortably possible.
- Use back spacer pads to make sure back of knee is not touching the edge of the seat.
- Align axis of rotation of knee joint with mid-silver knob, shin pad above ankle joint.
- More important than exact anatomic placement in the apparatus is the subject's ability to have comfortable and full range of motion. Allow the subject to practice in what you think is the appropriate setting and adjust as necessary for proper range of motion.

6. Contraindications

- Uncontrolled hypertension (160/100)
- Myocardial Infarction in the past 6 months
- Unstable angina.
- Aortic aneurysm
- Stroke or Transient Ischemic Attack in past 6 months
NEPS SOP: Isokinetic Cybex Equipment

7. SOP:

- Turn on the computer, monitor, printer and Cybex II Speed Selector.
- The monitor displays the Main Menu options in colored blocks:
  - Patient Selection – Red
  - Testing/Exercise – Blue
  - Patient’s Data – Light Blue
  - Report Generation – Purple
  - System Functions – Brown
  - Database Functions – Green
- When reading the Speed Selector, be sure to read the dial according to degrees per sec (deg/sec) instead of revolutions per minute (RPM).
- Be cautious when adjusting the dynamometer, it is spring-loaded. If you don’t hold it down when your raise or lower it, it will rise automatically.

Calibration

- The message on the bottom of the screen tells you to “Enter the number for the desired function,” Select 41 – Calibrate the HUMAC and press <F10> to enter.
- HUMAC Calibration Menu is displayed, Select #1 (Calibrate HUMAC Timer) <F10>, and wait until the computer goes through its calibration.
- The screen returns to the HUMAC Calibration Menu, Select #2 (Calibrate Position Sensor) <F10>.
- Position Channel Calibration screen appears, follow directions: position arm for right knee extension/flexion test, set speed selector to “ON” position and turn up the dial to any speed to the arm can be moved through a full range of motion while the marker stays in the green area, <F10>.
- Position Channel Calibration screen appears again, make sure arm is hanging straight down, <F10>.
- Position Channel Calibration screen appears again, move the arm straight up, and hold it up while you press <F10>. (The computer will read the value an then return to the calibration menu on its own.)
- HUMAC Calibration Menu appears again, Select #3 (Calibrate Torque Sensor) <F10>.
- Torque Channel Calibration screen appear, Turn the Cybex machine to the mid-point between the right and left test positions. Remove the leg pad from the dynamometer and replace it with the calibration arm. The arm should go into the dynamometer until c70 are the only figures showing, make sure that the arm “clicks” into the dynamometer and tighten the black knob.
- Set the speed selector to 12 degrees/second (not RPM) and allow the arm to rest on the floor, <F10>.
- Torque Channel Calibration screen appears, verify speed selector (12 deg/sec) and raise the arm to at least 45 degrees above horizontal, let go of the calibration arm Gently and press <F10> after it passes through horizontal.
Caution: 70 pounds is very heavy! Be sure to lift with the legs to avoid potential back injury!

- Torque Channel Calibration screen appears, <F10> repeat steps 9 and 10.
- Once back at HUMAC Calibration Menu, Select #5 (Check Torque Sensor Calibration) <F10>.
NEPS SOP: Isokinetic Cybex Equipment

- Raise the arm to above horizontal and let it fall. The value should be 178-182. Once it is vertical again, <F10>.
- Remove the calibration arm and replace it with the leg pad. Select #4 (Position Channel Calibration) from the HUMAC Calibration Menu <F10>.
- Follow directions and set up machine for a right knee flexion/extension test and position goniometer in the center of the green box <F10>.
- Move arm to horizontal so position equals zero, <F10>.
- Select 0 to exit to main menu
- Calibration completed!

Testing

- The monitor displays the Main Menu options in colored blocks:
  - Patient Selection – Red
  - Testing/Exercise – Blue
  - Patient’s Data – Light Blue
  - Report Generation – Purple
  - System Functions – Brown
  - Database Functions – Green

- The message on the bottom of the screen tells you to “Enter the number for the desired function,” Select 1 for new patient information and hit <F10> to enter.
- At the prompt, type the patient’s last name and <F10>.
- If they have never been tested and their name is not highlighted in red, Select N to add a patient. This brings you to a screen titled Patient Background Information. Inter data fr patient (name, ID, age, height, weight, sex, preferred side, involved side, and tester) <F
- The main menu should be on the screen with the patient’s name highlighted in the red box. At the prompt, “Enter the number for the desired function,” Select 10 for the Isokinetic Tests (in the blue box, titled Testing/Exercise Section).
- Select 30 for the knee extension/flexion test <F10>.
- Isokinetic Test Profile screen is displayed, the testing option include low, medium, and high speed for strength, power, and endurance.

Low Speed Tests (30°/sec or 60°/sec):

- For the low speed test, ascertain that the test speed is 30-60 and the number of repetitions is 6 <F10>.
- Once the test status screen appears, subject the number that corresponds to the side being tested <F10>.
- Torque and position baseline position screen appears – follow steps 1, 2, and 3 <F10>.
  - Speed selecter dial (labeled speed adjust) is on the left side of the Cybex II Speed Selector machine under the hard drive, turn the needle up to the appropriate speed.
  - Make sure that the patient’s heel is touching the pad behind their doot (knee in full flexion).
  - Goniometer is located on the moving arm of the Cybex machine labeled 0-340 degree (small black dial next to blue tape).
- The test instructions screen appears, give 2-3 warm-up reps and final instruction <F10>.
NEPS SOP: Isokinetic Cybex Equipment

- During the test, the patient is asked to extend and flex their knee as fast as they can through a full range of motion.
- Once the test is completed, the screen turns black and then the graph appears. Enter the number of the desired repetition to store (1-6), and <F10>.
- To test the other leg, be sure to select 4 or 8 on the Test Status screen to reset the goniometer and move the testing arm to the other side.

Medium Speed Test (120°/sec - 180°/sec):

- For the medium speed test, ascertain that the test speed is 120-180 and the number of repetitions is 27 <F10>.
- Once the Test Status screen appears select the number that corresponds to the side being tested <F10>.
- Torque and position baseline position screen appears – follow steps 1, 2, and 3 <F10>.
  - Speed Selector dial (labeled speed adjust) is on the left side of the Cybex II Speed Selector machine under the hard drive, turn the needle up to the appropriate speed.
  - Make sure that the patient’s heel is touching the pad behind their foot (knee in full flex)
  - Goniometer is located on the moving arm of the Cybex machine labeled 0-340 degree (small black dial next to blue tape)
- The Test Instructions screen appears, give 2-3 warm-up reps and final instruction <F10>.
- During the test, the patient is asked to extend and flex their knee as fast as they can through a full range of motion.
- Once the test is completed, the screen turns black and then the graphs appear <F10>.
- To test the other leg, be sure to Select 4 or 8 on the Test Status screen to reset the goniometer and move the testing arm to the other side.

High Speed Tests (180°/sec-360°/sec):

- For the high speed test, ascertain that the test speed is 180-360 and the number of repetitions is 27 <F10>.
- Once the Test Status screen appears select the number that corresponds to the side being tested <F10>.
- Torque and position baseline position screen appears – follow steps 1, 2, and 3 <F10>.
  - Speed Selector dial (labeled speed adjust) is on the left side of the Cybex II Speed Selector machine under the hard drive, turn the needle up to the appropriate speed.
  - Make sure that the patient’s heel is touching the pad behind their foot (knee in full flex)
  - Goniometer is located on the moving arm of the Cybex machine labeled 0-340 degree (small black dial next to blue tape)
- The Test Instructions screen appears, give 2-3 warm-up reps and final instruction <F10>.
- During the test, the patient is asked to extend and flex their knee as fast as they can through a full range of motion.
- Once the test is completed, the screen turns black and then the graphs appear <F10>.
- To test the other leg, be sure to Select 4 or 8 on the Test Status screen to reset the goniometer and move the testing arm to the other side.
NEPS SOP: Isokinetic Cybex Equipment

Printing Reports:

- After all the tests are completed, Enter 0 to exit, <F10>.
- You are given the option to store the test in the database or print a copy of the test, Enter <F10>.
- Select #1 (short report form-torque vs time curves) from the HUMAC Report Option menu <F10>.
- Enter P for printer, <F10>.
- Once you return to the HUMAC Report Option menu Enter 0, <F10>, when it asks you, "do you want to store the test in the database?" Select Y for yes, <F10>.
- Once you are at the main menu Enter 0, <F10> to exit the system.

8. Normal Values

Interpreting the data:

Attached is a copy of the printout obtained from the data reduction computer after testing a participant. Lines have been labeled with letters, and the explanation of their significance is below:

a=subject's name, test date, recent weight in kg and other data calculations and algorithms such as torque per pound body weight

b=number of torque tests; this means at which speed the movement will be for measurements; three speeds can be tested successively on one test; slow speed, such as 30 or 60 degrees second, represents strength; medium speed, such as 120-180 degrees per second, represents endurance; fast speed, such as 180-360 degrees per second, represents power

c=number of repetitions at each speed; usually there are 5 flexions/extensions at each trial

d=summary of involved limb and test type

e=peak torque to body weight ratio; 100% is ideal

The torque measurements are meant to represent the intensity of muscular tension. For research purposes, peak torque is used to compare differences in muscle function over time. If the subject's effort were sub maximal, it would be relatively easy to see because there would be greater than 10% variation in the curves produced on the recorder. Also of value on the curve tracings is the slope of the sides of the curves, which represent the time rate of development of the torque, or power. In clinical situations, other subtleties are detectable on the tracings, such as deficits in a previously injured limb. Data spewed out on the data reduction computer can also be calculated from the tracings. See bibliography for this information.

9. Data Collection Sheet (see appendix A)

10. Copy of Representative Printout (see appendix B)

11. Trouble Shooting
NEPS SOP: Isokinetic Cybex Equipment

If the value for the torque sensor is not within 178-182, recalibrate. Generally the value will be range if: you didn’t wait for the arm to pass the horizontal plane, the degrees/sec was not set at the goniometer on the Cybex machine was turned in the wrong direction.

(Refer to the white instruction manual for HUMAC related problems or the blue binder for mechanical problems, which is located in the cabinet below the computer)

13. Back up Procedures

The Cybex II and the data reduction computer should be calibrated monthly. Refer to the CYB Calibration Instructions and Record Form and the CYBEX DATA REDUCTION COMPUTER Calibration Instructions and Record Form.

14. Log Book for Maintenance and Calibration (see appendix C for sample log)

Log is located in the red binder in the cabinet below the computer.

15. Maintenance

The Cybex Company is a division of Lumex, Inc. 2100 Smithtown Ave., Ronkonkoma, NY 11779 516-585-9000; customer service number is 800-645-5392.

According to the manual, the following maintenance schedule is recommended. Since we use Cybex much less frequently than most clinical settings, the apparatus hasn't required maintenance as frequently in the past.

After each use:

The upholstery should be cleaned with a vinyl cleaner. The pedestal casters should be tightened. These are located on the base of the pedestal, attached to the bars that have wheels.

Weekly:

The flat surfaces of the input shaft should be lubricated weekly. This is where the arms (should and knee testing accessories) are attached. WD-40 can be used for lubrication and to prevent rust.

Monthly:

The locking knobs should be lubricated monthly. These are the black knobs on the shoulder and knee testing arms for adjusting the arms to the appropriate length. To lubricate, turn the knob counter clockwise until it either comes out or will not move further, then clean with a cloth and grease with either Vaseline or white lithium grease.

Every 6 months:

The pedestal clamp and the stabilization frame clamp should be lubricated every 6 months or when case wears away. These clamps make up the apparatus that allows for turning the goniometer. The pedestal clamp has a butterfly handle that should be turned counter-clockwise to loosen. The threads should be cleaned with a cloth, then lubricated with a general purpose white grease.
NEPS SOP: Isokinetic Cybex Equipment

or Lubriplate recommended). Also, the end of the screw where it contacts the V-block and the shafts of the allen head clamp bolts should be greased.

The upholstery and Velcro straps should be cleaned with a stiff brush. The stabilization frame clamp should be greased by turning the locking handle until about a 3 mm clearance is seen between the V and the pedestal upright bar. The exposed threads should be lubricated with machine oil, then the clamp should be re-tightened.

The yoke bolts, the pedestal mount tube, the stripper bolts, and the table leg bolts should be tightened every 6 months. The 4 yoke bolts attach the goniometer to the upright pedestal. The pedestal mount tube is the horizontal bar that runs between the two seats and attaches to the upright pedestal bar. The stripper bolts are on either side of the butterfly handle of the pedestal clamp. To tighten each of this requires a 1/4" standard length Allen wrench. The table leg bolt would require special wrenches for tightening.

16. Wording for Consent

Isokinetic strength test (Cybex test)

I will be asked to exercise different muscles of my legs in a specially designed chair that resists movements of the joints. I will be asked to apply as much force as possible. I will determine the intensity of the muscle contraction so there is little danger of straining or hurting my muscles. At the end of the test my muscles will be fatigued. While the risks of this test are minimal, they might include muscle tightness, soreness and fatigue, and rarely muscle strain.

I understand that the overall risks involved with the muscle function tests are muscle tightness, soreness, and fatigue, and rarely pulled muscles. All of these risks however will be minimized with proper warm-up and cool-down procedures.

17. Wording for Journal (from Frontera, Hughes, Fielding, Fiatarone, Evans, Roubenoff paper)

Muscle strength measurements. An isokinetic dynamometer (Cybex II, Medway, MA) was used to measure strength (N • m) of the knee extensors and flexors at 60 and 240°/sec and of the left and right flexors and extendors at 60 and 180°/sec, as previously reported. The placement of the lever with relation to the subject’s leg was carefully controlled. The subjects performed three (five in maximal voluntary contractions at each velocity on 2 testing days (the two tests were made 10-days apart at T1 and on consecutive days at T2), and the peak torque was recorded. In addition the subjects performed 25 maximal contractions at 240 °/sec, and the area under the curve was used to calculate total work as an index of local muscle endurance.
Study 1450
CYBEX
Baseline Final
Tester ______

Name __________________
HNRC __________________
Date __________________

Height ______  Weight ______  Age ______

Test Protocols
A. 30 degrees/sec
   Both R & L legs
   3 repetitions

B. 240 degrees/sec
   Both R & L legs
   25 repetitions

Dominant Leg  R   L

1st Leg Tested  R   L

Position Settings
Seat  Pad  No Pad

Lever Arm ______

Knee Pad ______

Other ______

Notes

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
Study 1450
Physical Performance Tests
Baseline  Final
Tester ______

Name_____________________
HNRC_____________________
Date_____________________

Chair Stands
Chair _____________ Hands Yes  No

Trial 1:
5 Chair Stands______ sec  10 Chair Stands ______ sec

Trial 2:
5 Chair Stands______ sec  10 Chair Stands ______ sec

Notes __________________________________

Margaria Stair Climbing
Hand Rail Yes  No

Trial 1:
7 steps ______ sec

Trial 2:
7 steps ______ sec

Notes __________________________________
1. Introduction
A critical component in assessing the effectiveness of a progressive resistance training (PRT) program is the proper assessment of muscular strength. In the NEPS Laboratory, muscular strength is assessed using the 1-repetition maximum (1-RM) test, as well as multi-RM tests. The RM test measures the maximal amount of resistance that a subject is able to lift one time through a full range of motion using proper lifting technique. This is accomplished by having the subject lift progressively heavy resistances until he/she cannot complete a single, or multiple, repetition using proper form.


2. Principle of Operation
The NEPS Laboratory uses Cybex selectorized weight stack systems, where the resistance is set by selecting the appropriate resistance with a pin. When the subject lifts the resistance the weight is moved through the range of motion using a combination of a cam and belt. This system allows for variation of the resistance throughout the range of motion. Currently, the NEPS Laboratory has seven Cybex machines that work the major muscle groups of the upper and lower body. The machines are listed below along with the muscle groups that they exercise.

Cybex Leg Press
Primary: quadriceps and gluteus maximus
Secondary: hamstrings, adductors

Cybex Leg Extension
Primary: quadriceps

Cybex Leg Curl
Primary: hamstrings
Secondary: gastrocnemius
NEPS SOP: Maximal Strength Testing

Cybex Chest Press
Muscles Trained
Primary: pectoralis major
Secondary: anterior deltoid and triceps

Cybex Upper Back Row
Primary: latissimus dorsi, teres major, biceps, and middle trapezius
Secondary: posterior deltoid, rhomboids

Cybex Back Extension
Primary: erector spinae, gluteus maximus

Cybex Abdominal Crunches
Primary: rectus abdominis
Secondary: internal oblique, external oblique

3. Supplies Needed, Ordering Information if Applicable
N.A.

4. Safety Issues
The primary risk with RM testing is muscular soreness, while the most severe injury could be a separated or dislocated joint. However, as long as proper warm-ups, form, technique, and resistances are used, as well as a little common sense, the incidence of injury with RM testing can be kept low. In order to minimize the risk to the subject, the general following procedures need to be followed:

1. Whole body warm-up of at least 5 minutes, generally on a bicycle ergometer.
2. Explanation and demonstration of proper form for the machine.
3. Familiarization on machine and form with subject without resistance.
5. A sensible, yet rapid, increase in weight until RM is obtained.
6. Explain proper breathing technique in order to avoid the Valsalva Maneuver
   a. Have subject exhale out when lifting the resistance.
   b. Have subjects inhale when lowering the resistance.
7. Follow the lifting protocol for the machine as described below.
8. Be aware of signs and/or symptoms for adverse events.
   a. Ask subject to report any symptoms or pain at time of occurrence.
      i. Cardiovascular
         2. Shortness of breath.
         3. Light-headed.
      ii. Musculoskeletal
         1. Pain in muscle or joint.
            a. Try to assess if pain is due to injury or exertion.
5. Subject preparation
Explain RM test to the subject:

Explain to the subject that they are performing a test that is measuring their muscular strength, and it will require them to lift a maximal amount of weight. Briefly, describe to the subject the procedure, as outlined below, that they will be undergoing in order to determine their maximal muscular strength. Emphasize that it is important for them to give a maximal effort during the test.

Positioning:

Cybex Leg Press
1. Adjust the back pad to the appropriate position so that the subject is comfortable, and have the subject sit on the machine.
   a. In general, the back pad will be positioned in the middle "neutral" position.
   b. The Principal Investigator may adjust the position of the back pad in order to accommodate the needs of their study
      i. Raising the angle of the back pad will emphasize hip muscles.
      ii. Lowering the angle of the back pad will emphasize the quadriceps muscle group.
2. Position the subject so that their feet are in the middle of the footplate.
3. Adjust the footplate to allow approximately a 90-degree bend in the subject's knees.
   a. The starting position of the plate should allow the subject's hips to remain firmly pressed against the back pad throughout the full range of motion.
4. Have the subject place the feet shoulder width apart on the footplate with toes and knees angled outward slightly at the same angle.

Cybex Leg Extension
1. Have the subject sit on the machine and adjust the back pad so that the subject's axis of rotation for the knees is aligned with the machine's axis of rotation.
2. While the subject is sitting on the machine, adjust the leg pad so that the leg pad is positioned comfortably above the ankles.
   a. Placement of the pad should be such that the bottom of the pad is aligned with the top of the malleolus.
3. Position the subject on the machine with their thighs parallel and feet in the neutral position.
4. Have the subject go through an un-weighted range of motion and set the start and stop position.
   a. The starting position should be as close to the "neutral" seated position of the lower leg as possible.
   b. The stop position should allow the subject to go through a full range of motion without hyperextending the knee.

Cybex Leg Curl
1. With the subject seated on the machine, adjust the back pad so that the axis of rotation for the knees is aligned with the machine's axis of rotation.
NEPS SOP: Maximal Strength Testing

2. Adjust leg pad so that when the subject is seated, the leg pad is positioned comfortably above the ankles.
   a. Placement of the pad should be such that the bottom of the pad is aligned with the bottom of the malleolus.
3. Position the subject in the machine with legs resting on leg pad.
4. Adjust the upper thigh stabilization pad to fit snugly across the subject’s thighs.
   a. Smaller individuals may need to have towels placed upon the upper thigh in order to secure the thigh under the thigh stabilization pad.
5. Have the subject go through an un-weighted range of motion and set the start and stop position.
   a. The starting position should be such that the subject’s leg is fully extended, but not hyperextended.
   b. The stop position should allow the subject to go through a full range of motion with the legs ending in position that is approximately perpendicular to the floor.

Cybex Chest Press
1. Adjust the seat height so that when the subject is seated on the machine the handles are at mid-chest and the knees are flexed at 90 degrees.
   a. Smaller individuals may need to use the footstool in order to bring the knees to a 90 degree angle, and so that the back is not arching.
2. Adjust the handle position so that when the subject grasps the handles, the upper arm is straight to side and the wrists are in line with the forearm.

Cybex Upper Back Row
1. Adjust the seat so that when subject is seated on the machine the horizontal handles are slightly below the shoulder height of the subject.
2. Adjust the chest pad to the center of the chest in order to allow the subject’s hands to grasp either handle with arms fully extended.
   a. Make sure the shoulders are not hyperextended.
   b. Make sure the subject is sitting up straight and not slouching.
3. Subjects will generally grasp the vertical hands, however, the hand positioning will be determined by the Principal Investigator.
   a. The vertical handles emphasize the latissimus dorsi.
   b. The horizontal handles emphasize the posterior deltoid, trapezius, & rhomboids.

Cybex Back Extension
1. While seated, have the subject place both feet on the footplates and the back against the pad.
2. Have the subject extend their legs until the posterior thighs are against the seat.
3. Check the hip joint alignment of the subject to ensure that the pivot point of the machine is aligned with the hip.
4. Adjust the footplate to align the subject’s hip while maintaining contact of the thigh against the seat.
5. Stabilize the subject in this position with the seat belt.
6. Have the subject go through an un-weighted range of motion and set the start and stop position.
NEPS SOP: Maximal Strength Testing

a. The starting position should be as close to the “neutral” seated position with hip
   joint at approximately a 90 degree angle
b. The stop position should allow the subject to go through a full range of motion
   without hyperextending the back

Cybex Abdominal Crunches
1. Adjust the seat height so that the arm pad is aligned with the shoulders just below the
   chin.
   a. Lower the seat to increase spinal motion.
   b. Raise the seat to decrease spinal motion.
2. Attach the seat belt only when lifting an amount near the subject’s body weight.
3. While seated, have the subject cross the arms over the arm pad.

6. Contraindications testing
1. Uncontrolled hypertension, ≥160/100.
2. Myocardial Infarction in the past 6 months.
3. Unstable angina.
4. Aortic aneurysm
5. Stroke or Transient Ischemic Attack in past 6 months

7. Standard Operating Procedure
   ♦ The person conducting the 1-RM test should not involved with the training aspect of
     the study, and should be blinded to the subjects group assignment as much as
     possible.

Warm-up
The subject should warm-up on a bicycle ergometer for at least 5 minutes using a light
(<50kP) resistance before stretching. Have the subject stretch the muscles that will be
involved in RM testing (this will be study specific) for 30 seconds.

Familiarization
Position the subject on the weight machine by following the appropriate instructions
outlined in Section 4: Subject Preparation. First, familiarize the subject to the
equipment using no resistance using the appropriate instructions found below in this
section. Explain to the volunteer what muscle group they should concentrate on, and
guide them through the specific movement, as outlined below. With a light resistance
have the subject move through the full range of motion that will be used during the test.
Explain to the subject that they should breathe out as they contract the muscle and lift
the weight, and that they should inhale when lowering the resistance. Further, explain
that the movement should be performed smoothly and without jerking or twisting their
extremity. Indicate to the subject the location of the prime muscles that will be worked
during the exercise. Have them focus their attention on the appropriate muscle
group(s).

Initial RM Testing Protocol*
1. Select a resistance that is approximately 50% of the subject’s estimated RM.
NEPS SOP: Maximal Strength Testing

2. Have the subject perform 4 to 8 repetitions as an exercise-specific warm-up.
3. Allow the subject to rest 30 seconds to 1 minute.
4. Increase the weight.
5. Have the subject perform one repetition using full range of motion and proper form.
6. Assess the subject’s self-perceived level of exertion using a Rating of Perceived Exertion (RPE) Scale.
   a. If the subject’s RPE is \( \leq 5 \), the rest period can stay 30 seconds to 1 minute
   b. If the subject’s RPE is \( > 5 \), then increase the rest period to 1 to 2 minutes
7. Repeat Steps 4 through 6 until subject can no longer lift the resistance.
8. Decrease the resistance by half of the previous increase.
   a. Conduct steps 4-6.
   b. If the subject can lift the new resistance, increase the weight & perform steps 4-6.
9. Continue until failure is achieved, as defined by:
   a. Not being able to move the resistance through their entire range of motion
   b. Not using proper lifting technique, as described below, during the lift.
   c. Entire range of motion is not completed in five seconds.
10. Ideally, the 1-RM should be obtained in no more than 6 trials.

- The second baseline RM Test will occur 4-7 days after the first 1-RM Test.
- If the first baseline 1-RM test has a value greater any value listed below, a 3-RM test will be conducted for the second baseline test for all machines, as well as throughout the rest of the training.

<table>
<thead>
<tr>
<th>Exercise</th>
<th>1-RM (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leg Press</td>
<td>370</td>
</tr>
<tr>
<td>Leg Extension</td>
<td>235</td>
</tr>
<tr>
<td>Leg Flexion</td>
<td>155</td>
</tr>
<tr>
<td>Chest Press</td>
<td>235</td>
</tr>
<tr>
<td>Upper Back Row</td>
<td>235</td>
</tr>
<tr>
<td>Back Extension</td>
<td>235</td>
</tr>
<tr>
<td>Abdominal Crunches</td>
<td>155</td>
</tr>
</tbody>
</table>

1-RM Testing for Second Baseline, Interim, and Final RM Testing Protocol
1. Select a resistance that is 50% of the subject’s RM from the last test.
2. Have the subject perform 4 to 8 repetitions as an exercise-specific warm-up.
3. Allow the subject to rest 30 seconds to 1 minute.
4. Set the weight to 75% of the subject’s RM from the last test.
5. Have the subject perform one repetition using full range of motion and proper form.
6. Assess the subject’s self-perceived level of exertion using a Rating of Perceived Exertion (RPE) Scale.
   a. If the subject’s RPE is \( \leq 5 \), the rest period can stay 30 seconds to 1 minute
   b. If the subject’s RPE is \( > 5 \), then increase the rest period to 1 to 2 minutes
NEPS SOP: Maximal Strength Testing

7. Repeat Steps 4 through 6 until subject can no longer lift the resistance.
8. Decrease the resistance by half of the previous increase.
   a. Conduct steps 4-6.
   b. If the subject can lift the new resistance, increase the weight & perform steps 4-6.
9. Continue until failure is achieved, as defined by:
   a. Not being able to move the resistance through their entire range of motion
   b. Not using proper lifting technique, as described below, during the lift.
   c. Entire range of motion is not completed in five seconds.
10. Ideally, the 1-RM should be obtained in no more than 6 trials.

1-RM Testing for Second Baseline, Interim, and Final RM Testing Protocol
1. Select a resistance that is 40% of the subject’s RM from the last test.
2. Have the subject perform 4 to 8 repetitions as an exercise-specific warm-up.
3. Allow the subject to rest 1 minute.
4. Set the weight to 70% of the subject’s RM from the last test.
5. Have the subject perform three repetition using full range of motion and proper form.
6. Assess the subject’s self-perceived level of exertion using the RPE Scale.
   a. If the subject’s RPE is ≤5, the rest period can stay at 1 minute
   b. If the subject’s RPE is > 5, then increase the rest period to 2 minutes
7. Repeat Steps 4 through 6 until subject can no longer lift the resistance three times.
8. Decrease the resistance by half of the previous increase.
   a. Conduct steps 4-6.
   b. If the subject can lift the new resistance, increase the weight & perform steps 4-6.
9. Continue until failure is achieved, as defined by:
   a. Not being able to move the resistance through their entire range of motion three times
   b. Not using proper lifting technique, as described below, during all three repetitions.
   c. Entire range of motion is not completed for all three repetitions
10. Ideally, the 3-RM should be obtained in no more than 6 trials.

* In order to elicit a maximal effort out of a subject, it is important to give them strenuous vocal encouragement throughout the entire test. It is also important to make this encouragement uniform from test to test, and between testers.

Cybex Leg Press
1. Have the subject grasp the handles lightly.
2. The subject should keep their feet flat, and push through the heels and toes with a smooth controlled motion until their legs are almost fully extended.
   a. There should be an approximately 5 degree bend in the knee at the end of the range of motion
   b. Subject should keep feet flat
      i. They should not push onto the toes
      ii. They should not rock back onto the heels.
3. Instruct the subject to slowly lower the weights until it is near the starting position without the weights touching the stack.
NEPS SOP: Maximal Strength Testing

4. Remind the subject to maintain hips and shoulders against the back pad with the knees pointing toward the toes throughout each repetition.
5. Remind the subject to breath out as they push against the footpad, and to inhale as they lower the footpad.
6. Coach the subject to lift/lower resistance with smooth, controlled movements.
7. During the lift, make sure the subject does not:
   a. Arch their back.
   b. Hyperextend their knee.
   c. Hold their breath.

Cybex Leg Extension
1. Have the subject grasp handles to remain firmly seated while performing this exercise.
2. Have the subject place their feet in the anatomically neutral position parallel to the floor.
3. The subject should extend the legs, straightening them to near full extension.
   a. Remind the subject that they should not kick.
4. On the first repetition, rotate the subject’s thighs to position the kneecaps pointing upwards.
   a. Remind the subject to maintain this position throughout exercise.
5. The subject should return to the starting position.
6. Coach the subject to lift/lower resistance with smooth, controlled movements.
7. Remind the subject to breathe out as they lift the leg pad, and to inhale as they lower the lower the leg pad.
8. During the lift, make sure the subject does not:
   a. Arch their back.
   b. Slide away from back pad.
   c. Hyperextend their knee.
   d. Lift their buttocks.
   e. Hold their breath.

Cybex Leg Curl
1. Tell the subject to grasp the handles to remain firmly seated while performing this exercise.
2. Have the subject place their feet in the anatomically neutral position.
3. Instruct the subject to pull back with their legs to full flexion.
   a. Legs should end about perpendicular to the floor.
4. Have the subject return to the starting position and repeat.
5. Remind the subject to lift/lower resistance with smooth, controlled movements.
   a. Relaxing the feet during movement can help emphasize hamstrings.
   b. Flexing the feet up will allow the gastrocnemius to assist with the movement.
6. Remind the subject to breathe out as they push down on the leg pad, and to inhale as they raise the leg pad.
7. For the subject to exit, release thigh stabilization detent pin and lift.
8. During the lift, make sure the subject does not:
   a. Arch their back.
NEPS SOP: Maximal Strength Testing

b. Slide down and away from back pad.
c. Lift their buttocks
d. Hold their breath

Cybex Chest Press
1. Tell the subject to grip the handles.
2. Advise the subject to position the elbows out to the side, level with handles.
3. Have the subject pinch their shoulder blades together.
   a. Explain to the subject that maintaining the shoulder blades pinched and the elbows at handle level throughout each repetition is important.
4. The subject should press the handles forward with a smooth controlled movement and return without resting.
5. Remind the subject to breathe out as they push on the handles, and to inhale as they lower the handles pad.
6. During the lift, make sure the subject does not:
   a. Arch their back.
   b. Drop their elbows.
   c. Push with their feet.
   d. Hold their breath.

Cybex Upper Back Row
1. Have the subject grasp the desired handles.
2. Remind the subject to pinch the shoulder blades backward and together.
3. Instruct the subject to maintain shoulder blade position and contact with the chest pad, while bending the arms and bring the elbows beside the body.
4. The subject should return the arms forward to full extension without changing shoulder blade position.
5. Remind the subject to breathe out as they lift the leg pad, and to inhale as they lower the lower the leg pad.
6. During the lift, make sure the subject does not:
   a. Pull away from chest pad.
   b. Hyperextend their shoulders.
   c. Slouch on the seat.
   d. Hold their breath.

Cybex Back Extension
1. Instruct the subject to cross the arms and straighten the spine by "lifting the chest."
2. Advise the subject to press against the pack pad and slowly extend the hips, maintaining proper spinal alignment.
3. Prompt the subject to control the return forward without resting and to keep the "chess up" to insure proper spinal alignment.
4. If the subject feels the back pad moving on back during the use of the machine, check hip alignment with pivot and adjust footplate accordingly.
5. During the lift, make sure the subject does not:
   a. Slouch on the seat.
   b. Hold their breath.
<table>
<thead>
<tr>
<th>Exercise</th>
<th>Seat</th>
<th>Leg Pad</th>
<th>Start</th>
<th>End</th>
<th>1RM</th>
<th>Reps</th>
<th>Percentage</th>
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<tr>
<td><strong>LEG EXTENSION</strong></td>
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<td><strong>CHEST PRESS</strong></td>
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Name: ___________________________  Baseline 1  Baseline 2

HNRC: ___________________________  Mid-Study  Final
Thigh CT Data sheet

Name_________________________ Week of study (circle one):

NEMC ID:______________________ 2
HNRC#________________________ 14
Dob:_________________________ Technician:

Date of Scan:__________________

Time of Scan:__________________

Exam #________________________ Series Image:

Leg Used (circle one): left right

Time First Supine:__________ Ct scanner: 1 2 3

Time Image Taken:______ (circle one)

Display Field of View:______

Femur Length:________________

50% Femur Length:_____

Thigh Circumference
at image level:__________ Right: / / Left: / /

Scan Parameters and set up:
kV: 120 (100) 1) as small a DFOV as possible
mA: 280 (170) 2) feet taped together
slice thickness: 10.0mm 3) velcro wrap out of the DFOV
time: 1 sec
Study 1450
Exercise Intervention - Draft

Mode
Progressive resistance training (PRT) will be performed using Keiser pneumatic equipment, body weight and free weights for resistance.

Exercise Selection and Order
1. Knee Extension
2. Lat. Pull Down
3. Knee Flexion
5. Leg Press
6. Trunk Flexion (Body weight)
7. Back Extension (Body weight)

Frequency
3 sessions per week on non-consecutive days (Monday, Wednesday, Friday)

Intensity
The target training intensity is 75% to 80% of the most recently determined one repetition maximum (1RM). Three sets will be performed for all exercises. Sets 1 and 2 will be performed for eight repetitions at the intensity indicated in the Resistance Training schedule (below). Set 3 will be performed to failure while maintaining proper technique but will not exceed 15 repetitions. The Borg scale rating of perceived exertion will be used to subjectively evaluate exercise intensity for the third set. Training intensity will be adjusted as needed between interim 1RM tests based upon the number of repetitions completed to failure and the rating of perceived exertion (also see Progression).

Duration
8 weeks beginning in Phase 3, Week 6, Day 36

Time
60-minute session

Protocol
Warm-up
A five-minute warm-up will be performed using either treadmill walking, hall walking or stationary bicycling

Resistance Training
The 50-minute session will begin with the smaller muscle groups of the lower extremity, knee extension and flexion, as these are historically difficult for novice exerciser to isolate and progress in intensity when compared to the multi-joint and multi-muscle group exercise, leg press. The initial training intensity will be based upon the subject’s highest 1RM value for each exercise, respectively. Lower body and upper body exercises will be performed in alternating sets, e.g., subjects will perform 1st set of Leg Press, followed by 1st set of Lat. Pull Down, followed by the 2nd set of Leg Press, etc. Rest between repetitions will be 2-3 seconds as needed. Rest between sets will be approximately 1 minute while subjects re-position to the alternating Keiser machine

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<th>Exercise Week</th>
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<th>Sets / Reps</th>
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# Study 1450
## Resistance Training Log

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| Cool-Down | Stretching for 5 min (hamstrings, calves, shoulders) |
Study 1450
Exercise Log Sheet

Exercise Prescription

Frequency  Only on days that you do not leave the building
Intensity   45% - 55% Heart Rate Reserve
Time       Up to ½ hour

Monarch Stationary Bicycle

Seat
Wheel Resistance  Kp
Target Heart Rate  beats per minute

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APPENDIX D
Subject Instruction & Worksheets
Study 1450  
Caltrac Log Sheet  
Caltrac Unit ___  

Name ___________________  
HNRC ___________________

Weight ____ lb  
Height ____ in  
Age ____ yr  

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**Instructions**

1. Clip the Caltrac to your belt or the waist of your pants just above the front of your RIGHT thigh. The display field for "CALS USED" must be at the top, closest to your waist.

2. Each morning, please record the Start Time (a.m.) and the "CALS USED" that appear on the display before that you start wearing the Caltrac.

3. Just before bed, remove the Caltrac and place it on a bureau or counter top. Please record the End Time (p.m.) and the "CALS USED" that appear on the display.

4. Please do not remove the tape or the batteries from the Caltrac.

5. The caltrac should be keep dry and is **not** worn in the shower.

6. If you have any questions, please call Jennifer @ 556-3329 or 424-9620.
Rating of Perceived Exertion Scale

6 No exertion at all

7 Extremely light

8

9 Very light - (easy walking slowly at a comfortable pace)

10

11 Light

12

13 Somewhat hard (It is quite an effort; you feel tired but can continue)

14

15 Hard (heavy)

16

17 Very hard (very strenuous, and you are very fatigued)

18

19 Extremely hard (You can not continue for long at this pace)

20 Maximal exertion
REFERENCES


Campbell, WW, Trappe, TA, Wolfe, RR, & Evans, WJ. (2001). The recommended dietary allowance for protein may not be adequate for older people to maintain skeletal muscle. *J Gerontology* 56A (6), M373-80.


