THE EFFECTS OF A SINGLE DOSAGE OF CREATINE HYDROCHLORIDE ON TOTAL TRAINING VOLUME IN RESISTANCE TRAINED MEN VERSUS WOMEN

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Researchers have reported that creatine monohydrate is an effective ergogenic aid. With a lack of research on women and creatine hydrochloride, there was a need for further research into creatine hydrochloride’s effect on men versus women during resistance training. This study compared the change in total training volume (TTV) from a control trial to an experimental trial between men and women who ingested either a placebo or a single dose of 0.033 grams per kilogram of body weight of creatine hydrochloride. Both sexes in the creatine group and the placebo group significantly increased TTV from the control trial to the experimental trial during the leg press, but there was no significant change in TTV for the bench press. The change in TTV for the leg press compared between the creatine and placebo groups was not significant. There was a significant difference between men and women’s TTV, with women in the creatine group performing more total repetitions than men in the creatine group during the leg press. The efficacy of creatine hydrochloride on resistance training remains unclear.
I would like to dedicate this text to my amazing friends and family who have helped me get to where I am today.
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CHAPTER I. INTRODUCTION

Introduction

The human body produces about one gram of creatine per day, and another gram can be obtained through the diet, mostly through meats (34). Skeletal muscle houses 95 percent of creatine stores while the other five percent is stored in the brain, liver, kidney, and testes (34). The amount of creatine an individual has stored in the body varies depending on muscle fiber type and the amount of muscle mass, but the average 70 kilogram young man houses around 120 to 140 grams of creatine (12). Total creatine is comprised of free creatine and phosphocreatine (creatine with a phosphate group) (8).

Creatine plays a large role in muscle contraction due to its contributions to the formation of adenosine triphosphate (ATP) (7, 13). It is well accepted that phosphocreatine has the ability to donate a phosphate group to adenosine diphosphate (ADP) to form ATP, a reaction catalyzed by creatine kinase (7, 13). Supplementation with creatine can increase the amount of both muscle creatine and phosphocreatine in the body (44), and ingesting creatine with glucose can increase the uptake into muscle by 60 percent (35).

Creatine supplementation by itself has been found to increase total training volume (TTV) (21, 36, 45), one repetition maximum (1RM) (5), lean body mass (32, 45), anaerobic work on a cycle (21, 22, 23), peak torque (9), force production (9), and neuromuscular activity (9). Creatine combined with resistance training can enhance the performance benefits to an even greater extent (1, 10, 15, 17, 26, 35, 40). Creatine supplementation ingested in conjunction with a resistance training program has been shown to increase TTV (1, 15, 40), 1RM (1, 10, 17, 26), muscle mass (1, 17, 40), isokinetic peak torque (40), total creatine content (15, 35), type two fiber area (15), and content of insulin-like growth factor one (15).
Several theories have been postulated to suggest the mechanism through which creatine elicits performance enhancements. One theory is attributed to supplementation increasing the human body’s creatine and phosphocreatine stores, which provides a rapid source for production of ATP during exercise (27). This increase in the phosphate metabolism, geared for high energy demands, allows for an increase in intensity during resistance training (15). Creatine supplementation, with an increase in muscular creatine content from which to synthesize ATP, can delay the time until muscular fatigue due to the enhanced ability to meet the physical demands on the muscle with a supply of ATP from the creatine kinase reaction. The increased supply of phosphate groups to form ATP from phosphocreatine thus explains how creatine supplementation provides a greater resistance to fatigue, which theoretically leads to an increase in TTV.

A second theory relates to creatine’s ability to consume hydrogen ions and reduce the acidity in working muscle during resynthesis of ATP (27). Proponents of this theory agree that supplementation provides an increase in free creatine for phosphocreatine resynthesis which improves recovery and muscle buffering (33). Exercise brings about an increase in acidity within the working muscle, but creatine may act as a buffer by using the hydrogen ions in the creatine kinase reaction and rephosphorylation of ADP to ATP (19). Since fatigue is associated with the accumulation of hydrogen ions related to an increase of acidity in the muscle, this would facilitate the maintenance of cellular homeostasis for a longer period of time. The increased ability to buffer the acidity of the muscle would be beneficial during exercise because it could allow for a greater resistance to fatigue, leading to an increase in TTV (27).

Most research on creatine supplementation has been conducted with creatine monohydrate (1, 3, 5, 9, 10, 15, 17, 23, 24, 27, 30, 32, 35, 36, 40, 45). Creatine monohydrate is a
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A hydrophilic molecule, making its bioavailability low (41). Creatine monohydrate has also been associated with water retention in the gastrointestinal tract which can cause stomach upset (26). Creatine hydrochloride on the other hand, may not cause stomach and gastrointestinal upset due to the properties of hydrochloride. Hydrochloride is a salt very commonly combined with substances to increase stability and solubility (16) which can allow the gastrointestinal tract to quickly and effectively metabolize the substance after ingestion (20). When combined with other substances, hydrochloride can also lower the pH to make the substance more acidic (16), which may increase the solubility of the creatine hydrochloride. Because of these properties, the theory for using creatine hydrochloride instead of creatine monohydrate is that an individual can ingest a smaller dose without a loading phase of creatine hydrochloride and still receive the performance benefits of taking a large dose of creatine monohydrate. Even though it shows promise to be a beneficial ergogenic aid, there is limited information on creatine hydrochloride. Additional investigation is needed on the effectiveness of a single dosage of this new form of creatine.

In men, there is consensus that creatine supplementation produces some sort of performance enhancing benefit (4, 5, 9, 10, 21, 26, 30, 35, 36, 40, 45). However, the effects that creatine supplementation has on women are much less clear. Some researchers have found that creatine supplementation produces an ergogenic effect in women for anaerobic work capacity (22, 23), maximal strength (1), training volume (1, 15), functional performance, (1), and fat free mass (1, 15). Those that have directly compared men and women have suggested that creatine supplementation does not benefit women to the same degree as men in terms of an increase in training volume and lean body mass (17, 32). Other researchers have found that creatine supplementation has no effect on women in regards to training volume, muscle mass, and lean
body mass (24). One possible reason for a difference in the effect of creatine supplementation on men and women is that women, in general, have a smaller muscle cross sectional area and a higher total creatine content compared to men (24). A higher starting total creatine store is linked to a lower uptake of supplemented creatine into skeletal muscle (27). Research in this area involving women is sparse and in need of additional investigation.

**Purpose**

The purpose of this study was to determine if ingesting a single dosage of creatine hydrochloride 30 minutes prior to exercise would increase TTV. A second purpose of this study was to determine if creatine hydrochloride affects men and women differently in regards to TTV.

**Significance**

Many athletes, both men and women, ingest creatine and expect it to benefit their training, but the effectiveness of one dose of creatine hydrochloride is unknown. With a lack of research in women, especially because resistance training is becoming more widely accepted and popular for women, it is important to analyze the effects that a possible training enhancer has on women. This study examined if it is possible to elicit an increase in TTV with a single dose of creatine hydrochloride, thus examining if creatine hydrochloride is beneficial for resistance training in both men and women.

**Hypothesis**

It was hypothesized that:

1) ingestion of creatine hydrochloride would increase TTV in both men and women,

2) ingestion of creatine hydrochloride would cause a greater increase in training volume in men than women, and

3) ingestion of creatine hydrochloride would increase TTV compared to placebo.
CHAPTER II. REVIEW OF LITERATURE

Natural Creatine

The human body produces about one gram of creatine per day, and another gram can be obtained through the diet, mostly through meats (34). Skeletal muscle houses 95 percent of creatine stores while the other five percent is stored in the brain, liver, kidney, and testes (34). The amount of creatine an individual has stored in the body varies depending on muscle fiber type and the amount of muscle mass, but the average 70 kilogram young man houses around 120 to 140 grams of creatine (12). Total creatine is found in muscle as free creatine and phosphocreatine i.e., creatine with a phosphate group (8).

The liver, kidneys, and pancreas synthesize creatine with the help of amino acids (glycine, arginine, and methionine) and enzymes (L-arginine, glycine amidinotransferase, guanidinoacetate, methlytransferase, and methionine adenosyltransferase) (14). Crea T1, an intracellular transporter of creatine, is responsible for transporting creatine that is ingested into the mitochondria. Crea T2 is another creatine transporter that is found and mostly active in the testes (39). The overall cellular uptake of creatine is regulated by phosphorylation, glycosylation, and intracellular and extracellular levels of creatine (39).

Creatine plays a large role in muscle contraction due to its contributions to the formation of ATP (7, 13). Phosphocreatine has the ability to donate a phosphate group to ADP to form ATP, a reaction catalyzed by creatine kinase (7, 13). Supplementation with creatine can increase the amount of muscle creatine and phosphocreatine in the body (44), and ingesting creatine with glucose can increase the uptake into muscle by 60 percent (35).
Performance Enhancement

Several theories have been postulated to suggest the mechanism through which creatine elicits performance enhancements. One theory is attributed to supplementation increasing the human body’s creatine and phosphocreatine stores which provides a rapid source for production of ATP during exercise (27). During short, high intensity exercise the body utilizes the phosphagen energy system to provide ATP to working muscle through the creatine kinase reaction which involves the breakdown of phosphocreatine and hydrolysis of ATP (7). The increase in phosphocreatine with supplementation allows for an increase in ATP synthesis during muscle contraction (36). The increase in the phosphate metabolism, geared for high energy demands, allows for an increase in intensity during resistance training (15). The creatine kinase reaction, which provides a phosphate group to ADP to form ATP, acts as a high energy source during resistance training (47). As one continues to exercise, fatigue will set in indicating that phosphocreatine and ATP stores have been depleted (47). However, with creatine supplementation, the creatine kinase reaction may take place for a longer period of time due to an increase in the muscular creatine stores, delaying fatigue (38). The increased supply of phosphate groups to form ATP from phosphocreatine, explains how creatine supplementation provides a greater resistance to fatigue which may lead to an increase in TTV.

A second theory is that supplementation can reduce the acidity in working muscle due to phosphocreatine consuming hydrogen ions in the resynthesis of ATP (27, 44). Fatigue is associated with the accumulation of hydrogen ions which increases the acidity in muscle (7). With supplementation, there is an increase in free creatine for phosphocreatine resynthesis which may improve recovery and muscle buffering (33). Exercise brings about an increase in acidity within the working muscle. Creatine can act as a buffer by using the hydrogen ions in the
creatine kinase reaction and rephosphorylation of ADP to ATP (19). This will help the cells maintain homeostasis for a longer period of time. The increased ability to buffer the acidity of the muscle is extremely beneficial during exercise because it allows the muscle to train harder and longer until reaching fatigue.

Creatine is associated with muscle anabolism due to a significantly larger increase in muscle mass when supplementation is combined with resistance training (10). Creatine supplementation plus resistance training has resulted in an increase in type two fiber area to a much higher extent (28% increase) than resistance training alone (5% increase) (15). There are several theories as to why supplementation increases the muscle fiber area, one of which being that supplementation may inhibit protein breakdown (30). Creatine supplementation combined with resistance training has been found to increase protein synthesis and muscle insulin-like growth factor 1 to a greater extent than resistance training alone in both men and women which contributes to a greater increase in muscle hypertrophy (15). Insulin-like growth factor 1 increases after high intensity resistance exercise, and it has been shown to increase muscle protein synthesis (2). The differences in muscular performance between those supplemented with creatine and those without, has been attributed to hypertrophy of the muscle which may be caused by the increased protein synthesis and insulin-like growth factor 1 (10). Hypertrophy, or muscle growth, is associated with an increase in strength because the larger the muscle, the stronger it is. Supplementation can augment muscle hypertrophy by allowing an individual to train at a high intensity for a longer amount of time until reaching fatigue (36).

Creatine supplementation has been associated with an increase in peak torque and a decrease in time needed to create tension (9). The speed of the reuptake of calcium into the sarcoplasmic reticulum is associated with force production (9). It has been suggested that
supplementation can assist in this task by means of facilitating the uptake of calcium via the calcium ATP pump (9). This can increase rapid force production by allowing faster detachment of the actomyosin bridges (9).

**Effects on Hormones**

Creatine supplementation produces metabolic reactions that may influence a hormonal response to exercise, resulting in hypertrophy of the muscle (43). Rahimi and associates (2010) performed a study in which participants ingested five grams of creatine monohydrate four times a day at breakfast, lunch, dinner, and bedtime for seven days (36). Participants did not participate in any exercise program throughout the study but were tested before and after the seven days of supplementation with an exercise protocol involving six sets of up to ten repetitions with 80% of the participant’s 1RM (36). Rahimi et al. (2010) analyzed body composition, blood samples, and exercise performance to find that creatine supplementation with no physical training increased the amount of repetitions and total volume (36). Growth hormone and testosterone, hormones that are released due to resistance exercise and associated with protein synthesis (28), were significantly higher in the creatine group compared to the placebo group (36). Therefore, the gain in muscle mass that creatine elicits with resistance training may be explained by creatine’s influence on hormonal responses during exercise, increasing muscle hypertrophy.

**Neurological Effects**

Creatine has a neurological role in the body, and creatine supplementation has been found to increase neuromuscular activity shown by enhanced muscle contractions (9). Phosphocreatine and the creatine kinase system help regulate brain and neural function by improving circulation in the brain (42). The role that creatine plays in the brain and neural function, may attribute to
subject’s feelings of increased focus and energy and decreased fatigue (46). Therefore, creatine supplementation may play a role in perceptual fatigue during exercise.

**Effects on Performance**

Creatine supplementation by itself has been found to increase TTV (21, 36, 45). Rahimi et al. (2010) had participants complete an exercise protocol that called for six sets of up to 10 repetitions using 80 percent of participant’s 1RM back squat (36). They observed a significant difference ($p = 0.01$) in the amount of repetitions performed and volume between the creatine (7.2 ± 1.3 repetitions) and placebo group (5.6 ± 2 repetitions) during the fifth set (36). Ernest et al. (1995) also found an increase in TTV with creatine supplementation during one set until exhaustion using 70 percent of participant’s 1RM for bench press (21). There was a significant 26 percent repetition increase in the creatine group compared to the placebo group who experienced no increase from pre to post testing ($p < 0.01$) (21). Volek et al. (1997) employed a five set exercise protocol using participant’s 10 repetition maximum for bench press performed until complete fatigue and found that the creatine group increased the number of repetitions performed throughout all five sets from pre to post testing ($p \leq 0.05$) (45). An increase in TTV due to creatine supplementation alone can be attributed to an increase in phosphocreatine stores which leads to an increase in ATP resynthesis (21).

It has also been shown that creatine without any training can increase 1RM (5, 21). Arazi and associates (2011) analyzed creatine supplementation for three, five, and seven days without implementing a resistance training program throughout the time of supplementation and found that the longer that supplementation is taken, the greater the increase in 1RM for bench press, back squat, and arm curl (5). There was a significant increase from baseline to post-supplementation (5). Earnest (1995) found that 1RM bench press was increased by six percent
after creatine supplementation, which was significantly different than the placebo group which experienced no increase in 1RM \((p < 0.05)\) (21).

Creatine supplementation alone can increase lean body mass (32, 45). Mihic et al. (2000) found that creatine supplementation, even without training, increased lean body mass more than the placebo group \((p < 0.05)\) (32). Volek et al. (1997) also found a significant increase in body mass with creatine supplementation when compared to the placebo group \((p \leq 0.05)\) (45). The gain in lean body mass is most likely due to water retention in cells, not an increase in contractile protein (26). Creatine supplementation has been shown to increase body mass from one to 2.2 kilograms due to water retention in skeletal muscle due to the increase of cellular osmolarity (8). Garazharian and Azimkhani (2014) saw a 0.74 L increase in intercellular water with creatine supplementation (26). The water retention caused by supplementation has been suggested to assist in cellular hydration which may be helpful during exercise by delaying dehydration (26).

Creatine supplementation without training has been found to increase anaerobic work on a cycle ergometer (5, 21, 22, 23). Eckerson et al. (2004) found that the creatine group increased anaerobic work capacity on a cycle to a significantly greater extent than the placebo group \((p < 0.05)\) from pre to post supplementation (23). In a similar study, Eckerson et al. (2005) found that the creatine group increased anaerobic work capacity on a cycle by 49.8 percent from baseline to six days after creatine supplementation while the placebo actually experienced a decline in anaerobic work capacity \((p < 0.05)\) (22). The increase in anaerobic work capacity was attributed to an increase in total creatine and phosphocreatine muscle stores due to supplementation (23).

Creatine supplementation without any training can significantly increase peak torque, force production, and neuromuscular activity \((p < 0.05)\) (9). It has been suggested that these performance enhancements are attributed to an increase in ATP resynthesis, increased buffering
of hydrogen ions, and a decrease in the amount of time needed to detach actomyosin bridges resulting in rapid force production (9).

Supplementation Combined with Resistance Training Program

Creatine supplementation combined with resistance training can enhance the performance benefits to an even greater extent. Creatine supplementation ingested during a resistance training program has been found to increase individual’s TTV more than resistance training alone (1, 15, 40). TTV is typically defined as the amount of repetitions completed throughout the number of sets during exercise (sets x repetitions) (21, 24, 36, 45). However, some researchers have defined training volume as the amount of weight lifted multiplied by the number of repetitions (15, 40), and others have defined it as the amount of weight multiplied by the number of repetitions multiplied by the number of sets (1). The differences in defining TTV are most likely due to whether or not the researchers used the same preset intensity (i.e. 70% of 1RM at pre-test) for both pre and post testing of training volume. Typically during a resistance training program participants will increase their 1RM. Therefore, if researchers retest 1RM post-supplementation and training, the given load used during the training volume test will increase and needs to be factored into the TTV sum.

Aguiar et al. (2013) implemented a 24 week, three days per week resistance training program focused on muscle hypertrophy in which the first 12 weeks for all participants consisted of only resistance training, and during the last 12 weeks participants ingested either creatine or placebo along with the resistance training (1). After the 24 weeks, the increase in training volume for bench press, biceps curl, and knee extension was two times greater for the creatine group (294.1 ± 85.8%) than the placebo group (129.9 ± 52.4%) ($p < 0.05$) (1). Similarly, during an eight week high volume, heavy load resistance training program, Burke and associates (2008)
found that supplementing with creatine increased TTV more than resistance training alone during the second and seventh weeks of the eight week program (15). These results show that individuals who ingest creatine while performing the same resistance training regimen as those not supplementing with creatine, will be able to achieve more repetitions per set, thus maximizing training and increasing benefits such as muscle hypertrophy and strength. After an eight week resistance training program and creatine supplementation, TTV during bench press and back squat was significantly increased to a greater extent in a program that involved a constant rest interval compared to a program that involved a decreasing rest interval during exercise (40). This suggests that creatine supplementation may be more beneficial during muscular strength based programs compared to muscular endurance exercise.

A greater increase in 1RM has been shown when creatine supplementation is combined with resistance training, particularly when compared to training without supplementation (1, 10, 17, 26). After 24 weeks of a resistance program in which the one group supplemented with creatine for the last 12 of those weeks, the increase in maximum strength during bench press, biceps curl, and knee extension for the creatine group was significantly higher than the placebo group ($p < 0.05$) (1). Chilibeck et al. (2004) saw a more significant increase in 1RM for bench press and leg press ($p < 0.01$) in the creatine group than the placebo group after a six week resistance training program aimed at muscle hypertrophy (17). Similarly, after a three week heavy volume, heavy load resistance training program, Garazhian and Azimkhani (2014) found that 1RM for squat, bench press, and arm curl increased more with creatine supplementation than with a placebo ($p < 0.05$) (26). Becque (2000) implemented a six week resistance training program periodized with heavy and light training sessions of a preacher curl performed twice a week and found that the creatine group increased 1RM on preacher curl to a greater extent than
the placebo group \(p < 0.01\) (10). The increase in strength with creatine supplementation combined with resistance training is associated with an ability to increase the work performed during training, allowing for a greater increase in 1RM (10).

During a resistance training program muscle mass can be increased more with creatine supplementation than without it (1, 15, 17, 26, 40). Muscle mass was significantly increased in the creatine group (3.7\% increase) during a 24 week resistance program with 12 weeks of creatine supplementation more than the placebo group (0.9\% increase) \(p < 0.01\) (1). Souza-Junior and associates (2011) also found that creatine supplementation significantly increased muscle mass during an eight week program and supplementation \(p < 0.0001\) (40). Chilibeck et al. (2004) observed a significant increase in lean tissue mass for the creatine group compared to the placebo \(p < 0.02\) (17), and similarly, Burke et al. (2008) found that creatine supplementation significantly increased body mass and lean tissue mass more than the placebo \(p < 0.05\) (15). Garazhian and Azimkhani (2014) also found a more significant increase in body mass and lean tissue mass for the creatine group than the placebo group \(p < 0.05\) (26). This increase was most likely due to an increase in water retention since there was a significant increase in total body water for the creatine group from pre to post testing \(p < 0.05\) (26).

A greater increase in isokinetic peak torque has been found when creatine supplementation is combined with resistance training when compared to resistance training alone (40). Souza-Junior et al. (2011) implemented an eight week resistance training program where participants ingested creatine every day for the length of the study and found that isokinetic peak torque during knee extension and flexion significantly increased from pre to post testing \(p \leq 0.0001\) (40).
A resistance training program and creatine supplementation resulted in an increase in type II fiber area to a much higher extent (28% increase) than resistance training alone (5% increase) (15). Burke et al. (2008) contributed this to an increase in total creatine stores which led to an increase in lean tissue mass because the two were significantly correlated ($r = 0.61, p < 0.05$) (15). A resistance training program and creatine supplementation increases insulin-like growth factor 1 content more than resistance training alone (15). A change in insulin-like growth factor 1 is significantly correlated to a change in intramuscular total creatine stores ($r = 0.82, p < 0.05$) (15). Insulin-like growth factor 1 increases after high intensity resistance training which increases muscle protein synthesis, playing a key role in muscle hypertrophy (2).

When creatine is ingested, total creatine content can increase (33). Preen et al. (2001) divided participants into three groups: one group only ingested creatine, the second group ingested creatine with glucose, and the third group ingested only creatine and performed repeated sprints every day for an hour (35). The group that ingested creatine with glucose increased skeletal muscle total creatine content the most, 60 percent more than ingesting creatine by itself (35). There were no significant differences in total creatine stores between the creatine only and the creatine plus exercise groups; both increased total creatine stores to about the same degree (35). This suggests that to receive the greatest possible benefit from creatine supplementation, ingestion with glucose improves the uptake of creatine increasing total creatine stores to a greater degree than without glucose.

**Recovery and Rehab**

It has also been suggested that creatine may aid in the temporary muscle damage experienced after a heavy resistance training session by enhancing calcium buffering (18). Creatine supplementation can improve the amount of recovery time needed between sets of
exercise due to its ability to restore ATP at a higher rate (40). The higher amount of anabolic hormone concentration that is brought about by the higher training volume due to creatine supplementation, increases repair and recovery of muscle after resistance training needed for muscle remodeling (36).

**Supplementation Dosage and Length of Time**

The dosage amount and the length of time supplementing creatine varies between studies, but these are usually dependent on the total time of the study. Longer studies ranging from six to 12 weeks typically employ a loading phase and a maintenance phase for supplementation (35, 10). Both Becque et al. (2000) and Preen et al. (2001) utilized a five day loading phase of 20 grams per day and a six week maintenance phase of two grams per day and found significant results (10, 35). Arazi et al. (2011) compared loading phases of three, five, and seven days of 20 grams of creatine monohydrate divided into four equal servings (5). They found that three days of loading was sufficient enough to provide a significant increase in strength (5). However, the longer the loading phase, the greater the improvement in performance (5). Eckerson et al. (2005) found similar results when comparing anaerobic work capacity after two and six days of creatine loading (22). Two days of loading was sufficient at eliciting an increase in anaerobic work capacity, but six days of loading was even more beneficial to improving performance (22). Eckerson et al. (2004) compared loading phases of two and five days of five grams of creatine monohydrate plus 18 grams of dextrose on anaerobic work capacity (23). In contrast to other research, Eckerson et al. (2004) found that only the five day loading phase produced a significant increase in anaerobic work capacity (23). These results indicate that a two day loading may be enough to elicit a response in performance, but the longer loading occurs the greater the response will be.
Other long term studies have implemented five grams of creatine per day throughout the entire study and have seen significant results (1, 3). Shorter studies ranging from five to 10 days typically use a higher dosage of 20 grams of creatine per day (5, 22, 27, 30, 32, 36). Some researchers have used an even higher dosage of 25 grams of creatine per day for their short term studies (9, 23, 45).

The most controlled studies have used a dosage based on each participant’s body weight (15, 17, 24). Burke et al. (2008) used 0.2 grams per kilogram of lean body mass for a seven day loading phase then used 0.06 grams per kilogram of lean body mass for 48 days of maintenance (15). Chilibeck et al. (2004) used 0.2 grams per kilogram of body weight for the full six weeks of the study (17), while Ferguson and Syrotuik (2006) used 0.3 grams per kilogram of body weight during a seven day loading phase and employed 0.03 grams per kilogram of body weight during the nine week maintenance phase (24). Burke et al. (2008) and Chilibeck et al. (2004) both found significant results (15, 17); whereas Ferguson and Syrotuik (24) did not find a significant difference between the placebo or creatine groups. This suggests that 0.03 grams per kilograms of body weight may not be a sufficient dosage for supplementation.

Some researchers utilized a carbohydrate with creatine supplementation to increase the uptake into the muscle (5, 9, 10, 15, 17, 22, 23, 24, 26, 30, 40). Some have used a fruit drink such as grape juice (5), orange juice (30) or flavored fruit drink (15). Others have used maltodextrin in an equal amount to the creatine dosage (40), additional researchers have used 0.5 grams per kilogram of body weight of maltodextrin in the form of a grape flavored sucrose drink (17), and some have used 15 grams of maltodextrin (9). Preen et al. (2001) used one gram per kilogram of body weight of glucose (35), while Garazhian and Azimkhani (2014) used 500

Types of Creatine

Most research on creatine supplementation has been conducted with creatine monohydrate (1, 3, 5, 9, 10, 15, 17, 23, 24, 27, 30, 32, 35, 36, 40, 45). Creatine monohydrate is a hydrophilic molecule, making its bioavailability low (41). Creatine monohydrate has also been associated with water retention in the gastrointestinal tract which can cause stomach upset (26). Creatine hydrochloride on the other hand, may not cause stomach and gastrointestinal upset due to the properties of hydrochloride. Hydrochloride is a salt very commonly combined with substances to increase stability and solubility (16) which can allow the gastrointestinal tract to quickly and effectively metabolize the substance after ingestion (20). The longer the loading phase, the more effective creatine monohydrate is at eliciting an improvement in training (5, 22, 23). The fast and effective uptake of creatine hydrochloride into skeletal muscle may allow for a more immediate response in training. The theory for using creatine hydrochloride instead of creatine monohydrate is an individual can ingest a smaller dose without a loading phase of creatine hydrochloride and still receive the performance benefits of taking a large dose of creatine monohydrate. There is limited information on creatine hydrochloride even though it shows promise to be a beneficial ergogenic aid. Additional investigation is needed on the effectiveness of a single dosage of this new form of creatine.

Men versus Women

In men, there is consensus that creatine supplementation produces some sort of performance enhancing benefit, whether it be an increase in strength, power, muscle mass, or training volume (3, 5, 9, 10, 21, 26, 30, 35, 36, 40, 45). Many studies may only use men to
reduce the variation of hormonal responses to exercise (36). The effects that creatine supplementation has on women are much less clear.

Some researchers have found that creatine supplementation produces an ergogenic effect in women (1, 15, 22, 23). Aguiar et al. (2013) saw that 12 weeks of resistance training and creatine supplementation in women increased their maximal strength, training volume (by twice the amount of the placebo group), functional performance, and fat free mass to a greater degree than resistance training alone (1). Burke et al. (2008) found that both men and women increased lean body mass and TTV to a greater extent with creatine supplementation combined with resistance training than just resistance training alone (15).

Those that have directly compared men and women have suggested that creatine supplementation does not benefit women to the same degree as men in terms of training volume and lean body mass (17, 32). Chilibeck and associates (2004) looked at the differences in the affects that creatine supplementation had on men versus women by having participants perform single arm and single leg training with only side of the body with ingesting 0.2 grams of creatine multiplied by the individual’s body weight in kilograms immediately after exercise (17). The other side of the body trained on different days and ingested a placebo after exercise (17). There were two other groups, creatine and placebo, which did not have differences of supplementation between limbs (17). To control for hormonal changes, all women in the study were eumenorrheic during the study (17). They did not find strength differences between limbs supplemented with creatine and limbs on the placebo which may be due to strength increases relying on an increase in neuromuscular improvements (17). Creatine supplementation and resistance training increased lean tissue mass in men but not women (17). Men may be able to restrict muscle catabolism with creatine supplementation while women may not (17).
Supplementation increased strength more than the placebo in both men and women, suggesting that creatine supplementation enhances exercise performance in both genders but only influences body composition in men (17). The relative increases in strength and muscle size were similar in between genders; however, men increased bone mineral content while women did not (17). This may be due to an increase in hormonal responsiveness in men (17). Mihic et al. (2000) found an increase in total body mass and fat free mass in men and women after acute supplementation, but men’s lean body mass was significantly higher after supplementation when compared to women \( (p < 0.05) \) (32). Even when total body mass and fat free mass are put into relative terms, men still had greater increases than women (32). This may be due to anti-catabolic effects on certain proteins in men and not women (17).

Yet, other researchers have found that creatine has no effect on women in regards to training volume, muscle mass, and lean body mass (24). Ferguson and Syrotuik (2006) recruited 26 women with at least a year of resistance training experience and assessed their bone mineral content, bone mineral density, lean tissue, fat mass, and strength (24). Urine samples were collected periodically to measure the concentrations of excreted creatine and creatinine (24). The researchers found that creatine supplementation combined with a ten week resistance training program did not increase muscle mass, lean body mass, training volume, or strength any more than the placebo (24).

One possible reason for a difference in effect on men and women is that women, in general, have a smaller muscle cross sectional area and about 10 percent higher total creatine content compared to men which may result in less uptake of the creatine supplemented (25). A higher starting total creatine store is linked to a lower uptake of supplemented creatine into skeletal muscle (27). Because five percent of creatine is stored in the brain, liver, kidney, and
testes, this may play a role in gender differences with creatine supplementation (34). The creatine transporter, Crea T2, is found in the testes which may also contribute to sex differences (39). Perhaps men have an increased sensitivity to creatine supplementation when compared to women. Testosterone contributes to protein synthesis and muscle contractile protein which build muscle hypertrophy (27). Men have higher levels of testosterone than women, so this may explain how men are able to build more lean body mass than women. Research in this area involving women is sparse and in need of additional investigation.

**Responders and Non-Responders**

Not all individuals respond to creatine supplementation in the same way. There are several studies with different findings on the effects of creatine which may be attributed to the large differences between the effects that it has on specific individuals. About 20 to 30 percent of individuals who consume oral creatine do not increase the cellular uptake of creatine (27). This may be attributed to an insufficient creatine load (24). Individuals that respond positively to creatine supplementation typically have a lower initial volume of total muscle creatine when compared to those who are not affected by creatine supplements (27). These individuals also have a higher percentage of type II fibers which provides them with a greater potential to increase performance (27). Those with higher amounts of fast twitch fibers and larger cross sectional area have a greater uptake of creatine (25). The most responsive participants are those who have low amounts of intramuscular creatine which may be due to a diet not containing meat (4). Antonio and Ciccone (2013) found that 16 to 21% of their participants were non-responders in regards to an increase in muscle strength and fat free mass with creatine supplementation (4).
Side Effects

Creatine supplementation has not been found to have any serious negative side effects in studies done for up to five years (26). The only negative side effects found are rare and occasional gastrointestinal upset during the loading phase (26). Any excess creatine ingested will be excreted through the kidneys. Therefore, those who have renal problems should be advised on their intake of creatine. Other long term studies have found no negative side effects in participants (17). Acute creatine supplementation of 20 grams per day did not affect blood pressure, plasma creatinine, plasma CK activity, or renal function (32). Therefore, creatine supplementation is considered safe with no serious side effects (32).

Conclusion

There are several theories as to how creatine supplementation elicits its ergogenic response during training including: supplementation increases the total creatine stores to supply ATP production (13, 15, 21, 27), supplementation increases in the buffering of hydrogen ions (9, 19, 27, 33), supplementation promotes hypertrophy of skeletal muscle due to enhanced protein synthesis (2, 30), supplementation influences hormonal responses to exercises which increases muscle hypertrophy (36), supplementation increases blood flow to the brain which lead to feelings of focus and energy (42), and supplementation increases the speed of detachment of the actomyosin bridges through the assistance of creatine in the reuptake of calcium into the sarcoplasmic reticulum associated with force production (9). There is a consensus that creatine supplementation in men enhances performance during resistance training in some form, whether it be by an increase in training volume (1, 15, 21, 36, 40, 45), an increase in strength (1, 3, 5, 10, 17, 26), an increase in power (9, 45), an increase in lean body mass (1, 10, 15, 17, 26, 45), or an increase in anaerobic work capacity (22, 23). However, the effects that creatine supplementation
EFFECTS OF A SINGLE DOSAGE OF CREATINE HYDROCHLORIDE ON TRAINING

has on women are much less clear. Some researchers have found that creatine supplementation produces an ergogenic effect in women (1, 15, 22, 23), but others have found that creatine supplementation does not benefit women to the same degree as men (17, 32). With a lack of research on women and creatine hydrochloride, there is a need for further research into creatine hydrochloride’s effect on men versus women during resistance training.
CHAPTER III. METHODS

Participants

Eighteen men and 17 women who were resistance trained and college-aged (18 to 30 years old) were recruited to participate in this study. To be included, the participants for this study must have had at least two years of resistance training experience and been weight training regularly (approximately two times per week for about 45 minutes at a high intensity). Participants were required to be healthy, without any orthopedic problems and injury free. To ensure that the participants were qualified for this study, they completed a medical history questionnaire (Appendix A). For participation, volunteers were required to be identified as low risk according to ACSM’s Risk Factor Stratification (Appendix B); those identified as moderate or high risk were excluded. Participants were recruited from the campus of Bowling Green State University, at the student recreation center, and by word of mouth.

During the study, participants were instructed to abstain from any exercises that would be tested (bench press and leg press) and to not participate in any other strenuous resistance exercise. They were asked not to ingest any form of creatine for at least one month prior to participation. In addition, information was collected on any supplements taken by participants in the last three months (Supplement History Questionnaire, Appendix C). During the study, participants were asked to not ingest any pre-workout supplements or other ergogenic aids and to refrain from caffeine for at least four hours prior to testing. To make the creatine and placebo groups as similar as possible, participants completed a Physical Activity Recall (Appendix D). Participants who performed similar workloads (sets, reps, and loads) were divided into opposing groups. The first participant for each sex was randomly assigned to either the creatine or placebo
EFFECTS OF A SINGLE DOSAGE OF CREATINE HYDROCHLORIDE ON TRAINING  

Following the first participant for each sex, participants were then counterbalanced among the groups (i.e., creatine and placebo).

One woman in the creatine group and one woman in the placebo group indicated that they had ingested creatine more than three months prior to this study. Five men in the creatine group and five men in the placebo group indicated that they had ingested creatine more than three months prior to this study. There were no significant differences between groups (Table 1). In the control trial, there were no significant differences in the TTV between the creatine group and placebo group ($p > 0.05$). There were no reports of gastrointestinal upset or cramping after supplementation.

Table 1. Participant Characteristics (mean ± standard deviation)

<table>
<thead>
<tr>
<th></th>
<th>Women</th>
<th>Men</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Creatine $n = 8$</td>
<td>Placebo $n = 9$</td>
</tr>
<tr>
<td>Age (years)</td>
<td>20.8 ± 1.7</td>
<td>21.6 ± 1.9</td>
</tr>
<tr>
<td>Height (inches)</td>
<td>65.9 ± 2.7</td>
<td>64.7 ± 2.1</td>
</tr>
<tr>
<td>Weight (kilograms)</td>
<td>69.6 ± 14.1</td>
<td>67.7 ± 6.7</td>
</tr>
<tr>
<td>Body Fat (%)</td>
<td>26.6 ± 9.2</td>
<td>28.1 ± 4.4</td>
</tr>
<tr>
<td>RT Experience (years)</td>
<td>7.5 ± 4.6</td>
<td>9.0 ± 3.5</td>
</tr>
<tr>
<td></td>
<td>Creatine $n = 9$</td>
<td>Placebo $n = 9$</td>
</tr>
<tr>
<td>Age (years)</td>
<td>22.1 ± 0.8</td>
<td>21.1 ± 1.8</td>
</tr>
<tr>
<td>Height (inches)</td>
<td>71.1 ± 1.8</td>
<td>71.0 ± 1.8</td>
</tr>
<tr>
<td>Weight (kilograms)</td>
<td>92.6 ± 23.4</td>
<td>87.8 ± 12.9</td>
</tr>
<tr>
<td>Body Fat (%)</td>
<td>15.4 ± 7.7</td>
<td>15.3 ± 6.2</td>
</tr>
<tr>
<td>RT Experience (years)</td>
<td>7.6 ± 2.3</td>
<td>6.8 ± 3.7</td>
</tr>
</tbody>
</table>

RT = Resistance Training

**Body Composition Measures**

Body composition (percent fat, lean body mass, and total body water) were assessed using bioelectrical impedance analysis (InBody 230, Biospace Inc., Cerritos, CA). This machine had four electrode contact points, two for the feet and two for the hands. The participant stood barefoot on the device while holding onto handles as a small electrical current passed through the
body. Lean body mass and total body water were determined based on the total resistance to the electrical current faced while passing through the body (26). Participants were instructed to fast with no food or water for two to four hours, avoid physical activity for four hours, and urinate within 30 minutes prior to bioelectrical impedance analysis. A verbal confirmation of these pre-test precautions was done upon participant arrival.

**Strength Measures**

This study examined TTV for free weight barbell bench press and incline leg press. To determine TTV, a five set repeat protocol with 70 percent of the participant’s 1RM was used. TTV was defined as the number of full repetitions completed throughout five sets. This protocol was used by Ferguson and Syrotuik (24) and produced reliable results with a test-retest reliability above 0.98. To obtain 70 percent of each participant’s 1RM, a 1RM test was completed.

Participant’s 1RM was determined for a free weight barbell bench press and an incline leg press. The incline leg press was performed on a machine (Hammer Strength Linear Leg Press, Life Fitness, Rosemont, IL). Participants sat at a 45 degree angle with their back flat against the chair. The 1RM protocol for incline leg press required participants to begin with their legs fully extended with feet placed hip width apart. The participant lowered the load until the knee joint was at approximately 90 degrees of flexion and then pressed to full extension. Each of these counted as one full repetition.

The 1RM protocol for the free weight barbell bench press required participants to grip the bar at 150 percent of their measured biacromial breadth. This was determined by measuring the distance from the left acromion to the right acromion using an anthropometer (Lafayette Instrument Company, Lafayette, IN). This distance was then multiplied by 1.5 to determine grip width. A standard tape measure was used to measure this distance for each participant to grip the
barbell. Participants lay flat on the bench with their feet flat on the ground. Following the liftoff (with the assistance of a spotter if needed), the participant lowered the bar to the chest. Without bouncing the bar off the chest, the participant then pressed the bar vertically to full extension while maintaining the five points of contact with the bench and floor (head, shoulders, back, buttocks, and both feet) (24). All 1RM$s were reported in five pound increments.

Each participant’s 1RM was multiplied by 70 percent (0.7) to find the weight to use for the five set repeat protocol for the respective exercise in the baseline and experimental trials. This value was rounded to the nearest five pound increment. If the calculated value was 2.5 or higher, the amount was rounded up, if less than 2.5 the value was rounded down. The five set repeat protocol was adapted from Ferguson and Syrotuik (24). TTV was determined by adding the total number of repetitions completed throughout five sets for each five set repeat protocol test (24).

**Treatment**

This study used 0.033 grams per kilogram of the participant’s body weight of creatine hydrochloride (18) (Con-Cret Creatine HCl) from Promera Sports. This was the amount recommended by the manufacturer. Using this product increased the ecological validity of this study due to its convenience and availability for the general public to purchase and use. This study sought to determine if a common supplement on the market for the general population was effective and beneficial for increasing training volume.

Creatine hydrochloride was mixed into a 20 ounce bottle of Gatorade G2. Each participant was able to choose the flavor that he or she would drink. The purpose of the Gatorade G2 was to mask any differences in taste between the placebo and the supplement. It also served to provide a carbohydrate, purported to increase the uptake of the creatine into skeletal muscle.
The placebo group received a 20 ounce bottle of Gatorade G2. The placebo or the given amount of supplement was measured and mixed with the Gatorade G2 by the same unblinded researcher for consistency and was provided to the participants by a blinded researcher. This study followed the product’s recommendations for timing of ingestion. Each participant received their given mixture on the final visit and ingested it 30 minutes prior to testing. Participants were informed on whether they received the supplement or the placebo by email after the study was completed.

**Procedures**

This was a double-blind, placebo controlled study. Participants were asked to come in for assessment on four separate sessions, each separated by 48 hours. All strength testing and experimental trials were completed at BGSU’s Student Recreation Center. Paperwork, anthropometric measures, and body composition analysis were performed in BGSU’s Exercise Physiology Laboratory. Participants were asked to write down the food and drink that they ingested the first night before strength testing. Participants were instructed to consume as similar a meal as possible on the night before all testing and experimental trial days. Participants were asked to abstain from food or drink, other than water, for two hours prior to testing. The order of testing (bench press then leg press or leg press then bench press) was randomly assigned to the first participant of each sex and each group (i.e., creatine and placebo). The testing order was then counterbalanced within group and sex. This order assignment was kept the same for each participant throughout the study. Testing was always conducted between the hours of 6:00 and 11:00 AM by the same tester.

**Paperwork, Body Composition, and Anthropometric Measures**

For the first session, participants were informed about the details and requirements of the study and signed an informed consent. Participants completed the Medical History Questionnaire
(Appendix A), ACSM’s Risk Stratification form (Appendix B), the Supplement History Form (Appendix C), and the Physical Activity Recall (Appendix D). Resting blood pressure was taken by auscultation using a blood pressure cuff and a sphygmomanometer. Resting heart rate was taken by palpating the radial artery for one minute. Biacromial breadth was measured posteriorly with participants standing upright with the arms relaxed at their sides in anatomical position. Body composition was measured using bioelectrical impedance analysis. Visit one took approximately 30 minutes to complete.

**Baseline Measures**

For the second session, following a warm up, participants completed a 1RM test for bench press and a 1RM test for incline leg press. The warm up consisted of five minutes on a cycle, dynamic stretching of the chest and legs, and two submaximal progressively heavier sets of ten and three repetitions of the given exercise (24). Participants cycled (Lifecycle Exercise Bike, Life Fitness, Rosemont, IL) on a stationary cycle at a low to moderate intensity to warm up muscles without tiring (rating of perceived exertion rating between two and five). Dynamic stretches included: 10 vertical arm swings, 10 arm hugs, 10 arm circles forward, 10 arm circles backward, 10 bodyweight squats, five lunges on each leg, 10 waiter’s bows, and 10 standing calf raises. The first warm up set of 10 repetitions used a submaximal load determined by asking the participant to choose a weight of approximately 25 percent of their 1RM. The second set of three repetitions was adjusted to approximately 60 percent of their predicted 1RM.

The participant’s 1RM was determined within four attempts with three minutes of rest between each attempt. The participant was given three attempts to lift each load successfully. The 1RM score was recorded as the heaviest amount of weight successfully lifted (3). A five minute rest period was given between 1RM exercise tests; then the second 1RM was determined
following the same procedures. Following the 1RM tests, participants completed a familiarization phase of the five set repeat protocol for both incline leg press and bench press by performing one set of each exercise with 70 percent of their given 1RM. Visit two took approximately 60 minutes to complete all testing.

**Control Trial**

Forty-eight hours after 1RM testing, participants reported for their third session. Participants ingested 20 ounces of water 30 minutes prior to the five set repeat protocol. Participants completed the same dynamic stretching and cycling warm up as the second session and then performed the five set repeat protocol for both bench press and incline leg press. The five set repeat protocol had the same form requirements as the 1RM tests. Participants used 70 percent of their 1RM to perform as many repetitions as possible at a consistent velocity. Velocity was controlled utilizing a metronome set at 60 beats per minute. Participants were instructed that they must complete a full repetition with the pace of the metronome. Once the participant was unable to keep up with the pace of the metronome for more than one repetition, he or she was instructed to rack the weight, completing the set. This was done five times (i.e., complete five sets) with a 75 second rest period between sets. Participants received five minutes of rest between the bench press and incline leg press five set protocol tests. The number of full repetitions completed with proper form was recorded for each set. Rating of perceived exertion (RPE) (Appendix E) was assessed after each set. Session RPE was assessed 15 minutes after completion of testing (Appendix E). Visit three took approximately 45 minutes to complete.

**Experimental Trial**

Forty-eight hours after the baseline trial, participants came in for their fourth session. Participants received and ingested either the placebo or creatine mixture and performed the same
warm up as the last two sessions. Thirty minutes after ingesting the mixture, participants completed the same five set repeat protocol at a consistent velocity and tempo for bench press and incline leg press as the control trial. The number of complete repetitions performed with proper form at the appropriate velocity was recorded for each set. RPE and perceived readiness were assessed after each set. Session RPE was assessed 15 minutes after completion of testing, and participants were asked if they experienced any gastrointestinal upset or cramping. Visit four took approximately 60 minutes to complete all testing.

Table 2. Design

<table>
<thead>
<tr>
<th>Sessions</th>
<th>Men (18) and Women (17) 20 oz Gatorade G2 or 20 oz Gatorade G2 + 0.033 g/kg Cr</th>
</tr>
</thead>
</table>
| Visit 1 (Paperwork, Anthropometrics, and Body Composition) | -Fill out paperwork  
-Anthropometric measures  
-Body composition analysis |
| Visit 2 (Baseline Measures) | -1RM bench press and incline leg press  
-Familiarization with 5 set protocol bench press and incline leg press |
| Visit 3 (Control Trial) | -5 set protocol bench press and incline leg press without supplement or placebo |
| Visit 4 (Experimental Trial) | -Ingest supplement or placebo  
-5 set protocol bench press and incline leg press |

Cr = Creatine Hydrochloride

**Statistical Analysis**

Results were compared between control and experimental trials for TTV and session RPE for bench press and incline leg press. Data analysis was performed using Statistical Package for the Social Sciences (Version 20.0, IBM Inc., Chicago, IL) to complete two independent t-tests and a multivariate general linear model. This involved a comparison of the change between the baseline and experimental trials, a comparison between groups (creatine and placebo), and a comparison between the men and women. Alpha was set at $p \leq 0.05$ value.
CHAPTER IV. RESULTS

Leg Press

Women in the creatine group and the placebo group significantly increased TTV from the control trial to the experimental trial (i.e., difference score) by 32.7% (creatine) and 21.8% (placebo) in the leg press ($p = 0.004, p = 0.02$, respectively) (Table 3). Men in both groups also significantly increased their TTV by 12.9% (creatine) and 21.9% (placebo) in the leg press ($p = 0.03, p = 0.003$, respectively) (Table 3). The difference in TTV between the control and experimental trials in the leg press was not significantly different between the creatine and placebo groups for women or men ($p = 0.23, p = 0.24$, respectively).

During the leg press, women in the creatine group had a significantly higher difference score from the control to the experimental trial than men in the creatine group ($p = 0.01$) (Table 3). There was no significant difference between men’s and women’s difference score in the placebo groups ($p = 0.7$) (Table 3).

Bench Press

There was no significant difference in TTV from the control trial to the experimental trial for women in the creatine group (4.8% difference) or the placebo group (4.6% difference) in the bench press ($p = 0.2, p = 0.21$) (Table 4). There was no significant difference in TTV from the control to the experimental trial for men in the creatine group (4.1% difference) or the placebo group (2.0% difference) during the bench press ($p = 0.12, p = 0.68$) (Table 4). The difference in TTV between the control and experimental trials in the bench press was not significantly different between the creatine and placebo groups for women or men ($p = 0.86, p = 0.74$).

During the bench press there was no significant difference between men’s and women’s difference score in the creatine groups ($p = 0.69$) or the placebo groups ($p = 0.66$) (Table 4).
**Session RPE**

Neither group of women had a significant difference in session RPE (Table 5). Men in the placebo group had a significantly lower session RPE in the experimental trial than the control trial ($p = 0.01$) (Table 5). Men in the creatine group had a significantly higher session RPE in the experimental trial than the control trial ($p = 0.05$) (Table 5).

**Table 3. Average TTV During Leg Press Trials (mean ± standard deviation)**

<table>
<thead>
<tr>
<th></th>
<th>Women</th>
<th>Men</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Creatine</td>
<td>Placebo</td>
</tr>
<tr>
<td>Control TTV</td>
<td>130.9 ± 64.0</td>
<td>119.3 ± 63.3</td>
</tr>
<tr>
<td>(reps)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Experimental</td>
<td>173.6 ± 70.2 *</td>
<td>145.3 ± 86.8*</td>
</tr>
<tr>
<td>TTV (reps)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Difference Score</td>
<td>42.8 ± 28.1 +</td>
<td>26.0 ± 27.5</td>
</tr>
<tr>
<td>(reps)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

TTV = Total Training Volume (total repetitions throughout five sets)
Difference Score = TTV Experimental – TTV Control
* $p \leq 0.05$ from control
+ $p \leq 0.05$ between sexes

**Table 4. Average TTV During Bench Press Trials (mean ± standard deviation)**

<table>
<thead>
<tr>
<th></th>
<th>Women</th>
<th>Men</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Creatine</td>
<td>Placebo</td>
</tr>
<tr>
<td>Control TTV</td>
<td>44.1 ± 9.4</td>
<td>38.7 ± 5.7</td>
</tr>
<tr>
<td>(reps)</td>
<td></td>
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</tr>
<tr>
<td>Experimental</td>
<td>46.3 ± 7.3</td>
<td>40.4 ± 7.4</td>
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<tr>
<td>TTV (reps)</td>
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<tr>
<td>Difference Score</td>
<td>2.1 ± 4.3</td>
<td>1.8 ± 3.9</td>
</tr>
<tr>
<td>(reps)</td>
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<td></td>
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</tbody>
</table>

TTV = Total Training Volume (total repetitions throughout five sets)
Difference Score = TTV Experimental – TTV Control
No significant differences
Table 5. Session RPE (mean ± standard deviation)

<table>
<thead>
<tr>
<th></th>
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<th>Men</th>
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<tr>
<td></td>
<td>Creatine</td>
<td>Placebo</td>
</tr>
<tr>
<td>Control</td>
<td>7.6 ± 0.9</td>
<td>6.8 ± 0.4</td>
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<tr>
<td>Experimental</td>
<td>8.0 ± 0.5</td>
<td>6.8 ± 1.0</td>
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</table>

Session RPE = Session Rate of Perceived Exertion
* $p \leq 0.05$ from control
CHAPTER V. DISCUSSION

This was the first study to examine the effects of ingesting a single dose of creatine hydrochloride 30 minutes prior to exercise on TTV. The second purpose of this study was to determine if creatine hydrochloride affects men and women differently in regards to TTV. When the creatine and placebo groups were compared, ingestion of creatine hydrochloride did not significantly increase TTV during either the leg press or the bench press. Women in the creatine group had a significantly greater difference in TTV than men in the creatine group during the leg press ($p = 0.01$). However, ingestion of creatine hydrochloride did not result in significant differences in TTV between sexes during the bench press. There are several hypotheses for why participants did not experience a significant increase in TTV following creatine supplementation, including time between ingestion and exercise and supplement dosage.

Supplementation

While findings from this study did not show an impact of creatine hydrochloride on TTV, previous researchers have implemented longer durations and higher dosages of creatine monohydrate to demonstrate that supplementation can significantly increase TTV (1, 15, 21, 36, 40, 45). It has been purported that creatine hydrochloride can be metabolized quickly and ingested in smaller doses without a loading phase like creatine monohydrate an produce an ergogenic effect (16, 20). However, the current findings did not support this. Most researchers that have found an ergogenic effect with creatine supplementation have tested a loading phase with creatine monohydrate which lasts from two days to an entire week (5, 23). It has been observed that the longer the duration that individuals supplement creatine monohydrate, the more their total creatine stores increase (to a certain extent) (33). Creatine hydrochloride may need to be ingested in multiple doses prior to exercise to produce an ergogenic effect on TTV. In
addition, it may be that individuals need longer than 30 minutes to allow complete gastric emptying of creatine hydrochloride.

Many of the researchers who found that creatine monohydrate supplementation increased TTV implemented a higher dosage (usually around 20 grams per day) than this study which used an average of 2.6 grams of creatine hydrochloride (the manufacturer’s recommended amount) (5, 22, 27, 30, 32, 36). It was hypothesized that creatine hydrochloride could be an effective ergogenic aid in small dosages that might not have been sufficient with creatine monohydrate (16, 20). However, the current findings are similar to those of Ferguson and Syrotuik, whose participants ingested a similar dosage of creatine monohydrate (0.03 grams per kilogram of bodyweight) for 10 weeks (24) and demonstrated no increase in TTV. These authors noted that their results may have been attributed to an insufficient creatine load to produce an ergogenic effect (24). In this study, 0.033 grams per kilogram of body weight of creatine hydrochloride was not an effective dosage to significantly increase in TTV.

**Creatine and Total Training Volume**

Even though these results indicate that a single dosage of creatine hydrochloride supplementation does not improve TTV, it is important to note that the variability between participants was quite large, particularly for the leg press, which may have made it more difficult to establish significance (Table 3). The women in the creatine group had an average difference in TTV between the control and experimental trials that was 60% greater than the difference for those in the placebo group (42.6 repetitions compared to 26.0 repetitions during the leg press). With this information, it may be of interest to examine individual data to determine if the recommended dose was effective in some individuals.
It has been reported that some individuals, typically those with lower starting creatine stores, are more responsive to the ergogenic effect of creatine than others (3, 27). Approximately 20 to 30 percent of individuals who consume oral creatine do not increase the cellular uptake of creatine (27). These non-responders typically have a high creatine content prior to supplementation, so the excess creatine is simply excreted through the kidneys (27). Those who consume high amounts of meat in their diet typically have a higher starting intramuscular creatine content (3). Further, Antonio and Ciccone found that 16 to 21% of their participants were non-responders to creatine supplementation (3). Therefore, responsiveness to supplementation may have been a factor to the large variabilities seen in the current study.

**Upper Body Compared to Lower Body Exercise**

Participants performed more repetitions during the leg press compared to the bench press, and TTV significantly increased for all groups during the leg press from the control trial to the experimental trial. This demonstrates that the muscles involved in the leg press were capable of performing more absolute work than the muscles involved in the bench press. The muscles of the lower body are typically more oxidative than the muscles of the upper body (6) which may explain why participants were able to achieve more repetitions during the leg press than the bench press.

The large difference in repetitions performed between trials during the leg press (difference score of 26.9 repetitions average for the creatine group and 23.8 repetitions average for the placebo group) compared to bench press (difference score of 1.8 repetitions for the creatine group and 1.3 repetitions average for placebo group) may be attributed to reaching true failure during the bench press trials. Participants were able to rack their own weight at the end of each set during the leg press which seemed to deter some participants from reaching complete
failure. However, during the bench press nearly each set for every participant resulted in a failed repetition. Another trend noticed by the researcher was the competitive nature of these resistance trained participants, many of whom stated that they wanted to perform better than they did during the control trial. Even though there was a large attempt to control for these factors, they may have contributed to the substantial change in the TTV from the control to the experimental trial during the leg press. These factors may explain why almost every participant was able to increase TTV of the leg press by such a great amount in the experimental trial. Thus, the bench press may be a more reliable exercise than the leg press to demonstrate the true effect of creatine supplementation.

**Men Compared to Women**

Creatine monohydrate supplementation by itself has been shown to increase TTV in men (21, 36, 45). Researchers that compared men and women have found that creatine monohydrate supplementation combined with resistance training increased strength in both sexes (17). It has been observed that creatine monohydrate supplementation alone increased lean body mass in men but not women (32). Other researchers have found that TTV increased in women who supplemented with creatine monohydrate and performed a resistance training program (1, 15). In this study it was hypothesized that women, who have a naturally higher starting total creatine content (25), would be less responsive to creatine supplementation than men, but the opposite was observed. Women in the creatine group had a significantly higher difference in TTV during the leg press than the men in the creatine group, which implies that creatine hydrochloride may have had a greater impact on women than men. Women have been shown to be more fatigue resistant than men (6, 37), which may be another explanation to why women had a higher TTV.
than men. The current findings suggest that some women may benefit from creatine supplementation.

**Limitations**

All groups had a significant change in their TTV from the control trial to the experimental trial during the leg press. All participants in this study were familiar with both exercises and performed them on a regular basis prior to the study. Further, all underwent a familiarization trial with the protocol prior to the control trial to reduce the potential of a learning effect. Because the experimental trial was the third time performing the five set repeat protocol, participants may have become more accustomed to the exercise protocol and performing repetitions until failure. During the leg press, both the placebo and the creatine groups demonstrated an increase in TTV between the control and experimental trials which may have significantly impacted these results. Counterbalancing participants between the control and experimental trials may have attenuated this.

**Future Directions**

Future research needs to be conducted on the efficacy of creatine hydrochloride. There is a need for a direct comparison between the more commonly studied creatine monohydrate and creatine hydrochloride. Future research may consider different dosages of creatine hydrochloride and examine a longer duration from ingestion to beginning exercise. Other directions for future research may utilize a higher percentage of the participant’s 1RM, particularly during the leg press trials, to reduce variability.

**Conclusion**

This study sought ecological validity to examine if a single dosage of creatine hydrochloride, ingested according to the manufacturer’s recommended dosage and timing, would
increase TTV more than a placebo. We did not find that a single dosage of creatine hydrochloride had a significant effect on increasing TTV. However, we did find that there was a significant difference between men and women’s TTV during a leg press exercise, with women in the creatine group having a greater difference in TTV than men in the creatine group. The efficacy of creatine hydrochloride remains unclear, but the results of this study suggest that women may benefit from a single dosage of creatine hydrochloride supplementation.
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Improved time to exhaustion following ingestion of the energy drink Amino Impact.  

APPENDIX A. MEDICAL HISTORY QUESTIONNAIRE

All information given is personal and confidential. It will enable us to better understand you and your health and fitness habits. In addition, we will use this information to classify your health status according to the American College of Sport Medicine (ACSM) recommendations for risk stratification (ACSM, 2014). Please let us know if and when you have changed your medication (dose & type), diet, exercise or sleeping habits within the past 24 or 48 hours. It is very important for you to provide us with this information.

NAME____________________________ AGE____________ DATE__________

OCCUPATION_________________________________________________________________

1. *FAMILY HISTORY

Check each as it applies to a blood relative:

Heart Attack yes______ no______ unsure______
If yes, age at onset____ yrs; relation to you____________

Sudden Death yes______ no______ unsure______
If yes, age at onset____ yrs; relation to you____________

Coronary Revascularization If yes, age at onset____ yrs; relation to you____________

Father’s Age_____ Deceased_____ Age at death_____
(*Before 55 yr. in father or first-degree male relative)

Tuberculosis yes______ no______ unsure______

Stroke yes______ no______ unsure______

Asthma yes______ no______ unsure______

High Blood Pressure yes______ no______ unsure______

Circulatory Disorder yes______ no______ unsure______

Heart Disease yes______ no______ unsure______

Mother’s Age_______ Deceased_____ Age at death______
2. PERSONAL HISTORY

Check each as it applies to you:

* Age (men ≥ 45 yr; women ≥ 55 yr) yes______no______
* Current Cigarette Smoking yes______no______unsure______
  (or quit within 6 mo or exposure to environmental tobacco smoke)
* Sedentary Lifestyle yes______no______unsure______
  Not participating in at least 30 min of moderate intensity physical activity on at least 3
days/wk for at least 3 months.
* Obesity – BMI > 30 kg·m-2 yes______no______unsure______
  If yes, give value:______ kg·m-2
* Waist circum. > 40” men; 35” women: yes______no______
* High Blood Pressure yes______no______unsure______
  Systolic Blood Pressure >140mmHg or diastolic >90mmHg
  (Note: values confirmed by measures on two separate occasions)
  If yes, give value: / mmHg.
* Dyslipidemia yes______no______unsure______
  Total Serum Cholesterol >200 mg·dl-1 ; value:______ mg·dl-1
  LDL-C ≥ 130 mg·dl-1 ; value:______ mg·dl-1
  HDL-C ≤ 40 mg·dl-1 ; value:______ mg·dl-1
  On lipid lowering medication: yes______no______unsure______
* PreDiabetes yes______no______unsure______
  If yes, age of onset: _____years
Impaired fasting glucose ≥ 100; <125 mg·dl⁻¹; value:_____ mg·dl⁻¹

Impaired glucose tolerance test: yes_____ no_____

(Note: values confirmed by measures on two separate occasions)

*Negative Risk Factor: yes_____ no_____ unsure_____

HDL ≥ 60 mg·dl⁻¹; value:_____ mg·dl⁻¹

Have you ever had:

Diabetes yes____ no____ unsure____

Tuberculosis yes____ no____ unsure____

Heart Attack yes____ no____ unsure____

Angina yes____ no____ unsure____

EKG Abnormalities yes____ no____ unsure____

Asthma yes____ no____ unsure____

Emphysema yes____ no____ unsure____

Surgery yes____ no____ unsure____

Stroke yes____ no____ unsure____

Severe Illness yes____ no____ unsure____

Hospitalized yes____ no____ unsure____

Black Outs yes____ no____ unsure____

Gout yes____ no____ unsure____

Nervousness yes____ no____ unsure____

Joint Problems yes____ no____ unsure____

Allergy yes____ no____ unsure____

Convulsions yes____ no____ unsure____
Paralysis yes____ no____ unsure____

Headaches yes____ no____ unsure____

Depression yes_____ no____ unsure____

Chest Pain yes_____ no____ unsure____

Arm Pain yes_____ no____ unsure____

Shortness of Breath yes_____ no____ unsure____

Indigestion yes_____ no____ unsure____

Ulcers yes_____ no____ unsure____

Overweight yes_____ no____ unsure____

Hernia yes_____ no____ unsure____

Back Pain yes_____ no____ unsure____

Leg Cramps yes_____ no____ unsure____

Low Blood Pressure yes_____ no____ unsure____

Insomnia yes_____ no____ unsure____

For Office Use Only:

——- Sum of positive and negative *CVD risk factors* (according to Table 2.2. ACSM (2014)

NOTE: All risk factors are explained verbally to each person completing the questionnaire.
Classification according to ACSM (2014, p. 26) (check one): Low risk < 2; Moderate risk > 2; High risk (known disease)

3. MEDICAL HISTORY

Name of your physician_____________________________________________________

Date of your most recent physical examination______________________________

What did the physical examination include? ________________________________

Have you ever had an exercise EKG? Yes_______ No________
Are you presently taking any medications? (Including over-the-counter medications and/or herbs) Yes_______ No_______

List name and dosage__________________________________________________________

Have you ever taken:

Digitalis yes______ no______ unsure______

Nitroglycerin yes______ no______ unsure______

High Blood Pressure Medication yes______ no______ unsure______

Sedatives yes______ no______ unsure______

Inderal yes______ no______ unsure______

Insulin yes______ no______ unsure______

Pronestyl yes______ no______ unsure______

Vasodilators yes______ no______ unsure______

Other yes______ no______ unsure______

If yes, list medications:____________________________________________________________________________________________

4. EXERCISE HISTORY

Do you exercise? Yes______ No______ What activity_________________________________________

How long have you been exercising?_________________________________________________________

How many days do you exercise?_____________ How many minutes per day?_____________

What kinds of shoes do you work out in?_________________________________________________________

Where do you usually exercise?_____________________________________________________________

Do you monitor your pulse during your workout?_________________________________________________

5. HEALTH HISTORY

Height______ Weight______
Do you use Health Foods? Yes______ No______
List___________________________________________________

Do you take Vitamin pills? Yes______ No______
List___________________________________________________

Approximate your daily intake: Coffee_______ tea_______ coke_______ beer_______
wine_______ liquor_______

Do you smoke or use tobacco products? Yes_____ No_____
If yes, approximate your daily usage: Cigarettes_______ Cigars_______ Pipes_______
Chewing Tobacco_______

Did you ever smoke? Yes_____ No_____ How many years?_______________ Age when you quit_______

Approximate the number of hours you work per week?_______________ Vacations weeks per year_______________

Home Status: Very happy__________ Pleasant__________ Difficult__________
Problem__________

Work Status: Very happy__________ Pleasant__________ Difficult__________
Problem__________

Do you feel you are stressed? Yes_______ No_______ Unsure_______
Are you worried about your health? Yes_______ No_______ Unsure_______

6. APPROXIMATE A TYPICAL 24 HOUR DAY FOR YOU

Number of hours:
_________________________________ Work
__________________________________ TV
Relaxation/Leisure activities
Driving/Riding
Eating
Exercise
Sleep
TOTAL

Additional information from client interview to further assess health/coronary risk status:

__________________________________________
__________________________________________
__________________________________________

_____________________________ ______________________
Signature of Tester Date
APPENDIX B. ACSM RISK FACTOR STRATIFICATION

Assess your health by marking all true statements.

You have had:

___ a heart attack
___ congenital heart disease
___ heart failure
___ any heart surgery
___ cardiac arrhythmia
___ coronary angioplasty
___ known heart murmur
___ heart palpitations

You have:

___ experienced chest pain with mild exertion
___ experienced dizziness, fainting, or blackouts with mild exertion
___ experienced unusual fatigue or shortness of breath during usual activities
___ been prescribed heart medications (please indicate):

Check all that apply:

___ you are a man older than 45 years
___ you smoke
___ your blood pressure is greater than 140/90
___ you take blood pressure medication
___ you are completely physically inactive
___ you currently have bone/joint problems
___ you have had a recent injury/surgery

___ you are a diabetic or take medicine to control your blood sugar

___ you have been diagnosed with high cholesterol >200 (or HDL is less than 35 mg/dL or LDL is greater than 169 mg/dL)

___ you have a close blood relative who had a heart attack before age 55 (father/brother) or age 65 (mother/sister)

___ Other (specify) ______________________________________________

Use the following risk stratification scoring table (page 17) to sum the total number of risk factors present in your patient in determining their current level of cardiovascular disease risk.

Risk Stratification Scoring

<table>
<thead>
<tr>
<th>Positive Risk Factors</th>
<th>Defining Criteria</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Men ≥ 45 years, Women ≥ 55 years</td>
<td>+1</td>
</tr>
<tr>
<td>Family History</td>
<td>Myocardial infarction, coronary revascularization, or sudden death before 55 years of age in father of other 1st degree male relative or before 65 years of age in mother or other 1st degree female relative</td>
<td>+1</td>
</tr>
<tr>
<td>Cigarette Smoking</td>
<td>Current cigarette smoker or those who quit within the previous six months, or exposure to environmental tobacco smoke (i.e., secondhand smoke)</td>
<td>+1</td>
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<tr>
<td>Sedentary Lifestyle</td>
<td>Not participating in at least 30 minutes of moderate-intensity physical activity on at least three days/week for at least three months</td>
<td>+1</td>
</tr>
<tr>
<td>Obesity</td>
<td>Body mass index ≥30 kg/m² or waist girth &gt;102 cm (40 inches) for men &gt;88 cm (35 inches) for men</td>
<td>+1</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>Dyslipidemia Low-density lipoprotein (LDL) cholesterol</td>
<td>+1</td>
</tr>
<tr>
<td>Negative Risk Factors</td>
<td>Defining Criteria</td>
<td>Points</td>
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<tr>
<td>----------------------------</td>
<td>--------------------------------------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>High HDL Cholesterol</td>
<td>≥60 mg/dL (1.55 mmol/L)</td>
<td>-1</td>
</tr>
<tr>
<td>Prediabetes</td>
<td>Fasting plasma glucose ≥100 mg/dL (5.50 mmol/L) but &lt;126 mg/dL (6.93 mmol/L) or impaired glucose tolerance (IGT) where a two-hour oral glucose tolerance test (OGTT) value is ≥140 mg/dL (7.70 mmol/L), but &lt;200 mg/dL (11.00 mmol/L)</td>
<td>+1</td>
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</table>

Total CVD Risk Score: ___________
APPENDIX C. SUPPLEMENT HISTORY QUESTIONNAIRE

1. In the past three months, have you ingested any substances to enhance your physical performance? Yes No
   If yes, what were the names of those substances?____________________________
                                                                 ______________________________________________________________________

2. In the past three months, have you ingested any pre-workout supplements? Yes No
   If yes, what were the names of those supplements?____________________________
                                                                 ______________________________________________________________________

3. In the past three months, have you ingested creatine in any form? Yes No
   If yes, what type(s) of creatine did you ingest (monohydrate, hydrochloride, blend, etc.)____________________________
                                                                 ______________________________________________________________________

4. Are you currently ingesting any pre-workout supplements and/or creatine? Yes No
   If yes, what are the names of those supplements and/or brand of creatine?_______
                                                                 ______________________________________________________________________
APPENDIX D. PHYSICAL ACTIVITY RECALL

Please list what you did in your last workout

<table>
<thead>
<tr>
<th>EXERCISE</th>
<th>SETS</th>
<th>REPS</th>
<th>WEIGHT USED</th>
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</table>
APPENDIX E. RATING OF PERCEIVED EXERTION SCALE

The Effects of Creatine Hydrochloride on Total Training Volume in Resistance Trained Men versus Women

Dear potential participant,

I am a graduate student in the School of Human Movement, Sport and Leisure Studies at Bowling Green State University. One of the requirements to fulfill my graduate degree is to complete a thesis. I am studying the effects of a creatine supplement on total training volume in resistance trained men and women. This study will benefit athletes and you by giving us information about whether a single dose of creatine can help improve your workout. You are invited to participate in my study.

If you agree to participate, you must:

- Be 18 years of age or older
- Have resistance training experience of at least two years
- Be resistance training regularly (about two times per week for about 45 minutes at a high intensity)
- Be healthy without any joint problems and injury free
- Not consume any form of a creatine supplement at least one month before participation
- Not consume any workout supplements throughout the study
- Not consume caffeine for at least four hours before each testing session
- Not eat or drink anything but water for two hours before each testing session
- Not perform any high intensity resistance exercise throughout the study (seven days total)
- Be available for testing for four separate sessions, each being separated by a 48 hour break
- Be able to perform a one repetition maximal effort bench press and leg press
- Be able to perform as many repetitions as possible throughout five sets of 70 percent of your one repetition maximum at a controlled tempo

If you meet the above requirements and agree to participate, I ask you to do the following:

- For the first session, report to the Exercise Physiology Laboratory in Eppler South for orientation, sign the informed consent, sign a waiver for BGSU’s Student Recreation Center (only if you are not a current member there), complete the medical history and supplement history questionnaires, have resting blood pressure and resting heart rate taken, and have body composition and shoulder width measured. This should take about 30 minutes to complete.
- For the second session, report to the BGSU Student Recreation Center to complete a one repetition maximum test on bench press and leg press. This should take about 60 minutes to complete.
- For the third session, report to the BGSU Student Recreation Center to complete a five set repeat protocol using 70 percent of your one repetition maximum for bench press and leg press. You will be asked to rate how difficult you perceive the tests to be and how prepared you are for another set. This should take about 45 minutes to complete.
• For the fourth session, report to the BGSU Student Recreation Center to consume either creatine or a placebo and again perform the five set repeat protocol using 70 percent of your one repetition maximum for bench press and leg press. This should take about 60 minutes to complete.

Risks: Since you already weight train regularly, what I am asking you to do is no riskier than what you experience daily. There is a chance of joint or muscle injury while performing the tasks which will be minimized by having you warm up prior to testing. There should be no additional risks to participating in my study beyond fatigue and muscle soreness experienced after performing the exercises. There will be spotters at all times minimizing any risk of injury. As with taking any supplement there are minimal risks. There is a small chance that you may experience some stomach upset from ingesting creatine.

Confidentiality: I will assign a coded participant number which will be used in place of names for all data collection, analysis, and reporting. All data will be stored on a password protected device. All informed consent documents will be stored in a locked room. All reports will remain confidential.

Voluntary Nature: Participation in this study is completely voluntary and you may stop at any time during any of the testing sessions. Deciding to participate or not participate in this study will not impact any relationship with Bowling Green State University.

Contact Information: If you have any questions about this study, please ask me at any time. You can contact me at: Emily Reuland (emilyr@bgsu.edu or 630-767-0922). You can also contact my advisor: Dr. Amy Morgan (amorgan@bgsu.edu or 419-372-3587). For questions regarding your rights as a participant, please contact the Human Subjects Review Board (HSRB@bgsu.edu or 419-372-7716).

I have been informed of the purposes, procedures, risks and benefits of this study. I volunteer to participate in this study, and I have been informed that I can quit at any time.

____________________________________________ ___________________
Participant’s Signature  Date

____________________________________________
Participant’s Name Printed
APPENDIX G. HSRB LETTER

DATE: August 31, 2015
TO: Emily Reuland
FROM: Bowling Green State University Human Subjects Review Board

PROJECT TITLE: [765569-3] The Effects of a Single Dosage of Creatine Hydrochloride on Total Training Volume in Resistance Trained Men versus Women

SUBMISSION TYPE: Revision
ACTION: APPROVED
APPROVAL DATE: August 31, 2015
EXPIRATION DATE: August 20, 2016
REVIEW TYPE: Expedited Review
REVIEW CATEGORY: Full Board

Thank you for your submission of Revision materials for this project. The Bowling Green State University Human Subjects Review Board has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a project design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

The final approved version of the consent document(s) is available as a published Board Document in the Review Details page. You must use the approved version of the consent document when obtaining consent from participants. Informed consent must continue throughout the project via a dialogue between the researcher and research participant. Federal regulations require that each participant receives a copy of the consent document.

Please note that you are responsible to conduct the study as approved by the HSRB. If you seek to make any changes in your project activities or procedures, those modifications must be approved by this committee prior to initiation. Please use the modification request form for this procedure.
You have been approved to enroll 50 participants. If you wish to enroll additional participants you must seek approval from the HSRB.

All UNANTICIPATED PROBLEMS involving risks to subjects or others and SERIOUS and UNEXPECTED adverse events must be reported promptly to this office. All NON-COMPLIANCE issues or COMPLAINTS regarding this project must also be reported promptly to this office.

This approval expires on August 20, 2016. You will receive a continuing review notice before your project expires. If you wish to continue your work after the expiration date, your documentation for continuing review must be received with sufficient time for review and continued approval before the expiration date.

Good luck with your work. If you have any questions, please contact the Office of Research Compliance at 419-372-7716 or hsr@bgsu.edu. Please include your project title and reference number in all correspondence regarding this project.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within Bowling Green State University Human Subjects Review Board's records.