

12-2011

Effect of Pseudoephedrine on 800-Meter Run Times of NCAA Division I Women Athletes

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EFFECT OF PSEUDOEPHEDRINE ON 800-METER RUN TIMES
OF NCAA DIVISION 1 WOMEN ATHLETES

by

Caroline Berry

A thesis submitted in partial fulfillment
of the requirements for the degree

of

MASTER OF SCIENCE

in

Health and Human Movement

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2011

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ABSTRACT

Effect of Pseudoephedrine on 800-Meter Run Times of
NCAA Division I Women Athletes

by

Caroline Berry, Master of Science

Utah State University, 2011

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Department: Health, Physical Education and Recreation

Pseudoephedrine is an over-the-counter drug commonly used as a decongestant, but also thought to have ergogenic effects. The World Anti-Doping Agency (WADA) has prohibited large doses ($> 150 \mu\text{g}\cdot\text{ml}^{-1}$) of pseudoephedrine, while the National College Athletic Association (NCAA) does not include it on the banned substance list. The purpose of this study was to examine the effect of body weight dosing of pseudoephedrine on 800-m run times of NCAA female runners. Fifteen NCAA female track runners volunteered to participate in the randomized, double blind, crossover design. In trials that were a week apart, participants were given both $2.5 \text{ mg}\cdot\text{kg}^{-1}$ pseudoephedrine and a placebo. Ninety minutes post-ingestion, participants completed an 800-m individual time trial on an indoor track. Finishing time was recorded with an automated video timing device. Heart rate and anxiety state scores were recorded immediately after each trial. Finally, a urine sample was taken from 5 participants about 2 hr post-ingestion. Placebo and pseudoephedrine running times were compared using a

paired t test. Heart rate and anxiety state scores were also compared using a paired t test. Fourteen runners completed both trials and one was an outlier, giving thirteen participants used for statistical analysis. Despite being dosed ($144 \text{ mg} \pm 17 \text{ mg}$) well above normal therapeutic levels, there was no significant difference ($p = 0.92$) in 800-m times between the placebo ($2:39.4 \pm 9.6$) and pseudoephedrine ($2:39.4 \pm 9.6$) trials, in post-exercise heart rate ($p = 0.635$, pseudoephedrine = $177.9 \pm 14.5 \text{ beats}\cdot\text{min}^{-1}$, placebo = $178.4 \pm 18.5 \text{ beats}\cdot\text{min}^{-1}$), or in anxiety state levels ($p = 0.650$, pseudoephedrine = 38.4 ± 11.6 , placebo = 38.1 ± 8.8). A $2.5 \text{ mg}\cdot\text{kg}^{-1}$ dose of pseudoephedrine had no effect on 800-m run times in NCAA female runners, and did not raise urine levels above $150 \mu\text{g}\cdot\text{ml}^{-1}$. This raises the question as to why pseudoephedrine is a specified prohibited substance by WADA.

(49 pages)

PUBLIC ABSTRACT

Effect of Pseudoephedrine on 800 M Run Times of NCAA Division I Women Athletes

The consumption of substances to aid with athletic performance has been a controversial issue for some time. The World Anti-Doping Agency (WADA) controls what substances are considered legal for athletes to use at the professional level, while the National College Athletic Association (NCAA) determines which substances are legal for college athletes. In 2010 WADA placed the substance pseudoephedrine on the list of banned substances if taken in large amounts. The NCAA does not have pseudoephedrine on the banned substance list in any amount. Pseudoephedrine is an active ingredient in over-the-counter medication that is used to treat symptoms of decongestion. It has been reported that pseudoephedrine can improve athletic performance through its ability to increase heart rate, assist the blood supply in going from the skin to the skeletal muscle.

While the effects of pseudoephedrine could enhance certain aspects of performance, most studies done previously have not found any positive results from its use. There is not a lot of research done with the use of pseudoephedrine, but the studies done have been varied in the types of performance tested. When looking at anaerobic or endurance performance, the majority of studies done found no effect from the pseudoephedrine when using the normal drug dose. However, two more recent studies done, have shown improvement in performance when using amounts higher than the regular dose of the pseudoephedrine medications.

The purpose of this study was to investigate the effects of a body weight dosing of pseudoephedrine on the performance of NCAA female track runners in an 800-m run. Fifteen female track runners from Utah State University participated in the study. Each participant ran the 800 m twice, a week apart, once with a placebo and once with pseudoephedrine. The results showed no difference in the 800-m run times when the participants took the pseudoephedrine compared to the placebo. The average time with pseudoephedrine was 2:39.4, while the average time with the placebo was also 2:39.4.

ACKNOWLEDGMENTS

I would like to give special thanks to all of my committee members who have given so much to help me accomplish this task. Special thanks need to go to Dr. Wagner, who helped me with step after step in this project. His knowledge and patience with me as we worked towards approaching deadlines have been a great aid as I have finally finished. I am also grateful to Dr. Bressel and Dr. Wolf for their valuable feedback and enthusiasm for the topic. Dr. Davis is the last committee member I would like to thank. He was so great to come on and help with all of the medical decisions. I could not have done it without my committee, and I was so glad to have them.

I would also like to thank the USU HPER faculty and grad students. You are all so great and willing to help. It was exciting learning from and studying with you. I loved working with all of you, and I have met many great friends through this program. I really enjoyed my graduate school experience.

I need to thank Greg Gensel, Steven Todd Reeder, and the other Utah State track coaches. Without them I would have not been able to accomplish this goal. They gave support in many ways and were always there when I needed advice. They helped me accomplish things at Utah State I could have never imagined.

Lastly, I want to thank my family, and my friends who are as close as family. My parents for their love, support, and patience as I try to figure out what to do with the rest of my life. They are always here for me, and I couldn't have done it without them. My siblings for their love, support, and praise. Without them it would have been hard to keep going. Finally, my friends and my teammates, who have been my family here in Logan.

Your support and love have helped me get through the hard times, but mostly, the fun we had helped me keep perspective and not get burned out.

Thanks you guys, I love you all.

Caroline Berry

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CHAPTER I

INTRODUCTION

There are many supplements, drugs, and nutrients that claim to enhance athletic performance. The World Anti-Doping Agency (WADA) controls which items are banned in every sport for professional athletes, and the National College Athletic Association (NCAA) controls the list for all college student-athletes (National College Athletic Association [NCAA], 2009; World Anti-Doping Agency [WADA], 2009). Each year WADA and the NCAA publish a list of banned substances that are illegal performance enhancers and can cause harmful side effects (NCAA, 2009; WADA, 2009). Although pseudoephedrine has been thought to be a stimulant and an ergogenic aid, it was removed from the banned substance list by WADA in 2004 and placed on a monitoring program (Hodges, Hancock, Currell, Hamilton, & Jeukendrup, 2006). In 2010 WADA reintroduced pseudoephedrine to the banned list in amounts that exceeded $150 \mu\text{g}\cdot\text{mL}^{-1}$ in a urinary drug test (WADA, 2010). Pseudoephedrine is not currently on the banned substance list for the NCAA (NCAA, 2009). A majority of research examining the ergogenic effects of pseudoephedrine has shown little to no athletic performance improvement resulting in its removal from the NCAA banned list (NCAA, 2009).

Pseudoephedrine is a sympathomimetic amine that comes from the plant genus *Ephedra*. Sympathomimetic drugs are substances that are known to exert additional effects on the actions of the sympathetic nervous system (SNS) by mimicking noradrenalin and adrenaline (Hodges, K. et al., 2006). Pseudoephedrine is mainly an alpha-adrenergic agonist that is typically used as an over-the-counter decongestant. The

adrenergic receptors are in the muscle lining of blood vessels and when activated by pseudoephedrine cause the blood vessels to constrict, allowing less fluid to leave them and enter the nose, throat, and sinuses (Hodges, A. et al., 2003). This reduces the severity of nasal congestion symptoms. Recommended doses of pseudoephedrine are 60 mg-120 mg, and most research studies have used these amounts.

This stimulation of the SNS by pseudoephedrine results in many factors that could aid in athletic performance including increased blood pressure, increased heart rate, increased oxygen consumption in the brain, increased glycogenolysis in the muscle and liver, vasoconstriction in the skin, vasodilation in muscle arterioles, and stimulation of the central nervous system (CNS) (Chu, Doherty, Parise, Milheiro, & Tarnopolsky, 2002). The ability of pseudoephedrine to increase heart rate and cardiac contractility, combined with the blood supply going from the skin to the skeletal muscle are main factors influencing the belief that pseudoephedrine could play a role as an ergogenic aid (Hodges, A. et al., 2003; Hodges, K. et al., 2006). The effect of pseudoephedrine on the CNS can cause an athlete to have an amphetamine-like reaction and suppress the feelings of fatigue, also acting as an aid in athletic performance (Gillies et al., 1996).

Sympathomimetics have greatly reduced lipid solubility, which greatly reduces their effects on the CNS when compared to amphetamines (Swain, Harsha, Baenzinger & Saywell, 1997). Most side effects of pseudoephedrine are minor and uncommon; although, excessive excitation of the CNS can occasionally be noticed with healthy individuals, which creates the slight risk of insomnia, nervousness, and excitability (Clemons & Crosby, 1993). For individuals who are sensitive to sympathomimetics, pseudoephedrine can increase the irritability of the myocardium and change the rhythm

of the ventricles, but research done previously states that, besides increased heart rate, no significant cardiovascular changes occurred in healthy subjects (Clemons & Crosby, 1993).

Despite the physiological response to pseudoephedrine making it a potential ergogenic aid, there has been very little research done that examines the performance enhancing ability of pseudoephedrine in athletics. Most previous research has compared the effects of pseudoephedrine to a placebo in the body during exercise. The most common change exhibited during exercise, when pseudoephedrine has been taken, is an increased heart rate. Other physiological factors have not been shown to change significantly with pseudoephedrine, compared to a placebo, making a true basis for improved performance with pseudoephedrine hard to determine (Chu et al., 2002; Gill, Shield, Blazeovich, Zhou, & Weatherby, 2000; Hodges, K. et al., 2006; Swain et al., 1997).

To date, most studies have found little or no effect on exercise performance with the use of pseudoephedrine. When using the recommended dose of 60 mg pseudoephedrine, there was no significant measurable ergogenic effect on high intensity exercise (Clemons & Crosby, 1993; Hodges, A. et al., 2003). By taking a higher, but still recommended, dose of 120 mg pseudoephedrine there was no performance enhancement during anaerobic exercise or with high-intensity exercise lasting for about 1 hr (Chu et al., 2002; Gillies et al., 1996). Other research notes that by taking pseudoephedrine according to the packaging, six times in a 36-hr period, no improvement was gained in 5000 m time trial times (Chester, Reilly, & Mottram, 2003). When looking at taking a larger than recommended dose of 180 mg of pseudoephedrine, Gill et al. (2000) observed

that maximal torque in isometric knee extension and peak power in an all-out Wingate test were enhanced. A dose based on body weight, $1 \text{ mg}\cdot\text{kg}^{-1}$ or $2 \text{ mg}\cdot\text{kg}^{-1}$ pseudoephedrine, did not affect VO_2 max or time to exhaustion tests significantly (Swain et al., 1997). Overall, these results seem to show that at recommended doses pseudoephedrine has little to no effect on performance, but higher doses may be effective as ergogenic aids.

Only one study observed a significant improvement in running times when pseudoephedrine was taken prior to performance. K. Hodges et al. (2006) concluded that $2.5 \text{ mg}\cdot\text{kg}^{-1}$ of body weight of pseudoephedrine ingested 90 min before the exercise bout improved performance in 1500-m times by a mean of 5.8 s. The K. Hodges et al. study used only male athletes, and only examined them at one distance. Given the inconclusive evidence regarding the ergogenic effect of pseudoephedrine at higher doses, the purpose of the present study was to examine the effect of $2.5 \text{ mg}\cdot\text{kg}^{-1}$ of body weight of pseudoephedrine on 800-m times of NCAA division 1 female distance runners to further the research done. Based on previous research, females were asked to participate for two main reasons. First, females, when compared to males, are suspected to absorb sympathomimetic amines more extensively in their gastro-intestinal tract, which may make the effects of pseudoephedrine more apparent (Clemons & Crosby, 1993). Secondly, according to Hopkins and Hewson (2001) female elite runners are also more reliable test subjects than elite men when looking at time trial results. According to the research done by K. Hodges et al. (2006), the research hypothesis of this study is that 2.5

mg·kg⁻¹ of body weight of pseudoephedrine will significantly improve athletic performance in the 800-m times of female distance runners.

With every athlete wanting to get an edge on the competition, knowing what truly aids in performance would be a significant finding. Also, if a substance does create a stimulating effect during an athletic performance, it needs to be regulated by the NCAA to make college competitions fair and keep athletes healthy. If there is no stimulating effect of a substance, even when administered at higher doses than the prescribed limit, WADA needs to look at the reasoning behind the restriction.

CHAPTER II

REVIEW OF LITERATURE

Introduction

Pseudoephedrine is an over-the-counter drug used to treat sinus and cold symptoms. Until recently pseudoephedrine had been on the banned substances list for the WADA and the NCAA because it was thought to increase athletes' performance capabilities, but it has now been approved for use on the NCAA level of athletics. The amount of research that has been done in using pseudoephedrine as an ergogenic aid is limited. Some studies have been done, but they are few and do not cover all of the options. This literature review will examine: (a) physiological effects of pseudoephedrine on the body, (b) the effect of pseudoephedrine on anaerobic and aerobic performance, (c) how pseudoephedrine compares to other ergogenic aids, and (d) variability in running performance.

Physiological Effects of Pseudoephedrine on the Body

The over-the-counter use of pseudoephedrine is to help symptoms of nasal and sinus congestion associated with allergies and the common cold. The properties that allow pseudoephedrine to deal with these symptoms affect the body physiologically. Some physiological effects of pseudoephedrine are respiratory stimulation, bronchial tube dilation, and relaxation of gastrointestinal muscles (Hodges, K. et al., 2006). When taking pseudoephedrine it functions mostly as a decongestant through indirectly stimulating the

alpha-receptors of the nasal mucosa to vasoconstrict, thereby reducing the blood flow to mucosa of the nasal cavity (Chu et al., 2002).

Pseudoephedrine is a sympathomimetic substance, so it has been assumed that it exerts additional effects on the SNS (Chu et al., 2002). Activation of the SNS results in increases in diastolic and systolic blood pressure, heart rate, oxygen consumption in the brain, glycogenolysis in the muscle and liver, vasoconstriction in the skin, and vasodilation in muscle arterioles (Chu et al., 2002; Gill et al., 2000). By increasing the heart rate and blood pressure, the cardiac output increases the blood flow to the working muscles (Gill et al., 2000). The vasoconstriction of the skin and vasodilation of the muscle arterioles also help to shunt more blood to the skeletal muscle. Glycogenolysis in the liver and muscles creates more glucose for the body to use during glycolysis. Through increased amount of glucose, the body can produce more energy to use during exercise or performance (Chu et al., 2002). In the majority of testing, all the proposed benefits of pseudoephedrine do not affect the body with a statistical significance, namely blood glucose and lactate show no difference (Bright, Sandage, & Fletcher, 1981; Bye, Hill, Hughes, & Peck, 1975; Chester et al., 2003; Chu et al., 2002; Gill et al., 2000; Gillies et al., 1996; Hodges, A. et al., 2003; Hodges, K. et al., 2006; Swain et al., 1997). Chu et al., Gill et al., and Clemons and Crosby (1993) are some of the only studies to find any effect of pseudoephedrine on the body; all three studies found a statistically significant difference in heart rate with the use of pseudoephedrine.

It is likely that some effects of pseudoephedrine on the SNS are mediated by neurons indirectly stimulating norepinephrine release from SNS neurons (Chu et al., 2002). Norepinephrine is a substance that works along side adrenaline, providing the

body quick bursts of energy in times of stress, also known as the fight or flight response. In theory, augmentation of norepinephrine caused by pseudoephedrine should enhance athletic performance (Chu et al., 2002). The body's increased ability to produce energy quickly would be beneficial during performance.

Pseudoephedrine can also have adverse effects on the body. The activation of the SNS, which can come from ingesting small amounts of pseudoephedrine, can increase sleeplessness, nervousness, excitability, dizziness, and anxiety (Clemons & Crosby, 1993). When taken in excess amounts, pseudoephedrine can be associated with hallucinations, arrhythmias, hypertension, seizures, and tachycardia (Clemons & Crosby, 1993). These affects have not been reported with any studies done so far.

Effect of Pseudoephedrine on Anaerobic and Aerobic Performance

The pill Sudafed, which comes in amounts of 60 mg per pill or 120 mg per pill, is the mostly widely used form of pseudoephedrine. The recommended daily dose is 60 mg every 4-6 hr, but not exceeding 240 mg in 24 hr. Overall, studies show no effect on high-intensity (anaerobic) performance when using the recommended dose of pseudoephedrine.

A. Hodges et al. (2003) and Bell, Jacobs, and Ellerington (2001) used Wingate tests, a 30-s maximal sprint on a bike, to test the anaerobic capacity of the body when taking pseudoephedrine. The test showed little to no improvement in the performance capabilities of the participants who were taking the recommended 60-mg dose of pseudoephedrine. The only difference between pseudoephedrine and the control was an elevated heart rate that took a longer time to settle. The participants in A. Hodges et al.

study ingested the pseudoephedrine and then waited 90 min before completing the Wingate test. The participants in Bell and colleagues' study ingested pseudoephedrine and waited only 60 min before performing the Wingate test. The difference in time between ingestion and performance did not make a difference in the results as both studies showed no improvement.

Chu et al. (2002) also used a Wingate test to determine the effect of pseudoephedrine on anaerobic performance. The results demonstrated that a 120 mg dose of pseudoephedrine did not enhance force production, time to fatigue, fatigue index, or power output in young men or women (Chu et al., 2002). The participants in the study were given pseudoephedrine 2 hr before they were tested, and rested until the test (Chu et al., 2002). The higher dose and longer time in between ingestion and test session still showed no improvement in performance. One maximal bike test found an improvement with the use of pseudoephedrine. Gill et al. (2000) had participants take 180 mg of pseudoephedrine 45 min before exercise, and then perform a 1-RM bench press, 70% 1-RM bench press, isokinetic knee extension, and a 30 s "all-out" cycle test. They reported that a dose of 180 mg of pseudoephedrine increased maximum torque in an isometric knee extension, and also increased peak power during an all-out cycle test. Gill et al. decided a reason for the improvement shown was the higher dose of pseudoephedrine, compared to the doses in other studies, see Gillies et al. (1996).

For aerobic performance benefits, most studies have also found no benefit from the use of pseudoephedrine. When participating in a 40-km time trial, well-trained cyclists found no improvement when taking a single therapeutic dose of 120 mg of

pseudoephedrine 2 hr before the testing (Gillies et al., 1996). The study was only done with the recommended dose and no more.

Chester et al. (2002) did a study using runners during which pseudoephedrine was administered according to the manufacturer's directions for 36 hr prior to the testing. The participants' testing session included a twenty-minute sub-maximal treadmill test followed by a 5000-m time trial. The results showed no statistical difference during the 20 min of perceived exertion; similarly there was no time difference in the 5000 m time when the control was compared to multiple doses of pseudoephedrine.

Other submaximal testing or time to exhaustion trials state that pseudoephedrine had no performance enhancing effect. Swain et al. (1997) studied the effects of $1 \text{ mg}\cdot\text{kg}^{-1}$ and $2 \text{ mg}\cdot\text{kg}^{-1}$ pseudoephedrine on participants during a cycle test to exhaustion, during which participants were expected to maintain 80 rpm with increasing workload; when they could not keep the pace the test was stopped. The test resulted in no change in time to exhaustion for either amounts of pseudoephedrine when compared to a placebo. In a submaximal treadmill test using the Bruce protocol, which consists of 3 min stages of increasing intensity, a 60 mg dose pseudoephedrine taken 60 min before testing showed no improvement in performance (Clemons & Crosby, 1993). Bright et al. (1981) also studied the effects of pseudoephedrine compared to a placebo on a timed multi-staged treadmill test to 85% of maximal heart rate. Participants took 60 mg or 120 mg of pseudoephedrine 60 min before the treadmill test, and were evaluated based on the time it took to reach 85% of maximal heart rate. Results showed no changes in length of time to maximal heart rate in either dose of pseudoephedrine when compared to the placebo.

In contrast, two studies have shown performance improvement when pseudoephedrine has been given in large doses. Pritchard-Peschek, Jenkins, Osborne, and Slater (2010) administered 180 mg of pseudoephedrine to well-trained athletes 60 min prior to a cycle time trial. Each participant had to complete a set amount of work ($7 \text{ J}\cdot\text{kg}^{-1}$ body mass) in the shortest amount of time possible. When compared to a placebo, the cycling time trial performance with pseudoephedrine improved by 5.1%. The authors concluded the higher dose was responsible for the drastic improvement (Pritchard et al., 2010).

K. Hodges et al. (2006) reported that pseudoephedrine helped lower 1500 m times in highly trained male runners. Instead of using the recommended dose, the study took the body weight of the participants and used that to determine the amount of pseudoephedrine given to each runner. The equation used was $2.5 \text{ mg}\cdot\text{kg}^{-1}$, which on average resulted in 180 mg per person (K. Hodges et al., 2006). When taken 90 min before the time trial, the pseudoephedrine improved performance times an average of 5.8 s, or 2.1%. The increased dose of pseudoephedrine was thought to be the main reason why performance improved in this study compared to previous pseudoephedrine studies (K. Hodges et al., 2006).

Pseudoephedrine in Use with Other Ergogenic Aids

There has been some testing to determine if pseudoephedrine is more effective when used with other ergogenic aids. Phenylpropanolamine is another over the counter decongestant. When used in conjunction with pseudoephedrine, the combination did not enhance performance (Chester et al., 2003). In the study, pseudoephedrine was given to

distance runners at the same time as the phenylpropanolamine and separately from each other before a 20 min sub-maximal test and a 5000 m time trial. Regardless of whether the substances were taken alone or together there was no difference in performance from the control group (Chester et al., 2003).

Swain et al. (1997) also did a study investigating the effects of pseudoephedrine and phenylpropanolamine. The participants took either, 1 mg·kg⁻¹ or 2 mg·kg⁻¹ pseudoephedrine, or 0.33 mg·kg⁻¹ or 0.66 mg·kg⁻¹ phenylpropanolamine 1 hr prior to a cycle test to exhaustion. The cycle test participants were expected to maintain 80 rpm with increasing intensities. The test was stopped when they could no longer maintain the cadence. The test resulted in no change in time to exhaustion for either supplement compared to a placebo.

Silk and Weatherby (2005) did a study using pseudoephedrine and caffeine. The study tested the isometric strength and time to fatigue in active young adult men when taking both 120 mg of pseudoephedrine alone, and 120 mg of pseudoephedrine combined with 300 mg of caffeine. When the two substances were combined there was no performance enhancements compared to the control. It was thought that the different mechanisms or actions of the pseudoephedrine and caffeine negate the individual ergogenic effects when the two are combined (Silk & Weatherby, 2005).

800-Meter Running Performance

The reliability of a performance test is important to a study because it can help determine the power of the study or the effectiveness of the treatment. Hopkins and Hewson (2001) examined the typical variation of runners' performances from race to

race. According to the data found, a standard was set that in distance races shorter than 12,000 m any change over 0.5% is significant for a top distance runner. The study also found that the faster a runner was, the more reliable they were in testing. Elite women runners were also found to be more reliable test subjects than elite men runners (Hopkins & Hewson, 2001).

Hopkins, Hawley, and Burke (1999) did a study where they found that when testing elite athletes, the results did not always carry into the field of their competition. The results that were obtained in a laboratory or field tests did not always match the results that came from competition scenarios with other athletes, but it was more apparent in the elite athletes and not as applicable in other groups of runners (Hopkins et al., 1999). When using sub-elite athletes the results were deemed to be more reliable.

The ability to race well during an 800 m race is considered 75% anaerobic (Paish, 2009). The anaerobic capacity of an athlete is greatly affected by the athlete's ability to utilize anaerobic glycolysis, the creation of glucose for energy in conditions with an oxygen deficit (Chu et al., 2002). Pseudoephedrine affects the SNS by increasing blood flow to skeletal muscle and increasing glycolysis. Thus, at a race distance of 800 m, pseudoephedrine could affect the anaerobic capacity of an athlete.

Summary

Pseudoephedrine is a theoretical ergogenic aid that has only been validated as an effective performance enhancer in a few studies while the majority of research indicates that it has no benefit, so removing it from the NCAA banned substance list may have been the right decision. However, the K. Hodges et al. (2006) study showed that

pseudoephedrine could have a significant ergogenic effect if given a sufficient dose.

These contradicting results suggest that more research should be done to determine if pseudoephedrine should really be banned. More studies need to be done to decide if the higher dose of pseudoephedrine can affect performance in athletics because most studies have been done with the recommended doses. Also, most studies have used men as test participants, so doing studies with females is also an area that needs more research. This study is patterned after the study by K. Hodges et al. In that study, a 1500-m distance was used to test the effects of pseudoephedrine. According to the research, distances less than 12,000 m are more reliable. The present study examined the 800 m to see if results were consistent for this distance. The 800-m distance is considered to use mainly anaerobic systems in order to complete the race distance. With the affects of pseudoephedrine on the SNS, namely increased blood flow to the skeletal muscles and increased glycolysis, the 800 m should be a good distance to test pseudoephedrine versus a placebo.

CHAPTER III

METHODS

Participants

Fifteen female student athletes from the Utah State University Track and Field team were recruited to participate in this study. Before testing each participant had an initial screening and medical history done by a physician. The valve function and consequent rhythm of the subjects was examined aurally. If it was not deemed safe for them to participate, they were excluded from the study. Participants who had blood pressure $\geq 140/90$ mmHg were also not allowed to participate. Each participant also signed an informed consent (Appendix A), outlining risks involved, before participating in the study. The Institutional Review Board of the University of Utah approved the study. The testing was done at the end of an aerobic training period for the athletes; so all subjects were assumedly fit.

Procedure

The study had a double blind, crossover design. Each participant completed two 800-m time trials, one with pseudoephedrine and one with a placebo. Testing took place seven days apart to allow for physical recovery and adequate drug wash out. Pseudoephedrine has a half-life of 5.2 – 8 hr, making 7 days sufficient for the drug clearance (Kuntzman, Tsai, Brand, & Mark, 1971). Each 800-m trial was performed on a 200-m indoor track at the Nielson Field house on the campus of Utah State University.

The indoor track was used in order to eliminate the variability of the weather between each testing session.

The week before the test session each athlete came to the Dale Mildenberg Training Room located at Utah State University for pre-assessment purposes. A doctor assessed all participants to ensure their health allowed them to participate in the study without adverse effects. All Subjects were cleared and then able to sign an informed consent and were given instructions for each testing session. Participants were asked to abstain from alcohol and caffeinated foods and beverages within 24 hr of testing, and to fast for 8 hr prior to testing in order to eliminate the chance of improved performance due to what each participant ate. Also, the student athlete was asked to abstain from prescription or over-the-counter medications that contain pseudoephedrine (e.g., Sudafed) or could react with pseudoephedrine the week prior to and during the week of testing. Student athletes were reminded of the time trial testing a week before the test and then again the day before the test. The reminder included information on eating and working out instructions for the day of the test.

At the pre assessment the weight was taken for each participant in clothes they were required to wear at the testing sessions. Weight was measured to the nearest 1 kg on a Seca 700 balance beam scale (Seca 700, Seca Corp., Ontario, CA). The weight of each participant was used to determine the amount of pseudoephedrine or placebo given to each participant. It was administered in doses of $2.5 \text{ mg}\cdot\text{kg}^{-1}$ of body weight of pseudoephedrine or placebo to each athlete. Maltodextrin was used as the placebo, and to mask the trials each substance was placed in a gelatin capsule and administered in the same amount of pills for each condition. A member of the research team then placed the

capsules in two different envelopes marked A or B, each containing one substance.

The contents of the envelopes were known only to this member and were recorded later.

Envelope A contained pseudoephedrine, while envelope B held the placebo.

Upon arriving at the indoor track having fasted for 8 hr, heart rate was measured on all participants by a polar heart rate monitor (T31, Polar Elector Inc., Lake Success, NY) in order to determine a baseline number. Weight was measured again in order to ensure no drastic weight changes. Each participant then flipped a coin in order to determine which capsule would be ingested that day. If the participant landed with a heads side up, envelope A was given. If tails side landed up, the participant was given envelope B. Along with the pseudoephedrine or placebo each participant was given an Ensure (Abbott Nutrition, Columbus, OH) high-energy shake at $7 \text{ ml}\cdot\text{kg}^{-1}$ of body weight. Nutrient distribution of the shake is as follows: protein 14%, carbohydrate 64%, and fat 22%. The shake was given in order to standardize the pretesting nutrition of each participant, so the effect of pseudoephedrine would not change according to the diet of the participant. Water was available ad libitum to all participants.

After ingesting the nutritional shake and the randomly assigned pseudoephedrine or placebo, the subjects each rested for 70 min, sitting and doing homework or reading. At the end of the rest, each participant completed a warm-up that lasted 20 min. The warm-up began with a 1600 m self-paced jog, followed by standardized plyometric drills. Immediately preceding the 800 m trial, the subject performed 3 x 50-m strides to finish the warm up. At 90 min after ingestion of pseudoephedrine or the placebo, the 800 m trial was run individually. The subjects were unable to wear watches and were given no encouragement during the run. Split times were given at every 200 m in order to simulate

a race. The time trial was timed to the nearest .01 second using the Pyro-bright System (Flash Timing, Hillsboro, OR) in order to have accurate timing. Pyro-bright uses a scope with an internal clock that started when the gun went off. The signal from the scope is sent to a VCR, which recorded the finish from a video camcorder, with the time overlaid on the screen.

Immediately after the trial, recovery heart rate was taken, again with a polar heart rate monitor, to assess the effects of pseudoephedrine on heart rate. The participants were then asked to complete the Self-Evaluation Questionnaire developed by Spielberger (1983) (Appendix B), in order to determine the anxiety state of each participant. The Self-Evaluation Questionnaire was chosen because it is a widely used tool to determine state anxiety; other tools are compared to it to determine their effectiveness in state anxiety levels (Balon, 2005; Houtman & Baker, 1989). The scoring was done based on the answer sheet given in the book, the higher the score the higher the anxiety level (Spielberger, 1983) (Appendix C).

Five participants were also chosen to give a urine sample, to determine how much pseudoephedrine was excreted through the urine with the high doses give. Each urine sample was taken approximately 2 hr after pseudoephedrine/placebo ingestion, when peak plasma levels should occur (Kuntzman et al., 1971). The participants with heaviest, lightest, and median weights were chosen as well as two others, whose names were drawn out of a hat. After the urine was collected it was stored in a storage closet on campus at room temperature according to the directions of the Associated Regional and University Pathologists (ARUP). After both trials had occurred, the urine associated with envelope A was taken to the Utah State University Health Center and sent to the ARUP

lab. A high performance liquid chromatography/tandem mass spectrometry urinalysis was performed by ARUP of Salt Lake City. The full sequence of events is shown in order in Table 1. Seven days later the same procedure was performed with each participant receiving the treatment she did not receive the previous week. Participants were asked to give a urine sample after both testing sessions in order to maintain the double blind testing procedure. Seven days between trials ensured no treatment contamination and that the athlete was fully recovered from the previous trial. Participants were encouraged to perform the same tasks and runs the 7 days previous to both trials. Blood lactate was not analyzed in this experiment because previous researchers found no change in blood lactate from pseudoephedrine (Chester et al., 2003; Chu et al., 2002; Gill et al., 2000; Prithchard-Peschek et al., 2010).

Data Analyses

An a priori statistical power analysis was performed using GPower 3.1 for sample size estimation, based on data from K. Hodges et al. (2006). The effect size (ES) was 1.3, extremely large using Cohen's (1988) criteria (K. Hodges et al., 2006). With a one-tailed $\alpha = 0.05$ and power = 0.80, the projected sample size for this ES (GPower 3.1) is approximately $N = 6$ for this simplest within group comparison. Thus, our proposed sample size of $N = 15$ should have been more than adequate for the main objective of this study. According to the same power analysis, each participant would have needed to differ by 3.1 s between the pseudoephedrine and placebo trials in order to achieve statistical significance.

Table 1

Timeline of Data Collection

Procedure Steps	Running Time
1. Participant arrives	00:00 min
2. Weight check	02:00 min
3. Treatments Selection	05:00 min
Flip coin	
-Heads Envelope A	
-Tails Envelope B	
4. Administration	10:00 min
-Envelope with capsules	
-Nutrition shake	
5. Rest/ Wait Period	80:00 min
6. Warm up	100:00 min
-1600 m self-paced jog	
-plyometric drills	
-3 x 50 m strides	
7. Time Trial	102:00-103:00 min (90:00 min post ingestion of capsules)
8. Post exercise heart rate recorded	104:00 min
9. Post exercise anxiety state written test	114:00-124:00 min
10. Post exercise urine sample	130:00 min (110:00-120:00) min post ingestion of capsules)
11. Cool down	Self Selected

Paired sample *t* tests were used to determine if the mean difference in 800-m run time was significant between pseudoephedrine and placebo trials, as well as to compare mean differences in post-exercise heart rate and anxiety state between trials. Statistical significance was set at $p < 0.05$. Statistical analysis was done using the Statistical Package for the Social Sciences (SPSS, version 18.0).

CHAPTER IV

RESULTS

The purpose of this study was to determine if pseudoephedrine acted as an ergogenic aid for women NCAA track and field athletes in the 800-m distance. The study started with 15 participants. No participants were deemed unable to begin the study for medical reasons. Due to injury, one participant was unable to finish the study. Another participant ran a 2:46.9 with pseudoephedrine and a 3:00.5 with the placebo, suffering from illness on testing day two. With a difference in 800-m times between trials exceeding standardized score of 3.29 this participant was considered an outlier (Tabachnick & Fidell, 1996). Thus the number of participants used for statistical analysis totaled 13 (see Table 2). Individual subject results are included in Appendix D.

Table 2

Participants Characteristics (N = 13)

Variable	Mean (SD)	Range (min-max)
Height (cm)	165.9 (10.6)	157.5 – 180.3
Mass (kg)	57.6 (6.4)	50.0 – 72.0
Age (years)	19.6 (1.3)	18 - 23
BMI (kg/m ²)	20.6 (1.5)	18.5 – 23.2
Dosage (mg)	144 (17)	130 - 170
800-m time Placebo	2:39.4 (9.6)	2:24.7 – 2:55.1
800-m time Pseudoephedrine	2:39.4 (9.6)	2:27.5 – 2:55.6

Despite being dosed (144 mg pseudoephedrine \pm 17 mg) well above normal prescribed levels, there was no significant difference ($p = 0.92$) in 800 m times between the placebo (2:39.4 \pm 9.6) and pseudoephedrine (2:39.4 \pm 9.6) trials. The difference between trials for each participant is illustrated in Figure 1.

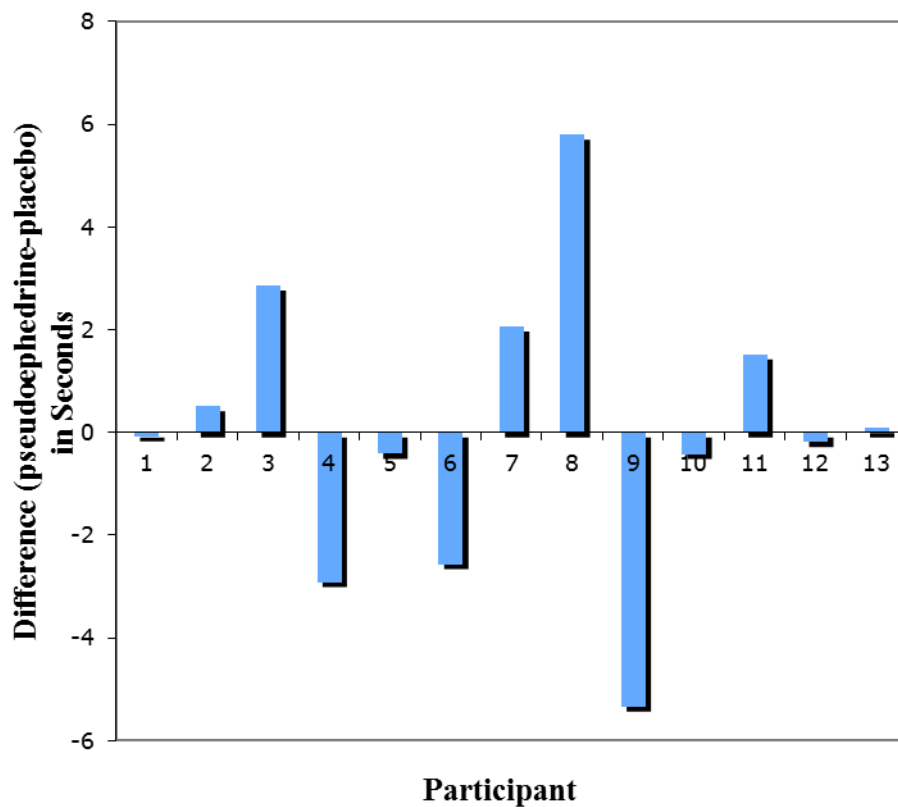


Figure 1. Time difference between trials (pseudoephedrine - placebo) for each participant.

The difference in post-exercise heart rates between the pseudoephedrine (177.9 ± 14.5 beats \cdot min $^{-1}$) and placebo (178.4 ± 18.5 beats \cdot min $^{-1}$) trials was not significant ($p = 0.635$). The mean of heart rates for each trial is illustrated in Figure 2. Also, there were no significant differences ($p = 0.650$) in anxiety state scores between the pseudoephedrine (38.4 ± 11.6) and placebo (38.1 ± 8.8) trials (Figure 3).

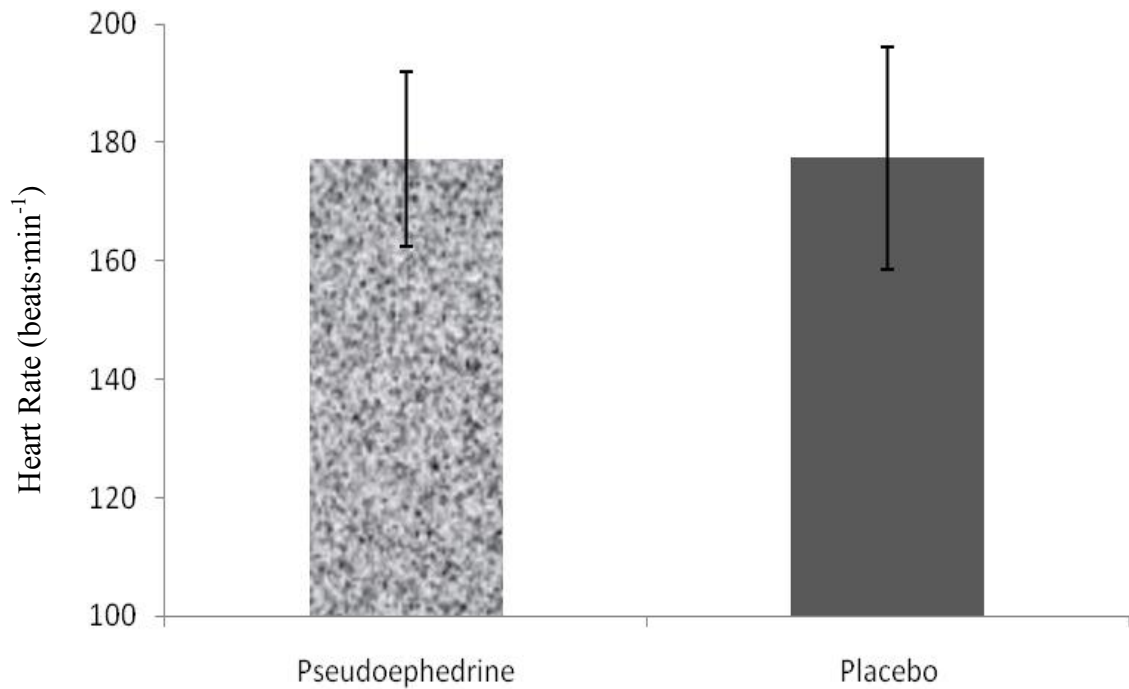


Figure 2. Post-exercise heart rates (mean \pm SE) for 800-m trials.

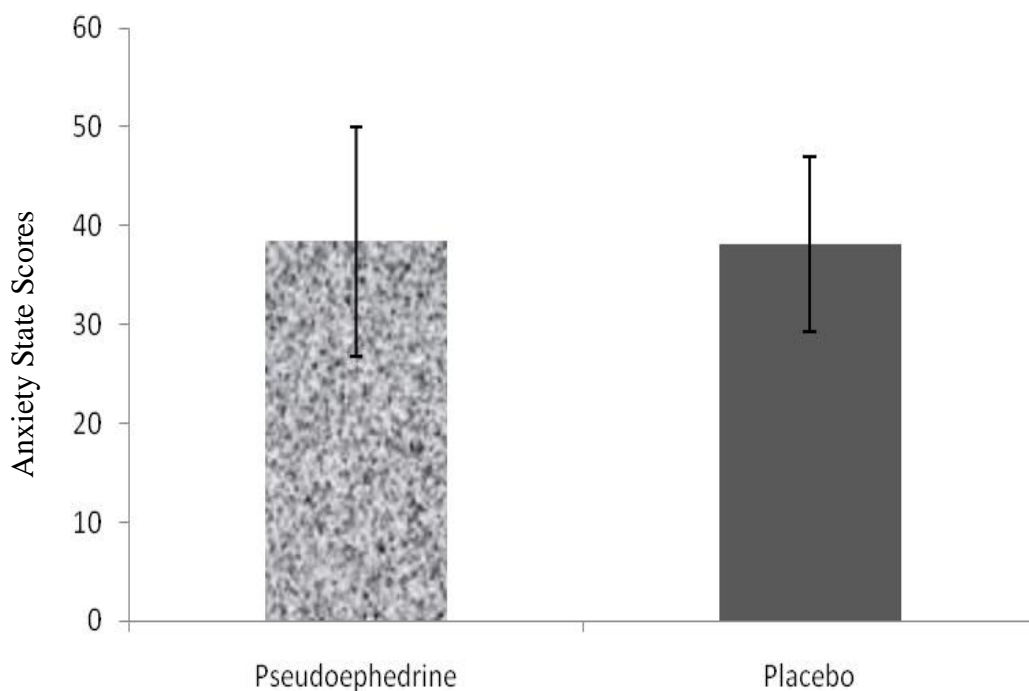


Figure 3. Anxiety state scores (mean \pm SE) for 800-m trials.

A urine excretion test was also done on five participants. The WADA limit is 150 micrograms of pseudoephedrine per milliliter of urine. The lab reported the pseudoephedrine excretion in nanograms per milliliter. When converted, participant 7 excreted $3.4 \mu\text{g}\cdot\text{ml}^{-1}$, participant 8 excreted $2.7 \mu\text{g}\cdot\text{ml}^{-1}$, participant 9 excreted $.11 \mu\text{g}\cdot\text{ml}^{-1}$, participant 11 excreted $7.3 \mu\text{g}\cdot\text{ml}^{-1}$, and participant 14 excreted $5.3 \mu\text{g}\cdot\text{ml}^{-1}$. These are very low numbers according to the doses given. The ARUP Lab, where the test was done, was contacted about a possible mistake in numbers and could not identify a problem.

Contrary to the hypothesis, the pseudoephedrine did not significantly lower the 800-m run times of women NCAA track athletes compared to a placebo. Furthermore, according to the results pseudoephedrine did not create a statistically significant change in heart rate or anxiety states when compared to a placebo during a performance situation.

CHAPTER V

DISCUSSION

The purpose of this study was to determine the effect of $2.5 \text{ mg}\cdot\text{kg}^{-1}$ of body weight of pseudoephedrine on 800 m run time of NCAA division 1 female distance runners. The hypothesis that stated pseudoephedrine would significantly improve 800 m run times was not supported in the research findings.

According to the Track & Field Results Reporting System (TFRRS; 2011) the top 500 times of NCAA women indoor track athletes were all faster than 2:16. The present study's mean time of 2:39 was slower than the top 500. Althetic.net (2011) reported 1,000 high school females out of 3510 submitted times ran under a 2:38, the website only reported the top 1,000 race times entered. The present study average of 2:39 was faster than two thirds of high school female track athletes. This study used NCAA female track athletes after an aerobic training period. The training they were doing was for distances longer than 800 m, which may have made the times slower than the top 500 times of college. The study still can be generalized for above average high school female track runners and mediocre NCAA track runners. The NCAA reported that 11,816 female athletes participated on an indoor track team in 2010, making an average time hard to find because all websites only present the best times available (NCAA, 2011).

Pseudoephedrine is thought to have some adverse effects, when taking high amounts of it. No participants in the current study reported any problems associated with the ingestion of pseudoephedrine.

The results of this study were not consistent with those of K. Hodges et al. (2006) who found that $2.5 \text{ mg}\cdot\text{kg}^{-1}$ body weight of pseudoephedrine improved elite male runner 1500-m times on average of 5.8 s. The present study was modeled after the K. Hodges et al. study, but was a shorter distance and different gender of participants. The differences in study design were thought to be able to enhance the effects of pseudoephedrine even further, but failed to give statistical improvement at all. A possible explanation for the differing results is the dosage given to the participants. Both studies gave $2.5 \text{ mg}\cdot\text{kg}^{-1}$ body weight of pseudoephedrine, but the larger athletes in the K. Hodges et al. study received 180 mg pseudoephedrine on average compared to the 145 mg pseudoephedrine in the current study. Giving a larger absolute value regardless of body mass compared to the regular dose (60-120 mg), may be needed for performance enhancement.

In a study done by Pritchard-Peschek et al. (2010), using a higher dose of pseudoephedrine was also the reason given for improvement in performance. When giving 180 mg pseudoephedrine, there was a 5.1% improvement in time during a cycling time trial. The effect of the higher dose on the body was the only reason found for improvement when compared to other studies (Pritchard-Peschek et al., 2010).

Gill et al. (2000) also used a 180-mg dose of pseudoephedrine per participant and found some increase in peak power during an all-out cycle test. The increased amount of pseudoephedrine was the reason for improvement found by Gill et al. when compared to other studies, further supporting the evidence that a higher dose could act as an ergogenic aid.

The present study does support the findings in many other studies, all of which the participants took the therapeutic dose or just barely above it. A. Hodges et al. (2003) and Bell et al. (2001) also showed no improvement in Wingate tests when taking only 60 mg pseudoephedrine. Similar to the present study, Swain et al. (1997) used $1 \text{ mg}\cdot\text{kg}^{-1}$ and $2 \text{ mg}\cdot\text{kg}^{-1}$ pseudoephedrine and saw no improvement in cycle tests to exhaustion. The relative amount per body mass may not be as important as the overall effect of having a higher absolute dose compared to what is recommended.

Heart rate is another variable considered in pseudoephedrine studies. In the present study there was no increase in heart rate immediately after completing the time trial when taking pseudoephedrine compared to the placebo. These results support a majority of previous research, but are contrary to the findings of Bye et al. (1975), Chu et al. (2002), Gill et al. (2000), and Clemons and Crosby (1993), which all found increased heart rate from pseudoephedrine. This study used NCAA athletes, whereas the other studies used participants labeled healthy adults or recreational athletes. The higher fitness level of the athletes may affect the magnitude of change pseudoephedrine can have on the heart rate of an individual. In K. Hodges et al. study of elite athletes with high fitness levels no difference was found in heart rate between the pseudoephedrine and placebo trials, even when using an average of 180 mg pseudoephedrine per person. This adds support to the theory that higher fitness levels are less affected by pseudoephedrine.

The present study compared the effect of pseudoephedrine to a placebo on anxiety states. No other studies reported looking at anxiety state levels of participants. Despite the effect of pseudoephedrine on the CNS there was no difference in anxiety states between trials. A higher score signifies a higher anxiety level at the time the test is taken.

For each trial, the mean score was 38. The average score for a college female on the Self-Evaluation Questionnaire is a 39 (Spielberger, 1983). This suggests that even after taking pseudoephedrine, the study participants had an anxiety level comparable to the average college-aged female. This may result from the fact that as a NCAA track athlete, the participants, are accustomed to the stressors related to race performance. The pseudoephedrine was not given in high enough amounts to affect the state of the athletes. The lack of increased heart rate shows the lack of effect of pseudoephedrine on the physiological systems of the body, which helped the athletes feel the same during each trial. With no direct changes in the body, feelings of anxiety would be the same as every other race or time trial.

The results of the urine test were not as expected. With the amounts of pseudoephedrine given, the amount in the urine was expected to be above or near the WADA limit of $150 \mu\text{g}\cdot\text{ml}^{-1}$. The results indicated that the levels were not near this limit; in fact, they were very near zero. Based on research done previously WADA stated that amounts over 120 mg dose in 12 hr would have a urine excretion rate over the limit (WADA, 2009). According to the results of the present study this may not be the case. At 2 hr after ingestion, pseudoephedrine should be at high levels in the urine (Kuntzman et al., 1971). Each participant gave the urine sample near 2 hr after ingestion, so the levels in the urine should have been higher. The lab where the urinalysis took place stated that each individual metabolizes pseudoephedrine differently and may result in varying times of maximum urine excretion. The low concentration of pseudoephedrine in the urine, despite the large dose given, could not be explained.

According to the results of this study, pseudoephedrine does not need to be on the banned list in the amounts listed by WADA. WADA stated that amounts over 120 mg dose in 12 hr would have a urine excretion rate over the limit, and is banned (WADA, 2009). The present study administered an average 144 mg of pseudoephedrine per person, which exceeds the amount stated by WADA, with no ergogenic effects exhibited. Based on the present study, if an athlete takes pseudoephedrine for a cold in amounts exceeding 120 mg per 24 hr there will be no performance benefit, but there could be repercussions from WADA. The NCAA is right by not putting it on the banned list, because no performance benefits were found despite the dosing above therapeutic levels.

Study Limitations

Some limitations should be listed for the current study to assist with further research. First, the participants were at the end of an aerobic training period, doing little to no anaerobic training. The aerobic training gave the participants fitness, but not in the exact area needed during an 800-m race. If the participants had been doing anaerobic training there may have been more consistent race times from person to person, creating a smaller standard deviation.

Another limitation of the study was relying on the honesty of the participants to follow the instructions outlined for the study. If participants changed the routine from week to week that could have changed results. Also, if participants didn't follow the dietary guidelines the results could have been affected as well.

The final limitation was the timing of the urine test. With each person metabolizing pseudoephedrine differently, there may be a need to do more than one urine

test. If the multiple urine tests could have been analyzed the results of the urinalysis could have shown more amounts of pseudoephedrine.

Future Research

Although the current study had few limitations, there are some recommendations that should be considered for future research. One recommendation would be to use athletes that are in or finishing an anaerobic training period. Another recommendation would be to do multiple urine tests on each participant to better assess if the WADA limits are reached. Lastly, if a test of norepinephrine could have been done on the participants more information could have been given about the effects of pseudoephedrine on the body. Future research done with these recommendations would help further the area of research dealing with pseudoephedrine and performance.

Conclusion

The results of this study do not support the hypothesis that stated pseudoephedrine would improve the 800-m race times of NCAA track and field female runners. Despite all the effects of pseudoephedrine on the CNS and SNS, pseudoephedrine also had no effect on heart rate or anxiety states of participants when compared to a placebo. If pseudoephedrine has no effect on performance, WADA may want to reconsider the inclusion of this over-the-counter drug on their banned substance list in the future.

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APPENDICES

Appendix A: Informed Consent

Consent Document

Effect of Pseudoephedrine on 800-m Run Times of NCAA Division-I Women Athletes

BACKGROUND

You are being asked to participate in a research study. It is important for you to understand why the research is being done and what will be asked of you before you make a decision about participating in this study. Please carefully read this information and ask the researcher if there is anything that is not clear or if you want more information.

The purpose of this research is to determine if pseudoephedrine, an over-the-counter drug and an ingredient commonly found in nasal decongestants, can improve 800-m run performance in NCAA female runners. You are being invited to participate in this study because you are a female runner on the Utah State University cross-country or track team. We anticipate having a total of 15 collegiate runners complete this study. This study is being conducted by Dr. Dale Wagner, Assoc. Professor of Exercise Physiology in the Health, Physical Education and Recreation Department at Utah State University, and Caroline Berry, a master's student in the same department.

STUDY PROCEDURES

If you decide to participate in this study you will be asked to come to the Dale Mildenberg training room once and the Nelson Fieldhouse indoor track twice. Both buildings are on the USU-Logan campus.

1) A week before testing you will be asked to come to the Dale Mildenberg training room to have an initial screening done by a physician. The physician will be examining your heart rhythm and sounds with a stethoscope and checking your blood pressure. If it is not deemed safe for you to participate, you will be excluded from the study and the physician will advise you of your medical options. Your weight will also be measured at this time. This is needed to determine the amount of pseudoephedrine that you will be given.

2) If you are cleared by the physician to participate in the study then you will make an appointment to meet at the Nelson Fieldhouse indoor track. You will be asked to follow pre-testing guidelines:

- a) Abstain from alcohol and caffeinated foods and beverages for 24 hours before testing
- b) Abstain from medication containing pseudoephedrine for 24 hours before testing
- c) Fast 8 hours prior to testing
- d) Do not exercise prior to testing on test day
- e) Come to the fieldhouse in the same running attire and shoes each testing session

3) 24-48 hours before each test session you will receive an email reminder of your appointment and the pre-testing guidelines.

- 4) Please arrive on time for your test sessions. Upon arriving the sequence of the test will be as follows:
- a) You will be administered pseudoephedrine or a placebo in the amount of 2.5 mg per kg of body weight; which one you get will be determined randomly from a computer-generated number (odd = pseudoephedrine, even = placebo) before you arrive. Pseudoephedrine is an over-the-counter stimulant commonly used in nasal decongestants. A placebo is a dummy treatment or “fake” pill. Neither you nor the test administrator will know which substance is being administered (although the test administrator will be able to find out in the event of an emergency).
 - b) You will also be given a Nutrament high-energy shake administered at 7 ml per kg of body weight.
 - c) Your resting heart rate and blood pressure will be taken.
 - d) You will rest for 70 minutes. (You can read a book, listen to music, take a nap, etc.).
 - e) Following the rest period, you will begin a 20-minute warm up that begins with a 1600 m self-paced jog, followed by standardized plyometric drills (bounding, skipping, etc.), and conclude with 3 x 50 m strides.
 - f) Following the warm-up and at 90 minutes after ingestion of the pseudoephedrine or the placebo, the 800 m time trial will begin. You will run the 800 m as fast as you can. You will receive split times at every 200 m, but no other encouragement.
 - g) Upon finishing the 800 m, you will cool-down at a self-selected pace and heart rate will be taken every minute for five minutes.

5) Seven days later at the same time, these exact steps (#4 a-g) will be followed, except that you will receive the treatment (pseudoephedrine or placebo) that you did not receive the previous week. Thus, if you complete both test sessions you will receive both the pseudoephedrine once and the placebo once.

RISKS

There are some risks associated with taking pseudoephedrine. In healthy individuals it can cause increased sleeplessness, nervousness, excitability, dizziness, and anxiety. When taken in excess amounts, pseudoephedrine may be associated with hallucinations, fast and irregular heart rates, high blood pressure, and seizures. These adverse effects have not been reported in any of the previous similar studies; however, if there are problems, a physician will be near the test site, and there is a phone in the fieldhouse to call “911” for an emergency.

REPRODUCTIVE RISKS

This study may involve risks to pregnant women or fetuses that are unknown at this time. To be included in the study, you must acknowledge that you are not knowingly pregnant. You are permitted to practice any form of birth control during the study. If you become pregnant during your participation in this study then you must inform one of the researchers immediately, and you will be withdrawn from the study.

BENEFITS

We cannot promise any benefits to you from your participation in this study. However, if you have abnormal heart sounds or abnormal blood pressure this may be identified

during the initial health screening by the physician. Also, we hope that both athletes and researchers will gain a better understanding of whether or not pseudoephedrine can enhance athletic performance from this study. We will provide you with your 800 m time for each trial.

CONFIDENTIALITY

The results of this study may be published, but your identity will not appear. This consent form with your signature will be filed in a locked cabinet in the researcher's office. Only Dr. Wagner and Caroline Berry will have access to the data. Computer analysis of the data will be numerically coded; your name will not appear on the researchers' computers. Your 800 m time will be revealed only to you; not to your teammates or coaches. Because this research involves the use of a drug, the possibility exists that the Food and Drug Administration (FDA) may inspect the research records.

PERSON TO CONTACT

If you have questions, complaints, or concerns about this study, or you think that you may be experiencing a medical problem as a result of your participation in this study, please contact Dale Wagner, Ph.D. at 435-797-8253 or by email at dale.wagner@usu.edu. You can also reach Caroline Berry at 801-694-0335 or by email at c.berry@aggiemail.usu.edu.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

RESEARCH-RELATED INJURY

If you are injured from being in this study, medical care is available to you at the University of Utah, as it is to all sick or injured people. The University of Utah does not have a program to pay you if you are hurt or have other bad results from being in the study. The costs for any treatment or hospital care would be charged to you or your insurance company (if you have insurance), to the study sponsor or other third party (if applicable), to the extent those parties are responsible for paying for medical care you receive. Since this is a research study, some health insurance plans may not pay for the costs.

The University of Utah is a part of the government. If you are injured in this study, and want to sue the University or the doctors, nurses, students, or other people who work for the University, special laws may apply. The Utah Governmental Immunity Act is a law that controls when a person needs to bring a claim against the government, and limits the amount of money a person may recover. See Section 63G -7-101 to -904 of the Utah Code.

VOLUNTARY PARTICIPATION

Your decision to participate in this study is entirely up to you. If you decide to take part, you are still free to withdraw at any time without giving a reason. You just need to inform the researchers of your desire to withdraw from the study. There are no consequences for declining to participate or deciding to withdraw from this study. Your participation decision will not affect your relationship with the coaches or your status on the team.

UNFORESEEABLE RISKS

In addition to the risks listed above, you may experience a previously unknown risk or side effect.

RIGHT OF INVESTIGATOR TO WITHDRAW

The investigator can withdraw you without your approval. Possible reasons for withdrawal include you becoming pregnant during the course of the study or the study being terminated early because of unforeseen negative effects of the pseudoephedrine.

COSTS AND COMPENSATION TO PARTICIPANTS

There is no cost to you for participating in this study. You will not be compensated for your participation.

NEW INFORMATION

Sometimes during the course of a research study, new information becomes available about the drug being studied. If this happens, the researcher will tell you about it and discuss with you whether you want to continue in the study. If necessary, you will be asked to sign an updated consent form.

NUMBER OF PARTICIPANTS

We expect to have 15 female collegiate runners participate in this study.

CONSENT

By signing this consent form, I confirm that I have read the information in this consent form and have had the opportunity to ask questions. I will be given a signed copy of this consent form. I voluntarily agree to take part in this study.

Participant's Name

Participant's Signature

Date

Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date

STUDY RESULTS

It may take several months after your participation is complete for the researchers to analyze the data and create a summary of the results. If you want, the researchers can send you a summary of the study results. Do you want a summary of the results mailed to you? yes no.

If yes, please provide your mailing address below:

Appendix B: Self-Evaluation Questionnaire

SELF-EVALUATION QUESTIONNAIRE

Developed by Charles D. Spielberger
 in collaboration with
 R. L. Gorsuch, R. Lushene, P. R. Vagg, and G. A. Jacobs

STAI Form Y-1

Name _____ Date _____ S _____
 Age _____ Sex: M _____ F _____ T _____

DIRECTIONS: A number of statements which people have used to describe themselves are given below. Read each statement and then blacken in the appropriate circle to the right of the statement to indicate how you feel *right now*, that is, *at this moment*. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your present feelings best.

VERY MUCH SO
 MODERATELY SO
 SOMEWHAT
 NOT AT ALL

- | | | | | |
|--|---|---|---|---|
| 1. I feel calm | ① | ② | ③ | ④ |
| 2. I feel secure | ① | ② | ③ | ④ |
| 3. I am tense | ① | ② | ③ | ④ |
| 4. I feel strained | ① | ② | ③ | ④ |
| 5. I feel at ease | ① | ② | ③ | ④ |
| 6. I feel upset | ① | ② | ③ | ④ |
| 7. I am presently worrying over possible misfortunes | ① | ② | ③ | ④ |
| 8. I feel satisfied | ① | ② | ③ | ④ |
| 9. I feel frightened | ① | ② | ③ | ④ |
| 10. I feel comfortable | ① | ② | ③ | ④ |
| 11. I feel self-confident | ① | ② | ③ | ④ |
| 12. I feel nervous | ① | ② | ③ | ④ |
| 13. I am jittery | ① | ② | ③ | ④ |
| 14. I feel indecisive | ① | ② | ③ | ④ |
| 15. I am relaxed | ① | ② | ③ | ④ |
| 16. I feel content | ① | ② | ③ | ④ |
| 17. I am worried | ① | ② | ③ | ④ |
| 18. I feel confused | ① | ② | ③ | ④ |
| 19. I feel steady | ① | ② | ③ | ④ |
| 20. I feel pleasant | ① | ② | ③ | ④ |



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Appendix C: Scoring Sheet for Self-Evaluation Questionnaire

**Scoring Key for
STAI Form Y-1**

		VERY MUCH SO	MODERATELY SO	SOMEWHAT	NOT AT ALL
1.	Be sure you have the correct side of the stencil on the test sheet.	4	3	2	1
2.	Then simply total the scoring weights shown on the stencil for each response category. A simple hand counter or ordinary desk calculator will make the task easier, but it can be done mentally. Refer to the Manual for appropriate normative data.	4	3	2	1
3.		1	2	3	4
4.		1	2	3	4
5.		4	3	2	1
6.		1	2	3	4
7.		1	2	3	4
8.		4	3	2	1
9.		1	2	3	4
10.		4	3	2	1
11.		4	3	2	1
12.		1	2	3	4
13.		1	2	3	4
14.		1	2	3	4
15.		4	3	2	1
16.		4	3	2	1
17.		1	2	3	4
18.		1	2	3	4
19.		4	3	2	1
20.		4	3	2	1

Appendix D: Raw Data

RAW DATA

NAME	A/B TT1	A/B TT2	Weight	Track Event	800m TT1	800m TT2	HR1	HR2
1	A	B	64 kg	800	2:29.843	2:29.912	182	183
2	A	B	60 kg	800/1500	2:55.622	2:55.110	165	145
3	A	B	52 kg	800	2:27.566	2:24.69	175	180
4	A	B	60 kg	800	2:34.877	2:37.788	200	191
5	A	B	57 kg	400/800	2:53.723	2:54.136	179	187
6	A	B	51 kg	800/1500	2:45.962	2:48.524	172	172
7	B	A	50 kg	800	2:29.201	2:31.271	135	152
8	A	B	58 kg	800	2:43.053	2:37.248	186	205
9	B	A	58 kg	800/1500	2:32.268	2:26.929	180	186
10	B	A	56 kg	800/1500	2:42.075	2:41.658	178	152
11	B	A	51 kg	800/1500	2:45.260	2:43.784	174	185
12	B	A	67 kg	800/1500	2:45.761	2:45.577	194	171
13	A	B	72 kg	800/1500	2:32.946	2:32.853	196	183
14	A	B	56 kg	800	2:46.845	3:00.543	188	192
15	A	N/A	54 kg	800/1500	2:45.282	N/A	209	N/A

