UNIVERSITY OF WISCONSIN-MADISON
Research Participant Information and Consent Form

Title of the Study: A feasibility/pilot trial of a motor attention training intervention for college students with ADHD

Principal Investigator: Alexander K. Converse, PhD (phone: 608/265.6604) (email: akconverse@wisc.edu)

DESCRIPTION OF THE RESEARCH

You are invited to participate in a research study about the effects of non-drug therapies on symptoms of Attention Deficity Hyperactivity Disorder (ADHD). You have been asked to participate because you are a UW-Madison undergraduate aged 18-23 with a diagnosis of ADHD. This research will be conducted at the Waisman Center and the Brogden Psychology building on the UW-Madison campus. Approximately 45 subjects will participate in this study.

Your participation in this research study is voluntary. If you decide not to participate, any relationship you have with the University of Wisconsin-Madison (UW-Madison) or the University of Wisconsin Hospitals and Clinics (UWHC) will not be affected in any way.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to examine whether an exercise class or a tai chi class might improve symptoms of ADHD in college students.

WHAT WILL MY PARTICIPATION INVOLVE?

If you decide to participate in this research you will be randomly assigned to one of three conditions: (1) an eight week long moderate exercise class, which involves non-contact kicking and punching to build aerobic and muscular fitness, (2) an eight week long tai chi class, which involves learning a series of slow flowing movements to build balance and coordination, or (3) an eight week period with no class for comparison. The classes will meet 2 times per week for one hour on campus. You will be asked to complete a 90 minute test session at the Brogden Psychology building on campus before and after the 8 week class period. In the 90 minute test sessions, you will respond to four questionnaires about ADHD symptoms, sleep, mindfulness, and health, complete an excerpt from a practice Graduate Record Exam (GRE), perform cognitive tests, perform a balance test, and wear a chest or wrist strap to measure your heartbeat. We will ask you for an unofficial copy of your UW-Madison transcript for the semester prior to the class and the semester of the class. We will ask you to identify someone familiar with your daily life, e.g. roommate, friend, or family member, whom we will invite to complete brief questionnaires about your ADHD symptoms. If you are assigned to a class, we will text you daily to ask if you practiced outside of class, and after the 8 week class we will give you a survey evaluating the class. After the 8 week class period, we will send you a brief online questionnnaire once a month for 3 months to ask about your ADHD symptoms.

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After the 8 week class period, you might be randomly invited to participate in a one hour assessment interview with a clinical psychology trainee. If you choose to participate in the interview, it would cover a variety of topics related to psychological well being and includes some sensitive questions, for example about illicit drug use.

If you are assigned to a study group that involves taking classes, your participation will require a total of approximately 20 hours. If you are assigned to a study group that does not require taking a class, your participation will require a total of approximately 3 hours. If you are invited and choose to participate in the assessment interview it will add approximately 1 hour.

ARE THERE ANY RISKS TO ME?

By taking part in the tai chi or exercise arms of the study, your ADHD status will be known to your instructors, classmates, and study staff. There is a minor risk for breach of confidentiality. If you permit us to contact someone familiar with you to ask about your symptoms, we will do so by email, which presents an additional risk for breach of confidentiality . The moderate exercise classes pose minor risk of discomfort, injury, muscle soreness, dizziness, or fainting typical of such classes. Please consult with your physician first if you have concerns about starting an exercise program.

In the event that you are physically injured as a result of participating in this research, emergency care will be available. You will, however, be responsible for the charges for the emergency care. There is no commitment to provide any compensation for research-related injury. You should realize, however, that you have not released this institution from liability for negligence. Please contact the investigator, Alexander K. Converse at 608/265.6604 if you are injured or for further information.

ARE THERE ANY BENEFITS TO ME?

We don't expect any direct benefits to you from participation in this study. Your participation in this research may benefit other people in the future by helping us learn more about potential therapies for ADHD.

WILL I BE COMPENSATED FOR MY PARTICIPATION?

You will be compensated $20 for completing first test session. Additionally, you will be compensated $20 for attending at least 80% of classes sessions and completing the second test session. If you are randomly selected for a psychological assessment interview following the second test session and agree to participate, you will be compensated an additional $20. Thus, You will receive up to $60 for participating in this study. All payments will be made at the end of the study.

HOW WILL MY CONFIDENTIALITY BE PROTECTED?

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Your name will not be directly linked to any research data. Data that we collect about you will only be stored with a subject code. Only the Principal Investigator will have access to the key linking your name to the subject code, and this key will be destroyed at the end of the study. While there will probably be publications as a result of this study, your name will not be used. Only group characteristics will be published.

To help us protect your privacy, we are applying for a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances: intent to hurt self or others.

WHOM SHOULD I CONTACT IF I HAVE QUESTIONS?

You may ask any questions about the research at any time. If you have questions about the research after you leave today you should contact the Principal Investigator Alexander K. Converse, PhD at 608/265.6604.

If you are not satisfied with response of the research team, have more questions, or want to talk with someone about your rights as a research participant, contact the UWHC Patient Relations Representative at 608-263-8009 or University of Wisconsin Medical Foundation Patient Relations Representative at 800-552-4255 or 608-821-4819.

Your participation is completely voluntary. If you decide not to participate or to withdraw from the study it will have no effect on any services or treatment you may be currently receiving.

AUTHORIZATION TO PARTCIPATE IN THE RESEARCH STUDY

Your signature indicates that you have read this consent form, had an opportunity to ask any questions about your participation in this research and voluntarily consent to participate. You will receive a copy of this form for your records.

Name of Participant (please print):_____

_____ _____

Signature of Participant Date

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_____ _____

Signature of Person Obtaining Consent Date

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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