

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

Accessible Ergometer Information

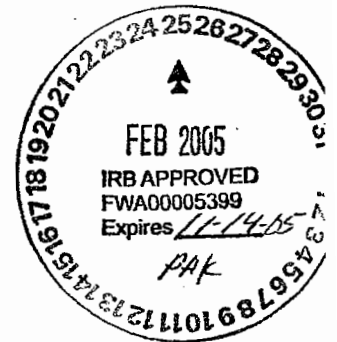
Invitation/Summary

You are invited to participate in a research project designed to evaluate how well people can use a special cyclic ergometer (exercise bike), perform proper entry and exit the device with little to no assistance and still obtain an aerobic workout.

You have been invited to participate in this research because you have one of the following conditions: Heart Failure, Diabetes, Low Vision, Overweight, Stroke, Parkinson's disease, Deafness, and/or Blindness. During the research study, you will be asked to enter the device and sit comfortably on the exercise seat. You will then perform a short workout in which you will perform a lower body workout by pedaling with your feet and/or perform an upper body workout by pushing and pulling the handles. During your exercise, the heart rate sensors in the handles will monitor your heart rate. Lastly, we will observe you as you exit the device. We are interested in learning how subjects with a variety of abilities would be able to use this device and if they can do it with minimal effort and still obtain a good workout. We intend to test the device on a maximum of 10 individuals with the conditions listed above, along with 4 control individuals that do not have any of the listed conditions.

What does my study participation involve?

If you decide to start the trial, you will be asked to enter the exercise bike and sit on the seat. You can make any adjustments you need to the seat height, its distance from the foot pedals, and arm handles until you are fully comfortable. We will observe how you enter the device as well as any necessary adjustments you make to the device. We will then ask you to perform a short workout (approximately five minutes) in which you can pedal with your feet and move the arm handles at the same time or separately. During your exercise, we will closely monitor your ability to use the machine and watch your heart rate from the heart rate sensors embedded in the handles. At the end of your exercise, we will ask you to exit the device with little to no assistance and, again, observe your ability to do so. At the start of the study, we will ask you to complete a general health questionnaire. At the end of the study, we will ask you to complete a post-survey. The information you provide will be kept confidential. Each test session should last a maximum of 30 minutes with about five minutes of actual exercise time.



Is there any discomfort or risk?

The same exercise bike will be used by several subjects. To prevent germs from being spread and to clean the heart rate monitor sensors, prior to each trial the device will be sanitized with antibacterial cleaners. There is also the risk of temporary muscle fatigue/strain and muscle soreness that can happen with new exercise routines. This soreness should diminish within 2 to 3 days without treatment.

Will compensation be paid in the event of an injury?

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 that you have not released this institution from liability for negligence. Please contact the Principal Investigator, Kreg Gruben Ph.D., at (608) 262-2711 if you are injured or for further information.

Where will the study take place?

The study will take place at the UW Hospital in G5/170-174. Sessions will last about 30 minutes with about five minutes of exercise.

Will my study results be confidential?

Your name or other identifying information will not be revealed in publications or reports that may result from this study, nor will your name be used in other research communications such as lectures or scientific meetings. Data obtained from the Health Questionnaire will be kept strictly confidential by placement in a locked drawer.

Will I be paid for my participation?

No, you will not be paid for being in this study.

Is there any benefit to participation?

You will not personally benefit from participation, but society may benefit from the creation of an assessable exercise bike that is usable by patients of various abilities and being universally applicable to all users.

What if I change my mind?

Participation in this study is voluntary. If you change your mind at any time you are free to end the session and to withdraw from the study. If you decide not to participate or to withdraw, it will not affect your status as a student or employee at the University of Wisconsin or your treatment at the University of Wisconsin Hospitals and Clinics.

You may take as much time as you need to make up your mind whether to participate in this study. Before you sign this form, please ask any questions you wish on the aspects of the study that are not clear to you. We will attempt to fully answer any questions you may have prior to, during, or following this study.

What if I have questions?

For questions regarding the research study, contact Dr. Kreg Gruben at (608)262-2711 or gruben@education.wisc.edu. For questions regarding your rights as a research subject, contact the UW Patient Relations Representative at (608)263-8009.

AUTHORIZATION:

I, _____, have read, or have had read to me, the above and I have decided to participate in the research project described above. My signature also indicates that I have received a copy of this consent form.

Signature

Date

I was present while this consent form was read to the subject and can confirm that what was read to the subject is the same information that is contained in the written document the subject has signed.

Signature of Witness

Date

Signature of Principal Investigator
or of person obtaining consent

Telephone