

CONSENT

FOR EXPERIMENTAL PROCEDURE/ RESEARCH STUDY:

1. **Title of research project**

Acute exercise effects on heart-rate and blood-pressure variability in post-menopausal women

2. **Name of the researchers**

Katarina T. Borer, Ph.D., Professor

3. **Why is this study being done? Describe purpose of the research**

The purpose of this research is to determine the effects of acute exercise on blood pressure (BP) and heart rate (HR) variability in post-menopausal women. High daily BP variability and low HR variability are associated with increased risk of coronary heart disease (CHD). Endurance exercise lowers BP and resting HR and raises HR variability more consistently in hypertensive than in normotensive subjects. In hypertensive subjects, BP changes last for several hours after exercise. Both systolic BP and HR increase (and HR variability decreases) in proportion to exercise intensity during acute exercise, but it is not clear whether and how exercise intensity affects these variables during recovery from exercise and how long any such changes last. This study examines how exercise intensity affects the time course of changes in BP and HR and their variabilities in normotensive post-menopausal women immediately following an exercise bout both at low intensity and at high intensity, and compares it to a control day when no special exercise is carried out.

4. **What is involved in the study.**

First we will measure your height, weight and several body dimensions (circumferences and skin-fold thickness) that will allow us to estimate your body fat level. Next, you will wear a BP and HR monitors for 24 hours to record the fluctuations in your blood pressure and heart rate over one day. You will undergo a walking treadmill test to establish your ventilatory threshold (VT). That is the speed at which you become winded. You will walk on the treadmill two other times, once at a low intensity and once at a high intensity. The low intensity walk will consist of three 15-minute walks at 95% of your VT with 4 minutes of standing rest in between. The high intensity walk will consist of three 10-minute walks at 115% of your VT with 4 minutes of slow-walking rest inbetween. After walking tests, you will wear HR and BP monitors for 48 hours to record how exercise has affected your blood pressure during the immediate post-exercise period. After each bout of HR and BP monitoring, you will need to come back to the lab so that we can remove the monitors and record the data.

5. **How long will the subjects participate in the study.**

The entire study can be completed in 9 days although it may take a few days longer depending on particular scheduling needs. The initial treadmill test to determine your aerobic fitness, along with body composition measurements and orientation to monitoring equipment, require between 30 minutes and one hour. The exercise tests

each require approximately one hour. Seven days have to separate high-intensity and low intensity tests. The two monitors need to be returned after 48 hours of use before they can be used again.

6. **What are the risks and/or discomforts of participating in this study.**

a. **Risks and discomforts of this study**

Wearing a HR-BP cuff for one to two days at a time may be slightly inconvenient in that it may affect the type of clothing you may wear over the cuff on the arm. Inflation of the blood pressure cuff will cut off circulation to your forearm for a few minutes every half an hour while you will wear ambulatory HR-BP monitor, and this may produce some discomfort or pain. A small chance of muscle soreness is possible from the walking. As in everyday locomotion, injuries of the ankle, and knee could occur but are unlikely. Risk of cardiovascular accidents (heart attacks and stroke) increases with intensity of acute exercise bouts but diminishes with regular submaximal exercise. The probability of experiencing a cardiovascular accident during submaximal exercise in this study is very low. Overall, the risks of participating in this study are minimal.

b. **Additional risks of participating in multiple studies**

Taking part in more than one research study may be harmful to you. If you are already taking part in another study, please let us know. You should not take part in more than one study at the same time, unless you and the investigators agree that you are not likely to be harmed, and the outcome of this study will not be disturbed. This is particularly important if you are receiving in another research study any investigational or non-investigational drugs. If taken at the same time, some drugs may change each other's effects on the body, so that one drug may become harmful because of another drug.

7. **Measures to be taken to minimize risks and discomforts:**

Risks of joint injuries will be prevented or minimized by inclusion of a warm-up and cool-down, recommendations to wear appropriate walking shoes and by walking on a level surface. You should be given clearance from your personal physician attesting that no conditions exist that would make exercise potentially hazardous to your health. Healthy people should experience no cardiac distress with any level of walking in this study. Your answers in Physical Activity Readiness Questionnaire also will help us identify conditions that would make exercise potentially hazardous. If at any time any subject develops chest pains or shortness of breath, exercise will be discontinued and a physician consulted. As an additional risk management measure, at least one person at each walking session will have minimal training in American Red Cross Adult CPR and Standard First Aid.

8. **Are there expected benefits to subjects or to others.**

You will gain information about your risk of developing cardiovascular morbidity based on the information about your level of body fat and changes in HR-BP variability in response to exercise. You also will learn how the intensity of acute bouts of exercise influence HR and BP variability. This study will define exercise intensity range that causes most beneficial changes in HR and BP variability so that you and other postmenopausal women will be able to use exercise to improve your cardiovascular health.

9. **Costs to subject resulting from participation in the study**
There will be no costs to you or your insurance carrier for participation in this study.
10. **Payments to subject for participating in the study**
There will be no financial remuneration for participation in this study.
11. **How will confidentiality of information collected be kept.**
We shall put the information collected about you during the study into a research record. This research record will not show your name, but will have codes entered in it that will allow the information to be linked to you. However, we shall keep your research record confidential, to the extent provided by federal, state and local law. We shall not allow anyone to see your record other than people who have a right to see it . You will not be identified in any reports on this study.
12. **Do you plan to audio/video tape your subjects?** No.
13. **Management of Physical Injury (where applicable)**
In the unlikely event of physical injury resulting from research procedures, the University will provide first-aid medical treatment. Additional medical treatment will be provided in accordance with the determination by the University of its responsibility to provide such treatment. However, the University does not provide compensation to a person who is injured while participating as a subject in research.
14. **Availability of further information**
If significant new knowledge is obtained during the course of this research which may relate to your willingness to continue participation, you will be informed of this knowledge.
15. **Whom does the subject call if they have questions or problems?**
If you have any additional questions or problems with this study, please contact study director, Dr. Katarina Borer, 3060G CCRB, Division of Kinesiology, 401 Washtenaw Ave, The University of Michigan, Ann Arbor, MI. 48109-2214, phone : (734) 647-2703, FAX: 936-1925, e-mail: katarina@umich.edu
- If you have have any questions about the study's approval or the research subject's rights, please contact the Institutional Review Board Administrator Kate M. Keever, Human Subjects Protection Office, UM Office of the Vice President for Research, Fleming Administration Building, Room 1040, phone (734) 936-0933, FAX: 647-9084 or e-mail umresearch@umich.edu
16. **Voluntary nature of participation**
Your becoming a subject in this study is entirely by your own free choice. You may refuse to enroll in the study, or drop out of the study at any time without any penalty even after having agreed to become a subject. By doing so, you will not lose any benefits that you may be entitled to up to that point in the study.

In case you withdraw from the study, you will not be harmed in any way. The investigators of this study may have to end your taking part in this study as a subject, if any of the following conditions came up:

1. you do not comply with the agreed-upon walking routine;
2. you do not cooperate in agreed-upon measurements;
3. you start taking medication that could interfere with physiologic responses to exercise;
4. you start smoking or dieting.

17. Documentation of the consent

One copy of this document will be kept together with the investigators' research records on this study. A second copy will be given to you to keep.

18. Consent of the subject

I have read the information given above. The investigator personally discussed with me and told me more about the study, and answered my questions. I understand the meaning of this information. I am aware that, like in any research, the investigators cannot always predict what may happen or possibly go wrong. I have been given sufficient time to consider if I should join this study. I hereby consent by my own free choice to take part in the study as a research subject.

ADULT SUBJECT OF RESEARCH

Printed Name

Consenting signature

DATE: _____

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