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Official Title: Effect of Outcome Expectations on Psychological and Physiological Responses to Interval Exercise Training

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INFORMED CONSENT

TITLE: Sprint to Fitness

PROJECT DIRECTOR: Dr. Kelsey Ufholz, Dr. James Roemmich

PHONE: 701-795-8272

DEPARTMENT: Grand Forks Human Nutrition Research Center

STATEMENT OF RESEARCH

A person who is to join in this study must give his or her informed consent. This consent must be based on a grasp of the nature and risks of the research. This form provides details that are key for such knowledge. Research projects include only those who choose to take part. Please take your time in making your decision whether to join. If you have questions at any time, please ask. You do not have to take part in the study.

WHAT IS THE PURPOSE OF THIS STUDY?

You are invited to be in a research study on high intensity exercise. The purpose of this study is to research the effects of exercising at high intensities for short periods of time. We will measure your fitness, body fat, activity level, and strength.

HOW MANY PEOPLE WILL PARTICIPATE?

About 60 people will take part in this study at the Grand Forks Human Nutrition Research Center (GFHNRC).

ELIGIBILITY: You may join if you are between the ages of 18 and 40 with a body mass index (BMI) of 25-35 kg/m^2. You must not be dieting to lose weight or exercising more than twice per week on a regular basis.

You cannot join in the study if you:

- are taking any medications that affect energy expenditure or to treat high blood pressure
- are diabetic
- use tobacco
- are pregnant or breast feeding or plan to become pregnant in the next 3 months
- have any medical conditions that prevent you from safely exercising

HOW LONG WILL I BE IN THIS STUDY?

You will first attend an information and screening visit (about 1 hour). If you qualify for the study and agree to join, you will visit Choice Health and Fitness Center (CHFC) or the GFHNRC

Date_____
Subject Initials: _____

for 5 baseline visits on separate days, each lasting about one hour. Then you will start an exercise program. You will exercise 3 separate days a week, for 6 weeks. Each exercise session will be a 30-minute interval workout. After the exercise program, the 5 baseline visits will be repeated. After these 4 visits you will return to the research center after a 4 week wash-out period for 5 more visits.

WHAT WILL HAPPEN DURING THIS STUDY?

Information visit: Two hours after eating; Dr. Ufholz or her designee will tell you about the study and answer any questions you may have. If you want to join the study, you will be asked to provide written informed consent. After signing this consent, your height and weight will be measured and you will be asked to fill out a demographic form which will be used to describe the group features, a W-9 which is required before a check can be issued for reimbursement, a medical history form, and other questionnaires. To determine if you are medically able to join, your resting blood pressure will be measured, your blood sugar checked by a finger stick (two hours postprandial), and a recording will be made of your resting heart rhythm. All of this information will be screened by our staff and our medical doctor to make sure you are healthy enough for exercise. You will be given an activity monitor to wear for 7 days to measure your daily activity. If it is determined you are healthy enough for exercise you will be scheduled for your 5 baseline visits.

Baseline Measurements:

During the 5 baseline visits we will

- #1 (usually < 60 minutes): have you come to our laboratory after a 12-hour fast, draw a small sample of your blood, measure your body composition (using a x-ray machine which gives off a very small amount of ionizing radiation), and have you complete some questionnaires.
- #2 (usually < 60 minutes): have you arrive a couple hours after eating and assess your Liking and the Reinforcing Value of physical activity – questionnaires and computer activities will be used to determine how much you like and value physical activity.
- #3 (usually less than 30 minutes): have you arrive a few hours after eating measure your leg strength (how hard you can press and pull – you will not be lifting any weights).
- #4 (usually < 60 minutes): have you arrive a couple hours after eating and complete a moderate intensity exercise test on a stationary bike to determine your aerobic fitness level. You will wear a face mask and a chest strap to measure how much energy you use and your heart rate.
- #5 (usually < 60 minutes): have you arrive a couple hours after eating and complete a high intensity exercise test on a stationary bike to determine your anaerobic capacity. You will wear a chest strap to measure heart rate.

Date_____
Subject Initials: _____

Exercise training program:
After a training orientation meeting, you will exercise 3 days a week for 6 weeks (on a stationary bike) following our planned workouts (18 training sessions). Each training session will be about 45 minutes long and take place at the GFHNRC. You will be able to sign up for exercise times that will work for your schedule, but each exercise session will be monitored by our research staff, so an appointment to exercise is necessary. If you are unable to attend a session you can make it up at another time or on another day. More than two weeks of 2 da/wk sessions or 1 week of 1 da/wk session will not constitute training for this study and you will be asked to terminate your participation in the study.

After 3 weeks of training we will schedule you for a post-12 hour fasting blood draw of < 3 ml.

Post- training:
After the 6-week exercise training you will complete the baseline measurements again.

Post-washout:
Then after a 4 week washout period when you are not required to exercise for us, you will complete the baseline measurements again.

WHAT ARE THE RISKS OF THE STUDY?
There may be some risk from being in this study.

Questionnaires: You may get frustrated when doing the surveys. Some questions may be sensitive, and you may become upset. If you become upset by questions you may stop at any time or choose not to answer a question.

Blood sampling: There is a small risk of local bruising or swelling from blood sampling. There may be pain as the needle passes through the skin. To minimize these problems, trained and experienced medical personnel will ask you about your blood draw history and draw your blood. They will follow standard medical precautions to reduce risk. Please tell them if you have had problems in the past. Tell them if you are having problems.

Exercise and Fitness Tests: You may not like participating in the exercise that is required. There is a small risk of sprains, strains, and broken bones as the result of exercise. To reduce this risk, you will be supervised by experienced staff. Some soreness may occur 24-48 hours after exercise but this will go away with time. Exercise can uncover or worsen hidden heart problems such as not enough blood flow to the heart muscle and irregular beats. It is unlikely you will have problems with your heart or circulatory system. Nausea, dizziness, and lightheadedness are common side effects of sprint training. These can be minimized with proper nutrition and hydration. Should you develop symptoms of any medical problems, testing will be stopped immediately.

Date_____
Subject Initials:_____

DXA Scan: The DXA scan is an x-ray and is considered to be a no greater than minimal risk procedure. The radiation dose of the whole-body scan is no more than 1.0 millirem. This dose is equivalent to approximately 1/620 of normal annual background radiation, ¼ of the radiation received in a long flight, or 1/10 of the radiation received in a chest x-ray. A quality assurance check will be completed on the DXA each day prior to its use; the software will not allow the use of the DXA if the quality assurance check fails. You will receive 2 DXA scans – one before, and another after, training. The effects of small doses of radiation on a fetus are not known; therefore, we will not knowingly allow a pregnant woman to have a DXA. Pregnancy tests will be done before the DXA if you are a woman of child-bearing age.

Armbands and chest straps: There is a slight chance of skin irritation from the chest strap. These devices will be cleaned between uses, and staff will instruct you on properly wearing the devices. If any discomfort occurs, please remove the device or adjust its position and report the discomfort to the research staff.

WHAT ARE THE BENEFITS OF THIS STUDY?
You may not benefit personally from being in this study. However, we hope that, in the future, other people might benefit from this study. We hope to gain insight into what causes people to change their physical activity when they start an exercise program. This knowledge could improve healthy activity efforts in the future.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?
Other than your time and energy, you will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?
You will be paid for being in this research study. You will receive reimbursement in the amount of $1327 for completion of the study. You may choose to receive your choice of a 24-month individual membership or 17-month family membership to Choice Health and Fitness to be paid at the end of the study. There is no reimbursement for screening procedures. If you complete the entire study, payment will be made at the end of the trial. In the event that you drop out of the project, you will be paid for partial participation based on the procedures that were done. You will receive compensation for wearing the physical activity monitor for those days that you wear the monitor for at least 10 waking hours. If you wear the activity monitor for at least 10 hours for 7 days and adhere to all other testing, then you will receive $282.50 for completing the baseline measures, $804.50 for completing the end of the exercise training and testing visits, and $240 for completion of follow-up tests. You will be required to provide your SSN and address to receive your payment (W9 form).

Date_____
Subject Initials: _____

WHO IS FUNDING THE STUDY?
There is no independent funding for this research study. The USDA ARS-GFHNRC will provide funds to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or an increase in salary for conducting this study.

CONFIDENTIALITY
The records of this study will be kept private to the extent permitted by law. In any report about this study that might be published, we will describe the study results in a summarized manner so that you cannot be identified. Your study record may be reviewed by Government agencies, the University of North Dakota (UND) Research Development and Compliance office, the UND Institutional Review Board, and the GFHNRC.

Any information that is obtained in this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of assigning study volunteers unique subject identification (ID) numbers that will not contain any personal identifiers. This subject ID number will be used on all data collection instruments, including questionnaires and computer records, so that no data can be connected to an individual subject. A master list linking the volunteers' names to the ID numbers will be kept in a separate locked file in the principal investigator's office, or in a computer file with a password protected access restricted to study personnel. Confidential information may be made available to the US Department of Agriculture as specified in the USDA/ARS Privacy Act System of Records, to UND, and as required by law or court order. Clinical trial information will be submitted to the National Institutes of Health/National Library of Medicine to be included in the clinical trial registry data bank (www.clinicaltrials.gov).

We will monitor you by video camera while you complete the computer activities used to determine how much you are motivated for food and physical activity, but you will not be recorded at any time during the study.

COMPENSATION FOR INJURY
In the event that this research activity results in an injury, treatment will be available including first aid, emergency treatment and follow-up care as needed. Payment for any such treatment is to be provided by you (you will be billed) or your third-party payer, if any (such as health insurance, Medicare, etc.). If you are injured while taking part in this research project as a result of the negligence of a United States Government employee who is involved in this research project, you may be able to be compensated for your injury in accordance with the requirements of the Federal Tort Claims Act. Compensation from individuals or organizations other than the United States might also be available to you. No funds have been set aside to compensate you in the event of injury. Also, the study staff cannot be responsible if you knowingly and willingly disregard the directions they give you.

Date_____
Subject Initials: _____

IS THIS STUDY VOLUNTARY?
Your participation is voluntary. You may choose not to join or you may stop taking part at any time without penalty or loss of benefits to which you are otherwise allowed. Your decision will not affect your current or future relations with UND or the GFHNRC.

If you decide to leave the study early, we ask that you call Bill Siders at 701-795-8430 or Dr. Roemmich at 701-795-8272 to inform them of your withdrawal.

You will be informed by the research investigator of this study of any significant new findings that develop during the study which may influence your willingness to continue to participate in the study.

There may be special circumstances that will result in your early withdrawal from the study without your approval. Such situations may include realization that exercise is not healthy for you or that other conditions might make continued participation harmful to you. You will also be withdrawn from the study if you are not willing or not able to follow the study directions.

SUPPLEMENTAL INFORMATION ABOUT SAMPLES FOR GENETIC TESTING
Your blood samples will be used for genetic testing. No individual information about genotypes will be made available to you or to a third party. Genotyping carries no medical or therapeutic value. There is no medical significance linked with the DNA test results. Your samples will not be sold in the future. Your samples will become the property of the GFHNRC and you do not have rights to them.

Please indicate below if you consent that your samples may be used in future genetic testing. You will not be paid an additional amount for these samples. If you choose not to allow the use of your samples for future testing, they will be destroyed at the end of the study.

(Please circle one) YES NO

Initials _____

CONTACTS AND QUESTIONS
The researchers conducting this study are Dr. Kelsey Ufholz and Dr. James Roemmich. You may ask any questions you have now. If you later have questions, concerns, or complaints about the research please contact Dr. Ufholz at 701-795-8229 during the day or the Metabolic Unit at 701-795-8488 after hours.

If you have questions about your rights as a research subject, you may contact the UND Institutional Review Board at (701) 777-4279. You may also call this number about any problems, complaints, or concerns you have about this research study. Please call this number if

Date_____
Subject Initials: _____

you cannot reach research staff, or you wish to talk with someone who is independent of the research team. General information about being a research subject can be found by clicking "Information for Research Participants" on the web site: http://und.edu/research/resources/human-subjects/research-participants.cfm.

REQUEST TO CONTACT FOR FUTURE STUDIES

We would like to alert you about studies you may qualify for in the future. Please indicate below if you consent to be contacted. This information will be kept in a separate file from the signed study consent form.

(Please circle one) YES NO

Initials _____

CONSENT

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Participant's Name: _____

_____ _____

Signature of Participant Date

I have discussed the above points with the participant or, where appropriate, with the participant's legally authorized representative.

_____ _____

Signature of Person Who Obtained Consent Date

Approval Date: MAR 1 2019
Expiration Date: FEB 28 2020
University of North Dakota IRB

Date_____
Subject Initials: _____