INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

Effect of Antibacterial Mouthwash on Muscle Function in Healthy Young Men and Women

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About this research

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this study is voluntary

You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled, and will not affect your relationship with Indiana University.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to explore the relationship between using different types of mouthwash and muscle strength and power. One mouthwash is marketed as antibacterial and the other is not marketed as antibacterial. Studies have shown that the ability to use certain nutrients from the diet may begin when they come in contact with normally present substances in the mouth. This study wants to find out if certain types of mouthwash may have a negative effect on muscle strength and power because it eliminates these substances in the mouth.

You will be randomly (like flipping a coin) assigned to receive one of two types of mouthwash and will perform an exercise test before and after using the mouthwash for about 7 days.

You were selected as a possible participant because you are a male or female between the ages of 18 and 30.

The study is being conducted by Andrew Coggan, Ph.D., Associate Professor, Department of Kinesiology, School of Health and Human Sciences. It is funded internally by the Diversity Scholars Research Program (DSRP).

HOW MANY PEOPLE WILL TAKE PART?

If you agree to participate, you will be one of 32 participants taking part in this research.

WHAT WILL HAPPEN DURING THE STUDY?

If you agree to be in the study, you will do the following things:

You will attend 3 research visits. Visits will be completed either in the Human Performance Laboratory in the National Institute of Fitness and Sports (NIFS) building at 250 University Boulevard, Indianapolis IN 46202, or in the IU-Health University Hospital, 550 University Boulevard, Indianapolis IN 46202, adjacent to the Clinical Research Center on the 5th floor.

Study Timetable

Activity	Visit 1		Visit 2	7 Days Between Visits 2 & 3	Visit 3
Review Study	X				
Sign consent and HIPAA form	X	**Minimum**			
Complete PAR-Q health screening form	X	**5 day wait**			
Blood pressure and heart rate measurement	X		X		X
Provide saliva sample			X		X
Perform exercise test	X		X		X
Use mouthwash				X	

Visit 1 (approximately 1 hour):

You will be told what is to be expected during the duration of the experiment and the risks of participating. During the study, for visits 2 and 3 only, you will be asked:

- to not consume caffeine or alcohol or use chewing gum during the 24 hour period prior to study visits.
- to avoid consuming foods (such as spinach, beets, collard greens) that are high in nitrate (a list will be provided) the evening before study visits.
- to not smoke, exercise the day of the visit prior to the visit, or come to the study visits in a fasting or hungry state.
- to use a mouthwash each day for 7 days and to not use any other mouthwash products other than those provided during the study. You will record your usage of the mouthwash on a form we provide you.
- provide saliva samples.

During all 3 visits, you will:

- perform an exercise test during which you will exercise one of your thigh muscles off and on for about 20 minutes.

You will also have your blood pressure and heart rate measured.

After reviewing this information if you decide to participate in the study, you will sign this consent form and then you will complete a screening form and your heart rate and blood pressure will be measured to determine if you are eligible to participate. If you are eligible to participate, then you will practice the exercise test and have your heart rate and blood pressure measured afterwards.

Visit 2 (approximately 1 hour):

Your resting heart rate and blood pressure will be measured. We will collect a saliva (spit) sample. The purpose of that test will be to measure substances in your saliva that might be changed by using the different types of mouthwash. You will then perform the exercise test you practiced during visit 1. Your blood pressure and heart

rate will be measured again. Finally, you will be given a mouthwash to take with you. You will be asked to use the mouthwash twice a day for seven days and to record on a log sheet when you do so. After the 7day period you will return for Day 3.

Visit 3 (approximately 1 hour)**:** you will be asked to return to undergo the same tests as described above for visit 2.

The total length of participation in this study will be approximately 14 days.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?
While participating in the study, the risks, side effects, and/or discomforts include:

Mouthwash: Mouthwash may cause surface staining of the teeth, an increase in systolic blood pressure, and the taste may be unpleasant to subjects.

Exercise Test: Your muscles may feel tired during the exercise test. You may also develop soreness in your muscles or joints. Very rarely, an exercise test, such as the muscular function test, may be associated with serious complications including, but not limited to:

- Fainting and disorders of the heart beat (too fast or too slow) which may require hospitalization; heart attack, stroke, or death; and muscle or joint pain. We will make every effort to minimize these rare risks by observing and monitoring during testing. However, no guarantees can be made. You may stop the exercise test at any time.

Another risk of this study is the possible loss of confidentiality, which is minimal. Even though the risk is small, a link exists between your protected health information and your sample. All records will be kept in a locked file cabinet inside a locked office and no identifiable electronic protected health information will be stored on electronic devices.

In addition to the risks listed above, there may be some unknown or infrequent and unforeseeable risks associated with participation in this study. You will be informed in a timely manner of any new information, findings or changes to the way the research will be performed that might influence your willingness to continue your participation in this study.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?
You will not receive any benefit from taking part in this study, but we hope to learn things which will help scientists in the future.

HOW WILL MY INFORMATION BE PROTECTED?
Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications about this study.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, and (as allowed by law) state or federal agencies, specifically the Food and Drug Administration (FDA) etc., who may need to access your medical and/or research records.

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

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

WILL I BE PAID FOR PARTICIPATION?

You will not be paid for participating in this study.

WILL IT COST ME ANYTHING TO PARTICIPATE?

There is no cost to you for taking part in this study.

WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?

In the event of physical injury resulting from your participation in this study, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

If you are participating in research that is not conducted at a medical facility, you will be responsible for seeking medical care and for the expenses associated with any care received.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, contact the researcher, Dr. Coggan, at 317 274-0656. After business hours, please call Dr. Coggan at 636-675-1692.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

CAN I WITHDRAW FROM THE STUDY?

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. The study team will help you withdraw from the study safely. You may withdraw by telling the study team you are no longer interested in participating in the study or in writing to Dr. Coggan at the following address:

Dr. Andrew Coggan
Department of Kinesiology
901 W New York Street
Indianapolis, IN 46202

Your participation may be terminated by the investigator without regard to your consent if it is determined to be in your best interest to do so. Your participation may be terminated if you fail to follow the instructions given to you or if you are unable to adequately perform the study procedures.

You will be told about new information that may affect your health, welfare, or willingness to stay in the study.

PARTICIPANT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Participant's Printed Name:_____

Participant's Signature:_____ **Date**:_____

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____ **Date**:_____