University of North Carolina at Chapel Hill  
Consent to Participate in a Research Study  
Adult Participants

Consent Form Version Date: 10/19/16  
IRB Study # 16-1397  
Title of Study: INFLUENCE OF PROBIOTICS ON BODY COMPOSITION AND HEALTH IN OCCUPATIONAL SHIFT-WORKERS  
Principal Investigator: Meredith Mock, BA  
Principal Investigator Department: Exercise and Sport Science  
Principal Investigator Phone number: (919) 962-0396  
Principal Investigator Email Address: meremock@live.unc.edu  
Faculty Advisor: Abbie Smith-Ryan, PhD  
Faculty Advisor Contact Information: (919) 962-2574  
Funding Source and/or Sponsor: National Strength and Conditioning Foundation

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to determine the effects of a multi-strain probiotic supplement on regional body fat, body composition, physical and psychological fatigue, and measures of metabolism and inflammation.

You are being asked to be in the study because you are a healthy, premenopausal female between 21 and 55 years old with a BMI ≥ 21 kg/m², who has been employed on a shift-working (rotating or night) schedule ≥ 6 months.

Are there any reasons you should not be in this study?
You should not be in this study if you have a history of medical or surgical events that may significantly affect the study outcome, including pancreatitis, cardiovascular disease, metabolic, renal, hepatic, or musculoskeletal disorders. If you are taking an antibiotic or have a history of chronic recurrent infection, you will not be eligible. You may not have impaired immune function, be taking immunosuppressant
drugs, or chemotherapy. If you are currently taking a probiotic supplement or have habitually taken a probiotic in the past 2 months, you will not be eligible to participate. If you have lost or gained more than 8 pounds within the last 2 months, you will not be eligible to participate. You should not be in this study if you are pregnant, planning to become pregnant over the next 8 weeks, or are sexually active and do not use a form of contraception.

**How many people will take part in this study?**
There will be approximately 60 people in this research study.

**How long will your part in this study last?**
Your participation in this study will include 3 visits to the Applied Physiology Laboratory (Fetzer Hall, Chapel Hill, NC) and 3 electronic (phone or email) conversations over the course of 6 weeks. Visit 1 will last approximately 30-45 minutes, visit 2 will last approximately 60-75 minutes followed by a 6-week supplementation period. During the supplementation period, electronic or phone correspondence (3 contacts) will last no more than 15 minutes. Visit 3 will be the same as visit 2.

If you decide to take part in the study, you will be asked to come into the Applied Physiology Laboratory in Fetzer Hall (ground floor, Rm 25) on the UNC-CH campus. Prior to enrollment, you will be asked to complete a health history questionnaire to make sure you are healthy for exercise as well as fill out a 4-day dietary food log. You will be asked to complete a series of measurements and an exercise test, on 2 separate visits before and after 6 weeks of supplementation. If you participate in this study you will be asked to perform the components within the visits below:

**Visit 1 (Consenting and Enrollment):**
You will provide written informed consent, complete a health history and physical activity questionnaire and go through the questionnaire with study personnel. Your height, weight, body mass index, and age will be recorded. You will also be asked to provide a urine sample for testing of pregnancy.

After you have provided your written consent, the four-day dietary food log you provided will be analyzed and the PI or a research assistant trained in nutrition will discuss basic dietary recommendations with you. You will then be scheduled for baseline testing (visit 2). You will be asked to maintain a similar diet throughout the remainder of the study.

**Visit 2:** During this visit you will complete 4 tests and it will take about an hour. You will be asked to arrive 8 hours fasted from food, caffeine, and tobacco, but will be encouraged to still drink water.

1. **Body Composition Testing:** You will be asked to participate in a series of tests to evaluate your body composition, including percent body fat, fat mass, muscle mass, bone mineral content, and total body water.
   a. **Dual energy x-ray absorptiometry (DEXA):** The DEXA uses two x-ray beams to measure differences in composition of different tissues in the body such as bones, muscle, and fat. The scan is performed while you are resting on your back and takes approximately 7-13 minutes.
   b. **Bioelectrical Impedance Spectroscopy (BIS):** These tests are used to determine your total body water. You will be asked to remove your right footwear, including sock, and lie on a table on your back. Small stickers will be placed on your right hand at your wrist and finger, as well as on your foot near the ankle and toe. There will be a small electrical current sent through your body, which is harmless and you cannot feel. This test takes about 5 minutes (BIS).
c. Ultrasound: While you are lying down, following the BIS test (describe above), an ultrasound probe will be placed on your abdomen, just above your belly button, to estimate visceral fat. Ultrasound gel will be used on the probe to help get a better image. While lying still, an image will be captured. This test takes about 1 minute.

2. Blood Draw: All blood draws will be done in the Applied Physiology Lab by an individual trained in phlebotomy. About a half of a teaspoon sample will be taken.

3. Exercise Time-to-Exhaustion: Your resting heart rate using a chest strap (Polar) and compatible wristwatch will be taken after you sit and rest for 10 minutes. The test consists of a 5-minute warm up at 2.5 mph on a treadmill, followed by a gradual increase in speed (0.5 mph every 30 seconds) until you reach a specified heart rate. You will then exercise at this speed until you can no longer continue.

**Intervention & Electronic Correspondence:** You will be randomly assigned (like flipping a coin) to either a probiotic group or placebo group. All participants will be given a six-week supply of daily packets, either probiotics or placebo, to be taken in the evening before bed. Both groups will be asked to complete a 24-hour diet log every two weeks in order to monitor supplement compliance and monitor for any changes in dietary intake. You will be contacted via phone or email every two weeks as well for a brief follow-up consultation to make sure everything is going well. You will be asked to return all empty packets.

**What are the possible benefits from being in this study?**
Research is designed to benefit society by gaining new knowledge. All participants will gain knowledge of their body composition and insulin sensitivity.

**What are the possible risks or discomforts involved from being in this study?**
The risk of physiological and psychological harm is very minimal and would not cost you physical or emotional loss. However, any research study does carry with it some potential for risk or discomfort, listed below:

During each testing session you will be exposed to radiation during the DEXA scan. This research study involves exposure to radiation from (2 DEXA scans). The dose that you will receive from participation in this research study is similar to one cross-country flight or the amount you would receive from one day of natural sources. Please note that this radiation exposure is not necessary for your medical care and is for research purposes only. The amount of radiation you will receive in this study has a minimal risk and is below the dose guideline established by The University of North Carolina Radiation Safety Committee for research subjects.

Due to the minimal radiation exposure, risk is increased during pregnancy, due to potential exposure to the fetus. Therefore, pregnant women or women planning to become pregnant are excluded from this study. Additionally, if sexually active, use of contraception throughout the study is required.

There is a very rare chance of reaction, such as soft stool or gas, to the probiotic supplement. You will be asked to report any known allergies during the health history questionnaire in order to prevent this from happening. Instances of stomach cramping, nausea, fever, or taste disturbance are extremely rare. Should you experience an allergic or other adverse reaction to the supplement, you should notify the researcher immediately. There may be other uncommon or previously unknown risks. You should report any problems to the researcher.

**What if we learn about new findings or information during the study?**
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

**How will information about you be protected?**
Upon agreement to participate in this study, you will be given a unique research ID number to be used on study documents, instead of identifying information or your name. A form will be created listing the research ID numbers with the corresponding names of participants and this document will be filed and kept in a locked cabinet in the faculty advisor’s office that is separate from the other research documents. Data from study documents will be transferred to a designated research computer with password protection. Access will only be granted to members of the research team. At the end of the study, all participant documents will be shredded and disposed of properly.

Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

**What will happen if you are injured by this research?**
All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.

**What if you want to stop before your part in the study is complete?**
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

**Will you receive anything for being in this study?**
You will receive a total of $25.00 for participation in the entire study. You will receive $5.00 for completing pre-testing. Completion of each bi-weekly food log and correspondence will result in $12.00 total, with completion of post-testing resulting in $8.00

**Will it cost you anything to be in this study?**
It will not cost you anything to be in this study. However, you will be responsible for covering any costs related to transportation to laboratory visits. Free parking in the form of public transportation or department parking passes are available.

**Who is sponsoring this study?**
This project is supported, in part, by the National Strength and Conditioning Association. This means that the research team is being paid by the sponsor for doing the study. In addition, Abbie Smith-Ryan, the faculty advisor on this study, participates in unpaid activities which are not part of this study for the National Strength and Conditioning Association. These activities may include service on advisory boards, giving speeches, or writing reports.
The project is also supported in part by Winclove, who will be providing the probiotic and placebo supplement free of charge.

A review of these arrangements was conducted at UNC-Chapel Hill. They concluded that the possible benefit to the person(s) listed above is not likely to affect your safety or the scientific quality of the study. If you would like more information, please ask the researchers listed in the first page of this form.

**What if you have questions about this study?**
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

**What if you have questions about your rights as a research participant?**
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

**Participant’s Agreement:**
I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

______________________________________________________
Signature of Research Participant Date

______________________________________________________
Printed Name of Research Participant

______________________________________________________
Signature of Research Team Member Obtaining Consent Date

______________________________________________________
Printed Name of Research Team Member Obtaining Consent