ID: 19049 NCT: not yet assigned

Effect of Dry Roasted Peanuts and Boiled Peanuts on Glycemic Control

November 11th 2019

NC STATE UNIVERSITY

Informed Consent for Participation in Research

Adult Informed Consent Form

Title of Study: Effect of dry roasted peanuts and boiled peanuts on glycemic control **(eIRB # 19049)**
Principal Investigator: Elizabeth Brooke Wilson, ebwilso2@ncsu.edu, 919-619-3309
Funding Source: USDA Market Quality and Handling Unit, Agriculture Research Science
Faculty Point of Contact: Jonathan C. Allen, jallen@ncsu.edu, 919-513-2257

What are some general things you should know about research studies?
You are invited to take part in a research study. Your participation in this study is voluntary. You have the right to be a part of this study, to choose not to participate, and to stop participating at any time without penalty. The purpose of this research study is to gain a better understanding of the impact on glycemic response by consuming dry roasted peanuts and/or boiled peanuts daily or before a meal. We will do this through eating dry roasted and/or boiled peanuts, glucose tolerance testing, and glucose levels testing.

You are not guaranteed any personal benefits from being in this study. Research studies also may pose risks to those who participate. You may want to participate in this research because you could learn more about your body and its glycemic control. You may not want to participate in this research because the study takes a lot of time and requires you to prick your finger numerous times during tests for blood glucose readings.

Specific details about the research in which you are invited to participate are contained below. If you do not understand something in this form, please ask the researcher for clarification or more information. A copy of this consent form will be provided to you. If, at any time, you have questions about your participation in this research, do not hesitate to contact the researcher(s) named above or the NC State IRB office. The IRB office's contact information is listed in the *What if you have questions about your rights as a research participant?* section of this form.

What is the purpose of this study?
The purpose of the study is to determine if consuming roasted or boiled peanuts daily has an impact on blood glucose control, or weight control. We also hope to determine if consuming a serving of peanuts before a standard amount of glucose will impact blood glucose response in the short term.

Am I eligible to be a participant in this study?
There will be approximately 15-20 participants in this study.

In order to be a participant in this study, you must agree to be in the study and
1. be between the ages of 18 to 65

2. have a body mass index (BMI) is between 18.5 and 24.9 kg/m2 for your height
3. not be pregnant

You cannot participate in this study if you do not want to be in the study or

1. your body mass index (BMI) is greater than >24.9 kg/m2 or under <18.5 kg/m2 for your height
2. you have type 1 or 2 diabetes
3. you have anemia
4. your fasting glucose is greater than >125 mg/dL
5. you take a medication that treats metabolic, renal, liver, pancreatic, or cardiovascular disease.
6. you have uncontrolled hypertension
7. you have esophageal or gastrointestinal motility issues
8. you have hypothyroidism or hyperthyroidism
9. you are allergic to peanuts
10. you are pregnant
11. your body weight is less than 110 pounds.
12. you have insulin Resistance
13. you have polycystic ovary syndrome (PCOS)
14. you have food intolerances, such as peanuts or sugary foods.

What will happen if you take part in the study?

If you agree to participate in this study, you will be asked to do all of the following:

1. Complete a health-screening questionnaire and then sign the consent form. The consent form must be signed before the oral glucose tolerance test to determine your eligibility. This will take 60 minutes.
2. Complete a screening oral glucose tolerance test (hereafter, OGTT). You will arrive to the lab without having eaten or drunk anything for at least 8 hours. You will be given a 50g glucose drink to consume. Your blood glucose levels will then be measured through self-administered finger pricks at 10, 20, 30, 40, 50, 60, 75, 90, 105, and 120 minutes after consuming the glucose beverage. The OGTT will take 3 hours of your time.
3. After the screening OGTT, your height, weight, and hip-to-waist measurements will be taken by Brooke Wilson and accompanying staff. This will take 10 minutes.
4. Based on the results of your health questionnaire, body measurements, and screening OGTT, you may be invited to further participate in this study. But it also is possible that you could pass the health screen questionnaire, sign the consent form, and then have an unhealthy oral glucose tolerance response. In those cases, you will not be allowed to continue in the study and will not be compensated in any form.
5. If you qualify and are interested in participating in this study, you will attend an orientation meeting, where the details of each of three phases of the research will be described to you, what you will do in each phase of the research, how much time you will be asked to commit to this research, and the risks and benefits of

participating will be discussed. This study will ask you to refrain from alcohol consumption for the duration of all study phases and from exercise 10 hours before a glucose test. The meeting will take 60 minutes.

6. Complete Phase 1 of the research. This phase consists of two 3-hour morning sessions over one week, for a total of 6 hours of your time for this phase. At each morning session, you will arrive at the lab without having eaten or drunk anything for at least 8 hours. You will consume either boiled or roasted peanuts, followed by a 50g glucose drink. Your blood glucose levels will then be measured through self-administered finger pricks at 10, 20, 30, 40, 50, 60, 75, 90, 105, and 120 minutes after consuming the nuts and the glucose beverage. Your height, weight, and hip to waist measurements will also be taken. Each session (2) of phase 1 will take 3 hours of your time, for a total of 6 hours.
7. Complete a wash out week, where for 1 week, you will not consume any peanuts or food products that contain peanuts (e.g. nut butter, trail mix, candy bars etc.). During this week, you will be asked to record everything you eat and your physical activity. We will provide you with a pedometer to track your steps if you do not own one.
8. Complete phase 2 of the research, which will take two weeks. During the two weeks, you will be asked to consume 48 grams of peanuts (either boiled or roasted) each day between lunch and dinner for 14 days. You will be asked to record everything you eat and your physical activity as measured by your step count each day. Consuming the peanuts and tracking what you eat and your physical activity will take about 10 minutes per day. At the end of the two weeks, you will arrive at the lab for one 3-hour session. You will arrive to the lab without having eaten or drunk anything for at least 8 hours. You will consume a 50g glucose drink. Your blood glucose levels will then be measured through self-administered finger pricks at 10, 20, 30, 40, 50, 60, 75, 90, 105, and 120 minutes after consuming the glucose beverage. Your height, weight, and hip to waist measurements will also be taken. Phase 2 will take 5 hours of your time.
9. Complete a second wash out week, where for 1 week, you will not consume any peanuts or food products that contain peanuts (e.g. nut butter, trail mix, candy bars etc.). During this week, you will be still be asked to record everything you eat and your physical activity. We will provide you with a pedometer to track your steps if you do not own one.
10. Complete phase 3 of the research, which will take 2 weeks. During the 2 weeks, you will be asked to consume 48 grams of peanuts (either boiled or roasted) each day between lunch and dinner for 14 days total. You will be asked to record everything you eat and your physical activity as measured by your step count. Consuming the peanuts and tracking what you eat and your physical activity will take about 10 minutes per day. At the end of the two weeks, you will arrive at the lab for one 3-hour session. You will arrive to the lab without having eaten or drunk anything for at least 8 hours. You will consume a 50g glucose drink. Your blood glucose levels will then be measured through self-administered finger pricks at 10, 20, 30, 40, 50, 60, 75, 90, 105, and 120 minutes after consuming

the glucose beverage. Your height, weight, and hip to waist measurements will also be taken. This phase 3 will take 5 hours of your time.

Through the course of this study, you will spend 15 hours at a lab testing your blood glucose levels (in 3-hour sessions) plus 10 minutes per day tracking your food and exercise. The total amount of time that you will be participating in this study is 21 hours.

Risks and benefits

There are minimal risks associated with participation in this research. The risks to you as a result of this research include:

1. **Finger bruising from blood glucose collection.** We will train you how to take your own blood samples to minimize pain and bruising; you will also be in control of where on your body you draw the blood.
2. **Reaction to study foods.** Participants with food allergies cannot participate in this study. All foods included in this study are generally recognized as safe (GRAS) and produced and prepared in inspected good manufacturing practices (GMP) facilities.
3. **Physical irritation from wearing the pedometer** if it pinches your skin while sitting or bending. We advise you to wear loose fitting clothing to prevent this from occurring. If you choose to use a smartwatch or smartphone app to track your steps instead of the pedometer we give you, please know that your data may not be safe. Researchers have been trained to keep all information regarding subject identity and links to data confidential. As employees of NC State University, they are covered by university liability insurance for damages inadvertently caused in performance of the job. However, we cannot promise any security for data generated in an identifiable format that is not solely managed by this research team on NCSU-managed research devices.
4. **Risks related to oral glucose tolerance test**: There is the possibility of sleepiness, nausea and/or an upset stomach due to glucose drink and prior fasting. You will not be left alone during this test, all participants, Brooke Wilson, and a second research member will be in the same room at all times. In case of emergency, Brooke Wilson will get help, call 911 if needed, and the other research member will stay with you.
5. **Risk of developing or discovering a peanut allergy:** There is a possibility that you do not believe (or have any past experience indicating) that you have a peanut allergy but could suddenly develop a peanut allergy within the duration of study. In case of emergency associated with allergies while in the lab, Brooke Wilson will get help, call 911 if needed, and the other research member will stay with you. There is a provided information sheet about the signs and symptoms of peanut allergies, along with information about when to contact emergency services or your medical provider.

There are no direct benefits to your participation in the research. Some of the indirect benefits are that the research data could contribute to new processing methods that could help improve peanuts'

nutrient profile or glycemic response impact for humans. The research results may also support diabetic patients' treatment in the future.

Right to withdraw your participation

You can stop participating in this study at any time for any reason. In order to stop your participation, please communicate this immediately via email, phone, or in person to Brooke Wilson or Jonathan Allen. If you choose to withdraw your consent and to stop participating in this research, you can expect to be required to return all medical devices given to you to be used in this study, such as the glucometer, and you will not receive full compensation. To receive partial compensation ($100) you must finish phase 1 and phase 2 of this study. To receive full compensation ($300) you must complete the phase 1, phase 2, and phase 3 components of the study.

Confidentiality, personal privacy, and data management

Trust is the foundation of the participant/researcher relationship. Much of that principle of trust is tied to keeping your information private and in the manner that we have described to you in this form. The information that you share with us will be held in confidence to the fullest extent allowed by law. Protecting your privacy as related to this research is of utmost importance to us.

How we manage, protect, and share your data are the principal ways that we protect your personal privacy. Data generated about you in this study will be de-identified.

> **De-identified**. De-identified data is information or bio-specimen(s) that at one time could directly identify you, but that we have recorded so that your identity is separated from the data. We will have a master list with your code and real name that we can use to link to your data. While we might be able to link your identity to your data at earlier stages in the research, when the research concludes, there will be no way your real identity will be linked to the data we publish.

Data that will be shared with others about you will be de-identified because we aim to keep your personal identity and health information confidential while being able to share the data you produce in our study.

To help maximize the benefits of your participation in this project, by further contributing to science and our community, your de-identified information may be shared with other people without additional consent from you.

Compensation

For your participation in this study, you will receive compensation of $300 in cash for the whole study. The participant must be eligible for the study and complete the entire study, 1 phase 2, and phase 3, to receive the full compensation.

If you withdraw before completing Phase 1, there will be no compensation. If you complete only Phase 1, you will receive $100. If you begin but do not complete Phase 2 and Phase 3, there is no additional compensation after you receive the $100 for completing Phase 1. To receive the total compensation of $300, you must complete all study activities in Phase 1, Phase 2, and Phase 3.

Emergency medical treatment

If you are hurt or injured during the study session(s), the researcher will call 911 for necessary care. There is no provision for compensation or free medical care for you if you are injured as a result of this study.

What if you are an NCSU student?
Your participation in this study is not a course requirement and your participation or lack thereof, will not affect your class standing or grades at NC State.

What if you are an NCSU employee?
Your participation in this study is not a requirement of your employment at NCSU, and your participation or lack thereof, will not affect your job.

Sponsorship and Funding
This research is funded by Market Quality and Handling Unit, Agriculture Research Science of the United States Department of Agriculture (USDA). This means that the sponsor is paying the research team for completing the research. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study. If you would like more information, please ask the researcher(s) listed on the first page of this form about the funding and sponsorship.

What if you have questions about this study?
If you have questions at any time about the study itself or the procedures implemented in this study, you may contact the researcher, Elizabeth Brooke Wilson, ebwilso2@ncsu.edu, 919-619-3309, or the NCSU faculty point of contact, Dr. Jonathan C. Allen, jallen@ncsu.edu, 919-513-2257.

What if you have questions about your rights as a research participant?
If you feel you have not been treated according to the descriptions in this form, or your rights as a participant in research have been violated during the course of this project, you may contact the NC State IRB (Institutional Review Board) Office. An IRB office helps participants if they have any issues regarding research activities. You can contact the NC State IRB Office via email at irb-director@ncsu.edu or via phone at (919) 515-8754.

Consent To Participate
By signing this consent form, I am affirming that I have read and understand the above information. All of the questions that I had about this research have been answered. I have chosen to participate in this study with the understanding that I may stop participating at any time without penalty or loss of benefits to which I am otherwise entitled. I am aware that I may revoke my consent at any time.

Participant's printed name _____

Participant's signature _____ **Date** _____

Investigator's signature _____ **Date** _____