Additive effects of honey and nuts in altering postprandial glycemia

NCT06107231

5/7/2025

CALIFORNIA EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

These rights are the rights of every person who is asked to be in a research study. If you choose to take part in research, you have all of these rights.

1. I have the right to be told what the research is trying to find out.

2. I have the right to be told about all research procedures. If there are drugs or devices being used in the research, I have the right to know about them. I have the right to know if anything is different from standard practice.

3. I have the right to be told about any risks or discomforts that might reasonably happen because of the research.

4. I have the right to be told if I can reasonably expect to benefit from taking part in the research. If there are or might be benefits, I have the right to be told about them.

5. I have the right to be told about other choices I have and how they may be better or worse than taking part in the research. These choices may include other procedures, drugs, or devices.

6. I have the right to be told what kind of treatment will be available if the research causes any complications.

7. I have the right to ask any questions I have about the research. I can ask these questions before the research begins or at any time during the research.

8. I have the right to say yes or no to taking part in the research. If I take part, I have the right to withdraw (quit) at any time. My decision will not affect my care or my relationship with my doctor. It will not affect my legal rights.

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9. I have the right to get a copy of the research consent form that I have signed and dated.

10. I have the right to be free of any pressure as I decide if I want to take part in the research.

Signature	Date

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Title of research study: Additive effects of honey and nuts in altering postprandial glycemia

Investigators: Mary Kable, PhD and Kevin Laugero, PhD

Key Information about This Research Study

You are invited to take part in a research study. The purpose of this research is to compare two snacks, one with honey and nuts and the other with sugar and nuts, on blood glucose levels before and after eating these snacks. You are invited to be in this study because you are an adult between the ages of 18 to 40 years with no digestive disease or allergy to nuts. Your participation in this research will include 8 visits to the research center and will last about 30 days. We expect about 80 people at UC Davis and surrounding areas to take part in this research.

Being in this study will involve having your weight and height measured, wearing a continuous glucose monitor, keeping records of foods you eat, and providing stool samples and saliva samples. You will also take tests for measuring memory and decision-making and fill out questionnaires related to your health and ethnic background. All research studies have some risk. The risks of this study are minimal and not different than those you encounter in daily life. These risks are described in detail later in this document. There is no possibility that you may benefit from participation in this study.

Here are some reasons you may not want to be in this research: The study visits may not fit with your schedule, and you may not like the snacks that are prepared for this study. Collecting stool samples may be too objectionable to you.

Your participation in this study is voluntary. You do not have to be in this study if you do not want to. There may be other choices available to you. Some other choices may include finding another study that is more to your liking. You will not lose any services, benefits, or rights you would normally have if you choose not to take part.

The rest of this form gives a more complete description of this study. Please read this form carefully. You can ask any questions you need to help you choose whether or not to join this study.

Information to help you understand research is online at

What if I have Questions?

The person in charge of this study is Dr. Mary Kable. If you have questions or concerns about this study, please contact Dr. Kable, at 530-752-1607. You may also contact the Study Coordinator, Denise Rodriguez at 530-754-5735 or Dr. Ellen Bonnel, Human Studies Coordinator at 530-752-4184.

For non-emergency issues you can call the UC Davis Health Hospital Operator (916-734-2011), tell the Operator you are in a research study and you wish to talk to the Internal Med Resident on-call. In the case of an emergency, dial 911 from any phone.

If you have any questions about your rights as a research subject or have complaints about the research study or study team, you may talk to a team member at the Institutional Review Board (IRB) by phone: (916) 703-9158, by email: hs-irbeducation@ucdavis.edu, or by mail: 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817. The IRB is a group of people who oversee research.

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How is this research funded?

This research is being funded by the National Honey Board also called the sponsor. Sponsors may change or be added.

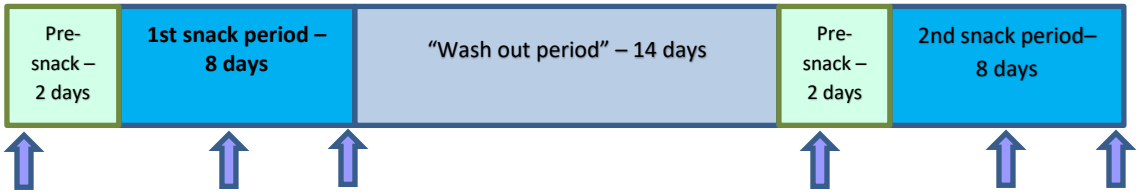
UC Davis is being paid to conduct this study, but the study investigators and research staff have not received any direct income from the sponsor.

What happens if I say yes, I want to be in this research?

If you decide to join this research study, the researchers will ask you to do the following procedures and activities:

1. Eat the foods provided for the study. This includes the snack items and a breakfast meal.
2. Record the foods you eat using an on-line system.
3. Collect stools on specified days.
4. Collect saliva at specified times.
5. Wear a continuous glucose monitor.
6. Record your feelings of appetite at specified times using a tablet.
7. Take tests of decision-making ability and other measures of brain function, called 'cognitive function'.

The study is designed to be a "cross-over" study, which means that you will be assigned to consume one of the snack options first, and then the other option second. The snack you get first will be chosen by chance, like flipping a coin. Neither you nor the study investigators will choose what type of snack you get first. When the second snack period begins, you will get the alternate snack. Therefore, you will receive both snack types if you participate in the full study. Only the kitchen personnel will know which snack you will receive and when. Here is the timeline for the study, with center visits indicated by arrows:



Foods provided by the study

Study foods include the snacks of honey alone, honey plus nuts, sugar syrup alone, sugar syrup plus nuts. For the first 4 days of the snack period, you will eat the honey alone or the sugar syrup alone. For the last 4 days of the snack period, you will eat the combined honey plus nuts or sugar syrup plus nuts. On the test days you will eat the combined snack along with a breakfast meal.

Food records

You will record the foods and beverages you eat using an on-line system called the ASA-24. You are free to eat any foods you want during this time, along with the provided snacks, and will record for the first 7 days of each snack period. You will receive training to use this system.

Stool collection

On the days before the 1st and 2nd snack periods we will give you a stool sample collection kit, containing a fecal collection vessel, a hard sided cooler, and cold packs. You will collect a stool sample at home 24 hours prior to starting to eat the snack food items. Once you have collected the sample, place it in the cooler with frozen cold

packs and return the cooler to WHNRC. Detailed instructions are provided in a separate document given to you during orientation. The stool samples will be used to characterize the bacteria living in your lower bowel and to assess if inflammation is present.

Saliva testing

Two methods will be used to collect your saliva. On the day before a snack period begins and days 4 and 8 after fasting overnight, right before eating the snack the passive drool technique will be used. On days 4 and 8 of a snack period you will place an oral swab in your mouth for 1-2 minutes to soak up your saliva and then place the swab into the tube provided. You will do this procedure for both snack periods and collect saliva 30 min, 60 min, and 90 min after eating the snack. Saliva is used to estimate your stress levels as well as hormones that affect stress levels.

Continuous glucose monitoring

You will wear a continuous glucose monitor (CGM) once for each snack period. The CGM measures your blood glucose level via a tiny sensor inserted through the skin on the back of the arm. The monitors will only collect glucose values and timestamps, no personal identification information is required. We will place a sterile adhesive dressing over the sensor, which is about the size of a quarter, to prevent any detachment of CGM, but if it falls off, please contact the Study Coordinator and we will replace it with a new sensor.

Appetite monitoring

This procedure will be done on the test days at the end of both snack periods. We will ask you to report immediate feelings of i) hunger, ii) fullness, iii) desire-to-eat, iv) satisfaction with snack, and v) how much you think you can eat at the moment. You will record your feelings using a tablet device with 100 mm horizontal answer lines depicting the extremes (0=not at all to 100=extremely). Nausea will also be queried to make sure there is no confounding effect of illness. You will make entries on the tablet twice before eating the snack and 5 minutes after eating the snack and every 30 minutes thereafter.

Cognitive function tests

These tests will be done on day 4 and day 8 of both snack periods. You will use a touch screen tablet to record your answers. The first test will establish your reaction time, and the following tests will evaluate your working memory, learning abilities, and visual processing. Each set of tests will take about seventy-five minutes to complete.

Menstrual Cycle Log

Female participants will be asked to complete a menstrual cycle log for the duration of the intervention.

How is being in this study different from my regular health care?

This study is not part of your regular health care.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for:

1. Arriving on time to study visits.
2. Eating study provided foods.
3. Wearing the CGM.

4. Communicating with the study team if you have a problem with the CGM, scheduling conflict, or if you become ill.
5. Treating staff and other study participants with respect.

Do I have to be in this study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. You can choose to be in the study or not be in the study. If you decide to be in the study, you can choose to leave the study at any time.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UC Davis Health or any services you receive from them. No matter what you decide, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Please let the researchers know if you choose to leave the study. If you are wearing a continuous glucose monitor when you leave the study, we will ask you to come in so it can be removed safely.

The data that we have collected from you up to the point of your leaving the study will be retained by the researchers for analysis.

What are my other choices if I do not take part in this study?

If you decide not to take part in this study, you have other choices. For example: You may choose to take part in a different study if it is more to your liking.

Can I be removed from the research without my OK?

The researchers may take you out of the study, even if you want to continue, if:

- you do not follow the study rules in particular, eating the study snacks or wearing the continuous glucose monitor.
- you behave disrespectfully to study personnel or other study subjects.
- the study is stopped by the sponsor or researchers.

Is there any way being in this study could be bad for me?

There are minimal risks to participating in this research. The study doctor and study team will monitor you to see if you are experiencing any harm related to your participation. If you experience any pain or discomfort, you must inform the study team as soon as possible.

There are potential physical, psychological and privacy risks, including:

- The chemicals in the stool collection tubes are non-toxic, but they have to be handled carefully to avoid getting in your eyes or on your skin. If you have chemicals contact your skin or eyes, flush with plenty of water and thereafter, contact the study coordinator.
- The snacks contain nuts. If you were unaware that you had a nut allergy, one might emerge after eating nut-containing snacks.

- Procedures may cause you to feel stressed or some questions may make you feel uncomfortable. Let the Study Coordinator know if you are experiencing stress.
- As with all research, there is a chance of a breach of confidentiality (your personal information could be seen by people outside of the research study without your permission). To minimize the risks of breach of confidentiality, we will not include any information that directly identifies you on the specimens and information we collect, and on the data resulting from the research. Instead, we will use a code on the bio-specimen and information, and we will keep a link between the code and your identity in a different secure location.

Researchers ***will not*** use your specimens for genetic or genomic testing.

Will being in this study help me in any way?

Being in this study will not help you directly. But your taking part in the study may benefit other people in the future by helping us learn if honey has a beneficial effect on blood glucose levels.

Will being in this study cost me anything?

There will be no cost to you for any of the study activities or procedures. Neither you nor your insurance carrier will be charged for your taking part in the research. All costs associated with the study will be paid by the sponsor/department.

If you need treatment for side effects while you are on the study, you or your insurance will need to pay for this treatment.

Will I be paid or receive anything for being in this study?

We will pay you $450 for participating in this study if you complete the entire study. Payment will be provided at the end of the last study visit as an electronic debit to your bank account. If you choose to leave or we take you off the study before you complete the study, you will receive payment for the portion(s) of the study you have completed as follows:

	If completed entirely
P*articipation in 1st test day ($15/hour)*	$12*0*
P*articipation in 2nd test day ($17.50/hour)*	$14*0*
Diet records $5/record	$*70*
F*ecal samples $5/sample*	$*30*
Saliva Samples $5/sample	$*90*
total	**$450**

You may be asked for your social security number for payment purposes. It will not be used for any other reason without your permission.

If you receive $600 or more during a calendar year from the University for taking part in research, you may receive a 1099 for tax reporting purposes. Reimbursements for travel and other expenses are not included in this amount.

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Biospecimens (such as stool or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.
If you are injured as a result of being in this study, the University of California will provide the necessary medical treatment. Depending on the circumstances, the costs of the treatment may be covered by the University or the study sponsor or may be billed to your insurance company just like other medical costs. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about compensation, you may contact the IRB Administration at (916) 703-9151 or HS-IRBAdmin@ucdavis.edu.

What happens to the information collected for the research?

We will do our best to limit the use or disclosure of your personal information, including information from this research study, to people who need to review this information. We cannot promise complete confidentiality. Some organizations may be required to inspect and copy your information including the IRB and other University of California representatives responsible for the management or oversight of this study.

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will remove identifiable information from the data we collect about you. After we remove all the identifiers, we will place a code on the information. The code will be linked to your identity, but the link will be kept in a location that is separate from your study data. We will maintain your study data on encrypted computers and access to the information will be limited to only members of the research team who need access to properly conduct the study. The information we send to the sponsor will not include information that directly identifies you. Instead, a code will be applied to the data and the link between the code and your identity will be kept at the research site.

However, we cannot promise complete confidentiality. If you agree to be in this study, Federal or state laws may permit or require us to show information to university or government officials and to study sponsors responsible for monitoring this study. The following is a list of individuals who may access your records:

- Members of the research team
- Offices and committees responsible for the oversight of research
- The study sponsor, the National Honey Board

A clinical trial is a study which assigns subjects to one or more interventions prospectively and evaluates the effect of the intervention for biomedical or behavioral health-related outcomes. A description of this clinical trial will be available on http://www.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 web site at any time.

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Will I receive any results from this research? You will not receive any results from this study.

Will information or leftover specimens be used for other research?

We will use your biospecimens and information to conduct this study. Leftover biospecimens and data collected for this research may also be used for future research studies. We will not share any personally identifiable information. Our goal is to make more research possible. These studies may be done by researchers at this institution or other institutions, including commercial entities. Data may be placed in one or more external scientific databases for access and use. Biospecimens may be placed in research repositories. We will not ask you for additional permission to share de-identified information or biospecimens.

May we contact you by e-mail?

We are requesting your email address so we can remind you of upcoming appointments. Email is generally not a secure way to communicate about your health, as there are many ways for unauthorized users to access email. You should not send sensitive, detailed personal information by email. Email should also not be used to send urgent information. If you need to talk to someone right away, please contact Dr. Mary Kable, 530-752-1607, or the Study Coordinator, Denise Rodriguez, 530-754-5735. You do not have to give your email address to be in this study. Please initial one of the lines below.

_____ Yes, you may use email to contact me for this study.

My email address is: _____

_____ No, I do not want to be contacted by email.

Are there other research opportunities?

If you are interested in being contacted for future research, please write your phone number and/or email below. <u>This is completely optional.</u>

_____(Initials) Yes, I am willing to be contacted for future research opportunities. My phone number and/or email is: _____

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Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

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