Fruit-based chewing gums for improving oral health

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UNIVERSITY OF WISCONSIN-MADISON
CONSENT TO PARTICIPATE IN RESEARCH

Title of the Study: Fruit-based chewing gums for improving oral health

Formal Study Title: Fruit-based chewing gums for improving oral health.

Lead Researcher: Bradley W. Bolling, PhD (phone: (608) 890-0212) (email: bwbolling@wisc.edu)

Where Lead Researcher Works: Department of Food Science

Invitation

You are invited to participate in a research study to better understand how health-promoting compounds are released from fruit-based chewing gum. You have been asked to participate because you are a healthy adult and meet other study participation requirements discussed.

The purpose of this consent form is to give you the information you need to decide whether to be in the study. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. Once we have answered all your questions, you can decide if you want to be in the study. This process is called “informed consent.”

Why are researchers doing this study?

The purpose of this research is to investigate the connection between cranberry and oral health. We will compare the release of cranberry compounds in our gum containing an ingredient called, phospholipid-polyphenol (PLP), to a control gum containing cranberry extract. We think that the PLP gum may prolong the delivery of important health-promoting cranberry compounds from the gum into your mouth. This study can help scientists better understand how PLP-made products potentially benefit oral health.

This study will include 10 healthy adults.

This research study will take place in the Department of Food Science at the University of Wisconsin-Madison campus in Madison, WI.

This study is funded by Discovery 2 Product, at the University of Wisconsin-Madison.

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Why are some reasons I might – or might not – want to be in this study?

You may want to be in this study if you are:	You might NOT want to be in this study if you:
Comfortable chewing gum for two 60-minute periods Comfortable providing multiple saliva samples and chewing gum samples Willing to make dietary modifications suggested by study personnel before both sample collections Interested in contributing to scientific knowledge even though you might not benefit directly from the study	Are nervous about chewing gum or providing saliva samples Won't be able to take time off work to go to all the study visits Unwilling to temporarily avoid consuming food and beverages, using tobacco products, or chewing additional gum

What will happen in the study?

If you decide to participate in this research, you will complete a brief verbal questionnaire to determine eligibility and allow the study team to determine your salivary flow rate. To determine your salivary flow rate, we will ask you to relax for a couple of minutes in a private setting. Next, you will provide as much saliva as possible in a single collection tube over the course of five minutes. This is important because we will need to collect saliva samples from you throughout the study. Additionally, you may skip any question on the questionnaire that you do not wish to answer. This visit is expected to take approximately 30 minutes to 1 hour.

If you are determined to be eligible to participate further and enrolled in the study, you will be randomly assigned the order you will receive the two chewing gums that are made with either PLP or cranberry extract. Gums will be labeled gum A and gum B. You will have the ingredient lists of both gums, but you will not know which gum contains the PLP or cranberry extract. This is considered a single-blind study.

Next, you will be scheduled to come back to our study center two more times for approximately 60 minutes each. You will be allowed to complete these visits anytime within normal workweek hours (i.e. 8 - 5 pm, Monday - Friday). However, we will ask you to adhere to dietary restrictions before each sampling period. These restrictions **are refraining from eating, drinking, using tobacco products , and vigorous exercise for 1 h before the sampling periods. Also, avoid chewing gum 48 h before the sampling periods. Water is acceptable up until 10 minutes before sample collection.**

On your first visit, you will be asked to chew the assigned gum based on a standardized chewing rate. While chewing, we will collect multiple chewed gum pieces at given time

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periods over the course of 60 minutes. After a chewed gum sample is collected, you will chew a new piece of gum for the next given period. This process will repeat until we collect a piece of chewed gum for each time interval. Each gum sample will be analyzed for the loss of cranberry compounds that was released while chewing.

We will also collect a saliva sample before chewing the first piece of gum and after you chewed the last piece of gum for the final time interval. We will ask that you carefully fill a collection tube with your sample by trying to minimize the number of bubbles in the tube. We will measure the saliva samples for changes to the pH (i.e. how basic or acidic it is).and for the compounds released into your saliva.

After your first visit, you will come back for the second visit at your convenience but will have to wait at least 48 hours to do so. However, we ask that you complete the second visit within two weeks of the first one. This visit will be the same as the first except you will chew the other gum. For example, if you chewed gum A on the first visit, you would chew gum B on the second visit.

After each visit, we would like you to complete a very brief online survey to share your opinions and give us feedback about each gum. Your answers to these surveys will be anonymous to the study staff.

During the study, we also ask that you maintain your normal dietary habits except for the restrictions specified above before each visit. **We also ask that you inform us if you are no longer eligible to participate,** though you will not be asked to provide the specific reason (e.g. pregnancy or change in health status).

How long will I be in this study?

You will be part of the study for a total of 3 visits including the first screening visit (~60 minutes) and two intervention visits (~60 minutes each). The total duration will depend on the time between visits, but no longer than 2 weeks. These visits will be completed at Babcock Hall.

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

- your health changes and the study is no longer in your best interest
- you do not follow the study rules or no longer meet the requirements to be in the study
- the study is stopped by the sponsor or researchers

Do I have to be in the 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. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time.

If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

Let the researchers know if you choose to leave the study.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect your academic standing or employment status at UW-Madison. Additionally, it will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Are there any risks to me?

There is a risk that your information could become known to someone not involved in this study.

There is a minor risk of a choking hazard associated with chewing gum.

You may be inconvenienced or feel discomfort in providing saliva samples. Refraining from smoking or nicotine use before collection visits could also cause discomfort or withdrawal symptoms (cravings, headaches, nausea, anxiety, irritability, difficulty concentrating, and tingling in the hands or feet).

The risks of allergic reaction to a component in the intervention foods are rare but potentially serious. If you experience any swelling and itching of oral mucosa in the throat, lips, or itching in the eyes, you may be having an allergic reaction. In addition, you may dislike the flavor and texture of both gums.

Berry-based foods may have interactions with certain medicines that are affected by grapefruit juice, but this is currently unknown.

Will being in this study cost me anything?

There will be no cost to you for any of the study activities or procedures, other than that you will have to pay for travel to and from the study center. You will not have to pay for parking if you park on campus.

Are there any benefits to me?

Being in this study will not help you directly. Your participation in the study may benefit other people in the future by helping us learn more about how cranberry compounds released from gum affect oral health.

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How is research different from health care?

When you take part in a research study, you are helping to answer a research question. Study tests and procedures are not for your health care.

Will I be compensated for my participation?

You will be eligible to receive various snacks / food items at the study center after completing each session.

Financial Interest Disclosure:

A member of this research team has a personal interest in or might profit financially from the results of this study. This is called a “conflict of interest.” The University of Wisconsin-Madison manages conflicts of interest so that they do not affect study participants or the quality of the data collected. We are telling you about the conflict of interest in case it affects whether you want to take part in this study.

What will happen to my data and biospecimens after my participation ends?

We will keep your data for at least seven years and biospecimens for five years. The data and biospecimens will be kept in a secure location for use by researchers. The data and biospecimens will be labeled with a code number that allows only the members of this research team to identify you.

How will my confidentiality be protected?

The study staff will keep all study records (including any codes to your data) locked in a secure location. Research records will be labeled with a code and all contents of the research record will be labeled with only that code. A master key that links names and codes will be maintained in a separate and secure location. All electronic files (e.g., database, spreadsheet, etc.) containing identifiable information will be stored on a secure server with password protection to prevent access by unauthorized users. While there will probably be publications as a result of this study, your name will not be used. Only group characteristics will be published.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials and study sponsors responsible for monitoring this study. These groups will maintain your confidentiality.

We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Who at UW-Madison can use my information?

Members of the research team
Offices and committees responsible for the oversight of research
Personnel who handle accounting and billing
The study sponsor, Discovery 2 Product

Who outside UW-Madison may receive my information?

None

Will information from this study go into my UW Health medical record?

None of the information we collect for this study will be put in your medical record.

A description of this clinical trial will be available at http://www.ClinicalTrials.gov. 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 I receive the results of research tests?

Most tests done as part of a research study are only for research and have no clear meaning for health care. In this study, you will not be informed of any test results or unexpected findings.

Whom should I contact if I have questions?

You may ask any questions about the research at any time. If you have questions about the research after you leave today you should contact the Principal Investigator Bradley W. Bolling, PhD at (608) 265-1494.

If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

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We are requesting your email address so we can contact you about scheduling study visits and send reminder emails about study visits. 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 avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact Bradley Bolling, Associate Professor, Department of Food Science at 608-890-0212. You do not have to provide your email address to participate in this study.

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

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

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Agreement to participate in the research study

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study.

If you sign the line below, it means that:

- You have read this consent form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.

_____
Printed Name of Participant

_____
Signature of Research Participant Date

_____
Signature of Person Obtaining Consent Date

****You will receive a copy of this form****

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