Informed Consent

Study Title: Mona: A Chewing Gum Study

This is a clinical trial, a type of research study. Your study investigator will explain this study to you. Clinical trials include only people who choose to take part. Please take your time to make the decision to join this study. You can discuss your decision with your friends and family. You can also discuss it with your doctor. If you have questions, ask the investigator to explain anything that you do not understand.

We are asking you to take part in this study because you have met the requirements below.

- Student at the University of the Science in Philadelphia (USP)
- Age between 18-35 years old
- Male, female, or nonbinary

Why are we doing this study?

We want to know what effect various flavors of Wrigley's® sugarless chewing gum has on how people behave.

How many people will take part in the study?

A minimum of 60 people will take part in this study. There is a maximum of 160 people that can join this study.

What will happen if I take part in this study?

1. First, you will choose a card from a jar. On the card will be your unique identification number. The study results will use this number to identify you instead of your name. The card also tells you what flavor of gum you will chew during the study.
2. You will chew the gum for one (1) minute. You might stand or sit.
3. The investigator will observe and document your behavior.
4. Next, you will choose a random adverse event (AE) from another jar. An AE is any negative outcome or experience that might occur.
5. If necessary, the investigator might ask you to chew the same flavor of gum again two more times. Three sticks of gum are the maximum dose.

Before you begin the study

For your safety, you must give us the following information before you start the study.

- Tell us if you have any known allergic or negative reaction to sugarless gum.
- Tell us if you have been diagnosed with phenylketonuria. This means your body cannot digest the amino acid phenylalanine. Amino acids are what proteins, like meat and dairy, are made from. Phenylalanine is an ingredient in sugarless gum.

- Tell us if you have or have ever had an allergic or negative reaction to foods or drinks that contain aspartame or sorbitol. These make foods and drinks taste sweet but are not sugars. Do have any negative reactions to foods that contain butylhydroxytoluene (BHT)? This is an ingredient that keeps the gum from spoiling.

During the study

You will be assigned at random to one of the study groups described below. Random means that you are put into a group by chance. The number you choose from a jar will place you in one of the flavor study groups. Neither you nor your investigator can choose the group you will be in. You will have a 25% chance of being placed in any group.

Sugarless gum study groups

- Extra Cinnamon
- Extra Peppermint
- Extra Wildberry Frost
- Extra Classic Bubble

When you finish chewing the gum

After a chewing the sticks of gum, you will select a random adverse event (AE) from a jar. Tell your investigator what AE you selected. Finally, you will complete a short survey about your experience in this study.

How long will you be in the study?

A maximum of **10** minutes is required for this study. You will be asked to chew the gum for a maximum of 1 minute per dose. There is a maximum of three doses. The maximum total chewing time is **3 minutes**.

There are no follow-up exams required.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study investigator if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely. Also, your doctor might need to check if there are any risks to you from the chewing gum.

The study investigator might stop you from taking part in this study at any time if:

- He or she believes it is in your best interest
- You do not follow the study rules
- The study ends for other reasons

What side effects or risks can I expect from being in the study?

You might have side effects while in the study. We will carefully watch everyone for any sign of side effects. However, doctors do not know all the side effects that might happen. Side effects might be mild or very serious. Your health care team might give you medicines to help lessen side effects. Many side effects go away soon after you stop chewing the

gum. In some cases, side effects can be serious, long lasting, or might never go away. There is little or no risk of death.[9]

You should talk to your study investigator about any side effects that you have while taking part in the study.

Risks and side effects related to sugarless chewing gum include those that are:

Likely

- Excess salivation (spit).[7]
- Flatulence (gas) (caused by excess swallowing of air).[7]
- Diarrhea (loose stools), dyspepsia (upset stomach) (from the sorbitol in "sugarless" gum).[7,16]

Less Likely

- Mouth ulcers or contact stomatitis (mouth inflammation) (from cinnamon flavouring)[7,8]
- Damage to the teeth from chewing[7]
- Overuse injury (TMJ, jaw pain)[7,11]
- Damage to veneers, bridges, implants, or dentures[7]
- Headache.[13]
- BHT (preservative) allergy[19]

Rare, but serious

- High blood pressure and low blood potassium (from liquorice flavoring)[7]
- Higher blood mercury levels (from dental amalgam already in your mouth, but only in cases of excessive chewing)[7,14,15]
- Death by the chewing gum blocking your breathing[9]
- There are known reproductive risks caused by chewing sugarless chewing gum[17]

For more information about risks and side effects, ask your study investigator.

Are there benefits to taking part in the study?

The duration of this study is extremely short; therefore, you are not likely to receive the known benefits of chewing sugarless gum because of this study. However, the long-term benefits of chewing sugarless gum are listed for your information:

Benefits

- Improved mood
- Smiling
- Laughing

- Reduction of germ build-up in the mouth and improved breath[7]
- Slight reduction in risk of cavities (caries)[10]

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

Your other choices might include:

- Getting no treatment; that is, not chewing the sticks of gum

Talk to your investigator about your choices before you decide if you will take part in this study.

Will my medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information might be given out, if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that might look at or copy your medical records for research, quality assurance, and data analysis include:

- This is a learning activity and will be used by USP faculty and students. Your data will remain anonymous.
- The study might be videotaped.

What are the costs of taking part in this study?

There are no costs to you or your health plan or insurance company for being in this study. The investigators are responsible for:

- Providing gum samples
- Paper, pens, and pencils
- Study sites and facilities

You will not be paid for taking part in this study.

What happens if I am injured because I took part in this study?

It is important that you tell your study investigator, Jane Doe, if you feel that you have been injured because of taking part in this study. You can tell the investigator in person or call him/her at 215-555-1234.

You will get medical treatment if you are injured because of taking part in this study. You or your health plan will be charged for this treatment. The study will not pay for medical treatment.

What are my rights if I take part in this study?

Taking part in this study is your choice. You might choose to take part or not to take part in the study. If you decide to take part in this study, you can leave the study at any time. No matter what decision you make, there will be no penalty to you, and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that might affect your health or your willingness to continue in the study.

In the case of an injury that is a result of this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study investigator about any questions or concerns you have about this study. Contact your study investigator, Jane Doe, at 215-555-1234.

For questions about your rights while taking part in this study, call the USP Institutional Review Board (a group of people who review the research to protect your rights) at 215-555-5678.

*You can also call Susanna Dodgson, Program Director of Biomedical Writing at USP, at (215) 596-8512 (from the continental US only).

Where can I get more information?

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You will get a copy of this form. If you want more information about this study, ask your study investigator.

Signature

I have been given a copy of all _____ *[insert total of number of pages]* pages of this form. I have read it, or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this study.

Participant _____

Date _____

Witness Signature

Witness _____

Date _____