Study Title: Evaluation of two mouth sprays for post-irradiation xerostomia in head and neck cancer survivors: a randomized, double-blind clinical trial

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Consent to Act as a Participant in a Research Study

STUDY TITLE: Blinded Dry Mouth Spray Crossover Study

PRINCIPAL INVESTIGATOR:

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QUESTIONS ABOUT THE STUDY:
If you have any questions about your rights as a research subject or wish to talk to someone other the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668.

SOURCE OF SUPPORT:
Financial support for this research study is provided by TJA Health, LLC.

SIGNIFICANT FINANCIAL CONFLICT OF INTEREST:
No significant financial conflict of interest has been identified.

INTRODUCTION:
We are conducting this research study to compare two mouth sprays that are used in treating dry mouth. Both of the products being used in this research are over the counter mouth sprays that do not require FDA approval for use. Dry mouth is a common symptom among people who have received radiation treatment for head and neck cancer (HNC). You are being asked to participate in this research study because you are an adult age 18 or older, who has received radiation as part of your treatment for head and neck cancer. We hope to enroll approximately 150 individuals to participate in this research.

RESEARCH ACTIVITIES:
If you decide to participate in this study, we will ask you to complete the following tasks in about a 6-week time period:

1. Participate in this study on your own, without in person visits with the help of study personnel.
2. Accept assignment to the study group by chance. Depending on the group that you are assigned, we will instruct you to use Mouth Spray A first or Mouth Spray B first.
3. Perform all study activities from your home and by phone or email. The study does not require you to return to the offices in Eye and Ear Institute.

A research staff member will collect your contact information (phone and/or email address), and information about any alcohol and smoking history that you may have. We will give you all the supplies that you will need for participation in this research before leaving the office today.

1st 1 Week Washout Period – Please do not use using any artificial aids such as gum, candy, mouthwash, mouth sprays, etc. that you typically use to relieve your dry mouth symptoms. For these 7 days, you may drink water/liquids or spray water into your mouth as much as you like during this time.

Survey – A member of the research staff will contact you (by email or by phone) to complete a survey about your dry mouth and other symptoms at the end of your seven-day washout period.

pH testing – A member of the research staff will direct you on how to test the acid level of your mouth/saliva and how to get the results to them.

2 Week use of Mouth Spray – After completion of your 1 Week Washout, we will advise you to begin using either Mouth Spray A or Mouth Spray B. For the next 2 weeks, we will ask you to use the same mouth spray as many times a day as you like following the recommended directions. Directions for each "use" is 4-8 sprays.

Survey – A member of the research staff will contact you again (by email or by phone) to complete a survey about your dry mouth and other symptoms at the end of this 2-week period of mouth spray use.

pH testing – A member of the research staff will once again direct you on how to test the acid level of your mouth/saliva and how to communicate the results to them.

2nd 1 Week Washout Period – Please do not use any artificial aids such as gum, candy, mouthwash, mouth sprays, etc. that you typically use to relieve your dry mouth symptoms. For these 7 days, you may drink water/liquids or spray water into your mouth as much as you like during this time.

Survey – A member of the research staff will contact you again (by email or by phone) to complete a survey about your dry mouth and other symptoms at the end of this 1-week washout period.

pH testing – A member of the research staff will once again direct you on how to test the acid level of your mouth/saliva and how to communicate the results to them.

2 Week use of Alternate Mouth Spray – After completion of your second washout week, you will be directed to begin using the other mouth spray (Mouth Spray A or Mouth Spray B, whichever one that you haven't used previously). For the next 2 weeks, you may use the same mouth spray as many times a day as you like following the recommended directions. Directions for each "use" is 4-8 sprays.

Survey – A member of the research staff will contact you one last time (by email or by phone) to complete a final survey about your dry mouth and other symptoms at the end of this 2-week period of mouth spray use.

pH testing – A member of the research staff will direct you on how to test the acid level of your mouth/saliva and how to communicate the results to them.

We are also requesting your permission to review your medical records to collect information about you. Information collected will include basic demographic information such as your age, gender, etc.), your date of diagnosis, your cancer stage, location of cancer, lab analysis of tissue, surgery information, date(s) of treatment (radiation start dates and stop dates), if you receive any other type of treatment in addition to your radiation, (and the dates associated with that treatment), sites and doses of radiation. Nothing will be entered in your medical record as a result of being in this study. This identifiable medical record information will be made available to members of the research team for an indefinite period of time. This authorization is valid for an indefinite period of time.

STUDY RISKS:

Risks of mouth spray use:

There is a rare risk of allergic reaction to either of the sprays. Please stop using and alert the study team if you think you are having a reaction to either.

Risks of washout periods:

It is possible and likely that you will experience a greater amount of dry mouth symptoms during the identified "washout periods". While you will not be able to use gum, candy, lozenges or your usual mouthwashes, rinses or sprays to treat your dry mouth, you may drink unlimited amounts of water and other beverages and can even use water in spray form to help hydrate/moisten the tissues of the mouth.

Risks of questionnaires and use of mobile app:

You may become tired or distressed when completing the questionnaires associated with your participation. You can take breaks if this happens.

Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed. It is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.

Risks of collection and storage of private health information:

It is possible that your confidentiality may be breached and your medical record information may be revealed to individuals not involved in this research. To protect your identity, research records will be coded with a random ID number. The link between your name and your research code will only be available to a select group of researchers involved in this project.

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC.

Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not give up any of your legal rights by signing this form.

STUDY BENEFITS:
There is a potential for benefit from using either mouth spray in relieving your dry mouth symptoms. The information you provide in this study may help patients who have dry mouth in the future.

ALTERNATIVE TREATMENTS:
You may continue to work with your clinical team for treatment options for your dry mouth, including using sprays and /or having frequent sips of water. Both of the products in the study are available over the counter.

PRIVACY (Person) and CONFIDENTIALITY (Data):
To protect your privacy, all the information and paper records pertaining to this proposed study will be stored in a locked cabinet in the School of Nursing or the Department of Otolaryngology. Any names or information that could identify you will be removed from the observational notes and survey. The identity of participants will be indicated in the surveys and on study documents by case number only. Any information about you and your participation in this research study will be handled in a confidential manner. You will not be identified by name or identifying characteristics in any publication of research results.

In addition to the investigators listed on the first page of this consent form and their research staff, the following individuals may or will have access to your medical record information as well as your identifiable information related to your participation in this research study:

- authorized officials from the University of Pittsburgh Office of Research Protections, for the purpose of monitoring the study
- authorized representatives of UPMC or affiliated health care providers may also have access to this information to provide services and address billing and operational issues.

We will share your de-identified data with the sponsor of this research, TJA Health, LLC. We may share your de-identified data with other researchers conducting similar research.

We will make every attempt to protect your privacy and the confidentiality of your records. All research data will be entered into an electronic database. All data will be stored on an encrypted, password protected computer In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

This authorization is valid for an indefinite period of time and there is no expiration on the access to medical records by the study team.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US 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 website at any time.

COSTS:
There is no cost to you for participating in this study.

PAYMENTS:
You will receive $10 after the completion of first washout week/survey completion. You will receive an additional $40 after all remaining study activities including the final study survey. The total amount you will receive for full participation is $50.

You will be paid on a reloadable debit card. Since you are being compensated for your participation in this study, your name, address, and social security number will be released to the Accounting Office. If the total reimbursement for your participation in research is greater than $600 in a year, this will be reported to the Internal Revenue Service (IRS) as income.

Your data used in this research study may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products. You will not retain any property rights, nor will you share in any money that the investigators, the University of Pittsburgh, or their agents may realize.

VOLUNTARY PARTICIPATION:
Your participation in this research study is entirely voluntary. You may also withdraw your permission to allow us to use and disclose health information from your medical records by contacting the investigator listed on the first page and making the request in writing, but if you do, you will not be able to continue to participate in this study. You can decline to participate without affecting your current or future relationship with the University of Pittsburgh or UPMC.

Your physician/clinician may be involved as an investigator in this research study. Before agreeing to participate, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your physician.

If you decide you no longer wish to participate you should contact Dr. Johnson or his research colleagues (412-647-2130). Your decision to withdraw from this study will have no effect on your current or future relationship with the University of Pittsburgh or UPMC. Any de-identified information collected prior to the date that you formally withdrew consent may continue to be used by the investigator Any recorded identifiable information will be destroyed after the required retention period.

The study team may decide to remove you from the study if you are unable to use the mouth sprays or complete the study assessments. You will only be paid for the initial survey if you do not complete the study.

VOLUNTARY CONSENT:
The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given.

I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation. By signing this form, I consent to participate in this research study and provide my authorization to share my medical records with the research team.

_____ _____

Participant's Signature Date

_____

Print Name

CERTIFICATION of INFORMED CONSENT:
I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date