Title of Research Study: Cleansing Device for the Treatment of Scalp and Hair Conditions

Investigator Team Contact Information:

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Investigator Name: Ronda Farah, MD Departmental Affiliation: Dermatology Phone Number: 612-625-8625 Email Address: rfarah@umn.edu	Study Staff: Irmina Wallander Phone Number: 612-624-5721 Email Address: dermresearch@umn.edu

Your doctor, who is also responsible for this research study, please note that she is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Supported By: This research is supported by the University of Minnesota Foundation.

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Key Information You Should Know Before Agreeing to Participate

The information below will help you learn about this research study and decide if you want to join. Make sure to read the whole consent form or have someone read it with you. If you have any questions or don't understand something, ask the researcher or study team before you sign the consent form.

What is this study about?

We are conducting this research study to test if an investigational device, a modified WaterPik® device, improves scalp health. The modified WaterPik® uses a brush and gentle water pressure to massage and cleanse the scalp. We are examining how effective this treatment is at reducing dandruff, redness, itchiness, and flaking on the scalp.
While the WaterPik® has been approved by the FDA as a dental medical device, its use in this study is investigational because it has not been approved by the FDA to cleanse the scalp as we have modified it to do.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are at least 18 years old and have one of the following scalp conditions: a healthy scalp, dandruff, seborrheic dermatitis, or hair loss disease.

What are the risks I should know about?

Potential risks of using the modified WaterPik® and brush device to massage and cleanse your scalp:

- Irritation
- Redness
- Headache
- Itching
- Tingling
- Abrasion of the skin

Privacy & confidentiality risks: There is some risk of a data breach involving the information we have about you. We comply with the University's security standards to secure your information and minimize risks, but there is always a possibility of a data breach.

Will this study benefit me or others?

- We cannot promise that you or others will benefit from this study.

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- Possible benefits include an improvement in scalp symptoms, such as reduced dandruff, redness, itchiness, and flaking on the scalp.

How is research different from clinical care?

- The goal of research is to learn new things to help people in the future.
- Researchers follow the same plan with many participants and usually don't change that plan for one research participant.
- By volunteering for a research study, you might or might not be helped personally.
- The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

Voluntary Participation and Right to Stop at Any Time

- You get to decide whether you participate or not.
- You can decide not to participate.
- You can say yes at first and then change your mind at any time.
- If you decide not to participate or to leave the study, it won't change your relationship with your doctors or the medical care you receive.

How long will the research last?

We expect that you will be in this research study for up to 4 weeks.

What will I need to do to participate?

You will be asked to have either one treatment or three treatments with the modified WaterPik® and brush device and then attend one follow-up visit one week after your last treatment. Study staff will take photographs of your scalp before and after the treatment and assess your scalp health/condition.

For more information about these activities, please see page 4.

What happens if I do not want to be in this research?

- You do not have to participate in this research. Instead of being in this research study, your choices may include alternative treatments for to reduce dandruff and symptoms of seborrheic dermatitis such as other types of scalp washes, massagers, and/or brushes.

Will it cost me anything to participate in this study?

- It will not cost you any money to participate in this study.
- Parking vouchers for the Delaware patient- parking ramp will be provided at each in-person visit.

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What happens if I am injured while participating in this research?

- In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study physicians know right away.

More Information About This Research Study

The following is more detailed information about this study in addition to the information listed

How many people will be studied?

We expect about 40 people here will be in this research study.

What happens if I say "*Yes, I want to be in this research*"?

If you agree to participate in this study, you will be randomly assigned to one of the following two groups:

- 1-Treatment: This group will receive 1 treatment with the modified WaterPik® device at the Baseline Visit and will complete the Follow-Up Visit one week later, for a total of 2 in-person visits.
- 3-Treatments: This group will receive 3 treatments (one treatment per week for three weeks) with the modified WaterPik® device. In addition to the Baseline Visit, this group will also come in for two more treatment visits before completing the Follow-Up Visit one week after their last treatment, for a total of 4 in-person visits.

The following information describes what will happen during each of the study visits:

Baseline (Treatment 1): This visit will last about 2 hours. It is important that you come to this visit with your scalp and hair dry.

- The study staff will discuss this consent form with you.
- The study staff will collect your demographic information and ask you questions about your medical history.
- You will complete questionnaires about your recent hair care practices, and you will rate the condition/health of your scalp and hair
- The study staff will examine and photograph your scalp.
    - To identify which area(s) of your scalp is in the photograph, the study staff will draw a small mark on your scalp using a purple surgical marker that will wash off on its own within a few days.

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- Your scalp will be treated with the WaterPik® and brush device for up to 30 minutes:
  - The modified WaterPik® uses a brush and gentle water pressure to massage and cleanse your scalp.
  - During the treatment, the study staff will also use the Venus Glow™ device to simultaneously suction the water from your scalp.
- The study staff will reexamine your scalp and take more photographs after the treatment.

Treatments 2 + 3: (3-Treatment Group ONLY)
Your 2nd and 3rd treatment visits will occur one week after the previous treatment, and each visit will last about 1.5 hours.

- The study staff will ask you about any possible adverse events from your previous treatment(s), such as headache, redness, tingling, etc.
- You will complete questionnaires about your recent hair care practices, and you will rate your scalp health and condition.
- The study staff will examine and photograph your scalp.
  - A small mark will be drawn on your scalp to identify the area(s) being photographed. The marker will wash off on its own within a few days.
- Your scalp will be treated with the WaterPik® and brush device for up to 30 minutes.
- The study staff will reexamine your scalp and take more photographs after the treatment.

Follow-Up Visit:

One week after your last treatment, you will come in for a follow-up visit that will last about 1.5 hours.

- The study staff will photograph and assess your scalp.
  - The study staff will again draw a small mark on your scalp to identify the area(s) being photographed, which will wash off on its own within a few days.
- You will complete a questionnaire about your scalp health.

If you miss your follow-up visit and are unable to reschedule, a study staff member may call you for a brief follow-up over the phone.

What are my responsibilities if I participate in this research?

If you take part in this research, you will be responsible for attending the study visits and

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following the instructions of the study team.

What happens if I say "Yes", but I change my mind later?

If you take part in this research study, and want to leave, you should tell us. Your choice not to be in this study will not negatively affect your right to any present or future medical care.

We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

If you stop being in the research, information about you that has already been collected may not be removed from the study database.

Can I be removed from the research?

It's possible that we will have to ask you to leave the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include:

- Failing to follow instructions from the study staff
- If you become pregnant while participating
- If you are no longer eligible to participate
- If the study doctor determines that it is in your best interest to stop participating.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What do I need to know about reproductive health and/or sexual activity if I am in this study?

The WaterPik device uses ultrasonic technology. Unnecessary exposure to ultrasound is not recommended for pregnant women as it can increase bone and tissue heat.

You should not be or become pregnant while on this research study. You should also not participate in the study if you are breastfeeding.

If you are sexually active woman of child bearing potential, you should use at least two effective means of birth control while participating in this research study. According to the World Health Organization and the United States Center for Disease Control and Prevention, the most effective forms of birth control include complete abstinence, surgical sterilization (both male

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and female), intrauterine devices (IUDs), and the contraceptive implant. The next most effective forms of birth control include injectables, oral contraceptive pills, the contraceptive ring, or the contraceptive patch. Acceptable, but least effective, methods of birth control include male condoms (with or without spermicide) and female condoms.

If you become pregnant while participating in this research study, it is important that you tell the study doctor or other research team member immediately. You might be required to stop participation in this study; however, other clinical care options will be discussed with you at that time if necessary.

If you are considered to be postmenopausal, you are not required to use contraception while participating in this research study. Postmenopausal women rarely become pregnant. If you or your partner become pregnant while participating in this research study, it is important that you tell the study doctor or other research team member immediately. You may be required to stop participation in this study; however, other clinical care options will be discussed with you at that time if necessary.

What happens to the information collected for the research, including my health information?

We try to limit the use and sharing of your information, including research study records, any medical records and any other information about you, to people who have a need for this information. But we cannot promise complete confidentiality.

Overview

If you participate in this study, your information, including your health information, will be used and shared for purposes of conducting this research. As described later in this Consent Form, your information may also be used and shared for publishing and presenting the research results, future research, and any optional elements of the research you agree to in this Consent Form, which may include creating audio and video recordings of you. If you sign this Consent Form, you are giving us permission to use and share your health information for these purposes, and if we are using your medical records, you are giving permission to any health care providers who are treating you to share your medical records with us.

What health information will be made available?

Health information about you to be used and shared for the research includes those items checked by the research team below:

☒ Your medical records, which may include records from hospital and clinic visits, emergency room visits, immunizations, medical history and physical exams, medications, images and imaging reports, progress notes, psychological tests, EEG/EKG/ECHO reports, lab and

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pathology reports, dental records and/or financial records. These records may be used and shared for as long as this research continues.

☒ Information collected as part of this research study, including research procedures, research visits, and any optional elements of the research you agree to, all as described in this Consent Form. This information might not be part of your medical record, and may include things like responses to surveys and questionnaires, and information collected during research visits described in this Consent Form.

What about more sensitive health information?

Some health information is so sensitive that it requires your specific permission to be collected and used by study teams as part of the research study you are participating in.

If this research study requires any of the sensitive information below, **the applicable boxes will be checked by the study team**.

Below, you will be asked if you agree to the collection and/or use of this information by the research team, as described in this Consent Form, by providing your initials under #1 at the end of this section.

If you change your mind, you are able to cancel your consent at any time; however, you may no longer be able to participate in the study if the information is required by the study team.

If the research study you are participating in will **not** be collecting the sensitive information below, **the N/A box will be marked by the study team**, and you will be asked to provide your initials under #2 at the end of this section.

Sensitive Information Collected and/or Used

The following will be collected or used as part of this study:

☐ My drug and alcohol abuse, diagnoses, and treatment records

☐ My HIV/AIDS testing records

☐ My mental health diagnosis and/or treatment records

☐ My genetic testing records

☐ My sickle cell anemia records

☒ **Not Applicable**. The sensitive information listed above is not collected or used as part of this study.

Research Participant Initials

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- If the study team requires my sensitive health information to participate, I understand what sensitive information they will collect and/or use based on the boxes checked by the team.
- If the study team selected "N/A," I understand that my sensitive health information will not be collected and/or used as part of this study.
- By providing my initials below, I confirm that I have had the opportunity to ask questions and receive explanations if I request them.

Research participant, please initial one of these two options:

1. **Yes, I allow the collection and/or use of the selected "sensitive health information" items as part of this study:**

   Participant's Initials: _____
2. **It has been explained to me that there will be no collection and/or use of my "sensitive health information" as part of this study:**

   Participant's Initials: _____

Who will access and use my health information?

If you agree to participate in this study, your information will be shared with:

- The University of Minnesota research team and any institutions or individuals collaborating on the research with us;

- Others at the University of Minnesota and M Health/Fairview who provide support for the research or who oversee research (such as the Institutional Review Board or IRB which is the committee that provides ethical and regulatory oversight of research at the University, systems administrators and other technical and/or administrative support personnel, compliance and audit professionals (Such as the Quality Assurance Program of the Human Research Protection Program (HRPP)) , individuals involved in processing any compensation you may receive for your participation, and others);

- The research sponsor(s), any affiliates, partners or agents of the sponsor(s) involved in the research, organizations funding the research, and any affiliates, partners or agents of the funding organization(s) involved in the research;

- Organizations who provide accreditation and oversight for research and the research team, and others authorized by law to review the quality and safety of the research (such as U.S. government agencies like the Food and Drug Administration, the Office of

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Human Research Protections, the Office of Research Integrity, or government agencies in other countries); and

- Organizations that process any payments that may be made to you for participating in this study, and any other individuals or organizations specifically identified in this Consent Form.

- If you agree to participate in this research study, a signed copy of this consent document and the HIPAA authorization form *may* be filed in your electronic medical record (EMR) and your study participation *may* be added to your EMR. This information will be used for your care and treatment and for healthcare operations, which may include billing and payment. Federal and state privacy laws give patients the right to access information about their care and treatment contained in their medical record. During this study, you may not be able to access certain information related to this study in your EMR until the study is complete to ensure that the study remains unbiased. By consenting to participate in this study, you are also consenting to this possible temporary withholding of your research records.

Additional sharing of your information for mandatory reporting

If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

How will my information be used in publications and presentations?

We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

What will be done with my data and specimens when this study is over?

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We will use and may share data and/or specimens for future research. In addition to using and storing data and/or specimens for future research within the University of Minnesota, specimens may also be shared with researchers/institutions outside of University of Minnesota. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data and/or specimens, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data.

Do I have to sign this Consent Form and give my permission to make my information, including my health information, available for use and sharing?

No, you do not have to sign this Consent Form. But if you do not sign, you will not be able to participate in this research study. Treatment available outside of the study, payment for such treatment, enrollment in health insurance plans and eligibility for benefits will not be impacted by your decision about signing this Consent Form.

Does my permission for making my health information available for use and sharing ever expire?

No, there is no expiration date.

May I cancel my permission for making my health information available for use and sharing?

If you consent to participate in this study by signing the bottom of this Consent Form, you are providing two forms of consent. The first is consent to participate in the research activities as described in this document. The second is consent to share your personal medical information, either taken from your medical records or collected as part of this research (or both), as described above. This second form of consent, sometimes referred to as "HIPAA authorization," is what is meant by "providing permission for making your health information available for use and sharing."

You may cancel your permission for either form of consent at any time, for any reason, and without penalty. You may revoke your consent to participate in research (sometimes referred to as "withdrawing from the study") simply by telling the researcher listed on the first page of this Consent Form that you no longer wish to participate. Verbal communication is sufficient to withdraw this first form of consent. However, canceling your permission to share your medical information, the second form of consent, must be done in writing to the researcher listed at the address on the first page of this Consent Form.

If you cancel either form of permission, you will no longer be in the research study. If you cancel permission to share your medical information, you may want to ask someone on the research team if doing so will affect any research-related medical treatment. If you cancel your permission, any health information about you that was already used and shared may continue

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to be used and shared for the research study and any optional elements of the study to which you agree in this Consent Form.

What happens to my health information after it is shared with others?

When we share your information with others as described in this Consent Form, privacy laws may no longer protect your information and there may be further sharing of your information.

Will I be able to look at my records?

It is possible that the research team may not allow you to see the information collected for this study. However, you may access any information placed in your medical records after the study is complete.

The sponsor, monitors, auditors, the IRB, the University of Minnesota Research Compliance Office and other University compliance units, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include your name or any other direct identifiers such as your contact information. The Web site may include a summary of the results of this research. You can search this Web site at any time.

Will I receive research test results?

NO

Most tests done on samples in research studies are only for research and have no clear meaning for health care. The investigator(s) will not contact you or share your individual test results.

Will anyone besides the study team be at my consent meeting?

You may be asked by the study team for your permission for an auditor to observe your consent meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g. name, date of birth) or confidential information about you. The auditor will not observe your consent meeting without your permission ahead of time.

Whom do I contact if I have questions, concerns or feedback about my

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experience?

If you have questions later regarding the study or your participation, you are encouraged to contact the research team. Please see the "Investigator Contact Information" section at the beginning of this form.

To reach someone outside of the research team: This research has been reviewed and approved by an IRB which is part of the Human Research Protections Program (HRPP). If there is an issue you would like to discuss with someone who is *not* on the research team you are encouraged to call the HRPP Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. For example:

- Your questions, concerns, or complaints are not being answered by the research team.
- You are having difficulty reaching the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to provide feedback about this research to someone who is not on the study team.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Will I be compensated for my participation?

If you agree to take part in this research study, we will pay you $90 for your time and effort. You will receive $30 for the Baseline Visit (Treatment 1) and $20 for each additional visit:

1-Treatment group:

- Baseline Visit (Treatment 1) $30
- Follow-Up Visit $20

For a Total: $50

3-Treatment group:

- Baseline Visit (Treatment 1) $30
- Treatment 2 $20

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- Treatment 3 $20
- Follow-Up Visit $20

For a total of: $90

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 6 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given your name, address, date of birth, and social security number. They will use this information only as part of the payment process. Greenphire will only need your social security number if the payment exceeds $599. Greenphire will not receive any information about your health status or the study in which you are participating.

Optional research activities:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

Yes, I agree	**No, I disagree**	
_____	_____	The investigator may contact me in the future to see whether I am interested in participating in other research studies by Dr. Farah and her research collaborators.

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Consent Form (includes HIPAA Authorization)

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

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